Food and Drug Administration, HHS

Subpart B—Requirements for Specific Standardized Milk and Cream

§131.110 Milk.

(a) Description. Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8½ percent milk solids not fat and not less than 3½ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) Vitamin addition (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) Optional ingredients. The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) Methods of analysis. Referenced methods are from “Official Methods of Analysis of the Association of Official Analytical Chemists,”' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., 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.


(2) Milk solids not fat content—Calculated by subtracting the milk fat content from the total solids content as determined by the method “Total Solids, Method I—Official Final Action,” section 16.032.

(3) Vitamin D content—“Vitamin D—Official Final Action,” sections 43.195–43.208.

(e) Nomenclature. The name of the food is “milk”. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in §101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) If vitamins are added, the phrase “vitamin A” or “vitamin A added”, or “vitamin D” or “vitamin D added”, or “vitamin A and D” or “vitamins A and D added”, as is appropriate. The word “vitamin” may be abbreviated “vit.”.

(ii) The word “ultra-pasteurized” if the food has been ultra-pasteurized.

(2) The following terms may appear on the label:

(i) The word “pasteurized” if the food has been pasteurized.

(ii) The word “homogenized” if the food has been homogenized.

(f) 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.


§131.111 Acidified milk.

(a) Description. Acidified milk is the food produced by souring one or more of the optional dairy ingredients specified in paragraph (c) of this section with one or more of the acidifying ingredients specified in paragraph (d) of this section, with or without the addition of characterizing microbial organisms.
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One or more of the other optional ingredients specified in paragraphs (b) and (e) of this section may also be added. When one or more of the ingredients specified in paragraph (e)(1) of this section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) Vitamin addition (optional). (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Optional acidifying ingredients. Acetic acid, adipic acid, citric acid, fumaric acid, glucono-delta-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) Other optional ingredients. (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: Provided, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner’s sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(f) Methods of analysis. The following referenced methods of analysis are from “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies are available from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection 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.


(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, “Method I—Official Final Action,” under the heading “Total Solids.”

(3) Titratable acidity—As determined by the method prescribed in section 16.023, “Acidity (2)—Official Final Action,” or by an equivalent potentiometric method.

(g) Nomenclature. The name of the food is “acidified milk.” The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The
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(name of the food) shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in §101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used, e.g., "acidified kefir milk", "acidified acidophilus milk", or when characterizing ingredients such as those in paragraphs (e) (6), (7), (8), and (9) of this section are used, the food may be named "acidified buttermilk".

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:
   (i) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit.".
   (ii) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

(b) 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.

§ 131.112 Cultured milk.

(a) Description. Cultured milk is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d) (1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) Vitamin addition (optional). (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Other optional ingredients. (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: Provided, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.