# TITLE 25 HEALTH SERVICES

# PART 1 DEPARTMENT OF STATE HEALTH SERVICES

# CHAPTER 217 MILK AND DAIRY

# 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) Abnormal milk--Milk that is visibly changed in color, odor, or texture. Abnormal milk includes lacteal secretions that:

(A) are expected to be unsuitable for consumption, such as milk containing colostrum or blood; or

(B) are unfit for human consumption due to treatment of the animal with veterinary products, antibiotics which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) or the Environmental Protection Agency.

(2) 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.

(3) 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.

(4) 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;

(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 (21 U.S.C. §342) exist; or

(H) it is deemed abnormal milk.

(5) Approved Source- A supply of food or products that complies with applicable state and federal laws and is licensed, if required, and inspected by the regulatory authority having jurisdiction over the processing and distribution of food or products.

(6) 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.

(7) 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 Adopted Regulations and Standards), so as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

(8) Automatic milking installation (AMI)--The entire installation of one or more milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning, and sanitization.

(9) Batch number--A designation that is printed on the label that allows the history of its production and packaging to be traced.

(10) Bulk milk hauler--A person who transports raw milk and raw milk products to and from a milk plant, receiving station, transfer station, frozen dessert manufacturer, or non-grade “A” dairy product manufacturer, and has in their possession a certification from the department.

(11) 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.

(12) Bulk milk sampler--A person who collected official samples and may transport raw milk and raw milk products to and from a farm, milk plant, receiving station, transfer station, frozen dessert manufacturer, or non-grade “A” dairy product manufacturer, and has in their possession a current sampler card from the department.

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

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

(15) 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.

(16) 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.

(17) 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.

(18) 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.

(19) Dairy farm--Any place or premises where one or more cows or goats are kept, and from which a part or all of the milk or milk products is provided, sold, or offered for sale to a milk plant or transfer station.

(20) Dairy plant sampler--A department employee responsible for the collection of official samples for regulatory purposes. (21) 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 Related Cheese Products (Title 21, CFR, Part 133).

(22) Department--The Department of State Health Services, the Commissioner of Health, or an authorized representative.

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

(24) 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.

(25) 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.

(26) Federal Food Drug and Cosmetic Act --The United States laws pertaining to food, drugs, and cosmetics as specified in 21 U.S.C. §301, *et seq.*

(27) Food allergen--A major food allergen is:

(A) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(B) A food ingredient that contains protein derived from a food specified in subparagraph (A) of this paragraph, except the following.

(i) Any highly refined oil derived from a food specified in subparagraph (A) of this paragraph, and any ingredient derived from such highly refined oil.

(ii) A food ingredient that is exempt under U.S.C. Title 21 Chapter 9, Subchapter IV, §343(w)(6) and (7).

(28) Food allergen cross-contact--The unintentional incorporation of a food allergen into a food.

(29) 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.

(30) Frozen dessert--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.

(31) 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.

(32) 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.

(33) 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."

(34) 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.

(35) 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.

(36) 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."

(37) 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."

.

(38) 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.

(39) Goat milk ice cream--The food defined in Title 21, CFR, §135.115.

(40) 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."

(41) 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, Consumer Protection Division , 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.

(42) Grade A raw milk and Grade A raw milk products--Milk products that are manufactured under the provisions of Subchapter B of this chapter(relating to Grade A Raw Milk and Raw Milk Products), and are offered for sale to the public without pasteurization.

(A)These products include: plain raw milk, raw flavored milk, raw low-fat milk, raw low-fat flavored milk, raw skim milk, raw skim flavored milk, raw cultured milk, raw cultured low fat milk, raw cultured skim milk, raw cream, raw heavy cream, raw light cream, raw sour cream, raw acidified sour cream, raw cultured sour cream, raw light whipping cream, raw heavy whipping cream, raw whipped cream, raw light whipped cream, raw plain yogurt, raw flavored yogurt, raw low fat yogurt, raw nonfat yogurt, raw drinkable yogurt, raw drinkable probiotic yogurt, raw buttermilk, raw half-and-half, raw sour half-and-half, raw acidified sour half-and-half, raw cultured sour half-and-half, raw eggnog, raw whey, raw flavored whey, raw whey protein, raw flavored whey protein, and raw keifer .

(B) Grade A raw milk and raw milk products do not include the following.

(i) Infant formula, ice cream or other desserts, butter, or cheese.

(ii) Raw milk or raw milk products that are a blend of raw milk from more than one raw milk processer dairy farm.

(43) Grade A raw milk processor--A person who processes milk as defined in paragraph (56) of this section, that is produced under the provisions of Subchapter B of this chapter and is offered for sale to the public without pasteurization.

(44) Grade A raw milk processor dairy farm--Any place or premise where one or more lactating animals (cows, goats, sheep, water buffalo, or other hooved animals) are kept, and from which a part of or all the raw milk and raw milk products are produced, processed, bottled, and provided, sold, or offered for sale to the public.

(45) 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.

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

(47) 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.

(48) Homogenized--The term "homogenized" means that milk or a milk product has been treated to ensure 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.

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

(50) Label--A display of written, printed, or graphic matter upon the immediate container or wrappers accompanying such article.

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

(52) 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.

(53) 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."

(54) 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.

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

(56) 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.

(57) Milk hauler--Any person who transports raw milk and raw milk products to or from a milk plant, receiving station, transfer station, frozen dessert manufacturer, or non-grade “A” dairy product manufacturer.

(58) 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.

(59) Milk producer--Any person who operates a producer dairy farm and provides, sells, or offers milk for sale to a milk plant, receiving station, transfer station, frozen dessert manufacturer, or non-grade A dairy product manufacturer.

(60) 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.

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

(62) 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.

(63) 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.

(64) 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, transfer station, frozen dessert manufacturer, or non-grade A dairy product manufacturer to another milk plant, receiving station, transfer station, frozen dessert manufacturer, or non-grade A dairy product manufacturer.

(65) Milk transportation company--A milk transportation company is the entity responsible for milk tank trucks.

(66) 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 this chapter;

(C) milk is not labeled in accordance with §217.24 of this title (relating to Labeling) for Grade A Raw l Milk and Raw Milk Products; §217.43 of this title (relating to Labeling) for Rules for the Manufacture of Frozen Desserts; and §217.81 of this title (relating to Labeling) for Dairy Products and Milk for Manufacturing Purposes; or

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

(67) 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.

(68) 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, propulene glycol alginate, pectin, psyllium seed husk, and sodium carvoxymethylcellulose.

(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.

(69) 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.

(70) Non-grade A dairy product manufacturer--Any place, premise, or establishment where dairy products are produced or prepared for distribution for human consumption but not subject to Grade A requirements.

(71) 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.

(72) Official laboratory--A biological, chemical or physical laboratory which is under the direct supervision of the department for the analysis of milk, milk products, milk for manufacturing, or frozen dessert. Official laboratories include full service laboratories.

(73) Officially designated laboratory--A commercial laboratory or a milk industry laboratory officially designated by the department for the analysis of milk, milk products, milk for manufacturing,or frozen desserts.

(74) 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.

(75) 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(75)(A)

|  |  |
| --- | --- |
| Temperature | Time |
| Batch Pasteurization | |
| 63ºC (145ºF)\* | 30 minutes |
| Continuous Flow Pasteurization (HTST, HHST) | |
| 72ºC (161ºF)\* | 15 seconds |
| 89ºC (191ºF) | 1.0 second |
| 90ºC (194ºF) | 0.5 seconds |
| 94ºC (201ºF) | 0.1 seconds |
| 96ºC (204ºF) | 0.05 seconds |
| 100ºC (212ºF) | 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 3ºC (5ºF).

(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(75)(B)

|  |  |
| --- | --- |
| Temperature | Time |
| Batch Pasteurization | |
| 69ºC (155ºF) | 30 minutes |
| Continuous Flow Pasteurization (HTST) | |
| 80ºC (175ºF) | 25 seconds |
| 83ºC (180ºF) | 15 seconds |

(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 FDA as provided in 21 U.S.C. §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.

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

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

(78) Principal Display Panel--The part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

(79) 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 products is provided, sold, or offered for sale to a milk plant, transfer station, receiving station, frozen dessert manufacturer, or non-grade A dairy product manufacturer.

(80) 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%.

(81) 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 before quiescently freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10%.

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

(83) 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.

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

(85) 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.

(87) Sale--The term “sale” or “sell” means a transaction, conveyance, exchange, barter, or trade that involves:

(A) the transfer or supplying of milk, milk products, raw milk, raw milk products, dairy products, or frozen dessert products;

(B) the acquisition of milk, milk products, raw milk, raw milk products, dairy products, and frozen dessert products; or

(C) the transfer or acquisition of milk through a contribution system.

(87) 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.

(88) Sherbet--The food defined in Title 21, CFR, §135.140.

(89) 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.

(90) 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.

(91) 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.

(92) 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.

(93) 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.

(94) 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.

(95) Thermometer--A temperature measuring device that is either mercury-in-glass, alcohol/spirit-in-glass, electronic/digital, or dial immersed in liquid and accurate within the appropriate range of designated use.

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

(97) 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.

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

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

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

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

(102) 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. Adopted Regulations and Standards.

(a)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.

(b) The Department of State Health Services adopts by reference, 21 CFR Part 117, Subparts A General Provisions, B Current Good Manufacturing Practice, and C Hazard Analysis and Risk-Based Preventative Controls, as amended.

The existing rules for the Grade A Raw for Retail Milk and Milk Products in Texas Administrative Code Title 25, [Chapter 217, Subchapter B](https://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=5&ti=25&pt=1&ch=217&sch=B&rl=Y) are being repealed entirely. The new rules for the Grade A Raw Milk and Raw Milk Products will be located in the same subchapter of Texas Administrative Code Title 25, Chapter 265, Subchapter B. This draft includes the new rules for Chapter 265, Subchapter B.

# TITLE 25 HEALTH SERVICES

# PART 1 DEPARTMENT OF STATE HEALTH SERVICES

# CHAPTER 217 MILK AND DAIRY

# SUBCHAPTER B GRADE A RAW MILK AND RAW MILK PRODUCTS

§217.21. Purpose.

The purpose of these rules is to regulate the production, handling, sampling, examination, grading, labeling and sale of Grade A raw milk and Grade A raw milk products at the dairy farm; the inspection of dairy herds and dairy farms; and the issuing and revocation of permits and related penalties.

§217.22. Adulterated or Misbranded Milk or Milk Products.

No person shall, within the State of Texas, produce, sell, offer for sale, or have in possession with intent to sell, any milk or milk product which is adulterated, misbranded, or ungraded.

§217.23. Permits.

A person must have a permit to sell or provide Grade A raw milk and Grade A raw milk products. A person must comply with the provisions of this subchapter to receive a Grade A Raw for Retail Milk permit.

§217.24. Labeling.

(a) All bottles, containers, and packages enclosing Grade A raw milk and Grade A raw milk products as defined in §217.1(42) of this title (relating to Definitions) must be conspicuously labeled immediately upon bottling on the principal display panel to include:

(1) the name that must contain the phrase “Grade A Raw” and include the product name as given in the definition in §217.1(42) of this title;

(2) the batch number of the Grade A raw milk and Grade A raw milk products, which must consist of the date and time the Grade A raw milk or Grade A raw milk product was bottled or packaged;

(3) the quantity of the contents;

(4) the name, address, zip code, telephone number, and permit number of the Grade A raw milk processor;

(5) all ingredients listed in descending order of predominance;

(6) the allergens that must be identified by bolding the letters in the ingredient statement or having a “Contains” statement immediately after the ingredient statement; and

(7) the following statement that must appear on the principal display panel: “This product contains unpasteurized milk. Consuming raw foods, including raw dairy products, may increase your risk of foodborne illness. Persons at higher risk for foodborne illness include pregnant and nursing women, children, the elderly, and people with weakened immune systems.”

(b) Labeling information is required on all bottles, containers or packages of Grade A raw milk and Grade A raw milk products and must be in letters of an acceptable size, font, and color satisfactory to the department and must contain no marks or words which are misleading. All labeling must be easily legible under ordinary conditions of purchase. All labeling on Grade A raw milk and Grade A raw milk product containers must be approved by the department, Milk and Dairy Unit before the use of the Grade A raw milk or Grade A raw milk product.

§217.25. Inspection of Grade A Raw Milk Processor Dairy Farms.

(a) Each Grade A raw milk processor dairy farm whose milk is produced and intended for consumption within the State of Texas must be inspected by the department before the issuance of a permit.

(b) Following the issuance of a permit, each Grade A raw milk processor dairy farm is inspected at a frequency determined by the department.

(c) A violation of the requirements set forth in §217.27 of this title (relating to Standards for Grade A Raw Milk and Raw Milk Products) is denoted on the Grade A raw milk processor dairy farm inspection form.

(d) A copy of the inspection report must be posted in a conspicuous place on an inside wall of the Grade A raw milk processor dairy farm.

(e) Every Grade A raw milk processor must allow access of officially designated persons to all parts of the dairy farm to determine compliance with the provisions of this subchapter.

(f) Every Grade A raw milk processor must furnish the department, upon request, for official use only, a true statement of the actual quantities of Grade A raw milk and Grade A raw milk products sold, records of inspections, and temperature records.

(g) When a condition is found, which constitutes an imminent health hazard, the department may take immediate enforcement action.

§217.26. Examination of Grade A Raw Milk and Grade A Raw Milk Products.

(a) Each Grade A raw milk processor dairy farm whose Grade A raw milk and Grade A raw milk products are produced and intended for consumption within the State of Texas are sampled at a frequency determined by the department.

(b) At a minimum, cooling temperature checks, antibiotic tests, somatic cell counts, bacterial counts, coliform counts, pathogenic bacteria, aflatoxin and water adulteration are performed on Grade A raw milk and Grade A raw milk product samples.

(c) Samples are analyzed at an official or officially designated laboratory as defined in §217.1(72) and §217.1(73) of this title (relating to Definitions).

(d) Whenever bacteria counts, coliform counts, somatic cell counts, water adulteration, or cooling temperatures, exceed the limit of the standard for the Grade A raw milk or Grade A raw milk product, an additional sample is collected on a date determined by the department.

(e) A product detention, issue of a recall order, cessation from commerce, or issue of an emergency order may take place in accordance with §217.92 of this title (relating to Enforcement) or court action, and may be instituted whenever the standard of a consecutive sample is violated by bacteria counts, somatic cell counts, coliform counts, water adulteration, or cooling temperatures.

(f) A product that has a Grade A raw milk sample exceeding standards in §217.27 of this title (relating to Standards for Grade A Raw Milk and Raw Milk Products) for antibiotic, pathogenic bacteria, or aflatoxin must be removed from supplies intended for human consumption. A product detention, issue of a recall order, cessation from commerce, or issuance of an emergency order may take place until the milk is free of antibiotics, pathogenic bacteria, or aflatoxin.

§217.27. Standards for Grade A Raw Milk and Raw Milk Products.

All Grade A raw milk and Grade A raw milk products must be produced and handled to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements stated in §217.28 of this title (relating to Sanitation Requirements for Grade A Raw Milk and Raw Milk Products).

(1) Temperature: Cooled to 45 degrees Fahrenheit (7 degrees Celsius) or less within two hours after milking.

(2) Antibiotics: No positive results on drug residue detection methods.

(3) Somatic Cells: Individual raw milk shall not exceed 750,000 cell count per milliliter (ml). Goat milk shall not exceed 1,500,000 per ml.

(4) Bacteria Limits: 20,000 per ml. Cultured products are exempt from this standard.

(5) Coliform: Not to exceed 10 per ml.

(6) Pathogen: Zero.

(7) Aflatoxin: less than 0.5 parts per billion (ppb).

(8) Water Adulteration: cryoscope reading of -0.524 or above.

§217.28. Sanitation Requirements for Grade A Raw Milk and Raw Milk Products.

(a) Abnormal milk.

(1) Milk from animals treated with or exposed to insecticides not approved for use on dairy cattle by the U.S. Environmental Protection Agency must not be offered for sale.

(2) The department may require additional tests for the detection of abnormal milk.

(3) Abnormal milk must be handled and disposed of to prevent the infection of other animals and the contamination of milk utensils and equipment. Abnormal milk may not be offered for human consumption.

(4) Animals secreting abnormal milk must be milked last or with separate equipment, which effectively prevents the contamination of the wholesome supply.

(5) Equipment, utensils, and containers used for the handling of abnormal milk must not be used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

(b) Milking barn, stable, parlor, or Automatic Milking Installation (AMI)--construction.

(1) A milking barn, stable, parlor, or AMI must be provided on all Grade A raw milk processor dairy farms to house the milking herd during milking time operations. The areas used for milking purposes must:

(A) have floors constructed of concrete or equally impervious material graded to drain, which are smooth, easily cleanable, maintained in good repair, and free of excessive breaks or worn areas that may create pools of water, wastes, or other liquids;

(B) have gutters and feed troughs constructed of good quality concrete or equally impervious material;

(C) be constructed to ensure manure does not pile or pool in the milking barn, stable, parlor, or AMI and is approved by the department;

(D) have finished walls and ceilings that are smooth, easily cleanable, impervious to moisture, light colored, dust tight, and in good repair;

(E) have ceilings that are dust tight;

(F) have wall partitions, doors, shelves, and windows kept in good repair, and surfaces must be refinished whenever wear or discoloration is evident;

(G) ensure feed stored overhead does not allow the sifting of chaff and dust into the milking barn, stable, parlor, or AMI;

(H) ensure hay openings have a dust-tight door, which is kept closed during milking operations;

(I) have separate stalls or pens for non-lactating animals;

(J) have lighting equivalent of at least 10 foot candles in all working areas during milking hours;

(K) provide sufficient air space and air circulation to prevent condensation and excessive odors throughout the milking barn, stable, parlor, or AMI;

(L) not be overcrowded; and

(M) have dust-tight covered boxes, bins, or separate storage facilities for ground, chopped, or concentrated feed.

(2) The department may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirements of subsection (c) of this section, concerning animals and fowl entering the barn. Animal-housing areas (stables without stanchions, such as loose housing tables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, wandering sheds) may be of shed-type construction, provided no milking is conducted therein.

(c) Milking barn, stable, parlor, or AMI-cleanliness.

(1) The interior of the milking barn, stable, parlor, or AMI must be kept clean.

(2) Leftover feed in feed mangers must appear dry and fresh.

(3) The bedding material, if used, must be free from excessive manure.

(4) Outside surfaces of pipeline systems located in the milking barn, stable, parlor, or AMI must be clean.

(5) All animal pens, if not separated from the milking barn, stable, parlor, or AMI, must be clean.

(6) Swine and fowl must be kept out of the milking barn, parlor, and AMI.

(7) Gravity flow manure channels in milking barns, if used, must be maintained and be clean.

(8) Floors must be cleaned after each milking.

(A) In barns provided with water under pressure, the floors must be scrubbed after each milking with a stiff-bristled brush.

(B) In barns in which water under pressure is not available, the floors may be brushed dry and limed, or have phosphate applied evenly in a thin coat. Care should be exercised to prevent caking of the lime.

(d) Animal yard.

(1) The animal yards, which are the enclosed or unenclosed areas adjacent to the milking barn, and AMIs in which the animals may congregate, including animal housing areas and feed lots, must be graded and drained and must have no standing pools of water or accumulations of animal manure.

(2) Animal lanes must be reasonably dry.

(3) Approaches to the barn door, surroundings of stock watering, and feeding stations must be solid to the footing of the animal.

(4) Loafing and animal housing areas must have animal droppings and soiled bedding removed, or clean bedding added, at sufficient intervals to prevent the soiling of the animal’s udders and flanks.

(5) Waste feed must not accumulate.

(6) Manure packs must be properly drained and must provide reasonably firm footing.

(7) Swine must be kept out of the animal yard.

(e) Milkhouse or room--construction and facilities.

(1) A milkhouse or room of sufficient size, a minimum of 30 inch spacing around equipment to allow for cleaning and inspection on all sides, must be provided for the cooling, handling, and storing of milk, and the washing, sanitizing, and storing of milk containers and utensils except as provided for in subsection (l) of this section.

(2) The milkhouse floor must be smooth, easily cleanable, and constructed of concrete or equally impervious material. The floors must be maintained in good repair free of cracks, breaks, depressions, and surface peeling.

(3) The floor shall be sloped to drain to prevent pools of standing water.

(4) The joints between the floor and walls must be watertight.

(5) Liquid waste shall be disposed of in a sanitary manner. All floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

(6) The walls and ceilings must be smooth, easily cleanable, impervious to moisture, covered with light colored paint, and in good repair.

(7) Surfaces and joints must be tight and smooth.

(8) The milkhouse must have a minimum of 20 foot candles of adequate natural or artificial light.

(9) The milkhouse must be adequately ventilated to minimize odors and condensation of floors, walls, ceilings, and clean utensils.

(10) Vents, if installed, and lighting fixtures must be installed to preclude the contamination of bulk milk tanks or clean utensil storage areas.

(11) The milkhouse shall be used for no other purpose than milkhouse operations.

(12) There shall be no direct opening into any barn, stable, parlor, AMI, or room used for domestic purposes. Except for permitting an opening between the milkhouse and milking barn, stable, parlor, or AMI when a tight-fitting, self-closing solid door is provided.

(13) A vestibule must comply with the applicable milkhouse construction requirements.

(14) Water under pressure must be piped into the milkhouse.

(15) The milkhouse must be provided with facilities for heating water in sufficient quantity and necessary temperatures, based on the cleaning agent’s specifications, for the effective cleaning of all equipment and utensils.

(16) The milkhouse shall be equipped with a two-compartment wash vat of sufficient size to accommodate the largest utensil and container used.

(17) A refrigerator of sufficient size must:

(A) be provided for storage of cooling bottled Grade A raw milk and Grade A raw milk products;

(B) be capable of maintaining the Grade A raw milk and Grade A raw milk products at the proper temperature; and

(C) be equipped with a suitable thermometer approved by the department before use.

(f) Milkhouse or room-cleanliness.

(1) The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment, and other milkroom equipment must be clean.

(2) Only articles directly related to milkroom activities are allowed in the milkroom. The milkroom must be kept free of trash, animals, and fowl.

(3) Vestibules must be kept clean.

(g) Toilet.

(1) Every Grade A raw milk processor dairy farm shall provide one or more toilets, conveniently located by the milking barn, parlor, stable, AMI, and the milkroom. The toilet room must be properly constructed with walls, floors, and ceilings that are smooth, easily cleanable, impervious to moisture, and light colored, and operated and maintained in a sanitary manner.

(2) There must be no evidence of human defecation or urination about the premises.

(3) The toilet room must not open directly into the milkroom.

(4) Doors to toilet rooms must be tight-fitting and self-closing and all outer openings in toilet rooms must be screened or otherwise protected against the entrance of flies.

(5) The toilet room shall be kept free of odors.

(6) The toilet must be connected to a public sewer system or to an individual sewage-disposal system and must be constructed and operated in accordance with the most current revision of the Texas Commission on Environmental Quality rules regulating on-site sewage facilities.

(h) Water supply.

(1) A water source that tests negative for the presence of coliform bacteria and meets the requirements in this subsection are considered a safe water source. The following requirements must be met.

(A) Water samples must be taken before the permit approval of the physical structure and found negative for the presence of coliform bacteria.

(B) Water samples must be taken after any repair, alteration, or maintenance of the water supply system and found negative for the presence of coliform bacteria.

(C) Water hauled to the Grade A raw processor dairy farm must be sampled for the presence of coliform bacteria at the point of use.

(2) Water for milkhouse and milking operations must be from a supply properly located, protected, operated, easily accessible, adequate sanitary quality, and meet the requirements of a safe water source.

(A) All water supply systems must be approved as safe and comply with the specifications of the Texas Commission on Environmental Quality 30 TAC §290.41.

(B) No cross-connections between a safe water supply and any unsafe or questionable water supply or any other source of pollution are permitted.

(C) There must be no submerged inlets through which a safe water supply may be contaminated.

(D) The water source must be located and constructed in a manner that neither the underground nor surface contamination from any sewerage systems, or other pollution can reach the water supply. Well casing and seal must be located above the ground surface.

(E) All new water supply systems, which have been repaired or otherwise become contaminated, must be thoroughly disinfected and approved as safe before being placed in use.

(F) All containers and tanks used in the transportation of water must be sealed and protected from possible contamination and must be approved by the department before use.

(i) The containers and tanks must be thoroughly cleaned and have a bacteriological treatment before filling with potable water to be used at the dairy farm.

(ii) To minimize the possibility of contamination of the water during the transfer from the potable tanks to the elevated or ground-water storage at the dairy farm, a suitable pump, hose, and fittings must be provided.

(iii) When the pump, hose, and fittings are not being used, the outlets must be capped and stored in a suitable dust proof enclosure to prevent contamination.

(iv) The storage tank at the dairy farm must be constructed of impervious material, provided with a dust and rainproof cover, and provided with an approved vent and roof hatch.

(v) All reservoirs must be disinfected before placing them into service.

(i) Containers, utensils and equipment--construction.

(1) All multi-use containers, equipment, and utensils used in the handling, or storage of Grade A raw milk and Grade A raw milk products must be made of smooth, nonabsorbent, corrosion resistant, nontoxic materials, free of breaks, and be easily cleaned. Safe materials of the following types are allowed:

(A) stainless steel of the American Iron and Steel Institute (AISI) 300 series;

(B) equally corrosion resistant, nontoxic metal;

(C) heat-resistant glass; or

(D) plastic or rubber and rubberlike materials, which:

(i) are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distorting, under normal use conditions;

(ii) are nontoxic, fat resistant, relatively nonabsorbent, relatively soluble, and do not release component or impart flavor or odor to the product; and

(iii) must maintain their original properties under repeated use conditions.

(2) All milk pails used for foremilk stripping must be seamless and of the hooded type.

(3) Strainers, if used, must be of perforated metal design, or constructed to utilize single-service strainer media. Multiple-use woven material must not be used for straining milk.

(4) All single-service articles must be manufactured, packaged, transported, and handled in a sanitary manner and obtained from an approved source. (5) Articles intended for single-service use must not be reused.

(6) Farm holding/cooling tanks with welded sanitary piping, must be smooth and free from pits, cracks, or inclusions.

(7) Cleaned-in-place milk pipelines and return solution lines must be self-draining.

(8) Gaskets, if used, must be self-positioning and of material meeting specifications described in this section, and must form a smooth, flush interior surface.

(9) If gaskets are not used, all fittings must have self-positioning faces designed to form a smooth, flush interior surface.

(10) All interior surfaces of welded joints in pipelines must be smooth and free of pits, cracks, and inclusions.

(11) Detailed plans for cleaned-in-place pipeline systems must be submitted to the department for written approval before installations. No alteration or addition must be made to any milk pipeline system without prior written approval from the department.

(12) All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces must be easily cleaned and inspected. Pipelines, milking equipment, and other equipment requiring a screwdriver or special tool must be easily accessible for inspection and the necessary tools must be available at the milkhouse.

(13) Farm holding/cooling tanks and welded sanitary piping must be complaint with all applicable requirements set forth in this section.

(j) Containers, utensils and equipment--cleaning. The product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk must be cleaned after each usage.

(k) Containers, utensils and equipment--sanitization. The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage, or transportation of milk must be sanitized before each usage by one of the following methods, or by any method, which has been demonstrated to be equally effective.

(1) Complete immersion in hot water at a temperature of at least 170 degrees Fahrenheit (77 degrees Celsius) as determined by use of a suitable accurate thermometer (at the outlet) for at least five minutes; or

(2) Complete immersion for at least one minute in, or exposure for at least one minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution and piping must be filled. Sanitizing sprays may be used.

(A) Chemical solution once used, may not be reused for sanitizing.

(B) When chemicals are used for sanitization, a test kit or device accurately measuring parts per million concentration must be provided and used. The solution must be tested before use.

(l) Containers, utensils and equipment--storage.

(1) All containers, utensils and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, must be stored to ensure complete drainage and be protected from contamination before use.

(2) Pipeline milking equipment, such as milk claws, inflations, weight jars, meters, milk hoses, milk receivers, and milk pumps, which are designed for mechanical cleaning, may be stored in the milking barn, parlor, or AMI only if the pipeline milking equipment is designed, installed, and operated to protect the product and solution contact surfaces from contamination at all times.

(3) When manual cleaning of product-contact surfaces is necessary, the cleaning must be done in the milkhouse.

(4) Clean cans or other containers may only be stored in the milkhouse.

(5) Strainer pads, parchment papers, gaskets, and similar single-service articles must be stored in a suitable container or cabinet and protected against contamination.

(6) Single service bottles must be stored at least six inches above the floor in a storage area.

(m) Containers, utensils and equipment--handling.

(1) After sanitizing, all containers, utensils, and equipment must be handled in such manner as to prevent contamination of any milk product-contact surfaces, including farm holding or cooling tank openings, and outlets.

(2) Any sanitized milk product-contact surface exposed to contamination must be cleaned and sanitized before use.

(n) Milking flanks, udders, and teats.

(1) Milking must be done in the milking barn, stable, parlor, or AMI.

(2) The flanks, udders, bellies, and tails of all milking animals must be free from visible dirt and other debris.

(3) The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.

(4) All brushing must be completed before milking.

(5) The udders and teats of all milking animals shall be cleaned and treated with an approved sanitizing solution just before the time of milking, and must be relatively dry before milking.

(6) Wet hand milking is prohibited.

(o) Milking--surcingles, milk stools, and antikickers.

(1) Surcingles, milk stools, and antikickers must be kept clean and stored above the floor in a clean place in the milking barn, stable, parlor, or milkhouse when not in use.

(2) Milk stools must not be padded and must be constructed to be easily cleaned.

(p) Protection from contamination.

(1) Equipment and operations must be located within the milking barn, AMI, and milkhouse to prevent overcrowding and contamination of cleaned and sanitized containers or utensils.

(2) No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

(3) During milking, pipelines and equipment used to contain milk and milk products must be effectively separated from tanks or circuits containing cleaning and sanitizing solutions.

(4) All milk, which has overflowed, leaked, spilled, or improperly handled must be discarded.

(5) All milk product-contact surfaces or containers, equipment, and utensils must be covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination.

(6) All openings, including valves and piping attached to milk storage and transport tanks, pumps, or vats, must be capped or otherwise properly protected. Gravity type strainers in the milkhouse do not have to be covered.

(7) Milk pipelines used to convey milk from pre-coolers to the bulk tank must be fitted with effective drip deflectors.

(8) The receiving receptacle must be raised above the floor or placed at a distance from the cows to protect it against manure and splash when milk is poured or strained in the milking barn. Receiving receptacle must have a tight-fitting cover, which must be closed except when milk is being poured.

(9) Each pail or container of milk must be transferred immediately from the milking barn, stable, parlor, or AMI into the milkhouse.

(10) Pails, cans, and other equipment containing milk must be properly covered during transfer and storage.

(11) Air under pressure, used for the agitation or movement or milk, or being directed at a milk-contact surface, must be free of oil, dust, rust, excessive moisture, extraneous materials, and odor.

(12) Antibiotics and medicinal products must be stored in a manner that does not contaminate the milk or any milk product-contact surface.

(q) Bottling and capping.

(1) All bottling and capping must be performed on approved mechanical equipment. Hand capping is allowed provided:

(A) milk is withdrawn through the bottom (outlet) valve of the tank, and dipping out of the tank is prohibited;

(B) containers for transporting milk from tank to filling area are constructed of seamless, stainless steel material, and sanitized before usage; and

(C) filling of food grade containers is performed in a sanitary manner to preclude possible contamination, and food grade container filling by the consumer is prohibited.

(2) Returnable food grade containers must be washed, rinsed, and sanitized before filling. Lids for returnable food grade containers must not be reused. Sanitized, food grade containers must be provided by the dairy farm.

(A) There shall be a separate room with three-compartment wash vat for washing, rinsing, and sanitizing of returnable food grade containers at the dairy farm.

(B) Single-service food grade containers, returnable food grade containers, and lids must come from a licensed and inspected entity. Single-service food grade containers may not be reused.

(C) All caps or single-service lids must be kept immersed in a 50 parts per million chlorine solution for a minimum of one minute and immediately placed on the container.

(D) The operator must wear disposable plastic gloves while filling and capping.

(r) Personnel--hand washing facilities.

(1) Adequate hand-washing facilities must be provided, maintained in good repair, and located convenient to the milkhouse, milking barn, stable, parlor, AMI, and flush toilet.

(2) Hand-washing facilities must include:

(A) a lavatory fixture with hot and cold running water;

(B) soap or detergent;

(C) single-service individual sanitary towels; and (D) utensil wash and rinse vats may not be used for hand-washing facilities.(s) Personnel--cleanliness.

(1) Employees hands must be washed, clean, and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities.

(2) Employees performing any activity inside the milkhouse or milking area shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(t) Cooling.

(1) Raw milk must be cooled to 45 degrees Fahrenheit (7 degrees Celsius) or less within two hours after milking.

(2) Recirculated cold water used in plate, tubular coolers, or heat exchangers must be from a safe source and protected from contamination. The water is tested semiannually and found free of bacteria by an official or officially designated laboratory.

(u) Insect and rodent control.

(1) Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents.

(2) Surroundings must be kept neat, clean, and free of conditions, which might harbor or create conditions conducive to the breeding of insects and rodents.

(3) During fly season, manure must:

(A) be spread directly on the fields;

(B) stored for not more than four days in a pile on the ground surface, and then spread on the fields;

(C) stored for not more than seven days in an impervious-floored bin, or on an impervious-curbed platform and then spread on the fields;

(D) stored in a tight-screened and trapped manure shed;

(E) effectively treated with larvicides; or

(F) disposed of in any other manner that controls insect breeding.

(4) Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing must be properly bedded and managed to prevent fly breeding.

(5) Milkrooms must be free of insects and rodents.

(6) Milkrooms must be effectively protected against the entrance of vermin.

(7) Exterior milkhouse doors must be tight and self-closing. Screen doors must open outward.

(8) Insecticides and rodenticides not approved for use in the milkhouse may not be stored in the milkhouse.

(9) Only insecticides and rodenticides approved for use by the department and registered with the U.S. Environmental Protection Agency may be used for insect and rodent control.

(10) Insecticides and rodenticides must be applied in accordance with state pesticide law, the manufacturer’s label directions, and to prevent the contamination of milk, milk containers, equipment, utensils, feed, and water.§217.29. Animal Health.

(a) All herds and additions thereto shall be tested and found free of tuberculosis and brucellosis before any milk therefrom is sold. All required tests in this section must be performed by a licensed veterinarian or a veterinarian in the employment of an official agency.

(b) All herds must be retested at least every 12 months and found free of tuberculosis and brucellosis. All test results must be provided to the department, Milk and Dairy Unit.

(c) All bovine herds must participate in the brucellosis milk ring testing program conducted by the Texas Animal Health Commission.

(d) For diseases other than brucellosis and tuberculosis, the department shall require physical, chemical, or bacteriological tests as it deems necessary.

(1) The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian or a veterinarian in the employment of an official agency.

(2) Any diseased animal disclosed by such tests shall be disposed of in a method approved by the department.

§217.30. Plans for Grade A Raw Milk Processor Dairy Farms.

Properly prepared plans for all milkhouses, milking barns, stables, Automatic Milking Installations (AMIs) and parlors, regulated under this subchapter, which are hereafter constructed, reconstructed, or extensively altered, shall be submitted to the department for written approval before work is begun.

§217.31. Selling of Raw Milk to the Consumer.

(a) Grade A raw milk and Grade A raw milk products may be sold by the Grade A raw milk processor directly to the consumer at the raw milk processor dairy farm, provided that such producer has been issued a Grade A Raw for Retail Permit in accordance with §217.91 of this title (relating to Milk Facilities and Operations Permit and Frozen Dessert License Procedures), and complies with this subchapter.

(b) Grade A raw milk and Grade A raw milk products may be delivered by the permitted processor, or the permitted processor’s employee, to the consumer’s residence, within the department Retail Foods jurisdiction, provided that the permitted processor:

(1) Ensures all Grade A raw milk and Grade A raw milk products are delivered in refrigerated sanitary equipment.

(A) If ice is used to keep Grade A raw milk and Grade A raw milk products cold, the ice must come from an approved source or made with approved potable water source and must not contain any dirt, debris, or other contaminations.

(B) Grade A raw milk and Grade A raw milk products must not be completely submerged in ice.

(2) Ensures the Grade A raw milk and Grade A raw milk products internal temperature is maintained at or below 45 degrees Fahrenheit during processing, transportation, and delivery. Grade A raw milk and Grade A raw milk products may not be frozen.

(3) Provides a temperature-control-sample, for each delivery and each product type, and ensures the internal temperature reading of the Grade A raw milk and Grade A raw milk product is maintained at or below 45 degrees Fahrenheit (7 degrees Celsius).

§217.32. Disease Control and Employee Health.

(a) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness; open lesion, including boils, sores, or infected wounds; or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations, which may be expected to result in such contamination until the condition is corrected, unless conditions, such as open lesions, boils, and infected wounds are adequately covered (e.g. by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk, the department is authorized to require any or all the following measures:

(1) the immediate exclusion of that person from milk handling;

(2) the immediate exclusion of the milk supply concerned from distribution and use; and

(3) adequate medical and bacteriological examination of the person, of the person’s associates, and their body discharges.

§217.33. Records.

Records for the production, processing, bottling, and all sales of Grade A raw milk and Grade A raw milk products must be maintained and provided to the department, upon request, and must include the following.

(1) The monitoring of all temperature controls during the production, processing, bottling, sale, and delivery.

(2) The corrective actions taken when there is a failure to maintain product at the required temperature of 45 degrees Fahrenheit (7 degrees Celsius).

(3) The amount of Grade A raw milk and Grade A raw milk products produced daily.

(4) The amount of Grade A raw milk and Grade A raw milk products processed daily.

(5) The amount of Grade A raw milk and Grade A raw milk products sold and delivered daily.

(6) The batch number for each Grade A raw milk and Grade A raw milk product that is bottled daily.

(7) A customer list to include the amount and types of Grade A raw milk and Grade A raw milk products sold and delivered. The customer list must include:

(A) the batch number;

(B) the delivered Grade A raw milk and Grade A raw milk products; and

(C) all internet sales.

(8) All herd health records must be provided to the department annually.

§217.34. New Technologies.

Technologies not addressed in current rule must be approved and accepted by the department, Milk and Dairy Unit before to the implementation and use.