

records are available for public disclosure when the notice of a permit or extension thereof is published in the FEDERAL REGISTER. Such disclosure shall be in accordance with the rules established in part 20 of this chapter.

(1) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 46 FR 37500, July 21, 1981; 54 FR 24892, June 12, 1989; 59 FR 15051, Mar. 31, 1994; 66 FR 17359, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001]

Subpart B—Food Additives in Standardized Foods

§ 130.20 Food additives proposed for use in foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in part 171 of this chapter shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in part 171 of this chapter.

PART 131—MILK AND CREAM

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- 131.160 Sour cream.
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- 131.170 Eggnog.
- 131.180 Half-and-half.
- 131.200 Yogurt.
- 131.203 Lowfat yogurt.
- 131.206 Nonfat yogurt.

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

SOURCE: 42 FR 14360, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 131 appear at 63 FR 14035, Mar. 24, 1998.

Subpart A—General Provisions

§ 131.3 Definitions.

(a) *Cream* means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) *Pasteurized* when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph 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):

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Temperature	Time
145 °F ¹	30 minutes
161 °F ¹	15 seconds
191 °F	1 second
204 °F	0.05 second
212 °F	0.01 second

¹ If the dairy ingredient has a fat content of 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F.

(c) *Ultra-pasteurized* when used to describe a dairy product means that such product shall have been thermally processed at or above 280 °F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

§ 131.25 Whipped cream products containing flavoring or sweetening.

The unqualified name “whipped cream” should not be applied to any product other than one made by whipping the cream that complies with the standards of identity for whipping cream (§§ 131.150 and 131.157 of this chapter). If flavoring and/or sweetening is added, the resulting product is a flavored and/or sweetened whipped cream, and should be so identified.

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 8¼ percent milk solids not fat and not less than 3¼ 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.

(1) Milkfat content—“Fat, Roesch-Gottlieb Method—Official Final Action,” section 16.059.

(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