

Legend: (Proposed New Rules)
Regular Print = Proposed new language

Subchapter A. Grade Specifications and Requirements for Milk.

§217.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Acidified milk--The food produced by souring cream, milk, partially skimmed milk, or skim milk or any combination, with acetic acid, adipic acid, citric acid, fumaric acid, glucono-delta-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, or tartaric acid, with or without the addition of characterizing microbial organisms. Acidified milk is further defined in Title 21, Code of Federal Regulations (CFR), §131.111.

(2) Acidified sour cream--The product resulting from the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria, and as further defined in Title 21, CFR, §131.162.

(3) Adulterated milk and milk products--Any milk or milk product shall be deemed to be adulterated if:

(A) it bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health;

(B) it bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal regulation, or in excess of such tolerance if one has been established;

(C) it consists, in whole or in part, of any substance unfit for human consumption;

(D) it has been produced, prepared, packed, or held under unsanitary conditions;

(E) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(F) any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is; or

(G) any milk or milk product shall be deemed to be adulterated if one or more of the conditions described in the Federal Food, Drug and Cosmetic Act, §402, as amended (Title 21 U.S.C., Part 342) exist.

(4) Aseptic processing--The term "aseptic processing," when used to describe a milk product, means that the product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of Title 21, CFR, Part 113 and maintain the commercial sterility of the product under normal non-refrigerated conditions.

(5) Aseptically processed milk and milk products--Products hermetically sealed in a container and so thermally processed in conformance with Title 21, CFR, Part 113 and the provisions of the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance), so as to render the product free of microorganisms capable of reproducing in the product under normal nonrefrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

(6) Bulk milk hauler/sampler--A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a certification from the department.

(7) Bulk milk pickup tanker--A vehicle, including the truck, tank and those appurtenances necessary for its use, used by a milk hauler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

(8) Certified milk sampler/collector--Any industry personnel, other than the milk hauler, or dairy plant sampler who collects more or stores an official milk sample.

(9) C-I-P or cleaned-in-place--The procedure by which sanitary pipelines or pieces of equipment are mechanically cleaned-in-place by circulation.

(10) Concentrated (condensed) milk--A fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming to the milkfat and milk solids not fat levels of milk as defined in this section.

(11) Concentrated (condensed) milk products--Homogenized concentrated (condensed) milk, concentrated (condensed) skim milk, concentrated (condensed) low fat milk, and similar concentrated (condensed) products made from concentrated (condensed) milk or concentrated (condensed) skim milk, and which, when combined with potable water in accordance with instructions printed on the container, conform to the definitions of the corresponding milk products in this section.

(12) Cream--The liquid milk product, high in milkfat, separated from milk, which may have been adjusted by adding thereto: milk, concentrated (condensed) milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk, and contains not less than 18% milkfat.

(13) Cultured milk--The food produced by culturing cream, milk, partially skimmed milk, or skim milk, used alone or in combination with characterizing microbial organisms. Cultured milk is further defined in Title 21, CFR, §131.112.

(14) Dairy farm--Any place or premises where one or more lactating animals (cows, goats or sheep, water buffalo, or other hooved animal) are kept, and from which a part or all of the milk or milk product(s) is provided, sold, or offered for sale to a milk plant, receiving station, or transfer station.

(15) Dairy plant or plant--Any place, premise, or establishment where milk or milk products are received or handled for processing or manufacturing.

(16) Dairy plant sampler--A department employee responsible for the collection of official samples for regulatory purposes outlined in §6 of the "Grade A Pasteurized Milk Ordinance."

(17) Dairy product--Butter, cheese, dry cream, plastic cream, dry whole milk, nonfat dry milk, dry buttermilk, dry whey, whey protein concentrates, evaporated milk (whole or skim), condensed whole milk and condensed skim milk (plain or sweetened), and such other products derived from milk, as may be specified under the statutory standard for butter (Title 21, U.S.C. Part 321a), and the Federal Standards of Identity for Cheese and Cheese Related Products (Title 21, CFR, Part 133).

(18) Dairy product manufacturer--Any place, premises or establishment where milk or milk products for manufacturing purposes are collected, handled, processed, dried, stored, pasteurized, ultra-pasteurized, aseptically processed, bottled, or prepared for distribution.

(19) Department--The Department of State Health Services, the Commissioner of Health, or his authorized representative. For purposes of this chapter, the Texas Department of Health is an equivalent term.

(20) Distributor--Any person who offers for sale or sells to another person any milk, milk products, or frozen dessert product.

(21) Drug--The term "drug" includes:

(A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States or official National Formulary, or any supplement to any of them;

(B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any articles specified in subparagraphs (A), (B) or (C) of this paragraph, but does not include devices or their components, parts or accessories.

(22) Eggnog--The food containing cream, milk, partially skimmed milk, or skim milk, used alone or in combination, liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing egg yolk containing products with liquid egg white or frozen egg white, and a nutritive carbohydrate sweetener. Eggnog is further defined in Title 21, CFR, §131.170.

(23) Federal Food Drug and Cosmetic Act (FFDCA)--The United States laws pertaining to food, drugs, and cosmetics as specified in Title 21 U.S.C., Chapter 9.

(24) Freezer--A piece of equipment which converts mix and/or other ingredients to a hardened or semi-hardened state using the technique of freezing during processing or manufacturing of those products commonly known as ice cream, ice cream mix, frozen dessert, frozen dessert mix, and nondairy frozen dessert mix.

(25) Frozen desserts--Any of the following: ice cream, light ice cream, ice milk, frozen custard, fruit sherbet, non-fruit water ice, frozen dietary dairy dessert, frozen yogurt, quiescently frozen confection, quiescently frozen dairy confection, mellorine, lorine, parevine, freezer-made milk shake, or nondairy frozen dessert. The term includes mix used in the freezing of one of those frozen desserts.

(26) Frozen dessert manufacturer or plant--A person who manufactures, processes, converts, partially freezes or freezes any mix, be it dairy, nondairy frozen desserts for distribution or sale at wholesale. This definition shall not include a frozen dessert retail establishment.

(27) Frozen dietary dairy dessert and frozen dietary dessert--A food for any special dietary use, prepared by freezing, with or without agitation, composed of a pasteurized mix which may contain fat, protein, carbohydrates, flavoring, stabilizers, emulsifiers, vitamins, and minerals.

(28) Frozen low fat yogurt and mix (also called low fat frozen yogurt)--Complies with the provisions of frozen yogurt, except that:

(A) the milk fat content of the finished food is not less than 0.5%, but not more than 2.0%; and

(B) the name of the food is "frozen low fat yogurt."

(29) Frozen low fat yogurt dry mix--The unfrozen dry powdered combination of ingredients which, when combined with potable water and when frozen while stirring, will produce a product conforming to the definition of frozen low fat yogurt.

(30) Frozen milk concentrate--A frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.

(31) Frozen skim milk yogurt--Complies with the provision of frozen yogurt, except that:

(A) the milkfat content of the finished food is less than 0.5%; and

(B) the name of the food is either "frozen skim milk yogurt" or "frozen nonfat yogurt".

(32) Frozen yogurt--

(A) Frozen yogurt is the food which is prepared by freezing, while stirring, a mix composed of one or more of the optional dairy ingredients provided for in ice cream and frozen custard, and which may contain other safe and suitable ingredients.

(B) The dairy ingredient(s), with or without other ingredients, is (are) pasteurized and subsequently cultured with bacterial cultures acceptable to the state health authority.

(C) The titratable acidity of the cultured frozen yogurt is not less than 0.5%, calculated as lactic acid, except if the frozen yogurt is flavored by the addition of a non-fruit characterizing ingredient(s).

(D) The milkfat content of frozen yogurt is not less than 3.25% by weight, except that when bulky characterizing ingredients are used the percentage milkfat is not less than 2.5%.

(E) The finished frozen yogurt shall weigh not less than five pounds per gallon.

(F) The name of the food is "frozen yogurt".

(33) Goats milk ice cream--The food defined in Title 21, CFR, §35.110(a)-(f).

(34) Goat milk--The normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5% milkfat and not less than 7.5% milk solids not fat. The word "milk" includes goat milk.

(35) Grade A dry milk and whey products--Products which have been produced for use in Grade A pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the most current revision of the "Grade A Pasteurized Milk Ordinance."

(36) Grade A Pasteurized Milk Ordinance--The document published by the United States Department of Health and Human Services, Public Health Service/Food and Drug Administration. The document consists of the following parts: The Grade A Pasteurized Milk Ordinance with Administrative Procedures; illustrations, tables, supplements, appendices; and an index. Copies are on file in the Milk Group, Division for Regulatory Services, Department of State Health Services, 8407 Wall Street, Austin, Texas, and are available for review during normal business hours. For purposes of this chapter, "U.S. Public Health Services Grade A Pasteurized Milk Ordinance" is an equivalent term.

(37) Grade A retail raw milk--Milk as defined in paragraph (49) of this section, that is produced under the provisions of Subchapter B (relating to Grade A Raw for Retail Milk and Milk Products), and is offered for sale to the public without benefit of pasteurization.

(38) Grade A retail raw milk products--Milk products that are manufactured under the provisions of Subchapter B (relating to Grade A Raw for Retail Milk and Milk Products), and are offered for sale to the public without benefit of pasteurization. These products include: cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, skim milk, low fat milk, eggnog, buttermilk, cultured milk, cultured low fat milk, cultured skim milk, yogurt, low fat yogurt, and nonfat yogurt.

(39) Half-and-half--The food consisting of a mixture of milk and cream which contains not less than 10.5% but less than 18% milkfat. Half-and-half is further defined in Title 21, CFR, §131.180.

(40) Heavy cream or heavy whipping cream--Cream which contains not less than 36% milkfat and as further defined in Title 21, CFR, §131.150.

(41) Hermetically sealed container--A container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

(42) Homogenized--The term "homogenized" means that milk or a milk product has been treated to insure breakup of the fat globules to such an extent that, after 48 hours of quiescent storage at 4.4 degrees Celsius (40 degrees Fahrenheit), no visible cream separation occurs on the milk; and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10% from the fat percentage of the remaining milk as determined after thorough mixing.

(43) Ice cream and frozen custard--The foods defined in Title 21, CFR, §135.110(a)-(f).

(44) Light cream--Cream which contains not less than 18% but less than 30% milkfat, and as further defined in Title 21, CFR, §131.155.

(45) Light whipping cream--Cream which contains not less than 30% but less than 36% milkfat, and as further defined in Title 21, CFR, §131.157.

(46) Lorine--The food prepared from the same ingredients and in the same manner prescribed for mellorine and complies with all the provisions for mellorine except that:

(A) its content of fat is at least 2% but less than 6%;

(B) its content of milk solids not fat is not less than 10%;

(C) caseinates may be added when the content of total milk solids is not less than 10%;

(D) the provision for reduction in fat and milk solids not fat from the addition of bulky ingredients in mellorine does not apply;

(E) the quantity of food solids per gallon is not less than 1.2 pounds; and

(F) the name of the food is "Lorine."

(47) Low fat yogurt--The food produced by culturing cream, milk, partially skimmed milk, or skim milk, used alone or in combination with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Low fat yogurt is further defined in Title 21, CFR, §131.203.

(48) Mellorine--The food defined in Title 21, CFR, §135.130(a)-(d).

(49) Milk--The lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, sheep, goats, water buffaloes or other hooved animals, and as further defined in Title 21, CFR, §131.110.

(50) Milk distributors--Any person who offers for sale or sells to another person any milk or milk products.

(51) Milk hauler--Any person who transports raw milk and/or raw milk products to or from a milk plant, receiving station, or transfer station.

(52) Milk plant--Any place, premises or establishment where milk or milk products are collected, handled, processed, dried, stored, pasteurized, ultra-pasteurized aseptically processed,

bottled, or prepared for distribution. This term also means a processing plant, manufacturing plant, or bottling plant in these sections.

(53) Milk producer--Any person who operates a dairy farm and provides, sells or offers milk for sale to a milk plant, receiving station, or transfer station.

(54) Milk products--

(A) Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half- and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, reduced fat milk, nonfat (skim) milk, low fat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured low fat milk, cultured nonfat (skim) milk, yogurt, low fat yogurt, nonfat yogurt, acidified milk, acidified low fat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium low fat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced low fat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this section, milk, low fat milk, or nonfat (skim) milk with added safe and suitable microbial organisms, and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification of milk products defined herein.

(B) Milk products also include those dairy foods made by modifying the federally standardized products listed in this section in accordance with Title 21, CFR, §130.10, Requirements for foods named by use of nutrient content claim and standardized term.

(C) This definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.

(D) Milk and milk products which have been retort processed after packaging or which have been concentrated, condensed, or dried are included in this definition only if they are used as an ingredient to produce any milk or milk product defined herein, or if they are labeled as Grade A.

(E) This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other desserts, butter, or cheese.

(55) Milk for manufacturing purposes--Milk and milk products for human consumption, but not subject to Grade A requirements.

(56) Milk tank truck--The term used to describe both a bulk milk pickup tanker and a milk transport tank.

(57) Milk tank truck driver--A milk tank truck driver is any person who transports raw or pasteurized milk products to or from a milk plant, receiving station, or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

(58) Milk transport tank or tanker--A vehicle, including the truck and tank, used by a milk hauler to transport bulk shipments of milk from a milk plant, receiving station, or transfer station to another milk plant, receiving station, or transfer station.

(59) Misbranded milk and milk products--Milk and milk products are misbranded if:

(A) its container(s) bear or are accompanied by any false or misleading written, printed, or graphic matter;

(B) milk does not conform to the definitions as contained in these rules;

(C) milk is not labeled in accordance with §217.25 of this title (relating to Labeling) for Grade A Raw for Retail Milk and Milk Products; §217.43 of this title (relating to Labeling) for Rules for the Manufacture of Frozen Desserts; §217.81 of this title (relating to Labeling) for Dairy Product Manufacturers; or

(D) one or more of the conditions described in §403 of the Federal Food, Drug and Cosmetic Act, as amended (Title 21, U.S.C., Part 343) exist.

(60) Milk transportation company--A milk transportation company is the person responsible for a milk tank truck(s).

(61) Multi-use container--Any container having a product contact-surface and used in the packaging, handling, storing, or serving of milk or milk products, which, if it remains in good repair and is properly washed and sanitized, may be utilized for multiple usage.

(62) Nondairy frozen dessert--

(A) Nondairy frozen dessert is the food which is prepared by freezing, while stirring, a nondairy frozen dessert mix composed of one or more of the optional characterizing ingredients specified in subparagraph (B) of this paragraph, sweetened with one or more of the optional sweetening ingredients specified in subparagraph (C) of this paragraph. The nondairy product, with or without water added, may be seasoned with salt. One or more of the ingredients specified in subparagraph (D) of this paragraph may be used. Pasteurization is not required. The optional caseinates specified in subparagraph (D)(i) of this paragraph are deemed not to be dairy products.

(B) The optional flavoring ingredients referred to in subparagraph (A) of this paragraph are natural and artificial flavoring and characterizing food ingredients.

(C) The optional sweetening ingredients referred to in subparagraph (A) of this paragraph are sugar (sucrose), dextrose, invert sugar (paste or syrup), glucose syrup, dried glucose syrup, corn sweetener, dried corn sweetener, malt syrup, malt extract, dried malt syrup, dried malt extract, maltose syrup and dried maltose syrup.

(D) Other optional ingredients referred to in subparagraph (A) of this paragraph are:

(i) casein prepared by precipitation with gums, ammonium, caseinate, calcium caseinate, potassium caseinate, or sodium caseinate;

(ii) hydrogenated and partially hydrogenated vegetable oil;

(iii) dipotassium phosphate;

(iv) coloring, including artificial coloring;

(v) monoglycerides, diglycerides, or polysorbates; and

(vi) thickening ingredients such as agar-agar, algin (sodium alginate), egg white, gelatin, gum acacia, guar seed gum, gum karaya, locus bean gum, oat gum, gum tragacanth, hydroxypropyl, cethyl cellulose, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, propylene glycol alginate, pectin, psyllium seed husk, and sodium carboxymethylcellulose.

(E) Such nondairy frozen desserts are deemed "processed" when manufactured as a dry powdered mix. The addition of water is merely the manner in which such nondairy frozen desserts are served.

(F) The label shall comply with labeling requirements for frozen desserts with the additional clear and concise statement that the product is nondairy.

(63) Nonfat yogurt--The food produced by culturing skim milk, used alone or in combination with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Nonfat yogurt is further defined in Title 21, CFR, §131.206.

(64) Novelties--Frozen desserts, either alone or in combination with other foods such as cookies, wafers, cones, coating, confections, etc., which are packaged in single-serving units.

(65) Official laboratory--A biological, chemical or physical laboratory which is under the direct supervision of the State or a local regulatory agency.

(66) Overrun--The trade expression used to reference the increase in volume of frozen product over the volume of the mix. This increase in volume is due to air being whipped into the product during the freezing process. It is expressed as a percent of the volume of the mix.

(67) Officially designated laboratory--A commercial laboratory authorized to do official work by the regulatory or supervision agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of milk, milk products, or frozen desserts.

(68) Pasteurization--

(A) The terms "pasteurization," "pasteurized," and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, and held continuously at or above a certain temperature for at least the corresponding specified time as shown in the following chart and referenced in the most current revision of the "Grade A Pasteurized Milk Ordinance."

Figure: 25 TAC §217.1(68)(A)

(B) Provided, that eggnog and frozen dessert mixes shall be heated to at least the temperature and time specifications in the following chart.

Figure: 25 TAC §217.1(68)(B)

(C) Provided further, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the United States Food and Drug Administration (FDA) as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(69) Permit--A license or certification to engage in the activity listed on the permit, license, or certificate.

(70) Person--The word "person" shall include any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

(71) Producer dairy farm--Any place or premises where one or more lactating animals (cows, goats or sheep, water buffalo, or other hooved animal) are kept, and from which a part or all of the milk or milk product(s) is provided, sold, or offered for sale to a milk plant, transfer station, or receiving station.

(72) Quiescently frozen confection--A clean and wholesome frozen, sweetened, flavored product in the manufacture of which freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing). This confection may be acidulated with food grade acid, may contain water, may be made with or without added natural or artificial flavoring, and with or without harmless coloring. The finished product shall contain not less than 17% by

weight of total food solids. In the production of this food, no processing or mixing shall be used that develops in the finished food mix any physical expansion in excess of 10%.

(73) Quiescently frozen dairy confection--A clean and wholesome frozen product made from water, milk products and sugar, with added harmless natural or artificial flavoring, with or without added coloring, with or without added stabilizer, with or without added emulsifier; and in the manufacture of which freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing). It contains not less than 13% by weight of total milk solids, and not less than 33% by weight of total food solids. In the production of quiescently frozen dairy confections, no processing or mixing prior to quiescently freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10%.

(74) Receiving station--Any place, premises, or establishment where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

(75) Reconstituted or recombined milk and milk products--Milk or milk products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

(76) Regulatory agency--The Department of State Health Services. For purposes of this chapter, Texas Department of Health is an equivalent term.

(77) Safe and suitable--Ingredients which perform an appropriate function in the food in which they are used, and are used at a level no higher than necessary to achieve their intended purpose in the food.

(78) Sale--Shall mean any of the following:

(A) the manufacture, production, processing, packing, exposure, offer, or holding of any milk, milk product, or frozen dessert product.

(B) the sale, dispensing, or giving of any milk, milk product, or frozen dessert product; or

(C) the supplying of any milk, milk product, or frozen dessert to a retail establishment or to a consumer.

(79) Sanitization--The application of any effective method or substance to a clean surface for the destruction of pathogens and other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers, and shall be acceptable to the regulatory agency.

(80) Sherbet--The food defined in Title 21, CFR, §135.140(a)-(i).

(81) Single service container--Any container having a milk product or frozen dessert, in contact with the containers surface and used in the packaging, handling, storing, or serving frozen desserts and/or milk products, which is intended for one usage only.

(82) Sour cream or cultured sour cream--The product resulting from the souring, by lactic acid producing bacteria, of pasteurized cream, and as further defined in Title 21, CFR, §131.160.

(83) Standard methods--Reference to the latest edition of "Standard Methods for the Examination of Dairy Products," a publication of the American Public Health Association, Washington, D.C.

(84) Sterilized--The term sterilized when applied to piping, equipment, and containers used for milk and milk products shall mean the condition achieved by the application of heat, chemical sterilant(s), or other appropriate treatment that renders the piping, equipment, and containers free of viable microorganisms.

(85) 3-A Sanitary Standards and Accepted Practices--Refers to the standards for dairy equipment and accepted practices formulated by the 3-A Sanitary Standards committees representing the International Association for Food Protection, the U.S. Public Health Service, and the Dairy Industry Committee that are published by the International Association of Milk, Food, and Environmental Sanitarians, 6200 Aurora Avenue, #200W, Des Moines, Iowa 50322.

(86) 3-A Sanitary Committee--The committee composed of appointees from the International Association for Food Protection, and the Food and Drug Administration/Public Health Service that reviews and establishes standards for production and processing equipment intended for use in this country.

(87) Milk tank truck cleaning facility--Any place, premise, or establishment, separate from a milk plant, receiving, or transfer station, where a milk tank truck is cleaned and sanitized.

(88) Transfer station--Any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

(89) Ultra-pasteurized--The term "ultra-pasteurized," when used to describe a dairy product, means that such product shall have been thermally processed at or above 138 degrees Celsius (280 degrees Fahrenheit) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

(90) Unloading station--Any receiving station, transfer station, or milk processing plant where milk or milk products are unloaded from milk tank trucks.

(91) Water ices--The foods defined in Title 21, CFR, §135.160.

(92) Whipped cream--Cream or light whipping cream, into which air or gas has been incorporated.

(93) Whipped light cream--Light cream into which air or gas has been incorporated.

(94) Yogurt--The food produced by culturing cream, milk, partially skimmed milk, or skim milk, used alone or in combination with a characterizing bacterial culture that contains the lactic acid- producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Yogurt is further defined in Title 21, CFR, §131.200.

§217.2. Grade A Pasteurized Milk Ordinance. The Department of State Health Services adopts by reference the document entitled, "Grade A Pasteurized Milk Ordinance," published by the United States Department of Health and Human Services, Public Health Service/Food and Drug Administration. The document consists of the following parts: The Grade A Pasteurized Milk Ordinance with Administrative Procedures; illustrations, tables, supplements, appendices; and an index. Copies are on file in the Milk Group, Division for Regulatory Services, Department of State Health Services, 8407 Wall Street, Austin, Texas, and are available for review during normal business hours.

Subchapter C. Rules for the Manufacture of Frozen Desserts.

§217.41. Introduction. These sections provide for uniformity of inspections of the premises of frozen desserts manufacturers; protect the health and safety of consumers by preventing the manufacture or distribution of frozen desserts, products sold in semblance of frozen desserts, or mixes for those products that do not meet state requirements or related requirements of purity or labeling; and assist manufacturers in meeting state requirements.

§217.42. Permits. Every frozen desserts manufacturer located in the State of Texas, and every frozen desserts manufacturer that exports frozen desserts into the State of Texas shall secure a permit. Only a person who complies with the requirements of these rules shall be entitled to receive and retain such a permit.

§217.43. Labeling.

(a) The labeling on all packages or containers of frozen desserts or mix designed for sale at retail shall clearly and conspicuously include:

(1) the name of the food as provided for in the definitions and standards established by this chapter;

(2) quantity of contents;

(3) name and address of the manufacturer, packer or distributor, provided that, in addition, the manufacturer's plant code number shall appear if the manufacturer's name and address are not included on the label; and

(4) flavor labeling, if the food contains any added characterizing ingredients.

(b) The label information shall be in letters of a size, style and color which are approved by the department, and shall contain no marks or words which are misleading. The label may contain ingredient and/or nutrition information, provided the information is in compliance with Title 21, Code of Federal Regulations.

§217.44. Inspection of Frozen Desserts Plants.

(a) Prior to the issuance of a permit, and at least once every three months thereafter, the department shall inspect all frozen desserts plants within the State of Texas, the products of which are intended for consumption within the State of Texas, and shall make as many additional inspections as are necessary for the enforcement of these rules. If the department representative discovers the violation of any sanitation requirement, a representative shall make a second inspection after a lapse of such time as the representative may deem necessary for the defect to be remedied, but not before the lapse of three days. The second inspection shall be used in determining compliance with these regulations. Any violation of the same sanitation requirement of these regulations on two consecutive inspections shall be the basis for immediate suspension of permit.

(b) The original copy of the inspection report shall be posted by the department in a conspicuous place upon an inside wall of the frozen desserts plant and said inspection report shall not be defaced or removed by any person except the department. Another copy of such inspection report shall be filed with the records of the department.

(c) Every processor or manufacturer of mix or frozen desserts shall permit upon request a department representative access to all parts of the frozen dessert or mix establishment; and shall furnish the department, upon request, a true statement of the actual quantities of mix or frozen desserts used or produced.

§217.45. Examination and Standards for Frozen Desserts.

(a) During any consecutive six months, at least four samples of raw milk intended for use in the manufacture of frozen desserts shall be collected and examined by the department. In addition, during any consecutive six months, the department shall collect and examine at least four samples of frozen desserts from dairy retail stores, food service establishments, grocery stores, and other places where frozen desserts are sold may be examined periodically as determined by the department. Proprietors of such establishments shall furnish the department, upon request, with the names of all distributors from whom frozen desserts, or frozen desserts mix are obtained. The examination of samples of pasteurized mix, and/or frozen desserts shall be performed in an official laboratory or in an officially designated laboratory.

(b) Bacterial counts, coliform determinations, phosphatase, tests, and other laboratory and screening tests shall conform to the procedures in the latest edition of "Standard Methods for the Examination of Dairy Products" of the American Public Health Association. Examinations and

tests shall include such other biological, chemical, and physical determinations as the department shall deem necessary for the detection of adulteration.

(c) Whenever two of the last four consecutive bacterial counts, coliform determinations, or cooling temperatures taken on separate days exceed the limit of the standard for the milk, cream, milk products, mix or frozen desserts, the department shall send a written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed the limit of the standards. An additional sample shall be taken within 21 days of the date of such notice, but not before the lapse of three days. Immediate product suspension or other appropriate department or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts, coliform determinations or cooling temperatures of samples collected within the six-month period.

(d) The department shall establish the frequency of sampling pasteurized mix or frozen desserts during each six month period for adequate pasteurization as determined by a phosphatase test. In the case of a confirmed positive result, the probable cause shall be determined by and corrected to the satisfaction of the department before the mix is frozen or the frozen dessert is sold.

(e) No process or manipulation other than pasteurization as set forth in §217.1 of this title (relating to Definitions) of these rules, processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating organisms, provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the United States Food and Drug Administration (FDA) as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(f) Raw milk for use in the manufacture of frozen desserts shall comply with all standards set forth in §217.73 of this title (relating to Raw Milk for Manufacturing Purposes).

(g) Frozen desserts and mix shall comply with the following standards:

(1) bacterial, coliform, and temperature standards for pasteurized mix and frozen desserts as shown in the following chart:

Figure: 25 TAC §217.45(g)(1)

(2) bacterial, coliform, and temperature standards for nondairy frozen desserts and nondairy frozen desserts mix as shown in the following chart:

Figure: 25 TAC §217.45(g)(2)

§217.46. Sanitation Standards for Frozen Desserts Plants.

(a) Floors. The floors of all rooms in which mix, frozen desserts, or their ingredients are manufactured, processed, or frozen, or in which containers and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material, and shall be smooth, properly drained, provided with trapped drains, and kept clean and in good repair; provided, that cold storage rooms used for storing frozen desserts and cold storage rooms used for storing milk, cream, or milk products, frozen fruits, frozen eggs, and comparable ingredients need not be provided with floor drains but the floors shall be sloped to drain to one or more exits, and shall be kept clean and in good repair; provided that, dry storage rooms need not be drained and tight wood floor construction is optional. Provided further, that the construction requirements of this item shall be waived in the case of frozen desserts establishments, if that portion of the room in which the freezer is installed and the room in which containers or utensils are washed have floors of metal, durable grades of linoleum or plastic, or tight wood impregnated with plastic in lieu of concrete.

(b) Walls and ceilings. Walls and ceilings of rooms in which mix, frozen desserts, or their ingredients are manufactured, processed, or frozen, or in which containers or utensils are washed shall have easily cleanable, washable light-colored surfaces, and shall be kept clean and in good repair.

(c) Doors and windows. Unless other effective means are provided to prevent the access of flies, all openings to the outer air shall be effectively screened, and all doors shall be self-closing.

(d) Lighting and ventilation.

(1) All rooms shall be well lighted.

(2) All rooms shall be well ventilated.

(e) Miscellaneous protection from contamination.

(1) Frozen desserts plant operations shall be located and conducted as to prevent any contamination of the ice cream, ice cream mix, frozen desserts, frozen desserts mix, or their ingredients, or of cleaned equipment.

(A) All milk, milk products, cream, mix or frozen desserts that have been spilled, overflowed, or leaked shall be discarded.

(B) All milk, milk products, cream or mix drained from equipment at the end of a run shall be handled in a sanitary manner and shall be repasteurized.

(C) All necessary and appropriate means shall be used for the elimination of flies, other insects and rodents.

(D) Rooms shall be free of flies.

(E) There shall be separate rooms for:

(i) pasteurization, processing, cooling, freezing, and packaging operations; and

(ii) the washing and bactericidal treatment of multi-use containers.

(F) Unless all milk, cream, mix or milk products are received in bulk transport tanks, a receiving room separate from rooms as defined in subparagraph (E)(i) and (ii) of this paragraph shall also be required; provided, that the requirement in subparagraph (E)(i) of this paragraph shall be satisfied when a frozen dessert manufacturer blends, freezes, and packages in a manner to prevent contamination; provided further, that frozen desserts, milk, milk products, and ingredients shall not be unloaded directly into the room or rooms used for pasteurizing.

(G) Pasteurized mix or frozen desserts shall not be permitted to come in contact with equipment or containers with which unpasteurized mix, frozen desserts, cream, milk or milk products have been in contact, unless such equipment has first been thoroughly cleaned and subjected to a bactericidal treatment.

(H) Rooms in which milk or milk products, cream, mix or frozen desserts are handled or stored shall not open into any stable or living quarters.

(I) The milk plant, frozen dessert plant, containers, utensils, and equipment shall be used for no purpose other than the processing of milk, cream, milk products, mix, and frozen desserts, and the operation incident thereto, except as may be approved in writing by the department.

(2) The pump-out of the transport tank shall be done in an area where a cover extends over the complete transport tank or, where climatic and operating conditions require, in a completely enclosed area. Pump-out operations must be protected in such a manner as to prevent product contamination. If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or the air inlet vent.

(3) The agitating and sampling of the transport tank milk shall be accomplished in such a manner as to provide maximum protection against product contamination. In no instance shall this be done at a place other than an approved unloading station.

(4) The frozen dessert plant shall record the following information on each load of milk received, and maintain these records for a period of not less than 90 days:

(A) the date the load was received;

(B) the time received;

- (C) the number of pounds in the load;
- (D) the temperature of the milk or milk products when received;
- (E) the permit number of the truck delivering the milk; and
- (F) the name of the station operator receiving the milk.

(5) If the frozen dessert plant is also utilized as the milk tank truck cleaning facility, the transport tank cleaning tag shall be removed and kept with the other records for a period of 15 days.

(6) In no case shall milk or milk products be received from a transport tank that appears to be damaged, dirty, or does not have a cleaning tag attached without the written permission of the department.

(f) Toilet facilities. Every frozen desserts plant shall be provided with conveniently located toilet facilities conforming with the state, local and county ordinances. Toilet rooms shall not open into any room in which mix is processed or handled. The doors of all toilet rooms shall be self-closing. Toilet rooms shall be kept in a clean condition, in good repair and well ventilated. A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms used by employees.

(g) Water supply. The water supply shall be easily accessible, adequate, and of a safe sanitary quality.

(h) Handwashing facilities. Convenient handwashing facilities shall be provided, including hot and cold running water, soap, and approved sanitary towels. Handwashing facilities shall be kept clean. The use of a common towel is prohibited. Employees shall not resume work after using the toilet room without washing their hands.

(i) Sanitary piping and fittings. All piping and fittings used to conduct milk, cream, milk products, mix or frozen desserts shall be of sanitary design and construction which meets 3-A Sanitary Standards and Accepted Practices. Mix, frozen desserts, fluid milk products, and ingredients shall be conducted from one piece of equipment to another only by sanitary piping and fittings.

(j) Construction and repair of containers, utensils, and equipment.

(1) All multi-use containers, utensils, and equipment with which mix, frozen desserts, milk, cream, and milk products, and ingredients come in contact shall be of smooth, impervious, noncorrodible, nontoxic, relatively low absorbent material; shall be easily cleanable and shall be kept in good repair.

(2) All single-service containers, closures, gaskets, and other articles shall be manufactured, packaged, transported, and handled in a sanitary manner.

(k) Disposal of wastes. All wastes shall be disposed of in a sanitary manner. All plumbing and appurtenances thereto shall be so designed and installed as to prevent the contamination of frozen desserts or any ingredient, utensil, container, or equipment by drip, condensation, or backflow.

(l) Cleaning and bactericidal treatment of multi-use utensils, containers, and equipment. All multi-use containers and utensils shall be thoroughly cleaned after each use and all equipment shall be thoroughly cleaned at least once each day of use, unless the department has reviewed and accepted information in writing, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one day or 72 hours in the case of storage tanks, or 44 hours in the case of evaporators, which are continuously operated. Supporting information shall be submitted to and approved by the department prior to initiating the qualification period if required. Any significant equipment or processing changes shall be communicated to the department, and may result in a re-verification of the extended run proposal, if it is determined that the change could potentially affect the safety of the finished milk or milk product(s).

(m) Storage of multi-use utensils, containers, and equipment. After cleaning, all multi-use utensils, containers, and equipment shall be stored to drain dry, and in such a manner as not to be contaminated before usage.

(n) Storage of single-service containers, utensils, and materials. Caps, parchment papers, wrappers, liners, gaskets and single-service sticks, spoons, covers, and containers for frozen desserts, mix, or their ingredients shall be purchased and stored only in sanitary tubes, wrappings, or cartons; shall be kept thereafter in a clean, dry place until used; and shall be handled in a sanitary manner. Reuse of single-service articles is prohibited.

(o) Handling of containers and equipment. Between bactericidal treatment and usage, and during usage, containers and equipment shall not be handled or operated in such a manner as to permit contamination of the mix, frozen desserts, or their ingredients. Pasteurized mix and frozen desserts shall not be permitted to come into contact with equipment with which unpasteurized mix, milk, cream, or milk products have been in contact, unless the equipment has been thoroughly cleaned and effectively subjected to an approved bactericidal process.

(p) Pasteurization of mix.

(1) Every particle of the combined milk, cream, milk product, or other ingredients used in the manufacture of a frozen dessert mix shall be heated and held at temperatures of not less than 155 degrees Fahrenheit for not less than 30 minutes; 180 degrees Fahrenheit for not less than 15 seconds; or 175 degrees Fahrenheit for not less than 25 seconds.

(2) All pasteurization equipment and related appurtenances shall meet construction and operational requirements outlined in the latest edition of the "Grade A

Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance).

(3) Nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the United States Food and Drug Administration (FDA) as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(q) Cooling and handling. All milk, cream, and milk products in fluid form received at the frozen desserts plant for use in frozen desserts mix shall be cooled to a temperature of 45 degrees Fahrenheit or less and maintained at that temperature until pasteurized; and all pasteurized mix shall be cooled in approved equipment to a temperature of 45 degrees Fahrenheit or less and shall be maintained thereat until frozen.

(r) Packaging and dispensing. Packaging, cutting, molding, dispensing, and other preparation of mix, or frozen desserts, or their ingredients shall be done in a sanitary manner. Containers shall be completely covered immediately after filling unless dispensed to a patron. Closures, covers, and wrappers shall be handled in such a manner as to prevent contamination of the package content.

(s) Returns. Packaged mix, or frozen desserts which have physically left the premises or the frozen dessert plant shall not be re-pasteurized to be sold or used for making frozen desserts.

(t) Overflow and spillage. Product drip or overflow, or spilled mix, or frozen desserts, or their ingredients, shall not be sold for human consumption.

(u) Personnel health. No person while affected with any disease in a communicable form, or while a carrier of such disease, or while afflicted with boils, infected wounds, sores, or an acute respiratory infection, shall engage in pasteurizing, handling of ingredients, filling, packaging, or freezing operations or in any capacity in which there is a likelihood of such person contaminating mix and frozen desserts, or mix and frozen dessert-contact surfaces with pathogenic organisms, or transmitting disease to other individuals; and no person known or suspected of being affected with any such disease or condition shall be employed in such a capacity. If the management of the frozen desserts plant has reason to suspect that any employee has contracted any disease in a communicable form or has become a carrier of such disease, the employee shall notify the department immediately.

(v) Personnel cleanliness. All persons who come in contact with milk, cream, milk products, mix, and frozen desserts containers or equipment, shall wear clean outer garments, hair restraints and shall keep their hands clean at all times while engaged in such work.

(w) Vehicles.

(1) All vehicles used for the transportation of mix, frozen desserts, cream, milk, and milk products shall be constructed and operated so as to protect their contents from the sun and contamination. Such vehicles shall be kept clean, and no substance capable of contaminating mix, frozen desserts, cream, milk, and milk products shall be transported therein. Such vehicles shall have the name of the distributor prominently displayed thereon.

(2) Tank cars and tank trucks used for transporting mix, cream, milk, and milk products shall comply with the construction, cleaning, bactericidal treatment, storing, and handling requirements of subsections (e), (j), (l), and (m) of this section (relating to Sanitation Standards for Frozen Desserts Plants). Each shipment shall be sealed and labeled in a manner approved by the department.

(x) Ingredients. All mix and frozen dessert ingredients shall be clean, have a fresh wholesome flavor and odor and normal appearance, be of satisfactory quality, and be stored, handled, and processed in a sanitary manner.

(y) Raw product storage.

(1) All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Raw milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45 degrees Fahrenheit or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(2) The bacteriological quality of commingled raw milk for use in the manufacture of frozen desserts shall not exceed 500,000 per milliliter.

§217.47. Frozen Desserts Which May Be Sold. No frozen desserts that have been manufactured in Texas shall be sold to the final consumer or to restaurants, soda fountains, grocery stores, dairy stores, or similar establishments within the State of Texas, unless it has been manufactured and frozen in a plant conforming with the requirements of this subchapter.

§217.48. Transferring and Dispensing Frozen Desserts. Except as permitted by the department, no person shall transfer frozen desserts from one container to another on the street, or in any vehicle or store, or in any place except under sanitary conditions.

§217.49. Mix and Frozen Desserts from Points Beyond the Limits of Routine Inspection.

(a) Generally. Frozen desserts from points beyond the limits of routine inspection of the State of Texas may be sold in the State of Texas, provided they are manufactured and/or pasteurized under provisions which are substantially equivalent to the requirements of this regulation as determined in writing by the department.

(b) Approval of supplies. Subject to laboratory tests upon arrival, the department shall approve, without inspection, supplies of frozen dessert mix, and frozen desserts from an area not under the department's routine inspection:

(1) when these products are manufactured and/or pasteurized under regulations equivalent to those of this regulation; or

(2) when these products are under routine official supervision.

§217.50. Plans for Construction and Reconstruction of Frozen Desserts Plants.

(a) All frozen desserts plants in the State of Texas, which are constructed or extensively altered, shall obtain signed approval from the department for said construction before work is begun.

(b) All new frozen desserts plants applying for a permit, and all new construction, reconstruction, or extensive alterations made shall comply with the requirements of this regulation.

§217.51. Procedure When Infection Is Suspected. When probable cause exists to suspect the possibility of infection from any person concerned with the handling of mix, frozen desserts, or their ingredients, the department is authorized to require any or all of the following measures:

(1) the immediate exclusion of that person from handling mix, frozen desserts, or their ingredients;

(2) the immediate exclusion of the mix or frozen desserts concerned from distribution and use; and

(3) adequate medical examination of the person before returning to frozen dessert handling.

Subchapter D. Bulk Milk Regulations.

§217.61. Bulk Milk Hauler/Sampler Qualifications and Requirements.

(a) Requirements for bulk milk hauler/sampler certifications.

(1) Each hauler/sampler shall complete a comprehensive training program provided by the department, which shall include a course teaching specific procedures necessary to properly handle milk from the dairy farm to the plant, receiving station, or transfer station. This program shall further include practical field training sufficient to develop a proficient working knowledge of proper bulk milk handling procedures.

(2) After training has been completed, each hauler/sampler shall pass a qualifying examination administered by the department. Candidates failing the exam with a score of less than 70%, shall be denied permits or licenses until they can achieve a passing score of 70%. The examination should be adequate enough to determine if a bulk milk hauler/sampler is competent. The exam shall be composed of a minimum of 20 total questions broken down into the following areas:

- (A) six questions relating to sanitation and personal cleanliness;
- (B) six questions relating to sampling and weighing procedures;
- (C) four questions relating to equipment, including proper use, care, cleaning, etc.; and
- (D) four questions relating to proper record keeping requirements.

(3) An industry sponsored training program may be used in lieu of this program, provided that:

- (A) such training program meets or exceeds the minimum standards and requirements set forth in these regulations;
- (B) the department has issued a letter indicating the acceptance of the training program; and
- (C) the qualifying examination is administered by the department.

(4) Bulk milk haulers/samplers successfully qualifying by examination and who have been satisfactorily evaluated in the field will be certified by the department to perform milk hauler/sampler duties. Only those milk haulers/samplers having certification issued by the department or by the authorized Regulatory Agency of another state will be allowed to remove milk from a farm bulk milk tank and collect milk samples for laboratory examination.

(5) All official milk samplers, including bulk milk haulers/samplers, shall be evaluated at least once every 24 months by the department or by the authorized Regulatory Agency of another state.

(6) The department may issue temporary hauler/sampler certifications in emergency situations without the prescribed examinations, evaluation and training program, provided acceptable certification of competence is made by the employer of the individual. A temporary permit is only valid for 30 days.

(7) The department may suspend a hauler/sampler certification when, upon investigation, the department finds a violation of any of the following:

(A) this subchapter; or

(B) §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance).

(b) Procedure and Handling Requirements.

(1) Each bulk milk pickup tanker shall be supplied with sanitized sample bottles or bags, other sampling equipment, and supplies necessary, as required in §217.2 of this title to clean and sanitize multi-use equipment used in sampling and pickup operations.

(2) All bulk milk haulers operating bulk milk pickup tankers shall make available to the department upon request a copy of the load manifest and a current list of producers for each route pickup load with the following information:

(A) the producer name and number in the order of milk pickup;

(B) the time of arrival at each dairy;

(C) the time of arrival at the unloading station;

(D) the name and address of the unloading station; and

(E) the hauler/sampler name and driver's license number.

§217.62. Bulk Milk Holding Tanks.

(a) Farm bulk milk tanks shall have a capacity adequate for production between routine pickups. The time between pickups shall not exceed every other day. Milk must be of sufficient quantity for adequate mechanical agitation at the completion of the first milking.

(b) Farm bulk milk tanks shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20% of its calibrated capacity.

(c) Farm bulk milk tanks will be equipped with easily accessible sampling ports or a sample cock.

(d) Farm bulk milk tanks shall comply with the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance).

§217.63. Milk Tank Trucks.

(a) Each milk tank truck used to transport milk or milk products to or from a dairy farm, milk plant, or receiving station, shall be permitted by the department or by the authorized Regulatory Agency of another state. Failure to obtain a permit may result in the milk tank truck and its contents being immediately removed from Grade A or food use.

(b) All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. The permit sticker issued by the department shall be placed near the outlet valve of the tanker truck or trailer.

(c) All milk tank trucks must be inspected prior to the issuance of a permit and a minimum of once each 12 months thereafter. The requirement for this annual inspection does not eliminate or supersede other licenses or permits required by any other official regulatory agency. The owner or manager of the milk transportation company will report verbally or in writing to the department, within ten days, any milk transport tanks taken out of service or severely damaged.

(d) Milk tank trucks must be operated in compliance with the following provisions.

(1) Permanently installed milk tank truck washing equipment must be in compliance with the current edition of the 3-A Sanitary Standards and Accepted Practices at the time of installation and be approved by the department. This equipment shall be so designed that it will properly clean and sanitize all milk-contact surfaces when connected to a cleaning system at an approved milk tank truck cleaning facility.

(2) Each bulk milk pickup tanker shall be provided with adequate space for sanitary storage, without overcrowding, of fittings, valves, milk pumps, racks for milk conducting equipment, wrenches, sample bottles, dippers, solutions for washing and sanitizing milk contact equipment, and all other equipment used for milk handling and sampling purposes.

(3) When compartment milk tank trucks are used, Grade A milk shall not be permitted to be hauled in one compartment while ungraded milk or another product is being hauled in another compartment on the same tanker.

(4) Agitating and sampling milk in a milk tank truck shall be accomplished in such a manner as to provide maximum protection against product contamination. In no instance shall these activities be performed at a place other than a location approved by the department.

(5) Milk tank trucks may not be used to transport poisonous or toxic substances.

(6) Milk tank trucks transporting pasteurized milk or milk products that will not be repasteurized at the receiving milk processing plant shall not be used to transport raw milk, raw egg products, or any other product determined by the department to be a source of microbiological or chemical contamination.

§217.64. Unloading Stations and Milk Tank Truck Cleaning Facilities.

(a) Milk tank truck unloading stations.

(1) When the milk tank truck unloading station is a receiving station or a milk processing plant, it shall comply with the following sanitation requirements for Grade A pasteurized milk as specified in the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance): floors; walls and ceilings; doors and windows; lighting and ventilation; toilet-sewage disposal facilities; water supply; hand-washing facilities; milk plant cleanliness; sanitary piping; construction and repair of containers and equipment; cleaning and sanitizing of containers and equipment; storage of cleaned containers and equipment; storage of single service containers, utensils, and materials; protection from contamination; cooling of milk; personnel cleanliness; and surroundings.

(2) When the unloading station is a transfer station, it shall comply with all the requirements of a receiving station except that the provisions for walls, ceilings, doors and windows are not required unless climatic and operation conditions interfere with safe handling of the milk. Overhead protection shall be provided in all cases.

(3) The pump-out of the milk tank truck shall be done in an area where a cover extends over the complete transport tank or, when climatic and operating conditions require, in a completely enclosed area. Pump-out operations must be protected in such a manner as to prevent product contamination. If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or the air inlet vent.

(4) The agitating and sampling of the transport tank milk shall be accomplished in such a manner as to provide maximum protection against product contamination. The unloading station shall provide the necessary equipment to adequately agitate the milk in the transport tank. The milk shall be agitated for a minimum of 15 minutes prior to obtaining samples. The department may approve alternative procedures to achieve adequate agitation. Samples shall be collected only by certified milk samplers. In no instance shall agitation and sampling be done at a place other than a location approved by the department.

(5) The unloading station shall record the following information on each load of milk received, and maintain these records for a period of not less than 90 days:

- (A) the date the load was received;
- (B) the time received;
- (C) the number of pounds in the load;
- (D) the temperature of the milk upon receipt;
- (E) the permit number of the milk tank truck delivering the milk;

(F) the name of the station operator receiving the milk; and

(G) the manifest with the driver's license number of the sample collector.

(6) In no case shall milk be received from a milk tank truck that appears to be damaged, dirty, or does not have a current cleaning tag without the permission of the department.

(b) Milk Tank Truck Cleaning Facilities.

(1) It shall be the responsibility of each unloading station to provide a milk tank truck cleaning facility. The milk tank truck cleaning facility may be an integral part of the unloading station or a separate facility. When the milk tank truck cleaning facility is a separate facility, it shall be located convenient to and in the proximity of the unloading station. All milk tank trucks that transport milk and milk products as permitted by the department, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility.

(2) The milk tank truck cleaning facility shall comply with the following sanitation requirements for Grade A pasteurized milk unloading stations of the "Grade A Pasteurized Milk Ordinance": floors; walls and ceilings; doors and windows; lighting and ventilation; toilet-sewage disposal facilities; water supply; hand-washing facilities; milk plant cleanliness; sanitary piping; construction and repair of containers and equipment; cleaning and sanitizing of containers and equipment; storage of cleaned containers and equipment; storage of single service containers, utensils, and materials; protection from contamination; cooling of milk; personnel cleanliness; and surroundings.

(3) An unloading station which receives milk in milk tank trucks equipped with permanently installed tank washers will provide a milk tank truck cleaning facility equipped with the following:

(A) adequate water heating facilities;

(B) tanks of an adequate size to hold the rinse, wash, and sanitizing solution;

(C) a wash pump which will deliver the cleaning and sanitizing solution to the milk-contact surface of the milk tank truck at an adequate rate and velocity;

(D) a removal pump which will remove rinse and cleaning solutions from the milk tank truck as fast as such solutions are pumped into the milk tank truck;

(E) a screening device shall be provided which will prevent the passage of any foreign material into the system that would adversely affect the performance of the spray device(s), and located so as to be easily cleaned and sanitized;

(F) a temperature recorder which meets the applicable requirements of the most current revision of the "Grade A Pasteurized Milk Ordinance" shall be provided. In addition, a pressure indicator should be provided. These may be an integral unit or separate units. The temperature sensor should be located in the return solution line. The pressure sensor shall be located in the solution-rinse line downstream from the pressure supply pump. Recording charts shall be properly identified (showing date, permit number of transportation tank cleaned, operator's initials, etc.) and kept on file for not less than 90 days;

(G) the necessary equipment shall be provided for the cleaning of transport tank pumps, gaskets, hoses, etc., which do not clean in place (CIP). Equipment shall be provided to clean the hoses by circulation of cleaning solution in conjunction with the clean-out-of-place (COP) vat that is equipped with a temperature recorder which meets the applicable requirements of the most current revision of the "Grade A Pasteurized Milk Ordinance;" however, if an integrated CIP system designed to clean transport tanker, milk pumps, gaskets, hoses and appurtenances, by circulation is provided, the following criteria must be met:

(i) a temperature recorder that complies with the applicable requirements of the most current revision of the "Grade A Pasteurized Milk Ordinance" and a pressure recorder shall be provided;

(ii) the extended tube holder for cleaning milk hoses and receiving hoses shall be of adequate length to accommodate hoses of 35 feet maximum length;

(iii) the CIP system shall provide a cleaning regimen for a pre-rinse, wash, post-rinse and sanitizing of the transport tanker, milk pumps, gaskets, hoses, receiving hose, and appurtenances;

(iv) the CIP system shall be capable of a minimum wash temperature of 135 degrees Fahrenheit and minimum circulation flow rate of five feet per second; and

(v) all equipment and utensils shall be in compliance with the standards outlined in the current edition of the 3-A Sanitary Standards and Accepted Practices at the time of installation;

(H) all equipment and utensils must be in compliance with the current edition of the 3-A Sanitary Standards and Accepted Practices at the time of installation; and

(I) a cleaning regimen shall be established and posted in the milk tank truck cleaning facility. This regimen shall provide for a pre-rinse and sanitizing of the milk tank truck. The wash solution must have a minimum temperature in the return line of 135 degrees Fahrenheit.

(4) The department may permit an unloading station to utilize a milk tank truck cleaning facility equipped only with portable tank washing equipment (drop in washers) or with the equipment and personnel necessary for manual tank cleaning, providing the station can demonstrate the capability of effectively cleaning and sanitizing the milk tank trucks. In no case will milk tank trucks equipped with installed tank washers be unloaded into said unloading stations without the permission of the department. This permission will be granted only in emergency situations.

(5) The milk tank truck and appurtenances shall be thoroughly cleaned after each use and all equipment shall be thoroughly cleaned at least once each day used. It is allowable to pick up multiple loads continuously within a 24-hour period, provided the milk tank truck is washed after each day's use.

(6) The milk tank truck and appurtenances shall be sanitized immediately after washing with an approved sanitizer. The milk tank truck shall be sanitized by pumping the sanitizing solution through the wash-rinse system. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds 96 hours, the tank must be re-sanitized.

(7) A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than 15 days. The tag shall bear the following information:

- (A) the milk tank truck permit number;
- (B) the date and time it was cleaned and sanitized;
- (C) the name and location of the cleaning station; and
- (D) the name of the person who cleaned and sanitized the milk tank truck.

§217.65. Responsibilities of the Bulk Milk Hauler/Sampler. Duties and responsibilities of the Bulk Milk Hauler/Sampler shall be in compliance with §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance). In addition the Bulk Milk Hauler/Sampler shall:

(1) agitate the farm bulk milk tank for a minimum of ten minutes. Larger tanks may require more time; and

(2) deliver producer samples to designated place and personnel as approved by the department.

Subchapter E. Dairy Products and Milk for Manufacturing Purposes.

§217.71. Permits. Every manufacturer of dairy products located in the State of Texas, shall obtain a milk plant permit. Farms producing milk for manufacturing purposes shall obtain a

producer dairy farm permit. Only a person who complies with the requirements of these rules shall be entitled to receive and retain a permit.

§217.72. Inspection of Dairy Product Manufacturers.

(a) Each dairy product manufacturer located within the State of Texas shall be inspected by the department prior to the issuance of a permit. Following the issuance of a permit, each dairy product manufacturer shall be inspected at least once every three months. When the violation of any of the requirements set forth in §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products) are found to exist, the violation will be brought to the attention of the dairy product manufacturer, and a second inspection shall be required after the time deemed necessary to remedy the violation, but not before the lapse of three days. This second inspection shall be used to determine compliance with the requirements of §217.74 of this title. Any violation of the same requirements of §217.74 of this title on the second inspection shall be the basis for permit suspension in accordance with §217.92 of this title (relating to Enforcement) and/or court action.

(b) One copy of the inspection report shall be provided to the operator, or other responsible person and be posted in a conspicuous place on an inside wall of the establishment. The inspection report shall not be defaced and shall be made available to the department upon request. An identical copy of the inspection report shall be filed with the records of the department.

(c) Every dairy product manufacturer, upon the request of the department, shall permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with these rules. A distributor or milk plant operator shall furnish the department, upon request, a true statement of the actual quantities of milk and milk products purchased and sold.

(d) All plans for the construction, reconstruction, or alterations other than those to repair or perform maintenance on existing facilities of a dairy product manufacturer must be submitted to the department for approval before construction is begun.

(e) When a condition is found which constitutes an imminent health hazard, the department shall suspend the permit immediately. A dairy product manufacturer found violating any requirement must be notified in writing. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator, or by the posting, of an inspection report, as required by this section. After receipt of a notice of violation, but before the allotted time has elapsed, the dairy product manufacturer shall have an opportunity to appeal or request an extension of the time allowed for correction.

§217.73. Raw Milk for Manufacturing Purposes.

(a) Raw milk for manufacturing purposes shall be produced from producer dairy farms that hold a valid Grade A permit. Dairies that are permitted to sell Grade A Raw Milk for

Pasteurization, but have had their permit temporarily suspended because of violations of Grade A standards for bacterial count, somatic cell count, or added water may be eligible to sell milk for manufacturing purposes for a period not to exceed 14 days, provided that the most recent bacterial count of milk does not exceed 500,000 per milliliter.

(b) The appearance of acceptable raw milk shall be normal and free of sediment when examined visually or by test procedure. It shall not show any abnormal condition (including, but not limited to curdled, ropy, bloody or mastitic condition), as indicated by sight or other test procedures. The milk shall be free from objectionable feed and other off-odors. It shall be free of excessive sediment.

(c) Milk for manufacturing purposes shall not contain aflatoxin residues of 0.5 parts per billion or greater.

(d) Milk for manufacturing purposes shall contain no drug residues.

§217.74. Requirements for Milk Plants Producing Dairy Products.

(a) General requirements.

(1) Plant cleanliness. All rooms in which dairy products are handled, processed or stored, or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only insecticides and rodenticides approved for use by the department and/or registered with the U.S. Environmental Protection Agency (EPA) shall be used for insect and rodent control. Only equipment directly related to processing operations or the handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms. All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment shall be clean. No trash, solid waste or waste dry product shall be stored within the milk plant, except in covered containers. Excessive product dust shall be kept under effective control by the use of exhaust and collective systems designed for in-plant dust control. Tailings and materials collected from exhaust collective systems shall not be used for human consumption.

(2) Surroundings. The adjacent surroundings shall be free from refuse, rubbish, and waste materials to prevent harborage of rodents, insects, and other vermin. The premises shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, or smoke. Construction and maintenance of driveways and adjacent plant traffic areas shall be of concrete, asphalt, or similar material to keep dust and mud to a minimum.

(3) Drainage. A suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard and in compliance with state, district, and local regulations.

(b) Buildings.

(1) The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs, and cats. All service pipe openings through outside walls shall be sealed around the opening or provided with tight metal collars.

(2) All openings to the outer air shall be effectively protected by: screening or effective electric screen panels; fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; properly constructed flaps where it is impractical to use self-closing doors or air curtains; or any effective combination of the above or by any other method which prevents the entrance of insects. All outer doors shall be tight and self-closing. Screen doors shall open outward. All outer openings shall be rodent-proofed to the extent necessary to prevent the entry of rodents.

(3) The walls, ceilings, partitions, and posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smooth with material that is light colored, resistant to moisture, and easy to keep clean.

(4) Floors.

(A) The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile laid with impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair.

(B) Sound, smooth wood floors which can be kept clean, may be used in rooms where new containers and supplies and packaged finished products are stored.

(5) Lighting and ventilation.

(A) Adequate light sources shall be provided (natural, artificial or a combination of both) which furnish at least 20 foot-candles (220 lux) of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five foot-candles (55 lux) of light.

(B) Ventilation in all rooms shall be sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls and ceilings.

(C) Pressurized ventilating systems, if used, shall have a filtered air intake.

(D) For milk plants that condense and/or dry milk or milk products, ventilating systems in packaging rooms, where used, shall be separate systems and where possible have the ducts installed in a vertical position.

(6) Rooms and compartments.

(A) Pasteurizing, processing, reconstitution, cooling, condensing, drying, and packaging of milk and milk products shall be conducted in a single room, or separate rooms, but not in the same room used for the cleaning of milk cans, portable storage bins, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks, provided that these rooms may be separated by solid partitioning doors that are kept closed. Cooling, either plate or tubular, may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where milk tank trucks are unloaded and/or cleaned and sanitized.

(B) Coolers and freezers. Coolers and freezers where dairy products are stored shall be clean, dry and maintained at a uniform temperature and humidity to protect the product from deterioration, and minimize the growth of mold. Circulation of air shall maintain uniform temperature and humidity at all times. Coolers and freezers shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(i) Bulk milk and milk products shall be handled and stored to maintain an internal temperature of 45 degrees F or below.

(ii) Packaged milk and milk products shall be handled and stored to maintain an internal temperature of 41 degrees F or below.

(iii) Freezers shall be maintained so that frozen food remains frozen at all times.

(C) Supply rooms. The supply rooms used for the storing of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold, and maintained in good repair. These items stored therein shall be adequately protected from dust, dirt, or other extraneous matter, and so arranged on racks, shelves, or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides and cleaning compounds shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

(D) Boiler and tool rooms. The boiler and tool rooms shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. The rooms shall be kept orderly and reasonably free from dust and dirt.

(E) Toilet and dressing rooms. Toilet facilities shall be provided and be conveniently located. Toilet rooms may not open directly into any room in which milk and/or milk products are processed, condensed or dried, and stored. Toilet rooms shall be completely enclosed and have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair and are well ventilated and well lighted. Toilet tissue and easily cleanable covered waste receptacles shall be provided in toilet rooms. All plumbing shall be installed to meet the applicable provisions of the state or local plumbing code. Sewage and other liquid wastes shall be disposed of in a sanitary manner, and non-water-carried sewage disposal facilities shall not be used.

(F) Starter facilities. Sanitary facilities shall be provided for the handling of starter cultures.

(7) Hand-washing facilities. Hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single-service towels or air dryers. The facilities shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as hand-washing facilities. Self-closing metal or plastic containers shall be provided for used towels and other wastes.

(8) Drinking water facilities. Drinking water facilities shall be provided in the plant and shall be conveniently located.

(c) Facilities.

(1) Water supply.

(A) Water for milk plant purposes shall be from an adequate supply, properly located, protected, and operated. It shall be easily accessible and of a safe, sanitary quality.

(B) The water supply shall be approved as safe by the State Water Control Authority and, in the case of individual water systems, complies with the specification outlined in Appendix D of the most current revision of the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance), and the Bacteriological Standards outlined in Appendix G of the most current revision of the "Grade A Pasteurized Milk Ordinance."

(C) There shall be no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank, such as for cooling or condensing, unless protected by an air gap or effective backflow preventer, constitutes a violation of this requirement. An approved air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle. The distance of the air gap is to be measured from the bottom of the potable inlet supply pipe or

faucet to the top of the effective overflow, i.e., flood level rim or internal overflow, of the vessel. In no case, may the effective air gap be less than one inch (2.54 cm).

(D) Condensing water for milk or milk product evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, shall be from a source complying with subparagraph (B) of this paragraph. When approved by the department, water from sources not complying with subparagraph (B) of this paragraph, may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment, or its contents, by condensing water or by water used to produce vacuum. Means of preventing such contamination are:

(i) use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate; or

(ii) use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least 35 feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

(E) Condensing water for milk or milk product evaporators, complying with subparagraph (D) of this paragraph, and water reclaimed from milk or milk products may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Appendix D, Part V of the most current revision of the "Grade A Pasteurized Milk Ordinance."

(F) New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, shall be disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

(G) Samples for bacteriological testing of individual water supplies shall be taken upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Samples shall be taken by the department and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated six month period plus the remaining days of the month in which the sample is due.

(H) Current records of water test results are retained by the department.

(I) A potable water supply, which meets the criteria of this section, may be connected to the product feed line of a steam vacuum evaporator, provided that the water supply is protected at the point of connection by an approved backflow prevention device.

(2) Air under pressure which is in direct contact with milk and milk products and milk product-contact surfaces.

(A) Filter media. Air intake and pipeline filters shall consist of fiberglass with a downstream backing dense enough to prevent fiberglass breakoff from passing through cotton flannel, wool flannel, spun metal, electrostatic material, or other equally acceptable filtering media, which are non-shedding and which do not release to the air, toxic volatiles or volatiles which may impart any flavor or odor to the milk or milk product.

(B) Filter performance. Intake air filter efficiency shall be at least 98% using air cleaner coarse test dust. Final filter efficiency shall be at least 99% as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns). When commercially sterile air is required, the final filter efficiency shall be at least 99.99% as measured by the DOP test.

(C) Air supply equipment. The compressing equipment shall be designed to preclude contamination of the air with lubricant vapors and fumes. Oil-free air may be produced by one of the following methods or their equivalent:

(i) use of a carbon ring piston compressor;

(ii) use of oil-lubricated compressor with effective provision for removal of any oil vapor by cooling the compressed air; or

(iii) water-lubricated or non-lubricated blowers. The air supply shall be taken from a clean space or from relatively clean outer air and shall pass through a filter upstream from the compressing equipment. This filter shall be located and constructed so that it is easily accessible for examination and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage, water, product spillage, and physical damage.

(D) Moisture removal equipment. Air under pressure systems in excess of one bar, i.e., 103.5 kPa (15 psi), shall be provided with methods of moisture removal. The removal of moisture may be achieved by condensation and coalescing filtration or absorption, or equivalent, to prevent free water in the system. If it is necessary to cool the compressed air, an after-cooler shall be installed between the compressor and the air storage tank for the purpose of removing moisture from the compressed air.

(E) Filters and moisture traps. Filters shall be constructed so as to ensure effective passage of air through the filter media only. The coalescing filter and associated traps shall be located in the air pipeline downstream from the compressing equipment, and from the air

tank, if one is used. The filter shall be readily accessible for examination, cleaning, and for replacing the filter media. The moisture trap shall be equipped with a petcock or other means for draining accumulated water. When coalescing filters are used, a means shall be provided to measure the differential pressure across the filter. The differential pressure device is required to indicate the need for filter media replacement. All coalescing filter housings shall be provided with a means of removing the condensed liquid from the filtration device. This can be accomplished by an automatic or manual drain installed on the base of the filter housing. The final filter media shall be disposable. The filter media shall be located in the air line upstream from, and as close as possible to, the point of application except that a final filter shall not be required where the compressing equipment is of a fan or blower type and operating at a pressure of less than one (1) bar, i.e., 103.5 kPa (15 psi). Electronic air cleaners utilizing electrostatic precipitation principles to collect particulate matter may be used. Disposable filter media shall not be cleaned and reused.

(F) Air piping. The air piping from the compressing equipment to the filter and moisture trap shall be readily drainable. A milk or milk product check-valve of sanitary design shall be installed in the air piping, downstream from the disposable media filter, to prevent backflow of milk or milk product into the air pipeline, except that a check-valve shall not be required if the air piping enters the milk or milk product zone from a point higher than the milk or milk product overflow level, which is open to the atmosphere, or is for dry product applications, or for other dry application where liquids are not present. When a check-valve is not required, plastic or rubber or rubber-like tubing and suitable compatible fittings and connections made of plastic or stainless steel may be used between the final filter and the point of application. Air distribution piping and fittings after the final filter shall be of corrosion-resistant materials. Air distribution piping, fittings and gaskets between the discharge of the sanitary check-valve to the processing equipment shall be sanitary piping.

(3) Culinary steam for milk and milk products. The following methods and procedures will provide steam of culinary quality for use in the processing of milk and milk products.

(A) Source of boiler feed water. Potable water or water supplies, acceptable to the department, shall be used.

(B) Feed water treatment. Feed water may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes. Pretreatment of feed waters for boilers or steam generating systems to reduce water hardness, before entering the boiler or steam generator by ion exchange or other acceptable procedures, is preferable to the addition of conditioning compounds to boiler waters. Only compounds complying with Title 21, Code of Federal Regulations (CFR), §173.310, may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal. Amounts of the boiler water treatment compounds greater than the minimum necessary for controlling boiler scale or other boiler water treatment purposes shall not be used. No greater amount of steam than necessary shall be used for the

treatment and/or pasteurization of milk and milk products. It should be noted that tannin, which is also frequently added to boiler water to facilitate sludge removal during boiler blow-down, has been reported to give rise to odor problems, and should be used with caution. Boiler compounds containing cyclohexylamine, morpholine, octadecylamine, diethylaminoethanol, trisodium nitrilotriacetate, and hydrazine shall not be permitted for use in steam in contact with milk and milk products.

(C) Boiler operation. A supply of clean, dry saturated steam is necessary for proper equipment operation. Boilers and steam generation equipment shall be operated in such a manner as to prevent foaming, priming, carryover and excessive entrainment of boiler water into the steam. Carryover of boiler water additives can result in the production of milk or milk product off-flavors. Manufacturers' instructions regarding recommended water level and blow-down should be consulted and rigorously followed. The blow-down of the boiler should be carefully watched, so that an overconcentration of the boiler water solids and foaming is avoided. It is recommended that periodic analyses be made of condensate samples. Such samples should be taken from the line between the final steam separating equipment and the point of the introduction of steam into the milk or milk product.

(4) Disposal of wastes. Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of in a manner in compliance with local and state regulations. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tight-fitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches above the floor. Alternatively, waste containers may be kept inside an enclosed, clean, and fly-proof room. Solid wastes shall be disposed of at regular intervals to prevent the unsanitary accumulation of waste.

(d) Equipment and utensils - General construction, repair, and installation.

(1) All multi-use containers and equipment that milk and milk products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material shall be constructed for ease of cleaning and shall be kept in good repair. All single-service containers, closures, gaskets and other articles that milk and milk products come in contact with shall be non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

(2) All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment shall be set away from any wall or spaced in such a manner as to facilitate cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, shall be accessible for inspection. Milk and dairy product pumps shall be of a sanitary type and easily dismantled for cleaning or shall be of approved construction to allow effective cleaning in place in accordance with 3-A Sanitary Standards.

(3) All CIP systems shall comply with the 3-A Sanitary Practices for permanently installed sanitary product, pipelines, and cleaning systems.

(4) All joints in containers, utensils and equipment shall be flush and finished as smooth as adjoining surfaces, or if the surface is vitreous, it must be continuous. Tile floors are not acceptable in dryers. Joints on equipment coming in contact with dry milk or milk products only or used for hot air piping may be sealed by other acceptable means. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close fitting. Grease and oil from gears, bearings, and cables shall be kept out of the milk and milk products. Where a thermometer or temperature sensing element is inserted through a surface with which milk or milk products come into contact a pressure-tight seal shall be provided ahead of all threads and crevices.

(5) Can washers. Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a uniform pressure and be equipped with pressure regulating valves.

(6) Product storage tanks or vats. Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be protected against the entrance of dust, moisture, insects, oil, or grease. The sight glasses, if used, shall be sound, clear, and in good repair. Vats which have hanged covers shall be so designed that moisture or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the 3-A Accepted Practices for Supplying Air Under Pressure. Storage tanks or vats intended to hold product for longer than approximately eight hours shall be equipped with refrigeration and/or have insulation. All new storage tanks or vats shall meet the appropriate 3-A Sanitary Standards and shall be equipped with thermometers in good operating order.

(7) Surface coolers. Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on non-product-contact surfaces away from product-contact surfaces. All gaskets or swivel connections shall be leak proof.

(8) Plate-type heat exchangers. Plate-type heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation. All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in good repair (e.g. free of dents, holes, broken gaskets and cracks). A cleaning regimen shall be posted to insure cleaning procedures between inspection periods.

(9) Internal return tubular heat exchangers. Internal return tubular heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation.

(10) Pumps. Pumps used for milk and dairy products shall be of the sanitary type and constructed to meet 3-A Sanitary Standards. Unless pumps are specifically designed for effective cleaning in place, they shall be disassembled and thoroughly cleaned after use.

(11) New equipment and replacements. New equipment and replacements, including all plastic parts, rubber and rubber-like materials for parts and gaskets having product-contact surfaces, shall meet the 3-A Sanitary Standards. If equipment or replacements are not approved by 3-A Sanitary Standards, such equipment and replacements shall meet the general requirements of this section.

(e) Personnel cleanliness. All employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. They shall keep their hands clean and follow good hygienic practices while on duty. Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy product, or supplies are prepared, stored, or otherwise handled. All persons shall wear clean outer garments while engaged in the handling, processing, storage, transporting, or packaging of dairy products. Clean outer garments shall also be worn by persons handling containers, utensils, and equipment used for these activities. Adequate hair coverings shall be worn by all persons engaged in receiving, testing, processing, packaging, or handling of dairy products.

(f) Personnel health. No person afflicted with a communicable disease shall be permitted in any room or compartment where milk and milk products are prepared, manufactured, or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms, or other exposed portion of the body shall work in any dairy processing rooms or in any capacity which brings them into direct contact with associated milk or milk product-contact surfaces. Milk plant operators who have received verifiable and confirmed reports from or about employees who have these conditions and who have handled pasteurized milk or milk products or associated milk or milk product-contact surfaces, shall immediately report these facts to the department. Milk plant employees or applicants to whom a conditional offer of employment has been made shall be instructed by the milk plant that the employee or applicant is responsible to report to the milk plant management, in a manner that allows the milk plant to prevent the likelihood of the transmission of diseases that are transmissible through foods, if the employee or applicant:

(1) is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norovirus, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1 or other infectious or communicable disease that has been declared by the U.S. Secretary of Health and Human Services (HHS) to be

transmissible to others through the handling of food, or has been clearly shown to be transmissible based upon verifiable epidemiological data; or

(2) is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in paragraph (1) of this subsection, including an outbreak at an event such as a family or communal meal, (e.g., church supper or ethnic festival) because the employee or applicant:

(A) prepared food implicated in the outbreak; or

(B) consumed food implicated in the outbreak; or

(C) consumed food at the event prepared by a person who is infected or ill.

(3) lives in the same household as a person who attends or works in a day care center, school or similar institution if the institution experiencing a confirmed outbreak of one of the diseases specified in paragraph (1) of this subsection. Similarly, milk plant employees shall be instructed by the milk plant management to report to the milk plant management if the employee, or applicant:

(4) has a symptom associated with acute gastrointestinal illness such as: Abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice; or

(5) has a pustular lesion such as a boil or infected wound that is:

(A) on the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier; or

(B) on other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

(g) Raw product storage.

(1) All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Raw milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45 degrees Fahrenheit or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(2) The bacteriological quality of commingled raw milk for use in dairy products for manufacturing purposes shall not exceed 500,000 per ml.

(3) During any consecutive six months, at least four samples of raw milk intended for use in manufactured milk products shall be taken by and examined by the department.

(h) Pasteurization. When pasteurization is required, or when a product is designated "pasteurized," every particle of the milk or milk product shall be subjected to such temperatures and holding periods in properly designed and operated equipment sufficient to ensure proper pasteurization of the product in accordance with the most current revision of the "Grade A Pasteurized Milk Ordinance." Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(i) Composition and wholesomeness. All necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing in accordance with these rules. All substances and ingredients used in the processing or manufacturing of any dairy product shall be subject to inspection and shall be wholesome and practically free from impurities.

(j) Cleaning and sanitizing treatment.

(1) All multi-use containers and utensils shall be thoroughly cleaned after each use and all equipment shall be thoroughly cleaned at least once each day used, unless the department has reviewed and accepted information, in consultation with FDA, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one day or 72 hours in the case of storage tanks, or 44 hours in the case of evaporators, which are continuously operated. Approval by the department will be conveyed in writing. Supporting information shall be submitted to and approved by the department prior to initiating the qualification period if required. Any significant equipment or processing changes shall be communicated to the department, and may result in a re-verification of the extended run proposal, if it is determined that the change could potentially affect the safety of the finished milk or milk product(s). The supporting information may include but is not limited to:

- (A) statement of proposal, including desired cleaning frequency;
- (B) product and equipment description;
- (C) intended use and consumers;
- (D) distribution and storage temperatures of product;
- (E) diagram of process of interest;
- (F) process parameters, including temperature and times;
- (G) hazard evaluation and safety assessment; and

(H) review of equipment for sanitary design.

(2) When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

(3) Storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours. Records must be available to the department to verify that milk storage in these tanks does not exceed 72 hours. These records shall be available for at least the previous three months or from the time of the last regulatory inspection, whichever is longer. Storage tanks, which are used to store raw milk or milk products or heat-treated milk products longer than 24 hours and silo tanks used for the storage of raw milk or milk products or heat-treated milk products shall be equipped with a seven day temperature recording device complying with the specifications of the most current revision of the Grade A Pasteurized Milk Ordinance.

(4) Evaporators shall be cleaned at the end of a continuous operation, not to exceed 44 hours, and records must be available to the department to verify that the operation time does not exceed 44 hours. Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers shall be cleaned at intervals and by methods recommended by the manufacturer and approved in writing by the department. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved in writing by the department. Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the department. Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.

(5) All milk tank trucks that transport milk and milk products shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds 96 hours, the tank must be re-sanitized. Whenever a milk tank truck has been cleaned and sanitized, as required by the department, it shall bear a tag or a record shall be made showing the date, time, place and signature or initials of the employee or contract operator doing the work, unless the milk tank truck delivers to only one receiving facility where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the milk tank truck is next washed and sanitized and kept on file for 15 days.

(6) Pipelines and/or equipment designed for mechanical cleaning shall meet the following requirements.

(A) An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

(B) A temperature recording device, complying with the most current revision of the Grade A Pasteurized Milk Ordinance, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen which is approved by the department in writing, shall be installed in the return solution line or other appropriate area to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing solutions. For purposes of this section, recording devices which produce records not meeting the specifications of the most current revision of the "Grade A Pasteurized Milk Ordinance" may be acceptable if:

(i) the device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle;

(ii) the record shows a typical pattern of each circuit cleaned, so that changes in the cleaning regimen may be readily detected; or

(iii) electronic storage of required cleaning records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available. Electronic records must meet the criteria of this section and those provisions of with the most current revision of the Grade A Pasteurized Milk Ordinance, which are determined to be applicable by the department and FDA. Except that, electronic storage of required cleaning records, with or without hard copy, shall be acceptable, provided the computer and computer generated records are readily available and meet the criteria of this section and Title 21, CFR, Part 11.

(k) Packaging and labeling.

(1) Containers:

(A) The size, style, and type of packaging used for dairy products shall be packaged in materials which will cover and protect the quality of the contents during storage and regular channels of trade and under conditions of handling. The weights and shape within each size or style shall be as nearly uniform as is practical.

(B) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. In addition, the wrapper shall be resistant to puncturing, tearing, cracking, or breaking under normal conditions of handling, shipping, and storage. When special-type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(2) Packaging and repackaging. Packaging dairy products or cutting and repackaging all styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and packaging material shall be free from mold and bacterial contamination. Methods for checking the level of contamination shall be as

prescribed by the most current edition of "Standard Methods for the Examination of Dairy Products" of the American Public Health Association as defined in §217.1 of this title (relating to Definitions).

(3) Labeling. All commercial bulk packages containing dairy products manufactured under the provisions of this subpart shall be adequately and legibly marked with the name of the product, name and address of processor or manufacturer or other assigned plant identification, lot number, and any other identification as may be required by the department. Consumer packaged products shall be legibly marked with the name of the product, name and address of packer, manufacturer, or distributor.

(l) Storage of finished product.

(1) Dry storage. The product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, in such a manner as to be orderly and easily accessible for inspection. Rooms should be cleaned regularly. Care shall be taken in the storage of any other product foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, or vermin or insect infestation. Control of humidity and temperature shall be maintained at all times to prevent conditions detrimental to the product and container.

(2) Refrigerated storage. The finished product shall be placed on shelves, dunnage, or pallets and identified. It shall be stored under temperatures that will best maintain the initial quality. The product shall not be exposed to anything from which it might absorb any foreign odors or be contaminated by drippage or condensation.

§217.75. Supplemental Requirements for Plants Manufacturing, Processing and Packaging Instant Nonfat Dry Milk, Nonfat Dry Milk, Dry Whole Milk, Dry Buttermilk, Dry Whey, and Other Dry Milk Products.

(a) Sanitation and construction requirements. Facility and equipment shall be constructed and maintained in compliance with §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products) and the most current revision of the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance).

(b) Operations and operating procedures for pasteurization. All milk, buttermilk, and whey used in the manufacture of dry dairy products shall be pasteurized at the plant where dried, except that condensed whey and acidified buttermilk containing 40% or more solids may be transported to another plant for drying without repasteurization. When pasteurization is required, or when a product is designated "pasteurized," every particle of the milk or milk product shall be subjected to such temperatures and holding periods in properly designed and operated equipment to ensure proper pasteurization of the product in accordance with the most current revision of the "Grade A Pasteurized Milk Ordinance." Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been

recognized by FDA as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(c) Product adulteration. All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry product with another shall be considered an adulteration of both products. This does not prohibit the standardization of like products or the production of specific products for special uses provided labeling requirements are met as set forth in 21 Code of Federal Regulations, Parts 133 and 135.

(d) Checking quality. All milk products and dry milk products shall be subject to inspection and analysis by the dairy plant for quality and condition throughout each processing operation. Line samples shall be taken as an aid to quality control in addition to the regular routine analysis made on the finished products.

(e) Requirements for instant nonfat dry milk.

(1) Sampling and testing. All instant nonfat dry milk offered for sale shall be sampled and tested by the department routinely for the purpose of ensuring that the product meets requirements in accordance with the most current edition of "Standard Methods for the Examination of Dairy Products" of the American Public Health Association, as defined in §217.1 of this title (relating to Definitions).

(2) Requirements for instant nonfat dry milk.

(A) Flavor and odor. The flavor and odor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree:

(i) chalky;

(ii) cooked;

(iii) feed; or

(iv) flat.

(B) Physical appearance. The physical appearance shall possess a uniform white to light cream natural color and shall be free-flowing and free from lumps except those that readily break up with very slight pressure.

(C) Bacterial estimate. The standard plate count shall not be more than 30,000 per gram.

(D) Coliform count. The coliform count shall not be more than 10 per gram.

(E) Milkfat content. The milkfat shall not be more than 1.25%.

(F) Moisture count. The moisture shall not be more than 4.5%.

(G) Scorched particle content. Scorched particles shall not be more than 15 milligrams per gram.

(H) Solubility index. The solubility index shall not be more than 1 milliliter.

(I) Titratable acidity. The titratable acidity shall not be more than 0.15%.

(J) Dispersibility. The dispersibility shall not be less than 85%.

(K) Direct microscopic clump count. The direct microscopic clump count shall not be more than 75 million per gram.

§217.76. Supplemental Requirements for Plants Manufacturing, Processing, and Packaging Butter and Related Products.

(a) Rooms and compartments - Coolers and freezers. The coolers and freezers shall be equipped with facilities for maintaining temperature and humidity conditions to protect the quality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from insects, rodents, and mold, and maintained in good repair. Coolers and freezers shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

(b) Churn rooms. Churn rooms, in addition to meeting standards of proper construction and sanitation, shall be equipped to ensure that the air is kept free from odors and vapors by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

(c) Print and bulk packaging rooms. Rooms used for packaging print or bulk butter and related products shall, in addition to meeting standards of proper construction and sanitation, provide an atmosphere relatively free from mold (no more than 10 mold colonies per cubic foot of air), dust or other airborne contamination and be maintained at a reasonable room temperature.

(d) Equipment and utensils - General construction, repair, and installation. All equipment and utensils necessary to the manufacture of butter and related products shall meet the same general requirements as outlined in §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products). In addition, the following requirements shall be met for other equipment.

(1) Continuous churn. All product-contact surfaces shall be of noncorrosive material. All nonmetallic product-contact surfaces shall comply with 3-A Standards for Plastic, Rubber, and Rubber-Like Materials. All product-contact surfaces shall be readily accessible for cleaning and inspection.

(2) Conventional churn. Churns shall be constructed of aluminum, stainless steel or equally corrosion-resistant metal, free from cracks, and in good repair. All gasket material shall be fat resistant, nontoxic and durable. Seals around the churn doors shall be tight.

(3) Bulk butter trucks, boats and packers. Bulk butter trucks, boats and packers shall be constructed of aluminum, stainless steel or equally corrosion-resistant metal free from cracks, seams and must have a surface that is smooth and easily cleanable.

(4) Butter, frozen or plastic cream melting machine. Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion-resistant metal, sanitary construction, and readily cleanable in accordance with 3-A Sanitary Standards.

(5) Printing equipment. All printing equipment shall be designed to be readily demountable for cleaning of product-contact surfaces. All product-contact surfaces shall be aluminum, stainless steel or equally corrosion-resistant metal, or plastic, rubber and rubber like material which meet 3-A Standards, except that conveyors may be constructed of material which can be properly cleaned and maintained in good repair.

(6) Brine tanks. Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank shall also be provided with a drainage outlet.

(7) Starter vats. Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and constructed according to applicable 3-A Sanitary Standards. The vats shall be in good repair, equipped with tight-fitting lids, and have temperature controls.

(e) Operations and operating procedures for pasteurization. The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product.

(1) Cream for buttermaking. The cream for buttermaking shall be pasteurized at a temperature of not less than 165 degrees Fahrenheit for not less than 30 minutes or at a minimum temperature of not less than 185 degrees Fahrenheit for not less than 15 seconds. Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the Food and Drug Administration (FDA) as provided in §343 (h)(3) of the Federal Food, Drug and Cosmetic Act (FFDCA). Only such FDA recognized processes and no other shall be considered by the department.

(2) Cream for plastic or frozen cream. The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in (a) above, except that the

temperature for the vat method shall be not less than 170 degrees Fahrenheit for not less than 30 minutes, or not less than 190 degrees Fahrenheit for not less than 15 seconds. Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in §343 (h)(3) of the FFDCa. Only such FDA recognized processes and no other shall be considered by the department.

(f) Composition and wholesomeness. All ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and free from impurities. Chlorinating facilities shall be provided for butter wash water if needed, and all other precautions shall be taken to prevent contamination of products.

(g) Containers.

(1) Containers used for the packaging of butter and related products shall be containers or packaging material that will protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing two pounds or less to protect the product from contamination during subsequent handling.

(2) Liners and wrappers.

(A) Supplies of parchment liners, wrappers, and other packaging material shall be protected against dust, mold, and other possible contamination.

(B) Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt in a container constructed of stainless steel or other equally noncorrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The solution should consist of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

(C) Other liners such as polyethylene shall be treated or handled in such a manner as to prevent contamination of the liner prior to filling.

(3) Filling bulk butter containers. The lined butter containers shall be protected from possible contamination prior to filling.

(4) Printing and packaging. Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions.

(5) General identification. Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor or other assigned plant identification (manufacturer's lot number, churn number, etc.). Packages of plastic or frozen cream shall be marked with the percent of milkfat.

(6) Storage of finished product in coolers. All products shall be kept under refrigeration at temperatures of 40 degrees Fahrenheit or lower after packaging and until ready for distribution or shipment. The products shall not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

(7) Storage of finished product in freezer.

(A) Sharp freezers. Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced in such a manner that air can freely circulate between and around the packages. The rooms shall be maintained at -10 degrees Fahrenheit or lower and shall be equipped to provide sufficient high-velocity air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(B) Freezer storage.

(i) The room shall be maintained at a temperature of 0 degree Fahrenheit or lower. Adequate air circulation is desirable.

(ii) Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced in such a manner as to permit rapid freezing and repiled, if necessary, at a later time.

§217.77. Supplemental Requirements for Plants Manufacturing and Packaging Cheese.

(a) Sanitation and construction requirements. Effective six months after adoption of these rules, facilities shall be constructed and maintained in compliance with §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products). In addition, the following requirements shall be met.

(1) Rooms and compartments.

(A) Starter rooms. Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of starter, of the room, equipment, and the air therein (such as filtered air, locked doors, and entry by only specified personnel).

(B) Make rooms. The rooms, or areas, in which the cheese is manufactured shall be of adequate size and the vats adequately spaced to permit movement around the vats and presses for proper cleaning and satisfactory working conditions. Adequate ventilation shall be provided.

(C) Drying rooms. If cheese is to be paraffined, a drying room, or area, of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Shelving and air circulation shall be provided for proper drying. Temperature and humidity control facilities shall be provided.

(D) Paraffining rooms. For rind cheese, a separate room or compartment shall be provided for paraffining and boxing the cheese. The room or compartment shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

(E) Rindless block wrapping area. For rindless blocks, a space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to an unsatisfactory packaging of the cheese.

(F) Coolers or curing rooms. Coolers, curing rooms, or areas where cheese is held for curing or storage shall be clean and maintained at the uniform temperature and humidity to protect the cheese. Circulation of air shall be maintained at all times. The rooms shall be free from rodents, insects, and pests. The shelves shall be kept clean and dry.

(G) Cutting and packaging rooms. When small packages of cheese are cut and wrapped, a separate room, or area, shall be provided for the cleaning and preparation of the bulk cheese. In addition, a separate room shall be provided for the cutting and wrapping operation. The rooms shall be well lighted, ventilated, and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room.

(2) Equipment and utensils – General construction, repair, and installation. All equipment and utensils necessary to the manufacture of cheese and related products shall meet the same general requirements as outlined in §217.74 of this title. In addition, for certain other equipment, the following requirements shall be met.

(A) Starter vats. Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls such as valves or indicating and/or recording thermometers. New vats shall be constructed according to the applicable 3-A Sanitary Standards.

(B) Cheese vats.

(i) The vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating in accordance with 3-A Sanitary Standards. The inner liner shall be minimum 16-gauge stainless steel or other equally corrosion-resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the

outer jacket. The outer jacket, when metal, shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed to prevent milk or cheese from entering the inner jacket.

(ii) The vat shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to the vat.

(C) Mechanical agitators. The mechanical agitators shall be of sanitary construction. The carriage and track shall be constructed to prevent the dropping of dirt or grease into the vat. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3-A Sanitary Standards for Plastic and Rubber or Rubberlike Materials, and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

(D) Curd mill and miscellaneous equipment. Knives, hand rakes, shovels, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3-A Sanitary Standards for Plastic and Rubberlike Material. The product-contact surfaces of the curd mill shall be of stainless steel. All pieces of equipment shall be so constructed that they can be kept clean. The wires in the curd knives shall be stainless steel, kept tight and replaced when necessary. All guards shall be in place.

(E) Hoops and followers. The hoops, forms, and followers shall be constructed of stainless steel, heavy tinned steel, or other approved suitable material in accordance with 3-A Sanitary Standards. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

(F) Press. The cheese press shall be constructed of stainless steel, and all joints welded and all surfaces, seams, and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single-service press cloths shall be used only once.

(G) Rindless cheese press. The press used to heat-seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and controls that shall provide uniform pressure and heat equally to all surfaces.

(H) Paraffin tanks. The metal tank shall be adequate in size, have wood rather than metal racks to support the cheese, heat controls, and an indicating thermometer. The cheese wax shall be kept clean.

(b) Operations and operating procedures.

(1) Cheese from pasteurized milk. When pasteurization is required, or when a product is designated "pasteurized," every particle of the milk or milk product shall be subjected

to such temperatures and holding periods in properly designed and operated equipment to ensure proper pasteurization of the product in accordance with the most current revision of the U.S. Public Health Service, FDA, Grade A Pasteurized Milk Ordinance. Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in §343(h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(2) Cheese from unpasteurized milk shall conform to the processing and aging requirements of the most current revision of Title 21, Code of Federal Regulations, Part 133.

(3) Whey disposal.

(A) Adequate sanitary facilities shall be provided for the disposal of whey. If outside, necessary precautions shall be taken to minimize flies, insects, and objectionable odors.

(B) Whey or whey products intended for human food shall at all times be handled in a sanitary manner in accordance with the procedures of this subpart as specified for handling milk and dairy products.

(4) Packaging and repackaging. Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be free from mold and bacterial contamination.

(5) General identification. Each bulk cheese shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number or name and address of manufacturer. Each consumer sized container shall be plainly marked with the name and address of the manufacturer, packer or distributor, net weight of the contents, and name of product.

§217.78. Supplemental Requirements for Plants Manufacturing, Processing, and Packaging Pasteurized Process Cheese and Related Products.

(a) Equipment and utensils - General construction, repair, and installation. All equipment and utensils necessary to the manufacture of pasteurized process cheese and related products shall meet the same general requirements as outlined in §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products). In addition for certain other equipment, the following requirements shall be met.

(1) Conveyors. Conveyors shall be constructed of material which can be cleaned, will not rust or otherwise contaminate the cheese, and maintained in good repair.

(2) Grinders or shredders. The grinders or shredders used in the preparation of the trimmed and cleaned natural cheese for the cookers shall be adequate in size. Product-contact surfaces shall be of corrosion-resistant material, and of such construction as to prevent contamination of the cheese and allow thorough cleaning of all parts and product-contact surfaces.

(3) Cookers. The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product-contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer and a temperature recording device. The recording thermometer stem may be placed in the cooker if satisfactory time charts are used; if not, the stem shall be placed in the hotwell or filler hopper. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product, only culinary steam shall be used.

(4) Fillers. The hoppers of all fillers shall be covered, but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side walls. The filler valves and head shall be kept in good repair, capable of accurate measurements.

(b) Operations and operating procedures.

(1) Trimming and cleaning. Natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surface, mold, unclean areas, or any other part which could contaminate or adulterate the product, shall be removed.

(2) Cooking the batch. Each batch of cheese within the cooker, including the optional ingredients, shall be thoroughly commingled and the contents cooked at a temperature of at least 158 degrees Fahrenheit and held at that temperature for not less than 30 seconds. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

(3) Forming containers. Containers, either lined or unlined, shall be assembled and stored in a sanitary manner to prevent contamination in accordance with 3-A Sanitary Standards. The handling of containers by filler crews shall be done with extreme care and observance of personal cleanliness. Preforming and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time containers are exposed to possible contamination prior to filling.

(4) Filling containers. Hot fluid cheese from the cookers may be held in hot wells or hoppers to ensure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or containers in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening.

A system shall be used to maintain weight control. Damaged packages shall be removed from production. The cheese may be salvaged into sanitary containers and added back to cookers.

(5) Closing and sealing containers. Pouches, liners, or containers having product contact-surfaces after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, to ensure against contamination. Each container shall be coded in such a manner to be easily identified as to date of manufacture by lot or subplot number.

§217.79. Supplemental Requirements for Plants Manufacturing, Processing, and Packaging Evaporated or Condensed Milk Products.

(a) Sanitation and construction requirements. Facility and equipment shall be constructed and maintained in compliance with §217.74 of this title (relating to Requirements for Milk Plants Producing Dairy Products), and the most current revision of the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance). In addition, for certain other equipment, the following requirements shall be met.

(1) Evaporators and vacuum pans. All equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids shall meet the requirements of the 3-A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. All new or used replacements for this type of equipment shall meet the appropriate 3-A Sanitary Standards

(2) Fillers. Both gravity-and vacuum-type fillers shall be of sanitary design and all product-contact surfaces, if metal, shall be made of stainless steel or equally corrosion-resistant material; except that certain evaporated milk fillers having brass parts shall be approved by the department if free from corroded surfaces and kept in good repair. Nonmetallic product-contact surfaces shall meet the requirements for 3-A Sanitary Standards for Rubber and Rubberlike Materials or for Multiple-Use Plastic Materials. Fillers shall be designed so that they will contaminate or detract from the quality of the product being packaged.

(3) Batch or continuous in-container sterilizers shall be equipped with accurate temperature controls and effective valves to regulate the sterilization process. The equipment shall be maintained in such a manner to ensure control of the length of time of processing and to minimize the number of damaged containers.

(4) Homogenizers, where applicable, shall be used to reduce the size of the fat particles and to evenly disperse them in the product. New homogenizers shall meet the applicable 3-A Sanitary Standards.

(b) Operations and operating procedures regarding pasteurization. When pasteurization is required, or when a product is designated "pasteurized", every particle of the milk or milk product shall be subjected to such temperatures and holding periods in properly designed and operated equipment as will ensure proper pasteurization of the product in accordance with the

most current revision of the "Grade A Pasteurized Milk Ordinance." Provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by FDA as provided in §343(h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department.

(c) Filling containers.

(1) The filling of small containers with product shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product. After filling, the container shall be hermetically sealed.

(2) Bulk containers for unsterilized product shall protect the product from contamination in storage or transit. The bulk container (including bulk tankers) shall be cleaned and sanitized before filling and filled and closed in a sanitary manner.

(d) Storage. Facilities shall be provided for the storage and handling of finished product.

§217.80. Drug Residue Monitoring. Dairy Product Manufacturers shall test for drug residues in their incoming raw milk supply fulfilling all industry responsibilities as outlined in the most current revision of the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance).

§217.81. Labeling.

(a) All bottles, containers and packages containing "milk" or "milk products" defined in §217.1 of this title (relating to Definitions) shall be labeled in accordance with the Title 21, Code of Federal Regulations, Subchapter B-Food for Human Consumption. In addition, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, they shall be conspicuously marked with:

(1) The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried.

(2) The words "keep refrigerated after opening" for aseptically processed milk and milk products.

(3) The common name of the hooved mammal producing the milk shall precede the name of the milk or milk product when the product is from or is made from other than cattle's milk such as "Goat," "Sheep," "Water Buffalo," or "Other Hooved Mammal" milk or milk products respectively.

(4) The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

(5) A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

(b) All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed. In addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

- (1) shipper's name, address and permit number on the weight ticket or manifest;
- (2) permit identification of hauler, if not an employee of the shipper;
- (3) point of origin of shipment;
- (4) tanker identification number;
- (5) name of product;
- (6) weight of product;
- (7) temperature of product when loaded;
- (8) date of shipment;
- (9) name of supervising Regulatory Agency at the point of origin of shipment;
- (10) whether the contents are raw, pasteurized, or in the case of cream, low fat or skim milk, whether it has been heat-treated;
- (11) seal number on inlet, outlet, wash connections and vents; and
- (12) grade of product.

(c) All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer. Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest.

Subchapter F. Permits, Fees, and Enforcement.

§217.91. Milk Facilities and Operations Permit and Frozen Dessert License Procedures.

(a) Permit/license required. A current permit/license is required for every dairy farm, milk plant, receiving station, transfer station, raw for retail milk dairy farm, milk tank truck,

dairy product manufacturer, and frozen dessert manufacturer located and operating in the State of Texas. Every milk plant and frozen dessert manufacturer that imports milk, milk products, or frozen desserts into the State of Texas is required to obtain a current permit/license. Permits are issued for a two-year term.

(1) All dairy farm, milk plant, receiving station, transfer station, raw for retail milk dairy farm, milk tank truck, dairy product manufacturer, and frozen dessert manufacturer, and operations located in Texas shall be approved by the department based on an inspection prior to the issuance of a permit.

(2) Permit or license fees once submitted are non-refundable.

(3) A current permit or license shall only be issued when all past due fees (including inspection fees under subsection (h) of this section) and late fees have been paid for all years of operation in Texas.

(b) Application. Applications may be obtained by visiting the Department of State Health Services at 8407 Wall Street, Austin, Texas or by contacting the Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347. Applications are also available on-line at www.dshs.state.tx.us/fdlicense. The applicant must submit an accurate and complete application accompanied with a permit or license fee payable to the department prior to an inspection.

(c) Permit/license fees.

(1) Permitted or licensed facilities and operations shall pay the following fees. If applications are made after March 1 of any year, the fee will be prorated.

(A) Milk plant:

(i) \$800 for a two-year license;

(ii) \$600 pro-rated; and

(iii) \$400 for a two-year license that is amended during the current licensure period due to minor change.

(B) Producer dairy farm:

(i) \$200 for a two-year license;

(ii) \$150 pro-rated; and

(iii) \$100 for a two-year license that is amended during the current licensure period due to minor change.

(C) Receiving and transfer station:

- (i) \$800 for a two-year license;
- (ii) \$600 pro-rated; and
- (iii) \$400 for a two-year license that is amended during the current licensure period due to minor change.

(D) Milk transport tanker:

- (i) \$200 for a two-year license;
- (ii) \$150 pro-rated; and
- (iii) \$100 for a two-year license that is amended during the current licensure period due to minor change.

(E) Grade A raw for retail:

- (i) \$800 for a two-year license;
- (ii) \$600 pro-rated; and
- (iii) \$400 for a two-year license that is amended during the current licensure period due to minor change.

(F) Frozen dessert manufacturers:

- (i) \$800 for a two-year license;
- (ii) \$600 pro-rated; and
- (iii) \$400 for a two-year license that is amended during the current licensure period due to minor change.

(G) Dairy product manufacturer:

- (i) \$800 for a two-year license;
- (ii) \$600 pro-rated; and
- (iii) \$400 for a two-year license that is amended during the current licensure period due to minor change.

(2) For all applications and renewal applications, the department is authorized to collect subscription and convenience fees in amounts determined by the Texas Online Authority to recover costs associated with application and renewal application processing through Texas Online.

(d) Renewal of a permit/license.

(1) Milk plants, producer dairy farms, receiving and transfer stations, Grade "A" raw for retail, dairy product manufacturer, and frozen dessert manufacturers must submit a renewal application and the required fee prior to September 1 of the year before the permit license expires. A person who submits a renewal application and required fee after the expiration date shall pay an additional \$100 as a delinquency fee.

(2) Milk transport tankers must submit a renewal application and required fee prior to September 1 of the year before the permit license expires. All tankers shall have an inspection no more than one year old on file prior to issuance of the renewal permit sticker.

(3) Milk plants, Grade "A" raw for retail, and frozen dessert manufacturers' permit or license shall only be issued when all past due inspection fees are current.

(e) Amendment of permit/license.

(1) Fee. A permit/license that is amended for a change of name or a change in location of a permitted place of business will require submission of an application for amendment, and the required fee for the "minor change" amendment pursuant to subsection (c) of this section.

(2) Change of ownership. A permit is not transferable and will require submission of a new application and fee as outlined in subsection (c) of this section.

(3) The department must be notified in writing at least 30 days prior to the effective date of the name, ownership, or location change and will require submission of a new application and two-year license as outlined in subsection (a) of this section.

(f) All applicants shall comply with Subchapter T, §1.301 of this title (relating to Suspension of License for Failure to Pay Child Support).

(g) Applicability of other law.

(1) Health and Safety Code (HSC), Chapter 431, applies to the conduct of a person licensed under HSC, Chapter 440, and to a frozen dessert, a product sold in semblance of a frozen dessert, or a mix for one of those products subject to HSC, Chapter 440. A frozen

dessert, a product sold in semblance of a frozen dessert, or a mix for one of those products is a "food" for purposes of HSC, Chapter 431.

(2) A person who holds a license under HSC, Chapter 440, related to the manufacturing of a product regulated under that chapter, and is engaging in conduct within the scope of that license, is not required to hold a license as a food manufacturer, food wholesaler, or warehouse operator under HSC, Chapter 431, Subchapter J.

(3) Health and Safety Code, Chapter 431, applies to the conduct of a person licensed under HSC, Chapter 435, and to milk or a milk product subject to HSC, Chapter 435. Milk or a milk product is a "food" for purposes of HSC, Chapter 431.

(4) A person who holds a license under HSC, Chapter 435, related to the processing, producing, bottling, receiving, transferring, or transporting of Grade "A" milk or milk products, or dairy products, and who is engaging in conduct within the scope of that permit, is not required to hold a license as a food manufacturer, food wholesaler, or warehouse operator under HSC, Chapter 431, Subchapter J.

(h) Inspection fees.

(1) All milk or milk products processed, manufactured, or bottled by milk plants, and offered for sale within the State of Texas shall be assessed a \$0.045 per hundredweight inspection fee or shall pay a minimum fee of \$5 each month, whichever is greater. This fee shall be assessed on a monthly basis. The inspection fee includes the cost of analyzing samples for milk or milk products. Milk plants shall submit monthly production data to the department no later than 15 days after the end of each reporting month as designated by the department, accompanied by the fee required by this section. Each milk plant is required to furnish, upon request from the department, production records for the preceding three years for auditing purposes. This fee shall be considered delinquent if it is not received by the department within 30 days after the end of the reporting period.

(2) All frozen desserts manufactured by frozen dessert manufacturing plants and offered for sale within the State of Texas shall be assessed a \$0.015 per hundredweight inspection fee or shall pay a minimum fee of \$5 each month, whichever is greater. This fee shall be assessed on a monthly basis. The inspection fee includes the cost for analyzing frozen dessert samples. Manufacturers shall submit monthly production data to the department no later than 15 days after the end of each monthly reporting period designated by the department, accompanied by the required fee. Also, each plant will be required to furnish, upon request, production records for the preceding three years for auditing purposes. This fee shall be considered delinquent if it is not received by the department within 30 days after the end of the reporting period.

(3) All dairy products manufactured in Texas shall be assessed a \$0.015 per hundredweight inspection fee or shall pay a minimum fee of \$5 each month, whichever is greater. This fee shall be assessed on a monthly basis. The inspection fee includes the cost for

analyzing samples. Manufacturers shall submit monthly production data to the department no later than 15 days after the end of each monthly reporting period designated by the department, accompanied by the required fee. Also, each plant will be required to furnish, upon request, production records for the preceding three years for auditing purposes. This fee shall be considered delinquent if it is not received by the department within 30 days after the end of the reporting period.

§217.92. Enforcement.

(a) Tagging unsanitary equipment, utensils, and rooms. The department representative may attach a tag or other appropriate marking device to any equipment, utensil, or room in a dairy farm, milk plant, receiving station, transfer station, raw for retail dairy farm, milk tank truck, or frozen dessert manufacturer that the representative determines is unsanitary or is a health hazard. No equipment, utensil, or room so tagged shall be used until a department representative removes the tag following adequate cleaning and sanitization. Such tag shall not be removed by anyone other than a department representative.

(b) Detained products. A department representative shall attach a tag or other appropriate marking device to any milk, milk product, dairy product, frozen dessert, Grade A retail raw milk, or Grade A retail raw milk product that is or is suspected of being adulterated or misbranded. The tag indicates notice that the product is detained. No person shall remove the tagged products from the premises or dispose of the product by sale or otherwise without prior written approval from the department or a court order.

(c) Suspension of Health and Safety Code (HSC), Chapter 435, permit. The department may suspend a permit issued under HSC, Chapter 435, whenever there is reason to believe that a public health hazard exists, or whenever a permit holder has violated any of the sections of this chapter, or whenever the permit holder has interfered with the department or its agents in the performance of its duties. A written notice of the violation will be provided to the permit holder, and the permit holder shall have 72 hours to correct the violation(s). The written notice may be served by a copy of the inspection report handed to the permit holder or operator or may be posted at the place of business. After receipt of the notice, but prior to the expiration of the 72 hours, the permit holder may request an extension of the time to correct the violation(s). The permit holder who has been served with a written notice of violation and suspension may request an informal regulatory conference on the facts of the violation. The informal regulatory conference shall be held within 72 hours of the request, notwithstanding any time allotted for correction. A permit holder who disagrees with the outcome of an informal regulatory conference may make a written request for a hearing. The hearing will be conducted pursuant to §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures) and the Administrative Procedure Act, Government Code, Chapter 2001.

(d) Immediate suspension of HSC, Chapter 435, permit. Immediate suspension of a permit under this subsection shall occur when the milk or milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit an inspection; or when the bacteria counts, coliform counts, somatic cell counts or cooling

temperatures are in violation of the requirements of §217.27(e) of this title (relating to Examination of Milk and Milk Products), §217.28 of this title (relating to Standards for Grade A Raw for Retail Milk and Milk Products), or §217.45 of this title (relating to Examination and Standards for Frozen Desserts); or when adulteration by inhibitors or water is identified; or if any pathogenic bacteria is isolated. A permit that is immediately suspended shall remain suspended until the department determines that the violation has been corrected. The permit holder may make a written request for a hearing to contest the suspension. The hearing will be conducted pursuant to §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures) and the Administrative Procedure Act, Government Code, Chapter 2001.

(e) Revocation of HSC, Chapter 435, permits. The department may revoke a permit issued under HSC, Chapter 435, if the permit holder is delinquent in the remittance of the permit fee or the inspection fee. The department may revoke a permit for noncompliance with the requirements of this chapter. The department will provide written notice of the reasons for the proposal to revoke, and the opportunity to request a hearing. The permit holder may make a written request for a hearing within 20 days of receipt of the written notice proposing revocation. The permit holder may also request an informal hearing conference without waiving the right to a hearing. The hearing will be conducted pursuant to §§1.21, 1.23, 1.25, and 1.27 of this title and the Administrative Procedure Act, Government Code, Chapter 2001.

(f) Denial, suspension, and revocation of license issued under frozen desserts, HSC, Chapter 440. The department may deny an application for a license, may suspend a license, or may revoke a license issued under HSC, Chapter 440, for violations of HSC, Chapter 440, or these sections. The license holder may request a hearing in writing to contest the denial, suspension, or revocation. The license holder may also request an informal hearing conference without waiving the right to a hearing. The hearing will be conducted pursuant to §§1.21, 1.23, 1.25, and 1.27 of this title and the Administrative Procedure Act, Government Code, Chapter 2001.

(g) Election of penalties. The penalty authorized by HSC, Chapter 435, is subject to either the sanctions prescribed in the "Grade A Pasteurized Milk Ordinance" which is adopted by reference in §217.2 of this title (relating to Grade A Pasteurized Milk Ordinance) for products covered by the "Grade A Pasteurized Milk Ordinance", or any civil or administrative penalty sanctions otherwise imposed by HSC, Chapter 431, or sanctions found in other law for products not covered by the Grade A Pasteurized Milk Ordinance.

(h) Administrative penalties. For products not covered by the "Grade A Pasteurized Milk Ordinance", administrative penalties, as provided in the Health and Safety Code, §§431.054 - 431.058, and in §229.261 of this title (relating to Assessment of Administrative Penalties), may be assessed against a person who violates HSC, Chapter 435 or 440, this chapter or a rule or order adopted under this chapter, who holds a permit or license under HSC, Chapter 435 or 440, or who is regulated under this chapter.

Figure: 25 TAC §217.1(68)(A)

Temperature	Time
Batch Pasteurization	
63°C (145°F)*	30 minutes
Continuous Flow Pasteurization (HTST, HHST)	
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or greater, or contains a total solids of 18% or greater, or contains added sweeteners, or is concentrated (condensed), the specified temperature shall be increased by 3°C (5°F).

Figure: 25 TAC §217.1(68)(B)

Temperature	Time
Batch Pasteurization	
69°C (155°F)	30 minutes
Continuous Flow Pasteurization (HTST)	
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Figure: 25 TAC §217.45(g)(1)

	Bacteria	Coliform	Temperature
Mix	50,000/ml	40/ml	45° F
Frozen Dessert	50,000/ml	40/ml	45° F

Figure: 25 TAC §217.45(g)(2)

	Bacteria	Coliform	Temperature
Nondairy Frozen Desserts	50,000/ml	40/ml	45° F
Nondairy Frozen Desserts Mix (Dry)	1,000/ml	10/ml	-----