

(d) *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) Enzymes of animal, plant, or microbial origin may be declared as “enzymes”; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms “milkfat and nonfat milk” or “nonfat milk and milkfat”, as appropriate.

[48 FR 2746, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 55 FR 6795, Feb. 27, 1990; 58 FR 2895, Jan. 6, 1993]

§ 133.196 Swiss cheese for manufacturing.

Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 133.195, except that the holes, or eyes, have not developed throughout the entire cheese.

[55 FR 6795, Feb. 27, 1990]

PART 135—FROZEN DESSERTS

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

Subpart A—General Provisions

§ 135.3 Definitions.

For the purposes of this part, a pasteurized mix is one in which every particle of the mix has been heated in properly operated equipment to one of the temperatures specified in the table in this section and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
155 °F	30 min.
175 °F	25 sec.

[42 FR 19132, Apr. 12, 1977]

Subpart B—Requirements for Specific Standardized Frozen Desserts

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided for in paragraph (d) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

(2) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids, except that when it contains milkfat at 1 percent increments above the 10 percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Percent milkfat	Minimum percent nonfat milk solids
10	10
11	9
12	8
13	7
14	6

Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than

10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 percent egg yolk solids by weight of the finished food: *Provided, however,* That when bulky flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e)(1) of this section.

(3) When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part-skim milk; nonfat dried milk; sweet cream buttermilk; con-

densed sweet cream buttermilk; dried sweet cream buttermilk; skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate; and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1N NaOH, and it has a Ph value in the range of 8.0 to 8.3.

(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section that may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) *Optional hydrolyzed milk proteins.* One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less than 20 percent total milk solids, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the

finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label shall comply with the requirements of §102.22 of this chapter.

(e) *Methods of analysis.* The fat content shall be determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 16.287 and 16.059, under "Fat, Roese-Gottlieb Method—Official Final Action," 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.

(f) *Nomenclature.* (1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard" or "french ice cream" or "french custard ice cream".

(2)(i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "Vanilla flavored", or "Peach flavored", or "Vanilla flavored and Strawberry flavored".

(iii) If the food contains both a natural characterizing flavor and an arti-

cial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla", or "artificially flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry".

(3)(i) If the food is subject to the requirements of paragraph (f)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial _____ flavor added", the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: *Provided, however,* That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: *And provided further,* That if the finished product contains more than one flavor of ice cream subject to the

requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., “Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added”.

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., “strawberry and artificial strawberry flavor”.

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in §169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of

bananas and less than 1 percent of almonds it would be “artificially flavored banana-almond ice cream”. However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be “banana-almond flavored ice cream”.

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., “Neapolitan” ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term “ice cream” but in any case no smaller than one-sixteenth of an inch. If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(g) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms “milkfat and nonfat milk” when one or any combination of two or more of the ingredients listed in §101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in §101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by §101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]