

§ 130.20

21 CFR Ch. I (4–1–12 Edition)

(f) The terms and conditions of the permit may be modified at the discretion of the Food and Drug Administration or upon application of the permittee during the effective period of the permit.

(g) The Food and Drug Administration may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Food and Drug Administration concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the FEDERAL REGISTER stating that fact. The notice will include an invitation to all interested persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the FEDERAL REGISTER granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person

who accepts the invitation to participate in the extended market test shall notify the Food and Drug Administration in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the FEDERAL REGISTER.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related 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.

(l) 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

Subpart A—General Provisions

Sec.

131.3 Definitions.

131.25 Whipped cream products containing flavoring or sweetening.

Subpart B—Requirements for Specific Standardized Milk and Cream

- 131.110 Milk.
- 131.111 Acidified milk.
- 131.112 Cultured milk.
- 131.115 Concentrated milk.
- 131.120 Sweetened condensed milk.
- 131.125 Nonfat dry milk.
- 131.127 Nonfat dry milk fortified with vitamins A and D.
- 131.130 Evaporated milk.
- 131.147 Dry whole milk.
- 131.149 Dry cream.
- 131.150 Heavy cream.
- 131.155 Light cream.
- 131.157 Light whipping cream.
- 131.160 Sour cream.
- 131.162 Acidified sour cream.
- 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, con-

centrated 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):

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