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(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in §101.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable concentration is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million (ppm or mg/kg) or more of the sulfite in the finished food. The concentration of sulfite in the finished food will be determined using either:

(1) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry; or

(2) AOAC Official Method 990.28.

(b) Any standardized food that, as a result of actions that are consistent with current good manufacturing practice, contains an indirectly added sulfiting agent that has no functional effect in the food and that would, in the absence of §101.100(a)(4) of this chapter, be considered to be an incidental additive for purposes of §130.8, conforms to the applicable definition and standard of identity if the presence of the sulfiting agent is declared on the label of the food.

(c) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51.

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All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850-3250. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

(1) AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method, Section 47.3.43, Official Methods of Analysis, 21st edition, 2019.

(2) Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study, Katherine S. Carlos and Lowri S. De Jager; *Journal of AOAC International*, Vol. 100, No. 6, 2017, pp. 1785–1794.

[58 FR 2876, Jan. 6, 1993, as amended at 63 FR 14035, Mar. 24, 1998; 87 FR 2547, Jan. 18, 2022]

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see §101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity but that do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of §101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section.

(b) *Nutrient addition.* (1) Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in

§101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(2) Yogurt containing less than 3.25 percent milkfat is exempt from compliance with paragraph (b)(1) of this section with respect to vitamin A fortification provided the product complies with all other requirements.

(c) *Performance characteristics.* Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food. Deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking"). Such statement shall comply with the requirements of §101.13(d) of this chapter. The modified product shall perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance

characteristics to the standardized food defined in parts 131 through 169 of this chapter.

(2) An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

(5) Water and fat analogs may be added to replace fat and calories in accordance with §130.10(c), (d)(1), and (d)(2).

(e) *Yogurt with modified milkfat and fat-containing flavoring ingredients.* Fat-containing flavoring ingredients may be added to yogurt for which the milkfat content has been modified in accordance with the expressed nutrient content claim regulations in §101.62(b) of this chapter. The name of the food includes the term "____ yogurt," the blank being filled in with the nutrient content claim in §101.62(b)(1)(i), (b)(2)(i), or (b)(4)(i) of this chapter corresponding to the milkfat content, and a descriptor of the fat-containing flavoring ingredient(s).

(f) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.

(g) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the

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applicable sections of part 101 of this chapter and part 130.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement “*Ingredient(s) not in regular _____” (fill in name of the traditional standardized food) or “*Ingredient(s) in excess of amount permitted in regular _____” (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

[58 FR 2446, Jan. 6, 1993, as amended at 86 FR 31137, June 11, 2021; 87 FR 76568, Dec. 15, 2022]

§ 130.11 Label designations of ingredients for standardized foods.

Some definitions and standards of identity for foods set forth below require that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives, and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase. Such requirements shall apply to a manufacturer, packer, or distributor of a standardized food only if the words or statements on the label of the standardized food significantly differentiate between two or more foods that comply with the same standard by describing the optional forms or varieties, the packing medium, or significant characterizing ingredients present in the food.

[58 FR 2876, Jan. 6, 1993]

§ 130.12 General methods for water capacity and fill of containers.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term *general method for water capacity of containers* means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68 °F to $\frac{3}{16}$ inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in paragraph (a)(2) of this section from the weight found in paragraph (a)(3) of this section. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraphs (a) (2) to (4) of this section, except that under paragraph (a)(3) of this section, fill the container to the level of the top thereof.

(b) The term *general method for fill of containers* means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to $\frac{3}{16}$ inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by subtracting the weight of the container found in paragraph (b)(3) of this section.

(5) Maintaining the water at the temperature recorded in paragraph (b)(4) of this section, draw off water from the container as filled in paragraph (b)(4) of this section to the level of the food found in paragraph (b)(2) of this section, weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in paragraph (b)(3) of this section.

(6) Divide the weight of water found in paragraph (b)(5) of this section by the weight of water found in paragraph (b)(4) of this section, and multiply by