

is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sodium content has been lowered from 300 to 150 mg per serving”).

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low sodium.”

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced sodium product—30% less sodium per 3 oz than our ‘regular product’”); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz”).

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for “low sodium.”

(c) The term “salt” is not synonymous with “sodium.” Salt refers to sodium chloride. However, references to salt content such as “unsalted,” “no salt,” “no salt added” are potentially misleading.

(1) The term “salt free” may be used on the label or in labeling of products only if the product is “sodium free” as defined in paragraph (b)(1) of this section.

(2) The terms “unsalted,” “without added salt,” and “no salt added” may

be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement “not a sodium free product” or “not for control of sodium in the diet” appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 213, Jan. 3, 1995; 60 FR 5762, Jan. 30, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products 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 §381.413; and

(3) The product for which the claim is made is labeled in accordance with §381.409.

(b) *Fat content claims.* (1) The terms “fat free,” “free of fat,” “no fat,” “zero fat,” “without fat,” “nonfat,” “trivial source of fat,” “negligible source of fat,” or “dietarily insignificant source of fat” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient

in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of fat,” “adds a negligible amount of fat,” or “adds a dietarily insignificant amount of fat”; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms “low fat,” “low in fat,” “contains a small amount of fat,” “low source of fat,” or “little fat” may be used on the label and in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not

more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced fat,” “reduced in fat,” “fat reduced,” “less fat,” “lower fat,” or “lower in fat” may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced fat—50 percent less fat than our regular ‘product’”); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fat content has been reduced from 8 g to 4 g per serving”).

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low fat.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced fat ‘product’, 33 percent less fat per 3 oz than our regular ‘product’”); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., “fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz”).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low fat.”

(6) The term “_____ percent fat free” may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for “low fat” in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words “fat free” are in uniform type size; and

(iii) A “100 percent fat free” claim may be made only on products that meet the criteria for “fat free” in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for “_____ percent fat free” is “_____ percent lean.”

(c) *Fatty acid content claims.* (1) The terms “saturated fat free,” “free of saturated fat,” “no saturated fat,” “zero saturated fat,” “without saturated fat,” “trivial source of saturated fat,” “negligible source of saturated fat,” or “dietarily insignificant source of saturated fat” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of saturated fat,” “adds a negligible amount of saturated fat,” or “adds a dietarily insignificant amount of saturated fat;” and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms “low in saturated fat,” “low saturated fat,” “contains a small amount of saturated fat,” “low source of saturated fat,” or “a little saturated fat” may be used on the label or in labeling of products, except meal-type products as defined in §381.413(1) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(1) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely

to the particular brand to which the label attaches.

(4) The terms “reduced saturated fat,” “reduced in saturated fat,” “saturated fat reduced,” “less saturated fat,” “lower saturated fat,” or “lower in saturated fat” may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced saturated fat ‘product’, contains 50 percent less saturated fat than the national average for ‘product’”); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “saturated fat reduced from 3 g to 1.5 g per serving”).

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low saturated fat.”

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent

such claim (e.g., “reduced saturated fat ‘product’, 50 percent less saturated fat than our regular ‘product’”); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz”).

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low saturated fat.”

(d) *Cholesterol content claims.* (1) The terms “cholesterol free,” “free of cholesterol,” “zero cholesterol,” “without cholesterol,” “no cholesterol,” “trivial source of cholesterol,” “negligible source of cholesterol,” or “dietarily insignificant source of cholesterol” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of cholesterol,” “adds a negligible amount of cholesterol,” or “adds a dietarily insignificant amount of cholesterol”;

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to

the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., “cholesterol free ‘product’, contains 100 percent less cholesterol than ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “contains no cholesterol compared with 30 mg in one serving of ‘reference product’”).

(2) The terms “low in cholesterol,” “low cholesterol,” “contains a small amount of cholesterol,” “low source of cholesterol,” or “little cholesterol” may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in

§ 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form); and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “low cholesterol ‘product’, contains 85 percent less cholesterol than our regular ‘product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 30 mg to 5 mg per serving”).

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or

reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced cholesterol,” “reduced in cholesterol,” “cholesterol reduced,” “less cholesterol,” “lower cholesterol,” or “lower in cholesterol” may be used on the label or in labeling of products or products that substitute for those products as specified in § 381.413(d), excluding meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “25 percent less cholesterol than ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 55 mg to 30 mg per serving”).

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low cholesterol.”

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product has been specifically formulated, altered, or processed to re-

duce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “25% less cholesterol than ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz”).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low cholesterol.”

(e) “Lean” and “Extra Lean” claims.

(1) The term “lean” may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m).

(2) The term “extra lean” may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined

in § 381.413(l) and main-dish products as defined in § 381.413(m).

[60 FR 214, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§ 381.463 Nutrient content claims for “healthy.”

(a) The term “healthy,” or any other derivative of the term “health,” may be used on the labeling of any poultry product, provided that the product is labeled in accordance with § 381.409 and § 381.413.

(b)(1) The product shall meet the requirements for “low fat” and “low saturated fat,” as defined in § 381.462, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for “extra lean” in § 381.462.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 381.413(m), and meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for “extra lean” in § 381.462.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 381.413(m), and meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 600 mg of sodium per labeled serving size;¹ and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 381.409 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A main-dish product, as defined in § 381.413(m), and including meal-type products that weigh less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 381.413(l), shall meet the level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 217, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003; 69 FR 58803, Oct. 1, 2004; 71 FR 1686, Jan. 11, 2006]

§§ 381.464–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

¹This regulation previously provided that, after January 1, 2006, individual poultry products bearing the claim “healthy” (or any derivative of the term “health”) must contain no more than 360 mg of sodium and that meal-type products bearing the claim “healthy” (or any other derivative of the term “health”) must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim “healthy” (or any derivative of the term “health”) has been deferred indefinitely due to technological barriers and consumer preferences.