

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

Subpart A—General Provisions

- Sec.
1210.1 Authority.
1210.2 Scope of act.
1210.3 Definitions.

Subpart B—Inspection and Testing

- 1210.10 Availability for examination and inspection.
1210.11 Sanitary inspection of dairy farms.
1210.12 Physical examination of cows.
1210.13 Tuberculin test.
1210.14 Sanitary inspection of plants.
1210.15 Pasteurization; equipment and methods.
1210.16 Method of bacterial count.
1210.17 Authority to sample and inspect.
1210.18 Scoring.

Subpart C—Permit Control

- 1210.20 Application for permit.
1210.21 Permit number.
1210.22 Form of tag.
1210.23 Permits granted on certificates.
1210.24 Temporary permits.
1210.25 Permits for pasteurized milk or cream.
1210.26 Permits for raw milk or cream.
1210.27 Permits waiving clauses 2 and 5, section 2 of the Federal Import Milk Act.
1210.28 Permits waiving clause 4, section 2 of the Federal Import Milk Act.

Subpart D—Hearings

- 1210.30 Hearing procedure for permit denial, suspension, and revocation.
1210.31 Hearing before prosecution.

AUTHORITY: 21 U.S.C. 141-149.

SOURCE: 38 FR 32104, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For Animal and Plant Health Inspection Service regulations concerning tubercular cattle, see 9 CFR parts 50 and 77. For Animal and Plant Health Inspection Service regulations, see 9 CFR chapter I. For customs regulations concerning importation of milk and cream, see 19 CFR 12.7. For regulations of the Agricultural Marketing Service (Marketing Agreements and Orders) covering marketing areas for milk, see 7 CFR chapter X.

Subpart A—General Provisions

§ 1210.1 Authority.

For the purposes of the regulations in this part the act (44 Stat. 1101; 21 U.S.C. 141-149) "To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" shall be known and referred to as "the Federal Import Milk Act."

§ 1210.2 Scope of act.

The provisions of the act apply to all milk and cream offered for import into the continental United States.

§ 1210.3 Definitions.

(a) *Secretary*. Secretary means the Secretary of Health and Human Services.

(b) *Commissioner*. Commissioner means the Commissioner of Food and Drugs.

(c) *Milk*. For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

(d) *Condensed milk*. Condensed milk, as the term is used in section 3, paragraph 2, of the Federal Import Milk Act, includes evaporated milk in the manufacture of which sterilization of the milk and cream is a necessary and usual process; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in section 3, paragraph 3, of the Federal Import Milk Act, means sweetened condensed milk.

(e) *Sweetened condensed milk*. Sweetened condensed milk conforms to the definition and standard of identity for

such food as set out in §131.120 of this chapter.

(f) *Evaporated milk.* Evaporated milk conforms to the definition and standard of identity for such food as set out in §131.130 of this chapter.

(g) *Cream.* Cream is that portion of the milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. (See §§131.150 through 131.157 of this chapter).

(h) *Pasteurization.* Pasteurization is the process of heating every particle of milk or cream to at least 143 °F., and holding it at such temperature continuously for at least 30 minutes, or to at least 161 °F., and holding it at such temperature continuously for at least 15 seconds.

(i) *Shipper.* A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

[38 FR 32104, Nov. 20, 1973, as amended at 42 FR 14091, Mar. 15, 1977]

Subpart B—Inspection and Testing

§ 1210.10 Availability for examination and inspection.

Dairy farms and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

§ 1210.11 Sanitary inspection of dairy farms.

The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms in the form prescribed by the Secretary.

§ 1210.12 Physical examination of cows.

(a) Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within one year previous to the time of the importation.

(b) The result of the physical examination shall be set forth in the form prescribed by the Secretary.

§ 1210.13 Tuberculin test.

(a) Except as provided in §1210.27 any and all animals in herds producing milk or cream which is to be shipped or transported raw into the United States shall be free from tuberculosis, as determined by a tuberculin test applied by an official veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced. Such test shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within 1 year previous to the time of the importation. All animals showing positive or suspicious reactions to the tuberculin test must be permanently removed from the herd.

(b) The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Secretary.

§ 1210.14 Sanitary inspection of plants.

The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points according to the methods for scoring as provided by the score card for sanitary inspection of such plants in the form prescribed by the Secretary.

§ 1210.15

21 CFR Ch. I (4-1-25 Edition)

§ 1210.15 Pasteurization; equipment and methods.

All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurization machinery of a type easily cleaned and of sanitary construction capable of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate time and temperature recording devices, which shall be kept at all times in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 2 years unless within that period they have been examined and released by such authorized agents as are designated by the Secretary.

§ 1210.16 Method of bacterial count.

The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

§ 1210.17 Authority to sample and inspect.

Inspectors engaged in the enforcement of the Federal Import Milk Act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.

§ 1210.18 Scoring.

Scoring of sanitary conditions required by §§ 1210.11, 1210.14 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

Subpart C—Permit Control

§ 1210.20 Application for permit.

Application for a permit to ship or transport milk or cream into the United States shall be made by the ac-

tual shipper upon forms prescribed by the Secretary. The request for forms of applications for permits should be addressed to Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

§ 1210.21 Permit number.

Each permit issued under the Federal Import Milk Act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

§ 1210.22 Form of tag.

Each container of milk or cream shipped or transported into the United States by such permittee shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

Product _____
 (State whether raw milk, pasteurized milk, raw cream, or pasteurized cream.)
 Permit number _____
 Federal Import Milk Act, Department of Health and Human Services.
 Shipper _____
 Address of shipper _____

Provided, That in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if sealed, may be tagged with the above tag, which should, in addition, show the number of containers and quantity of contents of each.

§ 1210.23 Permits granted on certificates.

In the discretion of the Secretary, a permit may be granted on a duly certified statement signed by a duly accredited official of an authorized department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Secretary, and shall have attached thereto, as a part thereof, signed copies of reports prescribed by §§ 1210.12, 1230.13, and also by §§ 1210.11, 1210.14, as applicable. The necessary inspections and examinations upon which the reports are based

shall be made by persons who are acting under the direct supervision of the certifying official.

§ 1210.24 Temporary permits.

A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the Federal Import Milk Act. Temporary permits shall be valid until the Secretary shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act have been complied with.

§ 1210.25 Permits for pasteurized milk or cream.

Permits to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11, 1210.12, 1210.14, as applicable.

§ 1210.26 Permits for raw milk or cream.

Except as provided in § 1210.27, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11 to 1210.14 as applicable.

§ 1210.27 Permits waiving clauses 2 and 5, section 2 of the Federal Import Milk Act.

A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the Federal Import Milk Act when the shipper is an operator of a creamery or condensery, or is a producer shipping or transporting to a creamery or condensery and the creamery or condensery is located in the United States within a radius of 20 miles of the point of production of such milk, and the milk, prior to its sale, use, or disposal, is pasteurized, condensed, or evaporated.

§ 1210.28 Permits waiving clause 4, section 2 of the Federal Import Milk Act.

The Secretary, in his discretion, will issue to a shipper who is an operator of a condensery a permit waiving the requirements of clause 4, of section 2 of the Federal Import Milk Act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensery is located within a radius of 15 miles of the point of production of the milk and cream and such milk and cream are to be sterilized in the manufacture of condensed milk.

Subpart D—Hearings

§ 1210.30 Hearing procedure for permit denial, suspension, and revocation.

Any person who contests denial, suspension, or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to subpart F of part 16 of this chapter.

[41 FR 48269, Nov. 2, 1976, as amended at 42 FR 15676, Mar. 22, 1977]

§ 1210.31 Hearing before prosecution.

Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

[41 FR 48269, Nov. 2, 1976]

PART 1230—REGULATIONS UNDER THE FEDERAL CAUSTIC POISON ACT

Subpart A—General Provisions

Sec.
1230.2 Scope of the act.
1230.3 Definitions.