

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 381.413(d), such as a "low calorie" version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

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22. Section 381.413 is amended by revising paragraphs (b), (g), (i), (j), (k), (p), and (q)(4) and adding new paragraphs (c), (d), (e), and (f) to read as follows:

§ 381.413 Nutrient content claims; general principles.

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(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use

by infants and children less than 2 years of age unless the claim is specifically provided for in subpart Y of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(c) Information that is required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(e)(1) Because the use of a "free" or "low" claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., "low sodium chicken noodle soup").

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to

qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., "chicken breast meat, a low sodium food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 381.413, 381.454, 381.456, 381.460, 381.461, 381.462, and 381.480, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 381.500(d)(2).

(h) [Reserved]

(i) Except as provided in § 381.409 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart Y of this part, for the nutrient that the label addresses. Such a claim might be, "less than 10 g of fat per serving;"

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not "low" in or a "good source" of the nutrient, such as "only 200 milligrams (mg) sodium per serving, not a low sodium product." The disclaimer must be in easily legible print or type and in a size no less than required by § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 381.462(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient