

that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived fats, oils, and stearins other than cacao fat. The fats, oils, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is "sweet chocolate and vegetable fat coating". Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., "sweet chocolate and _____ oil coating", the blank being filled in with the common or usual name of the specific vegetable fat used.

§ 163.155 Milk chocolate and vegetable fat coating.

(a) *Description.* Milk chocolate and vegetable fat coating is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in §163.130 or skim milk chocolate in §163.140, except that one or more optional ingredients specified in paragraph (b) of this section are used. Compliance with the requirement in §163.130(a)(2) that the product contains not less than 12 percent by weight of nonfat milk solids shall be calculated using only those dairy ingredients referred to in §163.130(b)(4), exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived oils, fats, and stearins other than cacao fat. The oils, fats, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is "milk chocolate and vegetable fat coating" or "skim milk chocolate and vegetable fat coating", as appro-

priate. Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., "milk chocolate and _____ oil coating", the blank being filled in with the common or usual name of the specific vegetable fat used.

PART 164—TREE NUT AND PEANUT PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

Sec.

164.110 Mixed nuts.

164.120 Shelled nuts in rigid or semirigid containers.

164.150 Peanut butter.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14475, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

§ 164.110 Mixed nuts.

(a) Mixed nuts is the food consisting of a mixture of four or more of the optional shelled tree nut ingredients, with or without one or more of the optional shelled peanut ingredients, of the kinds prescribed by paragraph (b) of this section; except that when 2 ounces or less of the food is packed in transparent containers, three or more of the optional tree nut ingredients shall be present. Each such kind of nut ingredient when used shall be present in a quantity not less than 2 percent and not more than 80 percent by weight of the finished food. For purposes of this section, each kind of tree nut and peanut is an optional ingredient that may be prepared by any suitable method in accordance with good manufacturing practice. The finished food may contain one or more of the optional nonnut ingredients provided for in paragraph (c) of this section.

(b) The optional shelled nut ingredients referred to in paragraph (a) of this section are:

(1) Almonds, black walnuts, Brazil nuts, cashews, English walnuts (alternatively “walnuts”), filberts, pecans, and other suitable kinds of tree nuts.

(2) Peanuts of the Spanish, Valencia, Virginia, or similar varieties, or any combination of two or more such varieties.

(c) The optional nonnut ingredients referred to in paragraph (a) of this section consist of suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Nonnut ingredients that perform a useful function are regarded as suitable, except that color additives are not suitable ingredients of the food.

(d) The name of the food is “mixed nuts”. If the percentage of a single tree nut ingredient or the total peanut content by weight of the finished food exceeds 50 percent but not 60 percent, the statement “contains up to 60% _____” or “contains 60% _____” or “60% _____” shall immediately follow the name “mixed nuts” and shall appear on the same background, be of the same color or, in the case of multicolors, in the color showing distinct contrast with the background, and be in letters not less than one-half the height of the largest letter in the words “mixed nuts”. The blank is to be filled in with the appropriate name of the predominant nut ingredient; for example, “contains up to 60% pecans” or “contains up to 60% Spanish peanuts”. The numbers “70” or “80” shall be substituted for the number “60” when the percentage of the predominant nut ingredient exceeds 60 but not 70, or exceeds 70 but not 80, respectively. Compliance with the requirements for percentage of nut ingredients of this section and the fill of container requirements of §164.120(c) will be determined by the following procedure:

(1) Take at random from a lot, in the case of containers bearing a weight declaration of 16 ounces or less, at least 24 containers, and for containers bearing a weight declaration of more

than 16 ounces, enough containers to provide a total quantity of at least 24 pounds of nuts.

(2) If compliance with §164.120(c) is to be determined, first follow the procedure set forth therein.

(3) Determine the percent by weight of each nut ingredient present in each container separately. Calculate the average percentage of each nut ingredient present. If the average percent found for each nut ingredient present is 2 percent or more and none of the individual nut ingredients exceeds 80 percent by weight of the finished food, the lot will be deemed to be in compliance with the percentage requirements of paragraph (a) of this section. If the average percent found for a single nut ingredient exceeds 50 percent by weight of the finished food and the average percent found is within the range indicated by the number declared on the label in accordance with this paragraph, the lot will be deemed to be in compliance with the labeling requirements of this paragraph.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) If the Spanish variety of peanuts is used, it shall be declared as “Spanish peanuts”. Other varieties of peanuts shall be declared as “peanuts”, or alternatively “_____ peanuts”, the blank being filled in with the varietal name of the peanuts used.

(2) If the peanut ingredient or ingredients as provided for in paragraph (b)(2) of this section are unblanched, the label shall show that fact by such statement as “Peanuts unblanched”, “Peanuts skins on”, or words of similar import, unless the vignette clearly depicts peanuts with skins on.

(f) The words and statements specified in paragraph (e) of this section showing the ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by part 101 of this chapter for the statement of net

quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire ingredient statement shall appear on at least one panel of the label. If the label bears any pictorial representation of the mixture of nuts, it shall depict the relative proportions of the nut ingredients of the food. If the label bears a pictorial representation of only one of each nut ingredient present, the nuts shall be depicted in the order of decreasing predominance by weight. A factual statement that the food does not contain a particular nut ingredient or ingredients may be shown on the label if the statement is not misleading and does not result in an insufficiency of label space for the proper declaration of information required by or under authority of the act to appear on the label.

[42 FR 14475, Mar. 15, 1977, as amended at 58 FR 2885, Jan. 6, 1993]

§ 164.120 Shelled nuts in rigid or semirigid containers.

(a)-(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill for shelled nuts in rigid or semirigid containers is a fill such that the average volume of nuts, from the number of containers specified in § 164.110(d)(1), is not less than 85 percent of the container volume as determined by the method in paragraph (c)(2) of this section.

(2) The method for determining the percent of fill is as follows:

(i) For the shelled nuts in each container, determine the loose volume, the settled volume, and the average volume in cubic centimeters. For the purposes of this subparagraph, consider volume in milliliters to be numerically equal to volume in cubic centimeters. Open the container and pour the nuts loosely into a vertical graduated cylinder (do not tilt) of appropriate size fitted with a funnel which has been modified, if necessary, to provide a minimum opening of 1½-inch diameter. (If the loose volume of the nuts is less than 500 milliliters, use a 500-milliliter cylinder with an inside diameter of approximately 1¾ inches; but if the loose volume is 500 milliliters or more, use a 1,000-milliliter cylinder with an inside diameter of approximately 2¼ inches.)

Without shaking the cylinder, estimate the location of a horizontal plane representing the average height of the product, read the volume of the nuts, and record as the loose volume. Raise the cylinder 2 inches and allow it a free vertical drop onto a level, firm, but resilient surface (do not tamp) for a total of 5 times and observe the volume as above. Repeat in successive five-drop increments until the nuts have so settled that the volume decreases less than 2 percent in the last five-drop increment. Read the last volume in the manner described above and record as the settled volume. The arithmetical average of the loose volume and the settled volume equals the average volume of nuts.

(ii) Classify the container by shape and determine its volume in cubic centimeters according to one of the following methods as appropriate:

(a) For containers of irregular shape, including glass jars, follow the general method for water capacity of containers as prescribed in § 130.12(a) of this chapter and determine the container volume, considering the water capacity in grams to be numerically equivalent to volume in cubic centimeters, or the water capacity in ounces (avoirdupois) to be equivalent to 28.35 cubic centimeters per ounce.

(b) For box-shaped containers (that is, with opposite sides parallel), measure the inside height, width, and depth and calculate the volume as the product of these three dimensions. For such containers used to enclose vacuum packs and containing 4 ounces or less of the product, consider the height to be the inside height minus three-eighths inch.

(c) For cylindrical containers, calculate the container volume in cubic centimeters as the product of the height times the square of the diameter, both measured in inches, times 12.87; or as the product of the height times the square of the diameter, both measured in centimeters, times 0.7854. For containers that do not have indented ends, use the inside height and inside diameter as the dimensions. For metal cans with indented ends (that is, metal cans with ends attached by double seams), consider the height to be the outside height at the double seam

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minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus one-eighth inch (0.318 centimeter). For fiber-bodied containers with indented ends (that is, fiber-bodied cans with metal ends attached by double seams), consider the height to be the outside height at the double seam minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus three-sixteenths inch (0.476 centimeter).

(iii) Calculate the percent fill of the container as follows: Divide the average volume of nuts found according to paragraph (c)(2)(i) of this section by the appropriate container volume found according to paragraph (c)(2)(ii) of this section and multiply by 100. The result shall be considered to be the percent fill of the container.

(3) If shelled nuts fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

§ 164.150 Peanut butter.

(a) Peanut butter is the food prepared by grinding one of the shelled and roasted peanut ingredients provided for by paragraph (b) of this section, to which may be added safe and suitable seasoning and stabilizing ingredients provided for by paragraph (c) of this section, but such seasoning and stabilizing ingredients do not in the aggregate exceed 10 percent of the weight of the finished food. To the ground peanuts, cut or chopped, shelled, and roasted peanuts may be added. During processing, the oil content of the peanut ingredient may be adjusted by the addition or subtraction of peanut oil. The fat content of the finished food shall not exceed 55 percent when determined as prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 27.006(a) under "Crude Fat—Official First Action, Direct Method," in paragraph (a), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave.,

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suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) The peanut ingredients referred to in paragraph (a) of this section are:

(1) Blanched peanuts, in which the germ may or may not be included.

(2) Unblanched peanuts, including the skins and germ.

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, and color additives are not suitable ingredients in peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogenated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(d) If peanut butter is prepared from unblanched peanuts as specified in paragraph (b)(2) of this section, the name shall show that fact by some such statement as "prepared from unblanched peanuts (skins left on)." Such statement shall appear prominently and conspicuously and shall be in type of the same style and not less than half of the point size of that used for the words "peanut butter." This statement shall immediately precede or follow the words "peanut butter," without intervening written, printed, or graphic matter.

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

applicable sections of parts 101 and 130 of this chapter.

[42 FR 14475, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 61 FR 9325, Mar. 8, 1996; 63 FR 14035, Mar. 24, 1998]

PART 165—BEVERAGES

Subpart A—General Provisions

Sec.

165.3 Definitions.

Subpart B—Requirements for Specific Standardized Beverages

165.110 Bottled water.

AUTHORITY: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

SOURCE: 60 FR 57124, Nov. 13, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 165.3 Definitions.

(a) A *lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B—Requirements for Specific Standardized Beverages

§ 165.110 Bottled water.

(a) *Identity*—(1) *Description*. Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in §165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as “water,” “carbonated water,” “disinfected water,” “filtered water,” “seltzer water,” “soda water,” “sparkling water,” and “tonic water.” The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) *Nomenclature*. The name of the food is “bottled water,” “drinking water,” or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is “artesian water” or “artesian well water.” Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is “ground water.” Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be “mineral water.” Mineral water shall be distinguished from other types