

ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-3-16
PRODUCTION, PROCESSING, HANDLING OR DISTRIBUTION OF
MILK, MILK PRODUCTS AND FROZEN DESSERTS

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420-3-16-.01 Purpose. Rules defining "milk and certain milk products," "frozen desserts," "milk producer," "pasteurization"

etc.; prohibiting the sale of adulterated and misbranded milk, milk products, and frozen desserts; requiring permits for the sale of milk, milk products and frozen desserts; and the manufacturers of single-service containers; and closures regulating the inspection of dairy farms, milk plants, and frozen dessert plants, and manufacturers of single-service containers and closures and the examination, labeling, pasteurization, aseptic processing and packaging, distribution, and sale of milk, milk products, and frozen desserts; providing for the construction of future dairy farms, milk plants, frozen dessert plants, and manufacturers of single-service containers, and closures the enforcement of these rules and the fixing of penalties. The following definitions shall appear in the interpretation and the enforcement of these rules:

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.02 Products which have a standard of identity defined in the Code of Federal Regulations are referenced in Appendix L.

(a) Milk - Milk is the product defined in the Code of Federal Regulations, Title 21, §131.110.

1. Goat Milk - Goat milk is the normal lacteal secretion, practically free from 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 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of these rules. The word "milk" shall be interpreted to include goat's milk, and should comply with all the requirements of these rules. The word "cow" shall be interpreted to include goats, and shall comply with all the requirements of these rules.

(b) Cream - Cream is the product defined in the Code of Federal Regulations, Title 21, §131.3(a).

1. Light Cream - Light Cream is the product defined in the Code of Federal Regulations, Title 21 §131.155.

2. Light Whipping Cream - Light whipping cream is the product defined in the Code of Federal Regulations, Title 21, §131.157.

3. Heavy Cream or Heavy Whipping Cream - Heavy cream or heavy whipping cream is the product defined in the Code of Federal Regulations, Title 21, §131.150.

4. Whipped Cream - Whipped cream is the product defined in the Code of Federal Regulations, Title 21, §131.150 or 131.157, into which air or gas has been incorporated.

5. Whipped Light Cream - Whipped light cream is the product defined in the Code of Federal Regulations, Title 21, §131.155, into which air or gas has been incorporated.

6. Sour Cream or Cultured Sour Cream - Sour cream or cultured sour cream is the product defined in the Code of Federal Regulations, Title 21, §131.160.

7. Acidified Sour Cream - Acidified sour cream is the product defined in the Code of Federal Regulations, Title 21, §131.162.

(c) Half-and-Half - Half-and-Half is the product defined in the Code of Federal Regulations, Title 21, §131.180.

1. Sour Half-and-Half or Cultured Sour Half-and-Half - Sour half-and-half or cultured sour half-and-half is the product defined in the Code of Federal Regulations, Title 21, §131.185.

2. Acidified Sour Half-and-Half - Acidified sour half-and-half is the product defined in the Code of Federal Regulations, Title 21, §131.187.

(d) Reconstituted or Recombined Milk and Milk Products - Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this rule which result from reconstituting or recombining of milk constituents with potable water when appropriate.

(e) Concentrated Milk - Concentrated milk is 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 with the milkfat and milk solids-not-fat levels of milk as defined above.

1. Concentrated Milk Products - Concentrated milk products shall be taken to mean and to include homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated

milk or concentrated skim milk, and which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding milk products in this rule.

2. Frozen Milk Concentrate - Frozen milk concentrate is 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.

(f) Skim Milk - Skim milk is the product defined in the Code of Federal Regulations, Title 21, §131.143.

(g) Lowfat Milk - Lowfat milk is the product defined in the Code of Federal Regulations, Title 21, §131.135.

(h) Eggnog - Eggnog is the product defined in the Code of Federal Regulations, Title 21, §131.170.

(i) Buttermilk - Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8 1/4 percent of milk solids-not-fat.

(j) Cultured Milk - Cultured milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.112.

1. Cultured Lowfat Milk - Cultured lowfat milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.138.

2. Cultured Skim Milk - Cultured skim milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.146.

(k) Acidified Milk - Acidified milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.111.

1. Acidified Lowfat Milk - Acidified lowfat milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.136.

2. Acidified Skim Milk - Acidified skim milk (buttermilk, etc.) is the product defined in the Code of Federal Regulations, Title 21, §131.144.

(1) Yogurt - Yogurt is the product defined in the Code of Federal Regulations, Title 21, §131.200.

1. Lowfat Yogurt - Lowfat yogurt is the product defined in the Code of Federal Regulations, Title 21, §131.203.

2. Nonfat Yogurt - Nonfat yogurt is the product defined in the Code of Federal Regulations, Title 21, §131.206.

(m) Low-Sodium Milk or Low-Sodium Lowfat Milk or Low-Sodium Skim Milk - Low-sodium milk or low-sodium lowfat milk or low-sodium skim milk is the product resulting from the treatment of milk, lowfat milk, or skim milk as defined in these rules by a process of passing the milk, lowfat milk, or skim milk through an ion exchange resin process or any other process which has been recognized by the Food and Drug Administration that effectively reduces sodium content of the product to less than 10 milligrams in 100 milliliters.

1. Lactose-Reduced Milk or Lactose-Reduced Lowfat Milk or Lactose-Reduced Skim Milk - Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk is the product resulting from the treatment of milk, lowfat milk, or skim milk as defined in these rules by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk, lowfat milk, or skim milk.

2. Lactose-Reduced Milk Products - Lactose-Reduced Milk Products are the milk products defined in this section that result from appropriate treatment with safe and suitable enzymes, so that the lactose content of the respective milk product has been reduced by at least 70%.

(n) Milk Products - 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 half-and-half; reconstituted, or recombined milk and milk products; concentrated milk; concentrated milk products; skim milk; lowfat milk; frozen milk concentrate; eggnog; buttermilk; cultured milk; cultured lowfat milk; cultured skim milk; acidified milk; acidified lowfat milk; acidified skim milk; frozen dessert mix; yogurt; lowfat yogurt; nonfat yogurt; low-sodium milk; low-sodium lowfat milk;

low-sodium skim milk; lactose-reduced milk; lactose-reduced lowfat milk, lactose-reduced skim milk; aseptically processed and packaged milk and milk products as defined in this Rule, milk; lowfat milk; or skim milk with added safe and suitable microbial organisms; and any other milk product made by the addition or subtraction of milk fat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification of milk products defined herein. Cottage cheese; dry curd cottage cheese; lowfat cottage cheese. This definition is not intended to include milk products such as evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), dietary products (except as defined herein), infant formula, dry milk products (except as defined herein), canned eggnog in a rigid metal container, butter or cheese except when they are combined with other substances to produce any pasteurized (or aseptically processed) milk or milk products defined herein.

1. Aseptically Processed Milk and Milk Products - Aseptically processed milk and milk products are products hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of these rules 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.

(o) Grade A Dry Milk and Whey Products - Grade A dry milk and whey products are products which have been produced for use in Grade A pasteurized, ultra-pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the "Grade A condensed and Dry Milk Products and Condensed and Dry Whey, 1978, Recommended Sanitation Ordinance for Condensed and Dry Milk Products and Condensed and Dry Whey Used in Grade A Pasteurized Milk Products."

(p) Cottage cheese - Cottage cheese is the product defined in the Code of Federal Regulations, Title 21, §133.128.

(q) Dry Curd Cottage Cheese - Dry curd cottage cheese is the product defined in the Code of Federal Regulations, Title 21, §133.129.

(r) Lowfat Cottage Cheese - Lowfat cottage cheese is the product defined in the Code of Federal Regulations, Title 21, §133.131.

(s) Frozen Desserts - A frozen dessert is any clean, frozen, or partially frozen combination of two or more of the following: milk, milk products, egg or egg products, sweetening

agents, water, fruit or fruit juices, vegetables, confections, nut meat, or other harmless and wholesome food products, certified natural or artificial flavors or colors, or harmless stabilizers and/or emulsifiers, and shall mean and include ice cream, frozen custards, ice milk, sherbets, icees, imitation frozen desserts, and any product used for similar purposes, and designated as a frozen dessert by the Health Officer. Milk and milk products in frozen desserts may be Grade A or ungraded.

(t) Ice Cream and Frozen Custard - Ice cream and frozen custard is the product defined in the Code of Federal Regulations, Title 21, §135.110.

(u) Goat's Milk Ice Cream - Goat's milk ice cream is the product defined in the Code of Federal Regulations, Title 21, §135.115.

(v) Ice Milk - Ice milk is the product defined in the Code of Federal Regulations, Title 21, §135.120.

(w) Goat's Milk Ice Milk - Goat's milk ice milk is the product defined in the Code of Federal Regulations, Title 21, §135.125.

(x) Sherbet - Sherbet is the product defined in the Code of Federal Regulations, Title 21, §135.140.

(y) Water Icee - Water icee is the product defined in the Code of Federal Regulations, Title 21, §135.160.

(z) Frozen Dessert Mix - Frozen dessert mix is the unfrozen combination of all ingredients of a frozen dessert with or without fruits, fruit juices, confections, nut meats, flavoring, harmless coloring, or emulsifiers and/or stabilizers either in the liquid or dry form.

(aa) Confection - Confections are candy, cakes, cookies, cereal products, and glazed fruits.

(bb) Mellorine - Mellorine is the product defined in the Code of Federal Regulations, Title 21, §135.130.

(cc) Adulterated Milk and Milk Products - Any milk or milk product shall be deemed to be adulterated if one or more of the conditions described in §402 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 342) exist. (See Appendix L).

(dd) Misbranded Milk, Milk Products, and Frozen Desserts - Milk, milk products, and frozen dessert products are misbranded: (1) when their container(s) bear or accompany any

false or misleading written, printed or graphic matter; (2) when such milk, milk products, and frozen desserts do not conform to their definitions as contained in these rules; and (3) when such products are not labeled in accordance with Rule 420-16-3-.05. When one or more of the conditions described in §403 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 343) exist. (See Appendix L).

(ee) 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 45° F. (7° C.), 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 percent from the fat percentage of the remaining milk as determined after thorough mixing.

(ff) Pasteurization - 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, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
*145° F (63° C)	30 Minutes
*161° F (72° C)	15 Seconds
191° F (89° C)	1 Second
194° F (90° C)	0.5 Second
201° F (94° C)	0.1 Second
204° F (96° C)	0.05 Second
212° F (100° C)	0.01 Second

(Ref.*) If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5° F. (3° C) -- Provided, that eggnog and frozen dessert mix shall be heated to at least the following temperature and time specifications:

Temperature	Time
155° F (69° C)	30 Minutes
175° F (80° C)	25 Seconds
180° F (83° C)	15 Seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has

been recognized by the Food and Drug Administration to be equally efficient and which is approved by the State Health Officer.

(gg) 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 280° F. (138° C) for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf-life under refrigerated conditions.

(hh) 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 21 CFR 113 and the provisions of Rule 420-3-16-.10(16)(iii) and maintain the commercial sterility of the product under normal nonrefrigerated conditions.

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

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

(kk) Milk Producer - A milk producer is any person who operates a dairy farm and provides, sells, or offers milk for sale to a milk plant, receiving station, or transfer station.

(ll) Milk Hauler - A milk hauler is any person who transports raw milk and/or raw milk products to or from a milk plant, frozen dessert plant, receiving station, or transfer station.

(mm) Milk Distributor - A milk distributor is any person who offers for sale or sells to another any milk or milk products.

(nn) Dairy Farm - A dairy farm is 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 product(s) is provided, sold, or

offered for sale to a milk plant, transfer station, or receiving station.

(oo) Frozen Dessert Plant - The term "frozen dessert plant" shall mean and include any place or premises where mix or frozen dessert is manufactured, processed, or frozen for distribution or sale.

(pp) Milk Plant - A milk plant is any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, bottled or prepared for distribution.

(qq) Transfer Station - A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

(rr) Receiving Station - A receiving station is any place, premises, or establishment where raw milk is received, collected, handled, stored, or cooled, and prepared for further transporting.

(ss) Bulk Milk Pickup Tanker - A bulk milk pickup tanker is 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 transfer station, receiving station, milk plant, or frozen dessert plant.

(tt) Milk Transport Tank - A milk transport tank is a vehicle, including the truck and tank, used by a milk hauler to transport bulk shipments of milk from a transfer station, receiving station, milk plant, or frozen dessert plant to another transfer station, receiving station, milk plant or frozen dessert plant.

(uu) Milk Tank Truck - A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

(vv) Official Laboratory - An official laboratory is a biological, chemical, or physical laboratory which is under the direct supervision of the State Health Department.

(ww) Officially Designated Laboratory - An officially designated laboratory is a commercial laboratory authorized to do official work by the State Health Officer, or a milk industry laboratory officially designated by the State Health Officer for the examination of producer samples of Grade A raw milk for

pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.

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

(yy) And/or - Where the term "and/or" is used, "and" shall apply where appropriate; otherwise "or" shall apply.

(zz) Board - The Board of Health of the State of Alabama as defined by Code of Ala. 1975, §§22-2-1, 22-2-2, and 22-20-7 or the State Health Officer or his designee, when acting for the Board--for the purpose of these rules, The Division of Environmental Program Management, Bureau of Environmental and Health Service Standards Administration, or County Board of Health as defined by Code of Ala. 1975, §22-3-1.

(aaa) Health Officer - The State Health Officer of the State of Alabama Department of Public Health or a County Health Officer as provided in Code of Ala. 1975, §22-2-8 and 22-3-4; or their authorized representatives and any officer or agent or employee of the said department authorized to act for the department with respect to the enforcement and administration of these rules.

(bbb) Health Department - The State of Alabama, Department of Public Health or County Health Department, as defined by Code of Ala. 1975, §§22-1-1 and 22-3-10 and any officer, agent or employee of the said department authorized to act for the department with respect to the enforcement and administration of these rules.

(ccc) Imitation Milk, Imitation Milk Products, or Imitation Frozen Desserts - Imitation milk, imitation milk products, or imitation frozen desserts shall be taken to mean any substance, mixture, or compound, in part or whole, regardless of name under which it may be processed, packaged, sold, or offered for sale in imitation or having the appearance or semblance of milk, milk products, or frozen desserts, and which does not contain any milk, milk product, or frozen desserts. Imitation milk, milk products, and frozen desserts shall contain the minimum percentages of wholesome fat or oil other than milkfat and solids-not-fat as the words "milk" and/or "milk products" or "frozen desserts" appear in these rules, they shall be interpreted to include "imitation milk" and/or "imitation milk products" and/or "imitation frozen desserts." Nothing herein is intended to make legal any food substance which is otherwise prohibited or illegal.

(ddd) Filled Milk or Filled Milk Products - Filled milk or filled milk products shall be taken to mean any substance, mixture, or compound, in part or whole, regardless of the name under which it may be processed, packaged, sold, or offered for sale in imitation or having the appearance or semblance of milk or milk products and which contains a mixture of any milk or milk product and any fat or oil other than milkfat. Filled milk and filled milk products shall contain the minimum percentages of wholesome fat or oil other than milkfat and solids-not-fat as defined in these rules for milk and milk products. Nothing herein is intended to make legal any food substance which is otherwise prohibited or illegal.

(eee) Hermetically sealed container - A hermetically sealed container is 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.

(fff) Drug - The term "drug" means (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; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (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 clause (A), (B), or (C), but does not include devices or their components, parts, or accessories.

Authors: Robert E. Shelton - G.M. Gallaspy, Jr.

Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7.

History:

420-3-16-.03 Adulterated Or Misbranded Milk, Milk Products Or Frozen Dessert.

(1) No person shall, within the State of Alabama or its jurisdiction, produce, provide, sell, offer or expose for sale, or have in possession with intent to sell, any milk, milk product, or frozen dessert which is adulterated or misbranded: Provided, that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by the Health Officer in which case such products shall be labeled "ungraded."

(2) Any adulterated or misbranded milk, milk product, or frozen dessert may be impounded by the Health Officer and disposed of in accordance with applicable laws or rules.

(3) Administrative Procedures: This rule shall be used in impounding the products of, or preferring charges against, persons who adulterate or misbrand their milk, milk products, or frozen desserts or label them with any grade designation not authorized by the Health Officer under the terms of these rules, or who sell or deliver ungraded milk or milk products except as may be permitted under this rule in an emergency. An emergency is defined as a general and acute shortage in the milkshed, not simply one distributor's shortage.

Author:

Statutory Authority:

History:

420-3-16-.04 Permit Prescribed.

(1) It shall be unlawful for any person who does not possess a permit from the Health Officer to bring into, send into, or receive into the State of Alabama or its jurisdiction, for sale, or to sell, or offer for sale therein, or to have in storage any milk, milk products, or frozen dessert defined in these rules--Provided grocery stores, restaurants, soda fountains, and similar establishments where milk, milk products, or frozen desserts are served or sold at retail but not processed, may be exempt from the requirements of this rule.

(2) Only a person who complies with the requirements of these rules shall be entitled to receive and retain such a permit. Permit shall not be transferable with respect to persons and/or locations.

(3) The Health Officer shall suspend such permit whenever he has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of these rules; or whenever the permit holder has interfered with the Health Officer in the performance of his duties--Provided the Health Officer shall, in all cases except where the milk, milk product, or frozen dessert product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by

the parties, or in the absence of agreement, fixed by the Health Officer before making any order of suspension effective. A suspension of permit shall remain in effect until the violation has been corrected to the satisfaction of the Health Officer.

(4) Upon notification acceptable to the Health Officer by any person whose permit has been suspended, or upon application within 7 days of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the Health Officer shall proceed to a hearing to ascertain the facts of such violation or interference and upon evidence presented at such hearing shall affirm, modify, or rescind the suspension or intention to suspend.

(5) Upon repeated violation(s), the Health Officer may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This section is not intended to preclude the institution of court action as provided in .06 and .07, of this rule.

(6) Administrative Procedures:

(a) Issuance of Permits: Every milk producer, milk distributor, milk hauler, and each milk plant and frozen dessert plant, receiving station, and transfer station operator shall hold a valid permit. Grocery stores, restaurants, soda fountains, and similar establishments where milk, milk products, or frozen desserts are served or sold at retail but not processed, may be exempt from the requirements of this rule.

(b) Suspension of Permit:

1. When any requirement(s) of these rules is violated, the permit holder is subject to the suspension of his permit.

2. The Health Officer may forego suspension of the permit, provided the product or products in violation are not sold or offered for sale.

(c) Administrative Hearing Procedure:

1. This rule adopted pursuant to Code of Ala. 1975, §22-20-7, as amended, is intended to accord an individual administrative hearing in any and all matters concerning those rules heretofore adopted and promulgated by the State Board of Health, and all such rules adopted and promulgated in the future by the State Committee of Public Health, where procedural due process is indicated and not otherwise provided.

2. Any person, partnership, corporation or other entity, who after proper application, is denied a permit, license, or authorization; or is in possession of a valid permit, license, or authorization, and is notified in writing of the intent to suspend, revoke or deny renewal of said permit, license or authorization; shall be provided the reasons therefore and may within seven days following receipt of said notice, apply in writing for an informal hearing to the Health Officer from which said denial or notice of intent was issued. If after the informal hearing the matter is not resolved to the satisfaction of the aforesaid person, written appeal may be made within seven days following said hearing to the State Health Officer. The informal hearing may be waived by applying in writing within seven (7) days following receipt of said notice directly to the State Health Officer, State Department of Health, Division of Food & Lodging Protection, 434 Monroe Street, Montgomery, Alabama, 36130-1701 with copy furnished the Health Officer from which said denial or notice of intent was issued.

(d) Reinstatement of Permits:

1. Any Producer, distributor, hauler, or plant operator whose permit has been suspended may make written application for the reinstatement of his permit.

2. When the permit has been suspended or revoked due to a violation of any of the bacterial, coliform, somatic cell count, or cooling temperature standards, the Health Officer shall, within one week, make an inspection of the facilities and operating methods, and collect a sample to determine that the conditions responsible for the violations have been corrected. The permit shall be reinstated if the sample is within acceptable limits; however, the notice shall be in effect so long as two of the last four samples exceed acceptable limits.

3. Whenever the permit suspension has been due to a violation of a requirement other than the bacteriological, coliform, somatic cell count, drug residue test, or cooling temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one week of the receipt of such notification, the Health Officer shall make an inspection of the applicant's establishment and as many additional inspections thereafter as are deemed necessary to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

4. When a permit suspension has been due to positive drug residues, the permit shall be reinstated in accordance with the provisions of Appendix N.

Author:

Statutory Authority:

History:

420-3-16-.05 Labeling.

(1) All bottles, containers, and packages enclosing milk or milk products, defined in §2 of these rules shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Fair Packaging and Labeling Act, and regulations developed thereunder, and in addition shall comply with applicable requirements of this section as follows:

All bottles, containers, and packages enclosing milk or milk products except milk tank trucks, storage tanks, and cans of raw milk from individual dairy farms shall be conspicuously marked with:

(a) The name of the contents as given in the definitions in these rules.

(b) The words "Grade A." (excluding frozen desserts)

(c) The identity of the plant where pasteurized, ultra-pasteurized or aseptically processed.

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

(e) The volume or proportion of water to be added for recombining in the case of concentrated milk or milk products.

(f) The word "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized.

(g) The word "pasteurized" if the milk or milk product has been pasteurized.

(h) The word "homogenized" if the milk or milk product has been homogenized.

(i) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk-derived nonfat solids.

(j) The ingredients in order of predominance by weight.

(k) The words "keep refrigerated after opening" and the term "UHT" in the case of aseptically processed milk and milk products.

(1) The dating of milk, milk products, and frozen dessert mix which is not frozen at the plant in which it was pasteurized shall be as follows: The expiration date (the date the product is to be removed from the market) shall be embossed or otherwise indicated on the outside of the carton or container so as to be easily readable and discernible. This date shall be expressed as the month and day (ex. Jan. 30). The management of each milk plant or frozen dessert plant shall provide the State Health Officer a list of the milk and milk products and frozen dessert mix to be marketed and the number of days each product shall remain on the market. Before changing any expiration date, the State Health Officer shall be notified in writing 14 days prior to the effective date of such change. In no case, during any 24-hour period, shall more than one expiration code date be assigned to a milk or milk product or frozen dessert mix which is to be processed and/or marketed by that plant. The State Health Officer shall conduct shelf-life studies of milk, milk products and frozen desserts as often as he deems necessary to determine the compliance with bacteriological standards at the end of the plant's specified product shelf-life. In case the products fail to meet the bacteriological standards at the specified shelf-life provided by plants, the State Health Officer shall require a reduction of shelf-life as he may deem appropriate. Shelf-life samples shall be collected from the plant where possible or from the distribution system while still in possession of the plant.

(m) The word "goat" shall precede the name of the milk or milk product when the product is, or is made from goat milk.

(2) All packages and other containers enclosing frozen desserts or other similar products defined in this rule shall be labeled in accordance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act, as amended; the Fair Packaging and Labeling Act, and regulations developed thereunder; and in addition shall bear the name and address or permit number of the plant where processed and packaged.

(3) All vehicles and milk tank trucks containing milk, milk products, or frozen dessert shall be legibly marked with the name and address of the plant or hauler in possession of the contents.

(4) Milk tank trucks transporting raw milk and milk products to a milk or frozen dessert plant from sources of supply not under the routine supervision of the Health Officer 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:

- (a) Shipper's name, address, and permit number.
- (b) Permit identification of hauler.
- (c) Point of origin of shipment.
- (d) Tanker identity number.
- (e) Name of product.
- (f) Weight of product.
- (g) Grade of product.
- (h) Temperature of product.
- (i) Date of shipment.
- (j) Name of supervising regulatory agency at the point of origin.
- (k) Whether the contents are raw, pasteurized, or in the case of cream, lowfat milk or skim milk, whether it has been heat treated.

(l) One copy of the shipping statement shall be retained by the consignor, one by the common carrier, and at least two copies shall be delivered to the consignee with the shipment. The consignee shall forward at least one copy to the Health Officer in the receiving area. Upon request, the Health Officer shall be notified by telegram or telephone message prior to delivery, such telephone message being promptly confirmed by letter of such shipments of raw milk. The telegram or telephone message, confirmed by letter, shall contain the information required on the shipping statement, the destination, and the expected time of arrival at the destination.

(m) Entries made on shipping statements by consignors or consignees shall be legible. When the interstate shipment is derived from more than one point of origin, separate shipping statements for each of the sources involved shall accompany the shipment. Shipping statements shall be retained on file for a period of at least 6 months.

(n) All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

(5) Administrative Procedures:

(a) Emergency Supplies - Labeling: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of 420-3-16-.03, the label must bear the designation "ungraded." When such labeling is not available, the Health Officer shall take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

(b) Identity Labeling:

1. "Identity," as used in this rule is defined as the name and address, or the milk or frozen dessert plant at which the processing pasteurization, ultra-pasteurization or aseptic processing takes place. The national uniform coding system for identification of pasteurization plants at which milk and milk products are packaged shall be used in order to provide a uniform system of codes.

2. In cases where several pasteurization plants are operated by one firm, the common farm name may be utilized on bottles or containers--Provided the location of the plant at which the contents were pasteurized, ultra-pasteurized or aseptically processed is also shown, either directly or by permit number. This requirement is necessary in order to enable the Health Officer to identify the source of the dairy product. The street address of the pasteurizing plant need not be shown when only one plant of a given name is located within the municipality.

3. The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk, milk products, and frozen desserts processed and packaged at another plant--Provided the label contains the name, address, and permit number of the manufacturer or that the label contains the name and address of the distributor and the statement "Processed or manufactured at _____" identified by the permit number of manufacturer.

(c) Misleading Labels: The Health Officer shall not permit the use of any misleading marks, words, or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to

obscure the labeling requirements of these rules. The use of super grade designations shall not be permitted. Grade designations such as "Grade AA Pasteurized," "Selected Grade A Pasteurized," "Special Grade A Pasteurized," "Premium," etc., give the consumer the impression that such a grade is significantly safer than Grade A pasteurized. Such an implication is false because the requirements for Grade A pasteurized, ultra-pasteurized or aseptically processed milk, when properly enforced, will insure that this grade of milk will be as safe as milk can practically be made.

Author:

Statutory Authority:

History:

420-3-16-.06 Inspection.

(1) Each dairy farm, milk plant, frozen dessert plant, receiving station, and transfer station whose milk, milk products, or frozen desserts are intended for consumption within Alabama or its jurisdiction and each milk hauler who collects samples of raw milk for pasteurization, for bacteriological, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, frozen dessert plant, transfer station, or receiving station and his bulk milk pickup tank and its appurtenances shall be inspected by the Health Officer prior to the issuance of a permit. Following the issuance of a permit, each bulk milk pickup tanker and its appurtenances used by a milk hauler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, frozen dessert plant, transfer station, or receiving station shall be inspected at least once every 12 months. Each hauler's pickup and sampling procedures shall be inspected at least once every 12 months. Prior to the issuance of a permit as specified in .04 of this rule, the Health Officer shall inspect all dairy farms, milk plants and frozen dessert plants the milk and/or milk products from which are intended for consumption, and which are subject to provisions of these rules. (Inspections of dairy farms shall be quarterly for dairies with a sanitation score of 90 or more. Dairies with a sanitation score of less than 90 shall be inspected monthly until such time as a score of 90 or more is received. At no time shall a period of 100 days lapse without an official inspection.) Six inspections per year of all milk and frozen dessert plants shall be required but in no instance shall two inspections in any one month be included in the required number of yearly inspections. At no time shall a period of 60 days lapse without an official inspection.

(2) The Health Officer having jurisdiction may require more frequent inspections of plants than the minimum number set forth in this rule. In case the Health Officer discovers the violation of any item of sanitation prescribed in .09 or .10 of this rule for the grade of milk being currently produced at any dairy farm or plant, he shall make a second inspection of the said dairy farm or plant after a lapse of such time as he deems necessary for the correction of the defect or violation discovered; but not before the lapse of three days. The Health Officer shall, upon finding the violation of the same item of .09 or .10 this rule on two consecutive inspections, serve upon the permit holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the permit holder a reasonable time to correct such violation.

(3) The violation of the same item in .09 or .10 of this rule on three consecutive inspection shall call for permit suspension or revocation after proper notification outlined above in accordance with .04 of this rule and/or court action--Provided, that when the Health Officer finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or

2. A cross connection exists whereby direct contamination of pasteurized milk or milk product is occurring;

3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring;

The Health Officer shall take immediate action to prevent further processing of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the regulatory agency shall take prompt action to suspend the permit as provided for in Section .04 of these rules. Provided in the case of dairy plants producing aseptically processed milk and milk products, when an inspection of the dairy plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the Health Officer shall take immediate action to suspend the permit of the plant for the sale of aseptically processed milk and milk products in conformance with .04 of this rule.

(4) A copy of the inspection report shall be posted by the Health Officer in a conspicuous place upon the inside wall of the dairy farm, and said inspection report shall not be removed or defaced by any person except the Health Officer. Also, copies of all laboratory analysis of samples from products entering the processing plant shall be maintained on appropriate ledger forms supplying all information specified by the Health Officer. All inspection reports of milk and frozen dessert plants shall be posted by the Health Officer in a conspicuous place upon an inside wall of the plant being inspected; said inspection reports shall not be removed or defaced by any person except the Health Officer. The inspection report shall be entered on appropriate ledger forms approved by the State Health Officer containing all information needed by the Health Officer, and this ledger shall be kept currently posted. A copy of each inspection shall be available to the Division of Food & Lodging Protection for records audit.

(5) Every milk producer, hauler, distributor, or plant operator shall, upon request of the Health Officer, permit access of officially designated persons to all parts of his establishment or facilities to determine compliance with the provisions of these rules. A distributor or plant operator shall furnish the Health Officer, upon request, for official use only, a true statement of the actual quantities of milk, milk products, and frozen desserts of each grade purchased and sold and a list of all sources of such milk, milk products, and frozen desserts, records of inspections, tests, and pasteurization time and temperature records.

(6) It shall be unlawful for any person, who in an official capacity, obtains any information under the provisions of this chapter which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of milk or milk products, or results of inspections or tests thereof) to use such information to his own advantage or to reveal it to any unauthorized person.

(7) Administrative Procedures:

(a) Inspection Frequency: One bulk milk pickup tanker inspection every twelve months; one hauler pickup and sampling procedures each twelve months; one producer inspection each quarter for dairies with a sanitation score of 90 or more; one producer inspection each month for dairies with a sanitation score of less than 90; one plant inspection every sixty days is a legal minimum. Milk haulers, dairy farms, milk plants, and frozen dessert plants experiencing difficulty meeting requirements should be visited more frequently. Inspections of dairy farms shall be made at milking time as often as possible

and of processing plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning, and other procedures comply with the requirements of these rules.

(b) Enforcement Procedure:

1. This rule provides that a dairy farm, milk hauler, frozen dessert or milk plant, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action if three successive inspections disclose a violation of the same requirement.

2. Experience has demonstrated that strict enforcement of these rules leads to a better and friendlier relationship between the health department and the dairy industry than does a policy of enforcement which seeks to excuse violations and to defer penalty therefor. The Health Officer's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the Health Officer should point out to the producer, milk hauler, or plant operator the requirement that has been violated, discuss a method for correction, and set a time for correcting the violated requirement.

3. The penalties of suspension or revocation of permit and/or court action are provided to prevent continued violation of the provisions of these rules but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the Health Officer is authorized in .04 of this rule to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the producer, milk hauler, milk plant, or frozen dessert plant upon the first violation of any of the sanitation requirements listed in .09 or .10 of this rule. A producer, milk hauler, milk plant, or frozen dessert plant found violating any requirement on two consecutive inspections must be notified in writing and given a reasonable time to correct the violation(s) before a third inspection is made. 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 rule. After receipt of a notice of violation, but before the allotted time has elapsed, the producer, milk hauler, milk plant, or frozen dessert plant shall have an opportunity to appeal the interpretation to the Health Officer or for an extension of the time allowed for correction.

4. Enforcement Procedures - Aseptic Processing Milk Plants - Because aseptically processed milk and milk products are stored at room temperature and not refrigerated after processing, they must be considered an imminent hazard to public health wherever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the Health Officer to suspend the permit must be initiated in order to protect the public health. The Health Officer shall stop the sale of all underprocessed product and follow at least the minimum requirements of 21 CFR 113.89 (see Appendix L) before releasing any product.

(c) Inspection Reports: A copy of the inspection report shall be filed by the Health Officer and retained for at least twelve months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection forms are included in Appendix M.

Authors: Robert E. Shelton - G.M. Gallaspy, Jr.

Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7.

History:

420-3-16-.07 Examination Of Milk And Milk Products.

(1) It shall be the responsibility of the milk hauler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck, or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station, or other location approved by the Health Officer.

(2) During any consecutive six months, at least four samples of raw milk for pasteurization, shall be collected in at least four separate months, and delivered in accordance with this section, from each producer. These samples shall be obtained under the direction of the Health Officer or shall be taken from each producer under the direction of the Health Officer. During any consecutive six months, at least four samples of raw milk for pasteurization, ultra pasteurization or aseptic processing, collected in at least four separate months, shall be taken, by the regulatory agency, from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra pasteurization or aseptic processing. During any consecutive six months, at least four samples of heat treated milk products, from plants offering such products for sale, shall be collected in at

least four separate months by the regulatory agency. During any consecutive six months, at least four samples of pasteurized milk, flavored milk, flavored lowfat milk, flavored skim milk, each fat level of lowfat milk and each milk product defined in these rules, except aseptically processed, shall be collected in at least four separate months, from every milk plant by the Health Officer. During any consecutive six months, at least four samples of each frozen dessert product defined in these rules shall be taken from every frozen dessert plant. In addition, the Health Officer shall collect and examine monthly at least one sample of each frozen dessert mix being manufactured for resale. Sample of milk, milk products, and frozen dessert shall be taken while in possession of the producer or distributor at any time. Samples of milk, milk products, and frozen dessert from dairy retail stores, food service establishments, grocery stores, and other places where milk, milk products, and frozen dessert are sold shall be examined periodically as determined by the Health Officer. Proprietors of such establishments shall furnish the Health Officer, upon request, with the name of all distributors from whom milk, milk products, or frozen desserts are obtained.

(3) Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, antibiotic tests on each producer's milk or on commingled raw milk shall be conducted at least four times during any consecutive six months. When commingled milk is tested, all producers shall be represented in the sample. All individual sources of milk shall be tested when test results on the commingled milk are positive. Required bacterial counts, antibiotic tests, coliform determinations, phosphatase, butterfat, and cooling temperature checks shall be performed on pasteurized milk, milk products, and frozen desserts.

(4) Whenever two of the last four consecutive bacterial counts (except those for aseptically processed milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for the milk, milk products, and/or frozen desserts, the Health Officer 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 standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of 3 days. Immediate suspension of permit in accordance with .04 of this rule and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed milk and milk products), coliform determinations, cooling temperatures or somatic cell counts.

(5) Laboratory facilities shall be provided at every plant to determine the presence of antibiotics in milk and/or frozen desserts. Every tank truck of raw milk shall be examined for the presence of antibiotics upon arrival at the plant. Such examinations shall be made before the milk is processed, and milk containing antibiotics shall not be processed. The Health Officer shall be notified immediately of all positive antibiotic tests. Appropriate records shall be maintained at the plant showing the results of all examinations. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk, milk product, or frozen dessert involved shall not be offered for sale. Whenever a product does not meet the butterfat standards as prescribed in these rules, the product shall not be offered for sale.

(6) Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk, milk product or frozen dessert shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

(7) Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.

(8) Whenever a container or containers of aseptically processed milk or milk product is found to be unsterile due to underprocessing, the Health Officer shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All product from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the Health Officer.

(9) Samples shall be analyzed at an official laboratory or approved officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the current Edition of Standard Methods for the Examination of Dairy Products of the American Public Health Association and the current Edition of Official Methods of Analysis of the Association of Official Analytical Chemists. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance the

Evaluation of Milk Laboratories Recommended by the United States Public Health Service/Food and Drug Administration. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with the FDA's Bacteriological Analytical Manual, Examinations and tests to detect adulterants, including pesticides, shall be conducted as the Health Officer requires. Assays of milk and milk products to which Vitamin(s) A and/or D have been added shall be made at least annually in a laboratory acceptable to the Health Officer.

(10) Administrative Procedures:

(a) Enforcement Procedures: All violations of bacteria, coliform, confirmed somatic cell counts, and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (See Appendix E, Examples of 3-out-of-5 Compliance Enforcement Procedures.) Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this rule. Therefore, whenever a breakdown in the processing or packaging of these products occurs, an imminent hazard to public health exists. Prompt action is needed by the Health Officer. Dairy plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered nonsterile after aseptic processing and packaging. The Health Officer may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of bacterial standards has existed.

(b) Laboratory Techniques:

1. Procedures for the collection and holding of samples; the selection and preparation of apparatus, media, and reagents; and the analytical procedures, incubation, reading, and reporting of results shall be in substantial compliance with Standard Methods for the Examination of Dairy Products and the Official Methods of Analysis. The procedure shall be those specified therein for:

(i) Standard Plate count at 32° C.

(ii) Alternate methods, including Plate Loop count with petrifilm, for viable counts for raw milk and the petrifilm method, for pasteurized milk and milk products, at 32° C.

(iii) Coliform test with solid media or petrifilm method at 32° for all milk and milk products.

(iv) Disc assay methods for drugs specified in Appendix G. In addition, methods which have been evaluated by AOAC and recommended by FDA at currently referenced levels shall be used for regulatory action for each drug of concern. FDA shall review the AOAC evaluation for each test kit and make a determination as to the acceptability of the use of the method in accordance with all applicable sections of these rules. Regulatory action shall be taken on all positive results (see Appendix N). A result shall be considered positive if it has been obtained by using a method which has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA as required by Section III of Appendix N.

(v) Screening and confirmatory methods for the detection of abnormal milk.

(vi) APHA or AOAC phosphatase tests.

(viii) Any other tests which have been approved by the Food and Drug Administration and the Health Officer to be equally accurate, precise, and practical.

2. The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, or if any doubt should arise as to the compliance of the equipment, standards, or methods outlined in .10(16) of this rule, the Health Officer should immediately conduct field phosphatase tests at the plant.

3. Any one of the following three tests may be used for screening raw milk samples to indicate a range of somatic cell levels: California Mastitis Test, Whiteside Test, Wisconsin Mastitis Test.

4. One of the following confirmatory tests shall be used: Direct Microscopic Somatic Cell Counting-single strip procedure, Electronic Somatic Cell Counting, Optical Somatic Cell Counting, or Membrane Filter DNA Somatic Cell Counting. Pyronine Y-methyl green stain shall be used in the confirmatory test for direct microscopic cell counts in goat milk.

5. Laboratories using acceptable screening tests shall confirm that the sample of herd milk exceeds any of the following screening test results:

- (i) California Mastitis Test 1.
- (ii) Modified Whiteside Test 1+.
- (iii) Wisconsin Mastitis Test 18n=.

6. The results of the screening test, or confirmatory test, shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

7. When a warning letter has been sent because of excessively high somatic cell counts, an official inspection of the dairy should be made by the Health Officer. This inspection should be made during milking time.

(c) Sampling Procedures:

1. When samples of raw milk for pasteurization are taken at a processing plant prior to pasteurization, they shall be drawn following adequate agitation from randomly selected storage tanks.

2. When bacterial counts except for aseptically processed milk and milk products and temperature determinations are made of several samples of the same milk or milk products collected from the same supply or processor, on the same day, these values are averaged arithmetically, and the results recorded as the count or temperature determinations of the milk or milk product for that day. All counts and temperatures should be recorded on a milk ledger form for dairy farms or milk plants as soon as reported by the laboratory.

3. A computer or other information retrieval system may be used.

4. See Appendix G, for a reference to antibiotics in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream.

(d) Farm Bulk Milk Hauling: The farm bulk milk hauler occupies a unique position in the producer-processor- Health Officer relationship. The milk hauler is a critical factor in the current structure of milk marketing. As a weigher and sample, he stands as the official and frequently the only judge of milk volumes bought and sold. As the milk receiver, the hauler's operating habits directly affect the quality of milk committed to his care. When the bulk milk hauler's obligations include the collection and delivery of samples to the laboratory

for analysis, he becomes a vital part of the quality control and regulatory programs. Any deviation from acceptable practices by the milk hauler may result in the suspension and/or revocation of his permit. (See Appendix B for reference to farm milk hauling program regarding training, licensing/permitting, routine inspection, and the evaluation procedure.)

NOTE: The industry should be encouraged by the Health Officer to achieve day-to-day compliance with the foregoing standards by performing tests on each producer's milk, including platform tests for odors, temperature, and sediment. Bacterial counts should be conducted following laboratory pasteurization as a check for thermophilic organisms. Examinations for the presence of psychrophilic bacteria are also recommended. Periodic screening tests for presence of added water, antibiotics, and pesticide residues should be performed on producer milk. Plants should reject milk of abnormal odor and high temperature as well as milk that is found to be unsatisfactory by the sediment test. Follow-up inspection on the dairy farm should be made by the fieldman to determine the cause and to institute corrective measures whenever milk is rejected by the plant.

Authors: Robert E. Shelton - G.M. Gallaspy, Jr.

Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7.

History:

420-3-16-.08 Standards For Milk And Milk Products.

(1) All Grade A raw milk for pasteurization, ultra-pasteurization or aseptically processing; and all Grade A pasteurized, ultra-pasteurized milk or aseptically processed milk and milk products and all frozen desserts shall be produced, processed, and pasteurized, ultra-pasteurized or aseptically processed to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this rule.

(2) No process or manipulation other than pasteurization, ultra-pasteurization or aseptically processed processing methods integral therewith, and appropriate refrigeration shall be applied to milk, milk products or frozen desserts for the purpose of removing or deactivating microorganisms: Provided, that in the bulk shipment of cream, skim milk, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52° C (125° F) but less than 72° C (161° F) for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and/or lowfat milk are labeled heat-treated.

TABLE 1
CHEMICAL, BATERIOLOGICAL, AND TEMPERATURE STANDARDS

Grade A Raw Milk for Pasteurization Ultra-pasteurization, or Aseptically processing	Temperature	Cooled to 45° F or less within 2 hours after milking provided that the blend temperature after the first and subsequent milkings does not exceed 50° F (10° C).
	Bacterial	Individual producer milk not to exceed 100,000 per ml. prior to commingling with other producer milk. Not to exceed 300,000 per ml. as commingled milk prior to pasteurization.
	Drugs	No zone greater than or equal to 16mm with <u>Bacillus Sterothermophilus</u> disc assay method specified in Appendix G.
	Somatic Cell Count	
Grade A Pasteurized Ultra-pasteurized Pasteurized Milk and Milk Products	Temperature	
	Bacterial Limits*	No positive results on drug residue detection methods as referenced in Section .07 Laboratory Techniques.
	Coliform	Individual producer milk not to exceed 1,000,000 per ml.
	Phosphatase**	
Grade A Aseptically Processed Milk and Milk Products	Drugs	Cooled to 45° F (7° C) or less and maintained and thereat. 20,000 per ml.
	Temperature	
	Bacterial Limits	Not to exceed 10 per ml. provided that in the case of bulk milk transport tank shipments shall not exceed 100 per ml.
	Drugs	Less than 1 microgram per ml. by the Scharer Rapid Method or equivalent.
Frozen Desserts	Temperature	No zone greater than or equal to 16mm with <u>Bacillus Sterothermophilus</u> disc assay method specified in Appendix G.
	Bacterial Limits*	
	Coliform	No positive results on drug residue detection methods as referenced in Section 6. Laboratory Techniques.
	Phosphatase	
	Drugs	None
		No growth by test specified in Section 6.
		No zone greater than or equal to 16mm with the <u>Bacillus</u>

Sterothermophilus disc assay
method specified in Appendix G.

No positive results on drug
residue detection methods as
referenced in Section 6.
Laboratory Techniques.

Cooled to 45° F (7° C) or less and
maintained thereat.

50,000 per gram.

Not to exceed 10 per gram

Less than 1 microgram per ml. by
the Scharer Rapid Method or
equivalent.

No zone greater than or equal to
16mm with
Bacillus Sterothermophilus disc
assay method specified in Appendix
G.

No positive results on drug
residue detection methods as
referenced in Section 6.
Laboratory Techniques.

**Not applicable to cultured products.*

*** Not applicable to bulk shipped heat treated milk products.*

Authors: Robert E. Shelton - G.M. Gallaspy, Jr.

Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7

History:

**420-3-16.09 Sanitation Requirements For Grade A Raw Milk For
Pasteurization, Ultra-Pasteurized Or Aseptically Processing.**

(1) Abnormal Milk:

(a) Cows which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment, and the milk shall be discarded. Cows treated with, or cows which have consumed chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the Health Officer, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Health Officer may direct.

(b) Public Health Reason:

1. The health of the cow is a very important consideration because a number of diseases of cattle, including salmonellosis, staphylococcal infection, and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash, or be blown into the milk.

2. Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (Type B), but the disease is often caused by a staphylococcus or other infectious agent. Occasionally, cows' udders become infected with hemolytic streptococci of human origin, which may result in milkborne epidemics of scarlet fever or septic sore throat. The toxins of staphylococci, and possibly other organisms in milk may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Milk from cows being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

2. Milk from cows treated with or exposed to insecticides not approved for use on dairy cattle by the U.S. Environmental Protection Agency is not offered for sale.

3. The Health Officer requires such additional tests for the detection of abnormal milk as he deems necessary.

4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other cows and the contamination of milk utensils.

5. Cows secreting abnormal milk are milked last or in separate equipment which effectively prevents the contamination of the wholesome supply.

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

7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal have been: (a) properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control officials; and (b) do not contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level which may be deleterious to human health.

8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

(2) Milking Barn or Parlor - Construction:

(a) A milking barn or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

1. Have floors constructed of concrete or equally impervious materials: Provided convalescent (maternity) pens

located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix B, V.

2. Have walls and ceiling which are smooth, painted, or finished in an approved manner, in good repair, ceiling dust tight.

3. Have separate stalls or pens for horses, calves, and bulls.

4. Be provided with natural and/or artificial light, well distributed for day and/or night milking.

5. Provide sufficient air space and air circulation to prevent condensation and excessive odors.

6. Not be overcrowded, and

7. Have dust-tight, covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed.

(b) Public Health Reason: When milking is done elsewhere than in a suitable place provided for this purpose, the milk may be contaminated. Floors constructed of concrete or other impervious materials can be kept clean more easily than floors constructed of wood, earth, or similar materials; and are, therefore, more apt to be kept clean. Painted or properly finished walls and ceiling encourage cleanliness. Tight ceilings and feed room reduce the likelihood of dust and extraneous material getting into the milk. Adequate light makes it more probable that the barn will be clean and that the cows will be milked in a sanitary manner.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. A milking barn or parlor is provided on all dairy farms.

2. Gutters, floors, and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned (brushed surfaces permitted) and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

3. Gravity flow manure channels in milking barns, if used, shall be constructed in accordance with the specifications of Appendix B, IV.

4. Stall barns, when used with gutter grates over manure storage pits are designed and constructed in accordance with the specifications of Appendix B, VI.

5. Walls are finished with tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light-colored surfaces--Provided existing barns with wood walls will not be considered a violation provided they are properly maintained. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Ceilings are constructed of smooth dressed lumber, plywood, or similar material. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, or parlor. If an opening is provided from loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

6. Bull pens, maternity and calf stalls, and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

7. The milking barn is provided with natural and/or artificial light to ensure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least 20 foot-candles of light in all working areas shall be provided.

8. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings.

9. Overcrowding is not evidenced by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.

10. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. Feed may be stored in the milking portion of the barn only in such manner as will not increase the dust content of the air, attract flies, or interfere with cleaning of the floor (as in covered, dust-tight boxes or bins). Open feed dollies or carts may be used for distributing the feed but not storing feed in the milking barn. When conditions warrant, the Health Officer may approve a barn without four walls extending from floor to roof; or a shed-type barn provided the requirement of Paragraph (3) of

this rule, prohibiting animals and fowl entering the barn is satisfied. Cattle-housing areas (stables without stanchions, such as loose-housing stables, 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. (They are classified as part of the cowyard under Paragraph (4) of this rule.

(3) Milking Barn or Parlor - Cleanliness:

(a) The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Swine, fowl, and other animals other than the milking herd shall be kept out of the milking barn.

(b) Public Health Reason - A clean interior reduces the chances of contamination of the milk or milk equipment during milking. The presence of other animals increases uncleanliness and the potential for spread of disease.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The interior of the milking barn or parlor is kept clean.

2. Leftover feed in feed mangers appears fresh and is not wet or soggy.

3. The bedding material, if used, does not contain more manure than has accumulated since the previous milking.

4. Outside surfaces of pipeline systems located in milking barn or parlor are reasonably clean.

5. Gutter cleaners are reasonably clean.

6. All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, are clean.

7. Swine, fowl, and animals other than the milking herd are kept out of the milking barn.

8. Gravity flow manure channels in milking barns, if used, shall be maintained in accordance with Appendix B, IV.

9. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of Appendix B, VI.

The method of cleaning is immaterial. Dairymen whose barns are provided with water under pressure should scrub the floors after each milking with a stiff-bristled brush. In barns in which water under pressure is not available, the floors may be brushed dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the sanitarian should require cleaning with water.

(4) Cowyard:

(a) The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic waste. Provided, that in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the cows' udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonable firm footing. Swine shall be kept out of the cowyard.

(b) Public Health Reason: The cowyard is interpreted to be that enclosed or unenclosed area in which the cows are apt to congregate, approximately adjacent to the barn including, cattle-housing areas. This area is, therefore, particularly apt to become filthy with manure droppings which may result in the soiling of the cow's udders and flanks. The grading and drainage of the cowyard as far as practicable, are required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the cows clean. If manure and barn sweepings are allowed to accumulate in the cowyard, fly breeding will be promoted; and the cows, because of their habit of lying down, will be more apt to have manure-soiled udders. Cows should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among cattle.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The cowyard, which is the enclosed or unenclosed area adjacent to the milking barn in which the cows may congregate, including cattle-housing areas and feed lots, is graded and drained; depressions and soggy areas are filled; cow lanes are reasonably dry.

2. Approaches to the barn door and the surroundings of stock watering and feeding stations are solid to the footing of the animal.

3. Wastes from the barn or milkhouse are not allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered as violating this item.

4. Manure, soiled bedding, and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of cows' udders and flanks. Cattle-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, shall be considered a part of the cowyard. Manure packs shall be solid to the footing of the animal (See Appendix B).

5. Cowyard are kept reasonably free of cattle droppings. Cattle droppings shall not be allowed to accumulate in piles that are accessible to the animals.

(5) Milkhouse or Room - Construction and Facilities:

(a) A milkhouse or room of sufficient size shall be provided in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted except as provided for in Rule 420-3-16.09(12).

(b) The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. All floor drains shall be accessible and shall be trapped.

(c) The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner.

(d) The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

(e) The milkhouse shall be used for no other purpose than milkhouse operations; There shall be no direct opening into any barn, or into a room used for domestic purposes--Provided a direct opening between the milkhouse and milking barn, or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided.

(f) Water under pressure shall be piped into the milk-house.

(g) The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

(h) When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control and general maintenance.

(i) Public Health Reason: Unless a suitable, separate place is provided for the cooling, handling, and storing of milk and for the washing, sanitizing, and storage of milk utensils, the milk or the utensils may become contaminated. Construction which permits easy cleaning promotes cleanliness. A well drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness, and proper ventilation reduces the likelihood of odors and condensation. A well equipped milkhouse which is separated from the barn and the living quarters provides a safeguard against the exposure of milk and milk utensils to infection from persons other than regular milk handlers, and from insects and dust.

(j) Administrative Procedures: This item is deemed to be satisfied when:

1. A separate milkhouse of sufficient size is 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 paragraph (12) of this rule.

2. The floors of all milkhouses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints, or other material the equivalent of concrete and maintained free of breaks, depressions, and surface peelings.

3. The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be water tight.

4. The liquid wastes are disposed of in a sanitary manner; all floor drains are accessible and are trapped and grated.

5. Walls are finished with tile, smooth, surfaced concrete, cement plaster, cement block or other equivalent

materials with light-colored surfaces. The surfaces and joints shall be smooth. Ceilings are constructed of smooth dressed lumber, plywood, or similar materials. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Walls (other than tile) and ceilings are well painted with a light-colored, washable paint.

6. A minimum of 20 foot-candles of light is provided at all working areas from natural and/or artificial light for milkhouse operations.

7. Windows and solid doors are closed during dusty weather.

8. The milkhouse is adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

9. Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.

10. The milkhouse is used for no other purpose than milkhouse operations.

11. There is no direct opening into any barn or room used for domestic purposes; except that an opening between the milkhouse and milking barn or parlor is permitted when a tight-fitting, self-closing solid door(s) hinged to be single or double acting is provided.

12. A vestibule, if used, complies with the applicable milkhouse construction requirements.

13. The transfer of milk from a bulk-holding/cooling tank to a transport tank is through a hose port located approximately 18 inches above the floor in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall sufficiently large to protect the milk hose from contamination.

14. Water under pressure is piped into the milkhouse.

15. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils. (See Appendix B)

16. The milkhouse is equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat--Provided the cleaning-in-place station rack in or on the vat and the milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Hot and cold water is piped to each compartment. A hose connected to a hot and cold mixing valve is provided for washing the bulk tank.

17. A suitable shelter is provided for a transportation truck used for cooling and storing milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance. (See Appendix B)

(6) Milkhouse or Room--Cleanliness:

(a) The floors, walls, ceilings, port holes, windows, tables, shelves, cabinets, wash vats, nonproduct-contact surfaces of milk containers, utensils, and equipment and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals, and fowl.

(b) Public Health Reason: Cleanliness in the milkroom reduces the likelihood of contamination of the milk.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The milkroom structure, equipment, and other milkroom facilities used in its operation or maintenance are clean at all times.

2. Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkroom provided they are kept clean, and ample space is available to conduct the normal operations in the milkroom and will not cause contamination of the milk.

3. Vestibules, if provided, are kept clean.

4. Animals and fowl are kept out of the milkroom.

(7) Toilet:

(a) Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in accordance with the rules of the State Board of Health. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply.

(b) Public Health Reason: The organisms of typhoid fever, dysentery, and gastrointestinal disorders may be present in the body wastes of persons who have these diseases. In the case of typhoid fever, well persons (carriers) also may discharge the organisms in their body wastes. If a toilet is not fly-tight and so constructed as to prevent overflow, infection may be carried from the excreta to the milk, either by flies or through the pollution of ground water supplies or streams to which the cows have access.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. There is at least one flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet, earth pit privy or other type privy. Such sewage systems shall be constructed and operated in accordance with plans and instructions of the State Board of Health.

2. A toilet or privy is convenient to the milking barn and the milkroom. There shall be no evidence of human defecation or urination about the premises.

3. No toilet opens directly into the milkroom.

4. The toilet room, including all fixtures and facilities, is kept clean and free of flies and odors.

5. Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of flies.

6. Vents of earth pits are screened.

7. All new or extensively remodeled barns must be provided with flush type toilet connected to a public sewer or an individual sewage disposal system.

8. Water Supply:

(a) Water for milkhouse and milking operations shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

(b) Public Health Reason:

1. A dairy farm water supply should be accessible in order to encourage its use in ample quantity in cleaning operations; it should be adequate so that cleaning and rinsing will be thorough; and it should be of safe, sanitary quality in order to avoid the contamination of milk utensils.

2. A polluted water supply used in the rinsing of the dairy utensils and containers may be more dangerous than a similar water supply which is used for drinking purposes only. Bacteria grow much faster in milk than in water, and the severity of an attack of a given disease depends largely upon the size of the dose of disease organisms taken into the system. Therefore, a small number of disease organisms consumed in a glass of water from a polluted well may possibly result in no harm, whereas, if left in a milk utensil which has been rinsed with the water, they may, after several hours growth in the milk, increase in such numbers as to cause disease when consumed.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The water supply for milkhouse and milking operations is approved as safe by the Board and, in the case of individual water systems, complies with the specifications outlined in Appendix D, and the bacteriological standards outlined in Appendix G.

2. No cross-connection exists between a safe water supply and any unsafe or questionable water supply or any other source of pollution.

3. There are no submerged inlets through which a safe water supply may be contaminated.

4. The well or other source of water is located and constructed in such a manner that neither underground or surface contamination from any sewerage system, privy, or other source of pollution can reach such water supply.

5. New individual water supplies and water supply systems which have been repaired or otherwise become contaminated are thoroughly disinfected before being placed in use. The

supply shall be made free of the disinfection by pumping to waste before any sample for bacteriological testing shall be collected.

6. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or ground-water storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust and rainproof cover, and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service (See Appendix D).

7. Samples for bacteriological examination are taken upon the initial approval of the physical structure based upon the requirements of these rules; and when any repair or alteration of the water supply system has been made, and at least annually thereafter--Provided water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than six months apart. Whenever such samples indicate either the presence of bacteria or the coliform group; or whenever the well casing, pump, or seal needs replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this paragraph: Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory each month. Bacteriological examinations shall be conducted in a laboratory acceptable to the Health Officer.

8. Current records of water test results shall be retained on file with the Health Department. Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory each month. Bacteriological examinations shall be conducted in a laboratory acceptable to the Health Officer.

9. Utensils and Equipment - Construction:

(a) All multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic

materials and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported, and handled in a sanitary manner and shall comply with the applicable requirements of Rule 420-3-16.10(11). Articles intended for single-service use shall not be reused.

(b) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Rule 420-3-16-.10(10) and (11).

(c) Public Health Reason:

1. Milk containers and other utensils without flush joints and seams, without smooth, easily cleaned, and accessible surfaces, and not made of durable, non-corrodible material, are apt to harbor accumulations in which undesirable bacterial growth is supported. Single-service articles which have not been manufactured and handled in a sanitary manner may contaminate the milk.

2. Milk pails of small-mouth design, known as hooded milk pails, decrease the possibility of hairs, dust, chaff, and other undesirable foreign substances getting into the milk at the time of milking.

(d) Administrative Procedures: This item is deemed to be satisfied when:

1. All multi-use containers, equipment, and utensils which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products, are made of smooth, impervious, nonabsorbent, safe materials of the following types:

(i) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(ii) Equally corrosion-resistant, nontoxic metal; or

(iii) Heat-resistant glass; or

(iv) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals, or

impart flavor or odor to the product, and which maintain their original properties under repeated use conditions.

2. Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Rule 420-3-16-.10.(11).

3. Articles intended for single-service use are not reused.

4. All containers, equipment, and utensils are free of breaks and corrosion.

5. All joints in such containers, equipment, and utensils are smooth and free from pits, cracks, or inclusions.

6. Cleaned-in-place milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in 1. (iv) above and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

7. Detailed plans for cleaned-in-place pipeline systems are submitted to the Health Officer for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Health Officer. (See Appendix B)

8. Strainers, if used, are of perforated metal design or so constructed as to utilize single-service strainer media.

9. Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size are used for hand milking and hand stripping.

10. All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces can be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances which require a screwdriver or special tool shall be considered easily accessible for inspection provided the necessary tools are available at the milkhouse.

11. Milk cans have umbrella-type lids.

12. Farm holding-cooling tanks, welded sanitary piping, and transportation tanks comply with the applicable requirements of Rule 420-3-16-.10(10) and (11).

Note: 3-A Sanitary standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association of Milk, Food and Environmental Sanitarians, Inc., and the Milk Safety Branch Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in Conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of the Ordinance.

(10) Utensils and Equipment-Cleaning:

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

(b) Public Health Reason: Milk cannot be kept clean or free of contamination if permitted to come into contact with unclean containers, utensils, or equipment.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk are cleaned after each usage.

(11) Utensils and Equipment-Sanitization:

(a) The product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be sanitized before each usage.

(b) Public Health Reason: Mere cleaning of containers, equipment, and utensils does not insure the removal or destruction of all disease organisms which may have been present. Even very small numbers remaining may grow to dangerous proportions, since many kinds of disease bacteria grow rapidly in milk. For this reason, all milk containers, equipment, and utensils must be treated with an effective sanitizer before each usage.

(c) Administrative Procedures: This item is deemed to be satisfied when: All product-contact surfaces of multi-use

containers, utensils, and equipment used in the handling, storage, or transportation of milk are 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° F (77° C) for at least five (5) minutes or exposure to a flow of hot water at a temperature of at least 170° F (77° C) as determined by use of a suitable accurate thermometer (at the outlet) for at least five (5) minutes.

2. Complete immersion for at least one (1) minute in, or exposure for, at least one (1) minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes. (See Appendix F)

(12) Utensils and Equipment-Storage:

(a) All containers, utensils, and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use--Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria may be stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

(b) Public Health Reason: Careless storage of milk utensils which previously have been properly treated is apt to result in recontamination of such utensils, thus rendering them unsafe.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All milk containers, utensils, and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution or on racks, until used. Milk pipelines and pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment as accepted by FDA, which meet these criteria may be mechanically cleaned, sanitized,

and stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product- and solution-contact surface from contamination at all times. Some of the parameters to be considered in determining protection are proper location of equipment, proper drainage of equipment, and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking, but the barn shall not be used for the housing of cattle. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse.

2. Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

3. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

4. Strainer pads, parchment papers, gaskets, and similar single-service articles are stored in a suitable container or cabinet and protected against contamination.

(13) Utensils and Equipment-Handling:

(a) After sanitization, all containers, utensils, and equipment shall be handled in such manner as to prevent contamination of any product-contact surface.

(b) Public Health Reason: Handling milk pails by inserting the fingers under the hood, carrying an armful of milk-can covers against a soiled shirt or jacket, or similar handling of utensils will nullify the effect of sanitization.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, are protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

2. Any sanitized product-contact surface which has been otherwise exposed to contamination is again cleaned and sanitized before being used.

(14) Milking-Flanks, Udders, and Teats:

(a) Milking shall be done in the milking barn, or parlor. The flanks, udders, bellies and tails of all milking

cows shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be cleaned and treated with a sanitizing solution and dried using individual towels just prior to the time of milking, and shall be relatively dry before milking. Wet hand milking is prohibited.

(b) Public Health Reason: If milking is done elsewhere than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the cows is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, cows contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are carefully cleaned just before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because cow manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain the organisms of typhoid fever and other intestinal diseases. Rinsing or wiping the udders and teats with a sanitizing solution has the advantage of giving an additional margin of safety with reference to such disease organisms as are not removed by ordinary cleaning, and it is helpful in the control of mastitis.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Milking is done in a milking barn or parlor.
2. Brushing is completed prior to milking.
3. Flanks, bellies, tails, and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.
4. Udders and teats of all milking cows are clean and dry before milking. Teats are treated with a sanitizing solution and wiped dry just prior to milking.
5. Wet hand milking is prohibited.

(15) Milking - Surcingles, Milk Stools, and anti-kickers:

(a) Surcingles, milk stools, and anti kickers shall be kept clean and stored above the floor.

(b) Public Health Reason: Clean milk stools, and clean surcingles (or belly straps) reduce the likelihood of contamination of milkers' hands between the milking of one cow and the milking of another.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Milk stools are not padded and are constructed to be easily cleaned.

2. Milk stools, surcingles, and anti kickers are kept clean and are stored above the floor in a clean place in the milking barn, parlor, or milkhouse when not in use.

(16) Protection from Contamination:

(a) Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

(b) Public Health Reason: Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort should be made to provide adequate protection for the milk at all times. This should include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air which is used for the agitation or movement of milk or is directed at a milk product-contact surface should be such that it will not contaminate the milk.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

2. During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.

3. All milk which has overflowed, leaked, been spilled, or improperly handled is discarded.

4. All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk storage and transport tanks, pumps, or vats, shall be capped or otherwise properly protected. Gravity type strainers in the milking barn do not have to be covered. Milk pipelines used to convey milk from pre-coolers to the farm bulk tank must be fitted with effective drip deflectors.

5. The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the cows to protect it against manure and splash when milk is poured and/or strained in the milking barn. Such receptacle shall have a tight-fitting cover which shall be closed except when milk is being poured.

6. Each pail or container of milk is transferred immediately from the milking barn, stable, or parlor to the milk-house.

7. Pails, cans, and other equipment containing milk are properly covered during transfer and storage.

8. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor, and shall otherwise comply with the applicable standards of Appendix H.

9. Cleaners and sanitizers used on dairy farms shall be purchased in containers from the manufacturer or distributor which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occur into a dedicated end-use container which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions and the name and address of the manufacturer or distributor.

10. Equipment used to administer medicinals/drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk contact surfaces of equipment.

11. Antibiotics and medicinals are stored in such a manner that they cannot contaminate the milk or milk

product-contact surface of the equipment, containers or utensils. Such products shall be properly labeled to include:

(i) The name and address of the manufacturer or distributor (for O.T.C. medicinals/drugs), or veterinary practitioner dispensing the product (for Rx and Extra-Label use medicinals/drugs), and,

(ii) Directions for use, and prescribed holding times,

(iii) Cautionary statements, if needed.

(iv) Active ingredient(s) in the drug product.

12. Unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, or parlor. Medicinals/drugs intended for treatment of non-lactating dairy animals are segregated from those medicinals/drugs used for lactating animals. (Separate shelves in cabinets, refrigerators, or other storage facilities satisfied this item.)

NOTE: Topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product surfaces of containers or utensils.

(17) Personnel-Handwashing Facilities:

(a) Adequate handwashing facilities shall be provided, including a lavatory fixture with running water, soap or detergent, and individual sanitary towels in the milkhouse and in/or convenient to the milking barn, parlor, or flush toilet.

(b) Public Health Reason: The hands of the milker in his preparation for milking come into contact with almost identically the same kind of material as may have contaminated the udders. During the course of his duties and natural habits outside of the milking barn, the dairyman's hands must be assumed to have been exposed to body discharges. Washing facilities are required in order to increase the assurance that milker's hands will be washed.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Handwashing facilities are located in the milkhouse and in/or convenient to the milking barn, parlor, or flush toilet.

2. Handwashing facilities include soap or detergent, running water, individual sanitary towels, and a lavatory fixture. Utensil wash and rinse vats shall not be considered as handwashing facilities.

(18) Personnel-Cleanliness:

(a) Hands shall 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. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(b) Public Health Reason: The reasons for clean hands of the persons doing the milking are similar to those for cleanliness of the cows' udders. The milker's hands must be assumed to have been exposed to contamination during the course of his normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing, it is important that the clothes worn during milking and the handling of milk be clean.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Hands are 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. Milkers and milk haulers wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(19) Cooling:

(a) Raw Milk for pasteurization shall be cooled to 45° F (7° C) or less within two (2) hours after milking - Provided that the blend temperature after the first milking and subsequent milkings does not exceed 50° F (10° C).

(b) Public Health Reason:

1. Milk produced by disease-free cows and under clean conditions usually contains relatively few bacteria immediately

after milking. These multiply to enormous numbers in a few hours unless the milk is cooled. When the milk is cooled quickly to 45° F (7° C) or less, however, there is only a slow increase in numbers of bacteria. In order to understand this, it is necessary to recall merely that bacteria are actually infinitesimal plants and that most plants do not grow in cold weather.

2. Usually, the bacteria in milk are harmless, and if this were always true, there would be no reason to cool milk except to delay souring. There is however, no way for the dairyman or Health Officer to be absolutely sure that no disease bacteria have entered the milk even though observance of the other items of these rules will greatly reduce this likelihood. The likelihood of transmitting disease is much increased then the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly so that small numbers of bacteria which may have entered will not multiply.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Raw milk for pasteurization is cooled to 45° F (7° C) or less within two (2) hours after milking--Provided that blend temperature after the first milking and subsequent milkings does not exceed 50° F (10° C).

2. Recirculated cold water which is used in plate or tubular coolers or heat exchanges is from a safe source and protected from contamination. Such water shall be tested semi-annually and shall comply with the current bacteriological standards established by the Environmental Protection Agency for drinking water.

(20) Vehicles:

(a) Vehicles used to transport milk from the dairy farm to the milkplant or receiving station shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; and no substance capable of contaminating milk shall be transported with milk.

(b) Public Health Reason: To protect milk during transportation, delivery vehicles must be properly constructed and operated.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Vehicles used to transport milk from the dairy farm to the milk plant or receiving station are constructed and operated to protect their contents from the sun, freezing and contamination.

2. Vehicles have bodies with solid enclosures and tight, solid doors.

3. Vehicles are kept clean, inside and out.

4. No substance capable of contaminating the milk is transported with the milk.

NOTE: See Paragraphs (9) and (10) of .09 of this rule for information on the construction of bulk milk pickup tankers.

(21) Insect and rodent control:

(a) Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin. Milkrooms shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

(b) Public Health Reason: Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection, by physical contact or through excrete, to milk or milk utensils. Flies visit insanitary places, may carry disease organisms on their bodies and may carry living bacteria for as long as four (4) weeks within their bodies and may pass them on to succeeding generations by infecting their eggs. Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk with disease germs, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean to encourage cleanliness and reduce insect and rodent harborages.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Surroundings are kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Manure shall be spread directly on the fields; or stored for not more than four (4) days in a pile on the ground surface and then spread on the fields; or stored for not more than seven (7) days in a impervious-floored bin, or on

an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.

2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing are properly bedded and managed to prevent fly breeding.

3. Milkrooms are free of insects and rodents.

4. Milkrooms are effectively screened or otherwise protected against the entrance of vermin.

5. Outer milkhouse doors are tight and self-closing. Screen doors shall open outward.

6. Effective measures are taken to prevent the contamination of milk, containers, utensils, and equipment by insects and rodents, and by chemicals used to control such vermin. Insecticides and rodenticides not approved for use in the milkhouse shall not be stored in the milkhouse.

7. Only insecticides and rodenticides approved for use by the Health Officer and/or registered with the U.S. Environmental Protection Agency are used for insect and rodent control. (See Appendix B)

8. Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed, and water.

NOTE: A convenient inspection form for producer dairy farms which summarizes the applicable sanitation requirements is found in Appendix M.

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Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7.

History:

420-3-16-.10 Sanitization Requirements For Grade A Pasteurized Milk, Frozen Desserts, Ultra-Pasteurized And Aseptically Processed Milk And Milk Products.

(1) Floors-Construction:

(a) The floors of all rooms in which milk, milk products, or frozen desserts are processed, handled, or stored, or in which milk containers, equipment, and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material; and shall be smooth, properly sloped, provided with trapped drains, and kept in good repair--Provided cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits--Provided further, that storage rooms for storing dry ingredients and/or packaging materials need not be provided with drains, and the floors may be constructed of tightly joined wood.

(b) Public Health Reason: Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are, therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing, and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the plant.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The floors of all rooms in which milk is handled, processed, or stored, or in which milk containers or utensils are washed, are constructed of good quality concrete or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

2. The floor surface is smooth and sloped so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious.

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients and/or packaging materials need not be provided with drains.

(2) Walls and Ceilings-Construction:

(a) Walls and ceilings of rooms in which milk, milk products, or frozen desserts are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed,

shall have a smooth, washable, light-colored surface in good repair.

(b) Public Health Reason: Painted or otherwise properly finished walls and ceilings are more easily kept clean and are, therefore, more apt to be kept clean. A light-colored paint or finish aids in the even distribution of light and the detection of unclean conditions.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored tile, smooth surface concrete, cement plaster, or other equivalent materials with washable light-colored surfaces.

2. Walls, partitions, windows, and ceilings are kept in good repair and refinished as often as the finish wears off or becomes discolored.

3. Doors and Windows:

(a) Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

(b) Public Health Reason: Freedom from flies in the milk or frozen dessert plant reduces the likelihood of contamination of the product. For information on disease transmission by flies see .09(7) of this rule.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All openings to the outer air are effectively protected by:

(i) Screening; or

(ii) Effective electric screen panels; or

(iii) Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of flies; or

(iv) Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or

(v) Any effective combination of (i), (ii), (iii), or (iv), or by any other method which prevents the entrance of flies.

2. All outer doors are tight and self-closing. Screen doors shall open outward.

3. All outer openings are rat proofed to the extent necessary to prevent the entry of rodents.

NOTE: The evidence of insects and/or rodents in the plant shall be considered under .10(9) of this rule.

4. Lighting and Ventilation:

(a) All rooms in which milk, milk products, or frozen desserts are handled, processed, or stored and/or in which milk containers, equipment, and utensils are washed shall be well lighted and well ventilated.

(b) Public Health Reason: Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Adequate light sources are provided (natural, artificial, or a combination of both) which furnish at least 20 foot-candles of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, or stored, or where utensils, containers, and/or equipment are washed. Dry Storage and cold storage rooms shall be provided with at least 5 foot-candles of light.

2. Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls, and ceilings.

3. Pressurized ventilating systems, if used, have a filtered air intake.

(5) Separate Rooms.

(a) There shall be separate rooms for:

1. The pasteurizing, processing, cooling and packaging of milk, milk products, and frozen desserts.

2. The cleaning of milk cans, bottles, and cases.

3. Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.

4. Receiving cans of milk and milk products and frozen dessert products in plants receiving such cans.

(b) Rooms in which milk, milk products, frozen dessert products are handled, processed, or stored, or in which milk or frozen dessert containers, utensils and equipment are washed or stored, shall not open directly into any stable or any room for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

(c) Designated areas or rooms shall be provided for the receiving, handling, and storage of returned packaged milk, milk products, and frozen desserts.

(d) Public Health Reason: If the washing and sanitization of containers are conducted in the same room in which the pasteurizing, processing, cooling, or bottling is done, there is opportunity for the pasteurized product to become contaminated. For this reason, separate rooms are required as indicated. The unloading of cans of raw milk directly into the pasteurizing room is apt to increase the prevalence of flies therein, as well as to render it too public.

(e) Administrative Procedures: This item is deemed to be satisfied when:

1. Pasteurizing, processing, cooling, and packaging are conducted in a single room(s), but not in the same rooms used for the cleaning of milk cans, bottles, and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks. Provided that, cooling (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 tank trucks are unloaded and/or cleaned and sanitized.

2. All returned packaged milk and milk products and frozen desserts which have physically left the premises of the processing plant shall be received, handled, and stored in separate areas or rooms isolated from the Grade A dairy operations. Such separate areas or rooms shall be clearly defined and marked for such use.

3. All bulk milk storage tanks are vented into a room used for pasteurization, processing, cooling, or packaging operations, or into a storage tank gallery room, provided that vents located elsewhere which are adequately equipped with air

filters so as to preclude the contamination of the milk, shall be considered satisfactory.

4. Solid doors installed in required partitions are self-closing.

5. Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the plant premises, these operations shall be performed at a receiving station, transfer station, or separate tank washing installation. (Items relating to facilities for cleaning and sanitizing milk tank trucks are listed on page 142).

6. Rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.

7. All rooms shall be of sufficient size for their intended purposes.

8. Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin, and kept in a clean condition.

(6) Toilet-Sewage Disposal Facilities.

(a) Every milk and frozen dessert plant shall be provided with toilet facilities conforming with the rules of the State Board of Health. Toilet rooms shall not open directly into any room in which milk, frozen desserts, and/or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

(b) Public Health Reason.

1. Human excreta is potentially dangerous and must be disposed of in a sanitary manner. The organisms causing typhoid fever, para-typhoid fever, and dysentery may be present in the body discharges of active cases or carriers. Sanitary toilet facilities are necessary to protect the milk, frozen dessert, equipment, and containers from fecal contamination which may be carried by flies, other insects, hands, or clothing. When the toilet facilities are of a satisfactory type, are kept clean, and in good repair, the opportunities for the spread of contamination

by the above means are minimized. The provision of an intervening room or vestibule between the toilet room and any room in which milk, milk products, or frozen desserts are processed makes it less likely that contaminated flies will enter these rooms. It will also minimize the spread of odors.

2. The wastes resulting from the cleaning and rinsing of containers, equipment, and floors, from flush toilets, and from washing facilities should be properly disposed of so as not to contaminate the milk and frozen dessert equipment, or to create a nuisance or a public health hazard.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The milk or frozen dessert plant is provided with toilet facilities conforming with the rules of the State Board of Health.

2. Toilet rooms do not open directly into any room in which milk and/or milk products are processed.

3. Toilet rooms are completely enclosed and have tight-fitting, self-closing doors.

4. Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair, and are well ventilated and well lighted.

5. Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.

6. All plumbing is installed to meet the provisions of applicable plumbing code.

7. Sewage and other liquid wastes are disposed of in a sanitary manner.

8. Non-water-carried sewage disposal facilities are not used.

(7) Water Supply.

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

(b) Public Health Reason: The water supply should be accessible in order to encourage its use in cleaning operations;

and it should be adequate so that cleaning and rinsing may be thorough; and it should be of safe, sanitary quality in order to avoid the contamination of milk and frozen dessert equipment and containers.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Water for milk and frozen dessert plant purposes is from an adequate supply, properly located, protected, and operated. It shall be easily accessible and of a safe, sanitary quality.

2. The water supply is approved as safe by the Health Officer and, in the case of individual water systems, complies with at least the specification outlined in Appendix D, and the bacteriological standards in Appendix G.

3. There is 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 preventor, constitutes a violation of this requirement.

4. Condensing water for milk evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, is from a source complying with 2. above--Provided when approved by the Health Officer, water from sources not complying with 2. above 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 compensated, 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 shut-off 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.

5. Condensing water for all milk evaporators complying with 2. above 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.

6. New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are 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.

7. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each six (6) months thereafter, and when any repair or alteration of the water supply system has been made. Samples shall be taken by the Health Officer and examination shall be conducted in an official laboratory.

8. Current records of water test results are retained on file with the Health Department.

9. Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.

(8) Handwashing Facilities.

(a) Convenient handwashing facilities shall be provided in toilet rooms, receiving rooms, or tank truck unloading areas and including hot and cold and/or warm running water, soap, and approved towels. Handwashing facilities shall be kept clean and in good repair. The use of a common towel is prohibited. No employees shall resume work after using the toilet room without first washing his hands.

(b) Public Health Reason: Proper use of handwashing facilities is essential to personal cleanliness, and reduces the likelihood of contamination of milk and milk products.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Convenient handwashing facilities are provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or other approved hand-drying devices.

2. Handwashing facilities are provided in all toilets and in all rooms in which milk plant operations are conducted.

3. Handwashing facilities are kept in a clean condition and in good repair.

4. Steam-water mixing valves and vats for washing bottles, cans, and similar equipment are not used as handwashing facilities.

(9) Milk and Frozen Dessert Plant Cleanliness.

(a) All rooms in which milk, milk products, and frozen desserts are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, shall be kept clean, neat, and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, packaging, and bulk milk storage rooms.

(b) Public Health Reason: Clean floors, free of litter, clean walls, ceilings, and all other areas of the dairy plant are conducive to clean milk and frozen dessert, handling operations. Cleanliness and freedom from flies, insects and rodents reduces the likelihood of contamination of the milk, milk product, or frozen dessert products. Excess or unused equipment or equipment not directly related to the plant operations can be detrimental to the cleanliness of the plant.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Only equipment directly related to processing operations or the handling of containers, utensils, and equipment is permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.

2. All piping, floors, walls, ceilings, fans, shelves, tables, and the nonproduct-contact surfaces of other facilities and equipment are clean.

3. No trash or solid waste is stored within the plant except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment.

4. All rooms in which milk, milk products, or frozen desserts are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat, and free of evidence of insects and rodents.

(10) Sanitary Piping.

(a) All sanitary piping, fittings, and connections which are exposed to milk, milk products, frozen desserts, or from which liquids may drip, drain, or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

(b) Public Health Reason:

1. Milk piping and fittings are sometimes so designed as to be difficult to clean; or they may be constructed of metal which corrodes easily. In either case, it is unlikely that they will be kept clean. Sanitary milk piping is a term which applies to properly designed and properly constructed piping.

2. The purpose of the third sentence is to prevent exposure of the pasteurized product to contamination.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk products, consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.

2. All sanitary piping, connections, and fittings consist of:

(i) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(ii) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(iii) Heat-resistant glass--Provided plastic, or rubber and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat

resistant, relatively nonabsorbent; which do not impart flavor or odor to the products; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications, and for short, flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

3. Sanitary piping, fittings, and connections are designed to permit easy cleaning, kept in good repair, and free of breaks or corrosion, and contain no dead ends of piping in which milk may collect.

4. All interior surfaces of demountable piping, including valves, fittings, and connections are designed, constructed, and installed to permit inspection and drainage.

5. All cleaned-in-place milk pipelines and return-solution lines are rigid, self-draining, and so supported to maintain uniform slope and alignment. Return-solution lines shall be constructed of material meeting the specifications of 2. above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in 2. above; and designed, finished, and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks, or inclusions. In the case of welded lines, all welds shall be inspected by the use of a boroscope or other appropriate available inspection device as they are made; and such welds shall be approved by the Health Officer. Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings, or other means of combinations that are adequate for inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the line. Detailed plans for welded pipeline systems shall be submitted to the Health Officer for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from the Health Officer.

6. Pasteurized milk and milk products are conducted from one piece of equipment to another only through sanitary milk piping--Provided cottage cheese, cheese dressings, or cheese ingredients may be transported by other methods which protect the product from contamination.

(11) Construction and Repair of Containers and equipment.

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

(b) Public Health Reason:

1. When equipment is not constructed and located so that it can be cleaned easily, and which is not kept in good repair, it is unlikely that it will be properly cleaned.

2. Single-service articles, which have not been manufactured and handled in a sanitary manner may contaminate the milk.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All multi-use containers and equipment with which milk or milk products come into contact are of smooth, impervious, corrosion-resistant, and nontoxic material.

2. All milk-contact surfaces of multi-use containers and equipment consist of:

(i) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(ii) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(iii) Heat-resistant glass; or

(iv) Plastic or rubber and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively non-absorbent, and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

3. All joints in containers, equipment, and utensils are flush and finished as smooth as adjoining surfaces. Where a

rotating shaft is inserted through a surface with which milk, milk products, or frozen desserts come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Where a thermometer or temperature sensing element is inserted through a surface with which milk, milk products, or frozen desserts come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

4. All openings in covers of tanks, vats, separators, etc., are protected by raised edges, or otherwise to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometers, or temperature sensing elements, and other equipment extending into a tank, bowl, vat, or distributor unless a water-tight joint is provided.

5. All surfaces with which milk or milk products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining. Wing nuts, bayonet locks, and similar devices shall be used whenever possible in lieu of bolts and nuts, to promote easy disassembly.

6. There are no threads used in contact with milk or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps, and separators. Such thread shall be of a sanitary type.

7. All multi-use containers and other equipment have rounded corners, are in good repair and free from breaks, crevices, and corrosion. Milk cans shall have umbrella-type covers.

8. Strainers, if used, are of perforated metal design and so constructed as to utilize single-service strainer media. Multiple-use woven material shall not be used for straining milk--Provided when required for functional reasons inherent to the production of certain milk products, such as buttermilk, whey, and dry milk products, woven material may be used where it is impractical to use perforated metal. However woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.

9. All single-service containers, closures, gaskets, and other articles with which milk or milk products come in contact, are nontoxic.

10. The manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with the requirements of Appendix J, Standards for the Fabrication of Single-Service Containers for Milk, and Milk Products. Inspections and tests shall be made by the Health Officer.

NOTE: 3-A Sanitary Standards - 3-A Sanitary Standards for Dairy Equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee; the Committee on Sanitary Procedures of the International Association of Milk, Food, and Environmental Sanitarians, Incorporated; and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance.

(12) Cleaning and Sanitizing of containers and Equipment.

(a) The product-contact surfaces of all multi-use containers, utensils, and equipment used in the transportation, processing, handling, and storage of milk, milk products, or frozen desserts shall be effectively cleaned after each usage and shall be sanitized before each use--Provided that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products beyond the final heat treatment process shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

(b) Public Health Reason: Milk, milk products, and frozen dessert cannot be kept clean and safe, if permitted to come into contact with containers, utensils, and equipment which have not been properly cleaned and sanitized.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All multi-use containers and utensils are thoroughly cleaned after each use, and all equipment is thoroughly cleaned at least once each day used: Provided that storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours. Storage tanks which are used to store raw milk or heat-treated milk products longer than 24 hours and silo tanks used for the storage of raw milk or heat-treated milk products, shall be equipped with a 7-day temperature recording device complying with the specifications of Appendix H.

2. Whenever a milk tank truck has been cleaned and sanitized, as required by the Health Officer, 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 truck delivers to only one receiving unit where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the tank truck is next washed and sanitized and kept on file for 15 days as directed by the Health Officer.

3. Pipelines and/or equipment designed for mechanical cleaning meet the following requirements.

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

(ii) A temperature recording device, complying with the specifications in Appendix H, or a recording device which has been reviewed by FDA and found to provide sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Health Officer, shall be installed in the return solution or other appropriate areas to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions.

(iii) Temperature recording charts shall be identified, dated, and retained for three (3) months.

(iv) During each official inspection, the Health Officer shall examine and initial temperature recording charts to verify the time of exposure to solutions and their temperatures.

4. Plants in which containers are washed manually equipped with a two-compartment wash-and-rinse vat for this purpose. Such plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers, or, if sanitizing is done with chemicals, a third treatment vat.

5. In plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment. By means of steam, hot water, or chemical treatment. Soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in the following table listing combinations of causticity, time, and temperature of equal bactericidal value, for soaker tank of soaker-type bottle washers:

TABLE 2

COMBINATIONS OF CAUSTICITY, TIME, AND TEMPERATURE OF EQUAL BACTERICIDAL VALUE, FOR SOAKER TANK OF SOAKER-TYPE BOTTLE WASHERS

(Based on NSDA Specifications for Beverage Bottles)

Time in Minutes	Temperature, Degrees						
	F 170	160	150	140	130	120	110
	C 77	71	66	60	54	49	43
Concentration of Na H, Percent							
3	0.57	0.86	1.28	1.91	2.86	4.27	6.39
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80
7	0.36	0.53	0.80	1.19	1.78	1.66	3.98

NOTE: The National Soft Drink Association (NSDA), Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the Health Officer.

6. When caustic is so used, subsequent final rinsing of the bottles shall be with water which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent recontamination of the treated bottles during the rinsing operation.

7. All multi-use containers, equipment, and utensils are sanitized before use, employing one or a combination of the methods prescribed under .09(11) of this rule. Assembled equipment must be sanitized prior to each day's run. Tests to determine the efficiency of sanitization should be made by the Health Officer at intervals sufficient to satisfy the Health Officer that the sanitization process is effective--Provided that all piping, equipment and containers used to conduct, process or package aseptically processed milk and milk products beyond the final heat treatment process shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and reesterilized whenever it has been contaminated by unsterile product.

8. The residual bacteria count of multi-use containers used for packaging pasteurized milk and milk products shall not exceed one per milliliter of capacity, when the rinse

test is used; or not over 50 colonies per 8 square inches (one per square centimeter) of product-contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All multi-use containers shall be free of coliform organisms. The residual bacterial count of single-service containers used for packaging pasteurized milk and milk products shall not exceed 50 per container, when the rinse test is used, except that in containers less than 100 ml, the count shall not exceed 10, or not over 50 colonies per 8 square inches (1 per square centimeter) of product contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All single-service containers shall be free of coliform organisms. When single-service containers are fabricated in another plant which conforms to the standard of Appendix J, the Health Officer may, accept the containers as being in conformance without additional tests. If no information is available or there is reason to believe that containers do not conform to the bacteriological standards, additional tests may be required. If containers are fabricated in the dairy plant, the Health Officer shall collect at least four sets of containers each six months and determine conformance.

9. Plants which utilize multi-use plastic containers for pasteurized milk, milk products, and frozen desserts shall comply with the following criteria:

(i) The plastic material from which the containers are molded shall be of safe material.

(ii) The plastic material shall comply with the material specifications of .10(11) of this rule.

(iii) All containers shall be identified as to plant of manufacture, date of manufacture, and type and class of plastic material used. This information may be by code--Provided the code is revealed to the Health Officer.

(iv) A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by the Health Officer to prevent the changing of its sensitivity functioning level. Models using an air-injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system, the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be

interconnected so that the system will not operate unless the detecting device is in proper operating condition--Provided that any other system so designed and operated will provide equal assurance of freedom from contamination and recognized by the Food and Drug Administration to be equally efficient may be accepted by the Health Officer.

(v) A standard must be available for the use of the Health Officer for testing the proper sensitivity functioning levels of the detection device.

(vi) The containers shall comply with the applicable construction requirements of .10(11) of this rule. The closure for the container shall be single-service. Screw-type closures shall not be used.

(vii) The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the Federal Food, Drug and Cosmetic Act, as amended and regulations issued thereunder.

(viii) The phrase "Use only for food" shall appear on all containers.

(13) Storage of Cleaned Containers and Equipment.

(a) After cleaning, all multi-use milk or milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

(b) Public Health Reason: If containers and equipment are not protected from contamination, the value of sanitization may be partly or entirely nullified.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All multi-use containers, equipment, and utensils, after cleaning, are transported and/or stored on metal racks or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, corrosion-resistant, nontoxic materials, or otherwise protected from contamination.

2. Floors are not flushed or washed when crates of clean bottles are stacked on them.

(14) Storage of Single-Service Containers, Utensils, and Materials.

(a) Single-service caps, cap stock, parchment paper containers, gaskets, and other single-service articles for use in contact with milk, milk products, and frozen desserts shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

(b) Public Health Reason: Soiled or contaminated caps, parchment paper, gaskets, and single-service containers nullify the benefits of the safeguards prescribed throughout these rules. Packing the caps in tubes which remain unbroken until they are placed in the bottling machine is the best method of assuring cap cleanliness.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk, milk products, and frozen desserts are purchased and stored in sanitary tubes, wrappings, or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

2. Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination.

3. Tubes or cartons are not refilled with spilled caps, gaskets, or parchment papers.

4. Cartons or boxes from which contents have been partially removed are kept closed.

5. Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures, or containers.

(15) Protection from Contamination.

(a) Milk and frozen dessert plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, milk products, or frozen desserts, ingredients, equipment, containers, and utensils. All milk, milk products, or frozen dessert products or ingredients

which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than milk and milk products in the pasteurization plant shall be performed to preclude the contamination of such milk, milk products, and frozen desserts. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk, milk products, and frozen desserts or ingredients of such milk, milk products, and frozen desserts or the product-contact surfaces of all equipment, containers, or utensils.

(b) Public Health Reason: Because of the nature of milk, milk products, and frozen desserts and their susceptibility to contamination by bacteria, chemicals, and other adulterants, every effort should be made to provide adequate protection for the milk, milk products, and frozen dessert at all times. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk, milk product, or frozen dessert or equipment with which the milk, milk product or frozen dessert comes in contact.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

2. Packaged milk, milk products, and frozen desserts which have physically left the premises or the processing plant are not repasteurized for Grade A or manufacturing use. The Health Officer may, on a specific individual request, authorize reprocessing of packaged milk, milk products, and frozen desserts provided all other aspects of this item, including proper storage temperature and container integrity are complied with. Provided, that the repasteurization of milk, milk products, and frozen desserts shipped in transport tankers which have been pasteurized at another plant and have been handled in a sanitary manner and maintained at 7° C (45° F) or less is permitted. Equipment, designated areas or rooms utilized for storage, processing, and handling of returned packaged milk, milk products and frozen desserts are maintained, operated, cleaned, and sanitized so as to preclude contamination of products and equipment and the operations.

3. All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping

attached to milk storage and milk tank trucks, pumps, or vats, etc., shall be capped or otherwise properly protected. While unloading at a receiving station, transfer station, or pasteurization plant, one of the following conditions shall be met:

(i) If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dust-cover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.

(ii) 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 air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. Direct connections from milk tank truck to milk tank truck must be made from valve to valve or through the manhole lid: Provided that, all connections are made ferrule to ferrule and adequate protection is provided for the air vent.

(iii) Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

4. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor, and shall otherwise comply with the applicable standards of Appendix H. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of Appendix H.

5. Standardization is done before the pasteurization process is started, unless pasteurized milk or milk products are used for standardization. Such pasteurized milk products shall be protected against contamination. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients. Standardization of Grade A milk

and milk products with other than Grade A milk and milk products is prohibited. These Rules permit standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or skim milk.

6. All multi-use cases used to encase packaged milk, milk product or frozen dessert containers are cleaned prior to their use.

7. All ingredients and non-product-contact materials used in the preparation or packaging of milk, milk products and frozen desserts are stored in a clean place and are so handled as to prevent their contamination.

8. Pasteurized milk is not strained or filtered except through a perforated metal strainer.

9. Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, and related cleaning compounds, and medicinal agents necessary for the maintenance of the dairy plant are present in the dairy plant.

10. Those poisonous or toxic materials that are necessary are not stored in any room where milk, milk products, or frozen desserts are received, processed, pasteurized or stored, or where equipment, containers or utensils are washed or where single-service containers, closures, or caps are stored.

11. Those poisonous or toxic materials that are necessary are not stored in a separate area of the plant in prominently and distinctly labeled containers: Provided that this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized.

12. Only insecticides and rodenticides approved by the Health Officer and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, equipment, and utensils.

13. During processing, pipelines and equipment used to contain or conduct milk, milk products and frozen desserts shall be effectively separated from tanks or circuits containing cleaning, and/or sanitizing solutions.

14. All milk, milk products, and frozen desserts which have overflowed, leaked, been spilled, or improperly handled are discarded. Milk, milk products and frozen desserts drained from processing equipment at the end of a run, collected from a defoamer system, and milk solids rinsed from equipment, containers, or pipelines shall be repasteurized only if such milk, milk products and frozen desserts are handled in a sanitary manner and maintained at 7° C (45° F) or less. When the handling and/or refrigeration of such milk, milk products and frozen desserts are not in compliance with this requirement, they shall be discarded. Milk, milk products and frozen desserts from damaged, punctured, or otherwise contaminated containers or product from out of code containers shall not be repasteurized for use.

15. Means are provided to prevent contamination of milk containers, utensils, and equipment by drippings, spillage, and splash from overhead piping, platforms, or mezzanines.

16. The processing of foods and/or drinks other than Grade A milk and milk products are performed to preclude the contamination of such milk, milk products and frozen desserts.

(16) Pasteurization - Aseptic Processing

(a) Pasteurization shall be performed as defined in .02, (ff) of this rule. Aseptic processing shall be performed in accordance with 21 CFR 113 and 108 and the administrative procedures of .10(16)(c) 2.(iii), (iv), and (v) of this rule.

(b) Public Health Reason:

1. The public health value of pasteurization is unanimously agreed upon by health officials. Long experience conclusively shows its value in the prevention of diseases which may be transmitted through milk. Pasteurization is the only practical commercial measure which, if properly applied to all milk, will destroy all milk-borne disease organisms. Examination of cows and milk handlers, while desirable and of great value, can be done only at intervals and, therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by these rules, if applied to every particle of milk, will devitalize all milk-borne pathogens. Compilations of outbreak of milk-borne disease by the U.S. Public Health Service, over many years, indicate that the risk of contracting disease from raw milk is approximately 50 times as great as from milk labeled "pasteurized."

2. A note of caution is in order. Although pasteurization devitalizes the organisms, it does not destroy the toxins that may be formed in milk when certain staphylococci are present (as from udder infections), and when the milk is not properly refrigerated before pasteurization. Such toxins may cause severe illness.

3. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

(c) Administrative Procedures: The pasteurization portion of this item is deemed to be satisfied when:

1. Every particle of milk, milk product, or frozen dessert is heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Temperature	Time
*145° F (63° C)	30 Minutes
*161° F (72° C)	15 Seconds
191° F (89° C)	1 Seconds
194° F (90° C)	0.5 Seconds
201° F (94° C)	0.1 Seconds
204° F (96° C)	0.05 Seconds
212° F (100° C)	0.01 Seconds

*If the fat content of the milk product is ten (10) percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5° F (3° C)--Provided eggnog and frozen dessert mix shall be heated to at least the following temperature and time specifications:

Temperature	Time
155° F (69° C)	30 Minutes
175° F (80° C)	25 Seconds
180° F (83° C)	15 Seconds

--Provided nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the State Health Officer.

2. The design and the operation of pasteurization equipment and all appurtenances thereto shall comply with the

applicable specifications and operational procedures of sub-items (i), (ii), (iii), (iv), and (v) as follows:

(i) Batch Pasteurization.

(I) All indicating and recording thermometers used in connection with the batch pasteurization of milk, milk products, or frozen desserts shall comply with the applicable specifications set forth in Appendix G. (Specifications for test thermometers and other test equipment appear in Appendix H).

(ii) Public Health Reason:

I. Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization must be performed in equipment which is properly designed and operated, and which ensures that every particle of milk, milk products, or frozen desserts will be held continuously at the proper temperature for the specified period of time.

II. Recording thermometers are the only known means for furnishing the Health Officer with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers due to their mechanical complexity are not entirely reliable. Therefore, mercury indicating thermometers which are much more reliable are needed to provide a check on the recording thermometers and assurance that proper temperatures are being applied.

III. The recording thermometer shows the temperature of the product immediately surrounding its bulb, but cannot indicate the temperature of the product in other portions of the holder. Similarly, it shows the holding time in manual-discharge vats but not in automatic-discharge systems. The pasteurizer must, therefore, be so designed and so operated and, where necessary, provided with such automatic controls as to assure that every portion of the milk will be subjected to the proper temperature for the required length of time.

IV. Unless the inlet and outlet valves and connections to vats and pockets are properly designed and operated, cold pockets of product may be held in the outlet valve or pipe-line; raw product may leak into the vat or pocket during the holding or emptying time; and raw or incompletely pasteurized product may leak into the outlet line during the filling, heating, or holding period.

V. Tests have shown that when foam is present on product in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms that may be in the foam will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, product frequently is splashed on the surfaces and fixtures above the product level as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the product, and since they may not have been at pasteurization temperature for the required time, they may contain living pathogenic organisms. Heating the air above the product, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing product from the upper vat walls, and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

VI. Many plant operators have reported that the use of airspace heaters, especially with partly filled vats with uninsulated lids, makes it easier to maintain the product at a uniform and sufficiently high temperature. It also helps to prevent the growth of thermophilic organisms, and promotes easier cleaning.

VII. Obviously, if the design and construction of pasteurization vat and pocket covers do not prevent leakage, condensation, and the entrance of water and dust, the product may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of dust, flies, sputum droplets, drip, and splash entering the product.

(iii) Administrative Procedures: This item is deemed to be satisfied when:

I. Time and Temperature Controls for Batch Pasteurizers.

A. Temperature Difference - The pasteurizer shall be so designed that the simultaneous temperature difference between the milk, milk product, or frozen dessert mix at the center and the coldest milk, milk product, or frozen dessert mix in the vat will not exceed 1° F (0.5° C) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk, milk product, or frozen dessert mix shall be pasteurized unless it covers a sufficient area of the agitator to ensure adequate agitation.

B. Location and Required Readings of Indicating and Recording Thermometers--Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer, The thermometers shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check daily the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer; this comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk, milk products, or frozen dessert mix shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometers.

C. Assurance of Minimum Holding Periods - Batch pasteurizers shall be so operated that every particle of milk, milk product, or frozen dessert mix will be held at not less than the minimum pasteurization temperature continuously for at least 30 minutes. When milk, milk products, or frozen dessert mix are raised to pasteurization temperature in the vat, and cooling is begun in the vat, simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least 30 minutes at not less than minimum pasteurization temperature. When milk, milk products, or frozen dessert mix are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30 minutes at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder after the opening of the outlet valve, or is done entirely outside the holder, the chart shall show at least 30 minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording-thermometer bulb. When the recorder time interval on the recorder chart at the pasteurization temperatures includes filling and/or emptying time, such intervals shall be indicated on the recorder chart by the operator, by removing the recording thermometer bulb from the product for a sufficient time to depress the pen or by turning cold water into the vat jacket at the end of the holding period or by inscribing the holding time on the chart. The filling time and the emptying time for each holder so operated shall be determined by the Health Officer, initially, and after any change which may affect these times. No product shall be added to the holder after the start of the holding period.

II. Airspace Heating.

A. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk, milk

products, and frozen dessert mix at a temperature not less than 5° F (3° C) higher than the minimum required temperature of pasteurization during the holding period. (See Appendix H.)

B. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk, milk product, or frozen dessert mix shall be at least one inch below the bottom of the thermometer bulb when the vat is in operation.

C. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart each time the pasteurizer is in operation.

III. Inlet and Outlet Valves and Connections: The following definitions shall apply to inlet and outlet valves and connections:

A. "Valve stop" shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

B. "90 stop" shall mean a stop so designed as to prevent turning the plug more than 90° .

C. "120 stop" shall mean a stop which prevents turning the plug more than 120° .

D. "180 stop" shall mean a stop which prevents turning the plug more than 180° , but which permits two fully closed positions, each diametrically opposite the other.

E. "Valve with an irreversible plug" shall mean one in which the plug cannot be reversed in the shell.

F. "Single-quadrant stop" shall mean a 90° stop in a valve with an irreversible plug.

G. "The fully open position" shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

H. "The closed position" shall mean any position of the valve seat which stops the flow of milk, milk product, or frozen dessert mix into or out of the pasteurizer.

I. "The fully closed position" shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

J. "The just closed position" shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, or any closed position within 0.078 inch thereof as measured along the maximum circumference of the valve seat.

K. "Leakage" shall mean the entrance of unpasteurized milk, milk product, or frozen dessert mix into a batch pasteurizer during the holding or emptying period or the entrance of unpasteurized product into any pasteurized product line at any time.

L. "Leak-protector valve" shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of product past the valve or, in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage of product past the valve or the leakage of product due to the leakage of air past the suction valve or the compressed air valve, as the case may be.

M. "Closed-coupled valve" shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no product in the valve inlet is more than 1° F (0.5° C) colder than the product at the center of the pasteurizer at any time during the holding period. A closed-coupled valve which is not truly flush, shall be considered as satisfying this requirement when: (1) the vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and (2) the greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and (3) in the case of batch pasteurizers, the outlet and the agitator are so placed as to ensure that product currents will be swept into the outlet.

IV. Design and Installation of Valves and Connections:
All valves and connections shall comply with the following requirements:

A. Valves and pipeline connections shall meet the requirements of .10(10) of this rule.

B. All pipelines and fittings shall be so constructed and so located that leakage will not occur. Dependence shall not be placed on soldered joints to prevent leakage.

C. To prevent clogging, and to promote drainage, all leak-protection grooves shall be at least 0.187 inch wide and at least 0.094 inch deep at the center. Mating grooves shall

provide these dimensions throughout their combined length whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat so as to divert leakage occurring at all points throughout the depth of the seat, and so as to prevent air bindings. Washers or other parts shall not obstruct leak-protector grooves.

D. A stop shall be provided on all plug-type outlet valves and on all plug-type inlet valves in order to guide the operator in closing the valve so that unpasteurized product may not inadvertently be permitted to enter the outlet line or the holder, respectively. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent unless duplicate, diametrically opposite grooves are also provided. In the case of two-way, plug-type valves (i.e., those having only one inlet and one outlet), a 180° stop, or any combination of stops permitting two fully closed positions, may be substituted for a 90° stop, provided that there are no air-relief grooves in the plug and that all leak grooves are located symmetrically with respect to the valve inlet. Stops shall be so designed that the operator cannot turn the valve beyond the stop position either by raising the plug or by any other means.

E. Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized product in the product passages of the valve when the valve is in any closed position.

F. All inlet pipelines and outlets from vat pasteurizers shall be equipped with leak-protector valves--Provided, installations not equipped with leak-protector inlet valves shall be accepted when the piping is so arranged that only one vat can be connected to the inlet line at a time, and such piping is disconnected during the holding and emptying periods.

G. Inlet and outlet connections other than through closed-coupled valves shall not enter or leave the pasteurizer below the level of the product therein.

H. In cases where the inlet line enters the holder above the product level, and in which the inlet line may be submerged and thus prevent its complete emptying when the inlet valve is closed, the inlet line shall be provided with an automatic air-relief, or vent located either at the valve or elsewhere, and so designed as to function in every closed position of the valve. A vent may be provided by drilling a hole

at least 0.125 inch in diameter in the vat pipe, below the vat cover, but above the maximum product level.

I. All leak-protector valves shall be installed in the proper position to ensure the function of the leak-diverting device. Inlet valves shall not be located in vertical pipelines, unless they can be so installed that one of the groove systems is at the lowest level of the valve; and pipelines between the inlet valve and the pasteurizer shall be as short as practicable and shall be sloped to drain.

J. All outlet valves shall be kept fully closed during filling, heating, and holding periods; and all inlet valves shall be kept fully closed during holding and emptying periods.

V. Recording Charts: All recording thermometer charts shall comply with all the applicable requirements of .10(16)(c)2.(v).

(ii) High-Temperature, Short-Time (HTST) Continuous-Flow Pasteurization.

(I) Public Health Reason - See Public Health Reason under .10(16) and .10(16)(c)2.(i) of this rule, page 105.

(II) Administrative Procedures: This item deemed to be satisfied when:

I. Indicating Thermometers and Recorder/Controller Instruments: All indicating thermometers and recorder/controller instruments and devices used in connection with the high-temperature, short-time continuous-flow pasteurization of milk, milk products, or frozen dessert mix shall comply with the applicable specifications, set fourth in Appendix G.

II. Automatic Milk Controller - Each high-temperature, short-time continuous-flow pasteurization system shall be equipped with an automatic milk-flow control of the diversion type which complies with the following definition, specifications, and performance requirements:

A. Automatic Milk-Flow Controls - The term "automatic milk-flow control" shall mean those safety devices which control the flow of product in relation to the temperature of the product or heating medium and/or pressure, vacuum, or other auxiliary equipment. Milk-flow controls shall not be considered as part of the temperature control equipment. Milk-flow controls shall be of the flow-diversion type which automatically cause the diversion of the product in response to a sublegal pasteurization

temperature. At sublegal temperatures, flow-diversion devices return the product to the raw product side of the heating systems continuously until legal pasteurization temperatures are obtained; at which time, the device restores forward flow through the pasteurizer.

B. Flow-Diversion Devices - All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(A) Forward flow of subtemperature product due to the omission or looseness of the connecting clip, shall be prevented by making the valve and its actuating mechanism integral; or, where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or, where there is a connecting device which may be omitted or shaken loose by providing for pushing instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the product is below the pasteurization temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means.

(B) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

(C) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak escape should lie between two valve seats, or between two portions of the same seat, one upstream and one downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside or to the constant-level tank through a line separate from the diversion line--Provided when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

(D) The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

(E) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of product.

(F) The flow-diversion device shall be located down-stream from the holder. The flow-control sensor shall be located in the product line not more than 18 inches upstream from the flow-control device.

(G) In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperatures of 191° F (89° C) and above and holding times of one second and less, the flow-diversion device may be located downstream from the regenerator and/or cooler section--Provided, when the flow-diversion device is located downstream from the regenerator and/or cooler section, the flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in .02(ff) of this rule.

(H) The pipeline from the diversion port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the diversion line cannot occur.

(I) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining and shall be free of restrictions or valves.

C. Milk-Flow Controller Instrumentation - The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(A) The thermal limit controller shall be set and sealed so that forward flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in .02(ff) of this rule for the milk or milk product and the process used nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the Health Officer after testing, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be by-passed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each days

operation and entered upon the recorder chart daily by the plant operator.

(B) In the case of HHST pasteurization systems utilizing the temperatures of 191° F (89° C) and above, and holding times of one second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be interwired with the thermal limit controller; and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in .02(xx) of this rule. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature. The seal shall be applied by the Health Officer after test and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

(C) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the product is above the required pasteurization temperature as defined in .02(ff) of this rule for the milk product and the process used, or when the diversion device is in the fully-diverted position.

D. Holding Tube.

(A) Holders shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in .02(ff) of this rule for the milk or milk product and the process used.

(B) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest product in any cross section of flow at any time during the holding period will not be greater than 1° F (0.5° C) This requirement may be assumed to have been satisfied without test in tubular holders of seven inches or smaller diameter which are free of any fitting through which the product may not be thoroughly swept.

(C) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

(D) The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 0.25 inch per foot.

(E) Supports for tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

(F) The holder shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.

(G) The holding time for the HHST processes must be determined from the pumping rate rather than by the salt conductivity test because of the short holding tube. The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.

(H) With the steam injection processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 120° F (66° C) increase by steam injection which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the pasteurizer does not reflect this volume increase in the holding tube. However, this volume increase; i.e., holding time decrease, must be considered in the calculations.

(I) With the steam injection process a pressure limit indicator is needed in the holding tube to keep the heated product in the liquid phase. The instrument must have a pressure switch so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 191° F (89° C) and 212° F (100° C), the pressure switch must be set at a pressure 10 psi

above the boiling pressure of the product at its maximum temperature in the holding tube.

(J) With the steam injection process a differential pressure limit indicator across the injector is needed to insure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 10 psi.

E. Indicating and Recording Thermometers.

(A) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where product between the two thermometers does not differ significantly in temperature.

(B) The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

(C) The recorder/controller charts shall comply with the applicable provisions of .10(16)(c)2.(v).

F. Flow-Promoting Devices.

(A) The pump, or pumps, and other equipment which may produce flow through the holder shall be located upstream from the holder, provided that pumps and other flow-promoting devices may be located downstream from the holder if means are provided to eliminate negative pressure between the holder and the inlet to such equipment. When vacuum equipment is located downstream from the holder, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the flow-diversion device and the vacuum chamber, shall be acceptable.

(B) The speed of pumps or other flow-promoting devices governing the rate of flow through the holder shall be so controlled as to ensure the holding of every particle of product for at least the time required as defined in .02(ff) of this rule for the milk or milk product and the process used. In all cases, the motor shall be connected to the metering pump by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by the Health Officer. This shall be accomplished by

the application of suitable seal(s) after tests by the Health Officer and such seal shall not be broken without immediately notifying the Health Officer. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed that wearing or stretching of the belt results in a slow-down, rather than a speed-up, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems as outlined in Appendix H. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump it shall be either:

(i) Of larger capacity than the timing pump. In which case an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line must be of at least the same or larger diameter than the inlet pipeline feeding product to the homogenizer. A check valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

(ii) Of smaller capacity than the timing pump. In which case a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return product to the balance tank or to the outlet of the balance tank upstream of any booster pump or other flow-promoting device.

(C) For those systems which do not homogenize all products and wish to utilize a by-pass line to by-pass the homogenizer while processing such product; the by-pass line must be connected with valves which are so designed that both lines cannot be open at the same time. This may be accomplished with 3-way plug valves with properly designed and operating pins or other automatic, fail-safe valves which accomplish the same objective.

(D) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature as defined in .02(ff) of this rule, for the milk or milk product and the process used, throughout the holder section; i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction, and is located upstream from the flow-diversion device. Tests for holding time shall be made

when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. For those systems which do not homogenize all products and utilize by-pass lines as outlined in (i) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted flow. If it is necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow, and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted flow by the regulatory agency initially; semi-annually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

G. Heating by Direct Addition of Steam - Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(A) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 10 psi (.703 kpa) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

(B) The product pressure in the holding tube must be of sufficient magnitude to condense the steam and keep the heated product in the liquid phase. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. A minimum product pressure in the holding tube of 10 psi (.703 kpa) for operating temperatures from

191° F (89° C) through 212° F (100° C) is satisfactory. For units which have operating temperatures above 212° F (100° C) the pressure of the product in the holding tube must be at least 10 psi (.703 KPI) above the boiling pressure of the product at its maximum temperature in the holding tube.

(C) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible of noncondensable gases.

H. Prevention of Product Adulteration with Added Water.

(A) When culinary steam is introduced directly into the milk or milk product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the product, unless the flow-diversion device is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the flow-diversion device controls that steam cannot flow unless the flow-diversion device is in the forward-flow position.

(B) When culinary steam is introduced directly into the milk or milk product, automatic means shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(C) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shut-off valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the in-flowing water if, for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

(iii) Aseptic Processing Systems.

(i) Public Health Reason: Aseptically processed milk and milk products are being packaged in hermetically sealed containers and stored for long periods of time under nonrefrigerated conditions. These conditions are favorable to the growth of many types of bacteria. (Pathogenic, toxin producing and spoilage types.) Because of this, every precaution must be taken to ensure that all viable organisms and their spores are destroyed by the chosen heat process for the particular milk or milk product and that the subsequent handling, packaging and storage processes do not provide an opportunity for recontamination of the product. The selected process must conform to the acceptable requirements for low acid canned foods.

(ii) Administrative Procedures: The aseptic processing portion of this item is deemed to be satisfied when the design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of sub-items C, D and E as follows--Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by the Food and Drug Administration to be equally effective and which is approved by the Health Officer.

I. Indicating Thermometers and Recorder/Controller Instruments: All indicating thermometers, recorder/controller instruments and devices used in connection with aseptic processing systems used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

II. Aseptic Processing Equipment.

A. Temperature Indicating Device - Each aseptic processing system shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device.

B. Temperature Recorded/controller - An accurate temperature recorded/controller shall be installed in the product at the holding-tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorded/controller.

(A) The temperature recorded/controller shall be set and sealed so that during product processing the forward flow of product cannot start unless the temperature at the controller sensor is above the required temperature for the product and the process used, nor continue during descending temperatures when

the temperature is below the required temperature. The seal shall be applied by the Health Officer after testing, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the controller sensor which shall not be removed from its proper position during the processing of aseptic milk and milk products.

(B) Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required temperature. The seal shall be applied by the Health Officer after test, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

(C) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required temperature for the product and the process used, or when the diversion device is in the fully-diverted position.

C. Metering Pump.

(A) A metering pump shall be located upstream from holding tube and shall be operated to maintain the required metering pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the regulatory agency. This shall be accomplished by the application of a suitable seal(s) after tests by the Health Officer and such seal shall not be broken without immediately notifying the Health Officer. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type, or shall comply with the specifications for magnetic flow meter systems.

(B) The holding time shall be taken to mean the flow time of the fastest particle of product throughout the holder section; i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the down-stream direction, and is located upstream from the flow-diversion device. Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. Where bypass lines are provided, either upstream or downstream from the metering pump, the holding time shall be tested with both the regular and bypass line open, unless the bypass valve is so designed that both lines cannot be open at the same time. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow, and the vacuum equipment adjusted to provide for maximum vacuum. The holding time shall be tested by the Health Officer initially, semi-annually thereafter, after any alteration or replacement that may affect the holding time, and whenever the seal of the speed setting has been broken.

D. Product Holding Tube.

(A) The product holding tube shall be designed to give continuous holding of every particle of product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 (2.1 cm/m) inch per foot. Supports for tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

(B) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of production flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate rather than by the salt conductivity test.

(C) The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time.

NOTE: Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during aseptic processing of high-viscosity

products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard. With the steam injection process, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the aseptically processed product is cooled in the vacuum chamber. For example, with a 120° F (66° C) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(D) With the steam injection process, a pressure limit indicator is needed in the holding tube to keep the heated product in the liquid phase. The instrument must have a pressure switch so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. The pressure switch must be set at a pressure 10 psi (.703 kpa) above the boiling pressure of the product at its maximum temperature in the holding tube.

(E) With the steam injection process, a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 10 psi (.703 kpa).

E. Heating by Direct Addition of Steam - injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below field process temperature. When culinary steam is introduced directly into milk or milk products as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(A) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 10 psi (.703 kpa) product pressure drop across the injector during a

simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

(B) The product pressure in the holding tube must be of sufficient magnitude to condense the steam and keep the heated product in the liquid phase. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. For units which have operating temperatures above 212° F (100° C), the pressure of the product in the holding tube must be at least 10 psi (.703 kpa) above the boiling pressure of the product at its maximum temperature in the holding tube.

(C) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible on noncondensable gases.

F. Prevention of Product Adulteration with Added Water.

(A) When culinary steam is introduced directly into the milk or milk product, automatic means shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(B) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the inflowing water, if, for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

G. Flow-Diversion Device: All flow-diversion devices used in continuous aseptic process systems shall comply with the following or equally satisfactory specifications:

(A) Forward flow of subtemperature product, due to the omission of looseness of the connecting clip, shall be prevented by making the valve and its actuating mechanism integral; or, where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or, where there is a connecting device which may be omitted or shaken loose by providing for pushing, instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the product is below the aseptic processing temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means.

(B) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

(C) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak escape should lie between two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line--Provided when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

(D) The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

(E) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

(F) The flow-diversion device shall be located down-stream from the regenerator and/or cooler section. The flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have

been held at or above the required sterilization temperature continuously and simultaneously for at least the required sterilization time.

(G) The pipeline from the diversion port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the diversion line cannot occur.

(H) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves.

(iv) Pasteurizers and Aseptically Processing Systems Employing Regenerative Heating.

(I) Public Health Reason: To prevent contamination of the pasteurized product in regenerators, the raw product must always be under less pressure than the pasteurized product or the heat-transfer medium. In the case of milk-to-milk regenerators, this requirement is necessary to prevent contamination of the pasteurized product by the raw product if flaws should develop in the metal or in the joints separating the two kinds of product.

(II) Administrative Procedure: This item is deemed to be satisfied when:

I. Milk-To-Milk Regenerative Heating.

A. Pasteurizers and aseptically processing systems employing milk-to-milk regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(A) Regenerators shall be constructed, installed, and operated so that pasteurized or aseptic product in the regenerator will automatically be under greater pressure than raw product in the regenerator at all times.

(B) The pasteurized or aseptic product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 12 (30.48cm) inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation.

(C) The overflow of the top rim of the constant-level raw product tank shall always be lower than the lowest product level in the regenerator.

(D) No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic product outlet from the regenerator and the nearest downstream point open to the atmosphere.

(E) No pump shall be located between the raw product inlet to the regenerator and the raw product supply tank, unless it is designed and installed to operate only when product is flowing through the pasteurized or aseptic product side of the regenerator, and when the pressure of the pasteurized or aseptic product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless: (1) the metering pump is in operation; (2) the flow-diversion device is in forward-flow position; and (3) the pasteurized or aseptic product pressure exceeds, by at least .070 kpa or 1 psi, the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw product inlet to the regenerator and the pasteurized or aseptic product outlet of the regenerator or the outlet of the cooler. The accuracy of required pressure gauges shall be checked by the Health Officer on installation, quarterly thereafter, and following repair or adjustment.

(F) The motor, casing, and impeller of the booster pump shall be identified, and such records thereof maintained as directed by the Health Officer. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of these rules.

(G) All raw products in the regenerator will drain freely back into the constant-level raw product tank when the raw product pump(s) are shut down and the raw product outlet from the regenerator is disconnected.

(H) When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized or aseptic product level in the regenerator during periods of diverted flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized or aseptic product inlet to the regenerator.

(I) In the case of HHST pasteurization systems utilizing the temperatures of 191° F (89° C) and above, and holding times of 1 second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section,

the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to a vertical elevation of 12 inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated--provided a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the flow-diversion device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in .02(ff) of this rule. In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed (.14 kpa) or 2 pounds per square inch on the working scale of not more than (1.4 kpa or) 20 pounds per square inch per (25.4 mm) or 1 inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the aseptic product regenerator outlet and the other pressure sensor shall be installed at the raw product regenerator inlet.

(J) When culinary steam is introduced directly into milk or milk products as the means of terminal heating to achieve pasteurization temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized or aseptic side of the regenerator may be eliminated: Provided, that the differential pressure controller is installed and wired to control the flow-diversion device as described in (I) above.

(K) When the differential pressure controller is installed and wired to control the flow-diversion device as described in (I) above, the raw product booster pump may be permitted to run at all times--Provided the metering pump is in operation.

II. Milk-To-Water-To-Milk Regenerative Heating

A. Milk-to-water-to-milk regenerators with both the product and the heat-transfer water in the raw product section closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(A) Regenerators of this type shall be so designed, installed, and operated that the heat-transfer-medium side of the regenerator in the raw product section will automatically be under greater pressure than the raw side at all times.

(B) The heat-transfer water shall be a safe water and the heat-transfer water shall be in a covered tank which is open to the atmosphere at an elevation higher by at least 12 inches (30.5 cm) than any raw product level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 12 inches (30.5 cm) above any raw product in the system and shall be open to the atmosphere at this or a higher elevation.

(C) The heat-transfer water circuit shall be full of water at the beginning of the run, and all loss of water from the circuit shall be automatically and immediately replenished whenever raw product is present in the regenerator.

(D) The overflow of the top rim of the constant-level raw product tank shall always be lower than the lowest product level in the raw product section of the regenerator. The regenerator shall be designed and installed so that all raw product shall drain freely back to the upstream supply tank when the raw product pumps are shut down and the raw product line is disconnected from the regenerator outlet.

(E) No pump shall be located between the raw product inlet to the regenerator and the raw product supply tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator, and when the pressure of the heat-transfer water is higher than the pressure of the raw product. This may be accomplished by wiring the booster pump so that it cannot operate unless: (1) the heat-transfer water pump is in operation; (2) the heat-transfer water pressure exceeds, by at least 1 pound per square inch, (.070 kpa), the raw product pressure in the regenerator. Pressure gauges shall be installed at the raw product inlet and the heat-transfer water outlet of the regenerator. The accuracy of the required pressure gauges shall be checked by the Health Officer on installation, quarterly thereafter, and following repair or replacement.

(F) In the case of aseptic processing systems used for producing aseptic milk and milk products, milk-to-water-to-milk regenerators alternatively shall be constructed, installed, and operated that the aseptic product in the regenerator will be

under greater pressure than the heat-transfer-medium in the aseptic product side of the regenerator.

(AA) The differential pressure recorder-controller shall be used to monitor pressures of the aseptic product and the heat-transfer medium. One pressure sensor shall be installed at the aseptic product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the aseptic product side of the regenerator. This recorder-controller shall divert the flow diversion device whenever the lowest pressure of aseptic product in the regenerator fails to exceed the highest pressure of heat-transfer-medium in the aseptic product side of the regenerator by at least 1 psi(.070 kpa). Forward flow of product shall be automatically prevented until all product-contact surfaces between the holding tube and the flow diversion device have been held at or above the required sterilization temperature continuously and simultaneously for at least the sterilization time.

(BB) The heat-transfer-medium pump shall be wired so that it cannot operate unless the metering pump is in operation.

NOTE: See Appendix G for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

(v) Temperature Recording Charts, Equipment Tests, and Examinations.

(I) Temperature Recording Charts - All temperature recording charts shall be preserved for a period of three months--Provided all records and recording charts for aseptic milk and milk products systems shall be retained for a period of three years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts as applicable:

1. Batch Pasteurizers.
 - A. Date.
 - B. Number or location of recorder when more than one is used.
 - C. Extent of holding period, including filling and emptying times when required (.10(16)(C)2(i)).

D. Reading of airspace thermometer within the holding period at a given time or reference point as indicated on the chart (.10(16)(C)2.(i)).

E. Reading of indicating thermometer within the holding period at a given time or reference point as indicated on the chart (.10(16)(C)2.(i)).

F. Quarterly, the initials of the Health Officer opposite the required readings of the indicating thermometer and airspace thermometer (.10(16)(C)2.(i)).

G. Quarterly, the time accuracy of the recorder, as determined by the Health Officer. (Appendix H., test 3, page H-5).

H. Amount and name of pasteurized milk or milk product represented by each batch or run on the chart.

I. Record of unusual occurrences.

J. Signature or initials of operator.

K. Name of milk plant.

II. High-Temperature, Short-Time Pasteurizers-Recording thermometer charts shall contain all the information specified in I above, except C, D, and reference to airspace thermometers in F and in addition, shall include the following:

A. A record of the time during which the flow-diversion device is in the forward-flow position.

B. The cut-in and cut-out product temperatures recorded daily by the operator at the beginning of the run and initialed quarterly by the Health Officer (.10(16)(C)2,(ii)0).

NOTE: The recorded temperature shown on the controller chart shall be used to determine that the required temperature for milk products containing higher fat and/or sweeteners has been achieved.

III. Aseptic Processing Systems - Recording charts shall contain all the information specified in I above, except C, D, and reference to airspace thermometers in item F, and in addition shall include the following:

A. A record of the time during which the flow-diversion device is in the forward-flow position.

B. Not later than one working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(II) Equipment Tests and Examination - The Health Officer shall perform the indicated tests on the following instruments and devices initially on installation, and at least once each three (3) months thereafter, and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device--Provided the holding time test shall be conducted at least every six (6) months.

TABLE 3

INSTRUMENT OR DEVICE	TEST#	TEST OBJECTIVE
Batch pasteurizer indicating thermometer	1	Accuracy
Batch pasteurizer recognizing thermometer accuracy	2	Temperature
Batch pasteurizer recording thermometer	3	Time accuracy
Batch pasteurizer recording thermometer recording thermometer	4	Check reading of recording thermometer against indicating thermometer
Airspace thermometer	1	Accuracy
Valves	6	Leakage in plug-type leak-protector valves and poppet-type valves
HTST & AP indicating thermometer	1	Accuracy
HTST & AP indicating thermometer	7	Thermometric response
HTST & AP recording thermometer	2	Temperature accuracy
HTST & AP recording thermometer	3	Time accuracy
HTST & AP recorder controller	2	Temperature accuracy
HTST & AP recorder controller	4	Check reading of recorder controller against indicating thermometer
HTST & AP recorder controller	8	Thermometric response
HTST & AP recorder controller	10	Confirm cut-in and cut-out temperature
HTST & AP Flow-diversion device	5	Assembly and function
HTST & AP auxillary (booster) pump control devices	9	Function of automatic control devices
HTST & AP auxillary pump gauges	9	Accuracy of pressure (booster)
HTST & AP system	11	Check holding time

HHST & AP system12Thermal limit control for sequence logic

HHST & AP system13Setting of control switches for product pressure in the holding tube

HHST & AP system14Setting of control switches for differential pressure across the injector

(17) Cooling of Milk.

(a) All raw milk and milk products shall be maintained at 45° F (7° C) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging in approved equipment to a temperature of 45° F (7° C) or less. All pasteurized milk and milk products shall be stored at a temperature of 45° F (7° C) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 7° C (45° F). Every room or tank in which milk, milk products, or frozen desserts are stored shall be equipped with an accurate thermometer--Provided aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirement of this item.

(b) Public Health Reason - When milk is not cooled within a reasonable time after it is received at the pasteurization plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk, milk products, and frozen desserts after pasteurization.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All raw milk and milk products are maintained at 45° F (7° C) or less until processed.

2. All pasteurized milk, milk products, and frozen dessert mix except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 45° F (7° C) or less. All pasteurized milk and milk products shall be stored at a temperature of 45° F (7° C) or less. On delivery vehicles the temperature of milk and milk products shall not exceed (7° C) 45° F. All frozen dessert products shall be stored at a temperature of 0° F(-19° C).

3. Each refrigerator room in which milk, milk products, or frozen desserts are stored is equipped with an indicating thermometer which complies with the applicable specifications of Appendix H. Such thermometer shall be located

in the warmest zone of the refrigerator room. Each storage tank 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 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.

4. All surface coolers comply with the following specifications:

(i) The sections of open-surface coolers shall be so installed as to leave a gap of at least 0.25 inch (6.4 mm) between the header sections to permit easy cleaning.

(ii) Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk, milk products, or frozen desserts by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers, or by shortening the bottom trough, or by some other approved method.

(iii) The location of supports of cooler sections shall prevent drip from entering the milk, milk products, or frozen desserts.

(iv) All open-surface coolers shall be provided with tight fitting shields which protect the milk, milk products, and frozen desserts from contamination by flies, dust, drip, splash, or manual contact.

5. Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semi-annually and shall comply with the current bacteriological standards of Appendix G. Samples shall be taken by the Health Officer and examination shall be conducted in an official laboratory. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, when used in recirculating systems, shall be nontoxic.

(18) Bottling and Packaging.

(a) Bottling and packaging of milk and milk products shall be done at the place of pasteurization in approved mechanical equipment.

(b) Public Health Reason - Manual bottling or packaging is very apt to result in the exposure of the milk or milk products, to contamination, which would nullify the effect of pasteurization. The transfer of milk from the place of pasteurization to another plant for bottling subjects the pasteurized product to unnecessary risks of contamination.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All milk and milk products, including concentrated milk and milk products, are bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

2. All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery but is interpreted to exclude methods in which the bottling and capping devices are not integral in one system.

3. Bottling or packaging machines are designed to minimize the need for adjustment during operation. All pipes, connections, defoaming devices, and similar appurtenances shall comply with .10(10) and .10(11) of this rule. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

4. Bottling or packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

5. A drip deflector is installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container.

6. Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. Such shields shall extend from the bottle washer discharge to the bottle feed star or, in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit, overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with covers off.

7. Container coding/dating devices are designed, installed and operated such that the coding/dating operations are

performed in such a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude contamination of open containers.

8. Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

9. Bottling and packaging machine floats are designed to be adjustable without removing the cover.

10. The filler pipe of all bottling and packaging machines have an apron or other approved device as close to the filler bowl as possible to prevent condensation or drip from reaching the inside of the filler bowl.

11. Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders, or other milk-contact surfaces, the lubricant shall be nontoxic, sterile, and shall be sparingly applied in a sanitary manner.

12. In the case of aseptic processing systems used for producing aseptic milk and milk products, the aseptic product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR 113.

13. Provided, that cottage cheese, dry curd cottage cheese, and lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging.

(19) Capping.

(a) Capping or closing of Grade A milk and milk product containers shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Frozen dessert containers shall be closed in a sanitary manner approved by the Health Officer.

(b) Public Health Reason: Hand-capping exposes the milk to contamination. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap,

including milk which has been forced out by temperature expansion and which may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the milk and milk products have not been contaminated after packaging.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. The capping or closing of Grade A milk and milk product containers is done in a sanitary manner on approved mechanical capping/closing equipment. The term "approved mechanical capping and/or closing equipment" shall not exclude manually operated machinery. Hand-capping shall be prohibited--Provided if suitable mechanical equipment for the capping or closing of specific container(s) of three (3) gallons 12.8 liters or more is not available, other methods which eliminate all possibility of contamination may be approved by the Health Officer.

2. All mechanical capping or closure mechanisms are designed to minimize the need for adjustment during operation.

3. Bottles and packages which have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk, milk products, or frozen desserts shall be protected from contamination, maintained at 45° F (7° C) or less, and subsequently repasteurized or discarded.

4. All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage, and when the containers are initially opened.

5. Caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock, and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operation period after removal from the cap tubes shall be a violation of this paragraph. Provided further that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese, and lowfat cottage cheese, other methods of capping which eliminate possible chance of contamination may be approved by the regulatory agency.

6. Closures for cottage cheese, dry curd cottage cheese, and lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.

7. Provided, that this requirement shall not apply to cottage cheese, dry curd cottage cheese, and lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.

(20) Personnel - Cleanliness.

(a) Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, frozen desserts, containers, equipment, and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk, milk products, or frozen desserts, shall wear adequate hair coverings and shall not use tobacco.

(b) Public Health Reason: Clean clothing and clean hands (including clean fingernails) reduce the possibility of milk, milk products, frozen desserts, containers, and equipment from becoming contaminated.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. Hands are thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination.

2. Each employee washes his hands following a visit to the toilet room and prior to resuming work.

3. All persons, while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, frozen desserts, containers, equipment, and utensils wear clean outer garments.

4. Tobacco is not used by any person while engaged in the processing of milk, milk products, or frozen desserts; and head coverings are worn.

(21) Vehicles.

(a) All vehicles used for transportation of pasteurized milk, milk products, and frozen desserts shall be constructed and operated so that the milk, milk products, and frozen dessert are maintained at 45° F (7° C) or less, and are protected from sun, from freezing, and from contamination.

(b) Public Health Reason: The exposure of milk to the sun will alter the flavor of milk, and will tend to increase the temperature, thus increasing the possibility of bacterial growth. Freezing alters the physical and chemical properties of milk. Milk and milk products, as well as empty containers, should be protected against contamination at all times.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. All vehicles are kept clean.
2. Material which is capable of contaminating milk, milk products, and frozen desserts is not transported with milk, milk products, or frozen desserts.
3. Vehicles have fully enclosed bodies with well-fitted solid doors.

(22) Surroundings.

(a) Milk and frozen dessert plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects, and rodents or which otherwise constitute a nuisance.

(b) Public Health Reason: The surroundings of a dairy plant should be kept neat and clean to prevent attracting rodents, flies, and other insects which may contaminate the milk, milk products, or frozen desserts. Insecticides and rodenticides not approved for use in dairy plants or approved insecticides and rodenticides not used in accordance with label recommendations may contaminate the milk, milk products, or frozen desserts processed by the dairy plant.

(c) Administrative Procedures: This item is deemed to be satisfied when:

1. There is no accumulation of trash, garbage, or similar waste in areas adjacent to the milk or frozen dessert plant. Waste material stored in suitable covered containers shall be considered in compliance.

2. Driveways, lanes, and areas serving milk and frozen dessert plant vehicular traffic are graded, drained, and free from pools of standing water.

3. Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain, and equipped with trapped drains of sufficient size.

4. Only insecticides and rodenticides approved for use by the Health Officer and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

NOTE: A convenient inspection form for milk and frozen dessert plants, receiving stations, and transfer stations, which summarizes the applicable sanitation requirements is found in Appendix M.

(23) A receiving station shall comply with .10 (1) through (15); (17); (20); and (22) of this rule except that the partitioning requirement of .10(5) of this rule shall not apply.

(24) A transfer station shall comply with .10(1), (4), (6), (7), (8), (9), (10), (11), (12), (14), (15), (20), and (22); and as climatic and operating conditions require, the applicable provisions of (2) and (3) of this rule--Provided in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of bulk transport tank shall comply with items .10(1), (4), (6), (7), (8), (9), (10), (11), (12), (14), (15), (20), and (22); and as climatic and operating conditions require, the applicable provisions of (2) and (3) of this rule--Provided in every case, overhead protection shall be provided.

Authors: Robert E. Shelton - G.M. Gallaspy, Jr.

Statutory Authority: Code of Ala. 1975, §§22-2-2 and 22-20-7.

History:

420-3-16-.11 Animal Health.

(1) All milk for pasteurization shall be (a) from herds which are located in a Modified Accredited Tuberculosis Area as determined by the U.S. Department of Agriculture--Provided herds located in an area that fails to maintain such accredited status shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test; (b) All milk for pasteurization shall

be from herds under a brucellosis eradication program which meets one of the following conditions:

(i) Located in a Certified Brucellosis-free Area as defined by the U.S. Department of Agriculture by the U.S. Department of Agriculture and enrolled in the testing program for such areas; or

(ii) Meet U.S. Department of Agriculture requirements for an individually certified herd; or

(iii) Participating in a milk ring testing program at least four times per year at approximately 90 day intervals, and all herds with positive milk ring results shall have the entire herd blood tested within 30 days from the date of the laboratory ring tests; or

(iv) Have an individual blood agglutination test annually with an allowable maximum grace period not to exceed 2 months.

(a) For diseases other than brucellosis and tuberculosis, the Health Officer shall require such physical, chemical, or bacteriological tests as he deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Health Officer directs.

(2) Public Health Reason:

(a) The health of the cow is a very important consideration because a number of diseases of cattle, including tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcic infection, and streptococcic infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash, or be blown into the milk.

(b) The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of cattle and removal of the reactors from the herds, and the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists, however; hence, constant vigilance against this disease must be continued by industry and health agencies.

(3) Administrative Procedures: This item is deemed to be satisfied when:

(a) Tuberculosis - All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and rules for establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine, as approved by the U. S. Department of Agriculture at the time of the adoption of these rules. For tuberculosis test purposes, the herd is defined as all adult cattle 24 months of age and over, including any commingled beef animals. Dairy cattle less than 2 years of age and already milking, shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test, and the results of the test signed by a U.S. Department of Agriculture accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Health Officer. (See Appendix A).

(b) Brucellosis - All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with Brucellosis Eradication "Recommended Uniform Methods and Rules," as approved by the U.S. Department of Agriculture. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd; the milk of these reactors shall not be used for human consumption.

A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the regulatory agency: Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within 30 days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, 13 months following the last annual blood tests, the regulatory agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the Brucellosis requirements within 30 days of written notice shall result in immediate suspension of the permit (See Appendix A).

(c) Other Diseases - Cows which show a complete induration of one quarter or extensive induration in one or more

quarters of the udder upon physical examination, whether secreting abnormal or not shall be permanently excluded from the milking herd--Provided this shall not apply in the case of a quarter that is completely dry. Cows giving bloody, stringy or otherwise abnormal milk based on bacteriological, chemical, or physical examination, but without entire or extensive induration of the udder, shall be excluded from the herd until re-examination shows that the milk has become normal. For other diseases such tests and examinations as the Health Officer may require shall be made at intervals and by methods prescribed by him or the Alabama State Veterinarian, and any diseased or dead animals or reactors shall be disposed of as either may require.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.12 Milk And Milk Products Which May Be Sold. From and after thirty-five days from the date on which these rules are adopted, only Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products and approved frozen desserts shall be sold to the final consumer, or to restaurants, soda fountains, grocery stores, or similar establishments--Provided in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by the Health Officer; in which case, such milk and milk products shall be labeled "ungraded."

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.13 Transferring; Delivery Containers; Cooling.

(1) Except as permitted in this section, no milk product, milk hauler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street in any vehicle, store, or in any place except a milk plant, receiving station, transfer station or milk house especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

(2) It shall be unlawful to sell or serve any milk or fluid milk product except in individual, original container received from the distributor, or from an approved bulk dispenser--Provided, that this requirement shall not apply to

milk for mixed drinks requiring less than 1/2 (236 ml) pint of milk, or to cream, whipped cream, or half-and-half which is consumed on the premises and which may be served from the original container of not more than 1/2 (1.9 l) gallon capacity, or from a bulk dispenser approved for such service by the Health Officer.

(3) It shall be unlawful to sell any pasteurized milk, milk product, or frozen dessert which has not been maintained at the temperature set forth in .09 and .10 of this rule. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

(4) Administrative Procedures: This item is deemed to be satisfied when:

(a) Transferring - The dipping or ladling of milk and fluid milk products is expressly prohibited except for immediate cooking purposes. Milk, milk product, and frozen dessert containers which have been filled and sealed at a milk or frozen dessert plant shall be used for the delivery of milk, milk products, or frozen desserts. Caps, closures, or labels shall not be removed or replaced during transportation.

(b) Bulk Dispensers - Bulk dispensers approved by Health Officer shall satisfy the following sanitary design, construction, and operation requirements:

1. All dispensers shall comply with the applicable requirements of .10 of this rule.

2. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust, or flies; but the delivery orifice may be exempted from this rule.

3. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant--Provided dispensing valves which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.

4. The dispensing container shall be filled at the milk or frozen dessert plant and shall be so sealed that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).

5. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products which remain homogeneous.

6. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 45° F (7° C) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected, and shall be under adequate refrigeration during transportation and storage.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.14 Distribution Of Milk And Milk Products From Points Beyond Local Jurisdiction.

(1) Milk, milk products, and frozen desserts from points beyond the limits of routine inspection of the State of Alabama or its jurisdiction, may be sold in Alabama or its jurisdiction, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed under regulations which are substantially equivalent to these rules. Milk and milk products must have been awarded an acceptable milk sanitation compliance and enforcement rating made by a state milk sanitation rating officer certified by the Food and Drug Administration.

(2) Administrative Procedures: This item is deemed to be satisfied when the Health Officer should accept, without their actual physical inspection, supplies of milk, milk products, and frozen desserts from an area or an individual shipper not under their routine inspection--Provided;

1. Upon arrival, raw milk and/or raw milk products for pasteurization shall comply with bacteriological, chemical and temperature standards of .08 as determined in accordance with .07 of this rule. Provided, that direct shipped producer milk that is under the supervision of more than one regulatory agency may be exempt from the bacteriological requirement for commingled samples. However, the receiving regulatory agency shall have the right to use the individual producer samples to determine compliance with the bacteriological standards using the individual producer raw milk standards.

2. After receipt, pasteurized, ultra-pasteurized milk, milk products, and frozen desserts shall comply with the bacteriological, chemical, and temperature requirements of .08 as determined in accordance with .07 of this rule.

NOTE: Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the Health Officer requires.

3. The milk, milk products, or frozen desserts are produced and processed under regulations substantially equivalent to these rules;

4. The supplies are under routine official supervision;

5. The milk supplies have been awarded by the State Milk Sanitation Rating Officer certified by the Food and Drug Administration, a milk sanitation compliance and enforcement rating equal to that of the local supply or equal to 90 percent or higher; and

6. All ratings are made on the basis of procedures outlined in Methods of Making Sanitation Ratings of Milk Supplies recommended by the United States Public Health Service/Food and Drug Administration.

NOTE: Names of interstate milk shippers and their ratings, as reported by state milk rating agencies, are contained in Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers, issued quarterly by the Food and Drug Administration for the information of interested persons. Copies of this list may be obtained from the state milk rating agency or from the Food and Drug Administration, Washington, D.C. 20204.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.15 Future Dairies, Milk Plants And Frozen

Dessert Plants. Properly prepared plans for all milk houses, milking barns, and parlors, transfer stations, receiving stations, milk, and frozen dessert plants regulated under these rules which are hereafter constructed, reconstructed, or extensively altered, shall be submitted to the Health Officer for written approval before work is begun.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.16 Personnel Health. No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm, milk plant, or frozen dessert plant in any capacity which brings him into contact with the production, handling, storage, or transportation of milk, milk products, frozen desserts, containers, equipment, and utensils; and no dairy farm or milk or frozen dessert plant operator shall employ in any such capacity any such person, or any person suspected of having any disease in a communicable form, or of being a carrier of such disease. Any producer or distributor of milk, milk products, or frozen dessert plant any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become a carrier of such disease shall notify the Health Officer immediately.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.17 Procedure When Infection Is Suspected. When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk and/or milk products, or frozen desserts, the Health Officer is authorized to require any or all of the following measures:

(a) The immediate exclusion of that person from milk or frozen dessert handling;

(b) The immediate exclusion of the milk or frozen dessert supply concerned from distribution and use; and

(c) Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16.18 Enforcement Interpretation. The Health Officer shall enforce this rule, a certified copy of which shall be on file in the office of the State Health Officer. Where the mandatory compliance with provisions of the Appendices is specified, such provisions shall be deemed a requirement of these rules.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.19 Penalty Fixed. Any violation of these rules shall constitute a misdemeanor as set forth and declared punishable in Code of Ala. 1975, §22-1-8.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.20 Application Of Rules.

(1) These rules shall apply only to milk, milk products, and frozen desserts intended for sale for human consumption and single-service containers and closures used for milk and milk products and shall become effective thirty-five (35) days after adoption by the State Board of Health and shall be in full force and effect within a county or municipality upon notification of the probate judge of the county and the officials of a municipality by the State Health Officer in accordance with Code of Ala. 1975, §22-20-5.

(2) These rules supersede all prior rules and all rules and parts of rules in conflict with this rule are hereby repealed upon the date these rules become effective.

Author:

Statutory Authority: Code of Ala. 1975,

History:

420-3-16-.21 Unconstitutionality Provided Against.

(1) Should any section, paragraph, sentence, clause, or phrase of these rules be declared unconstitutional or invalid by any court of competent jurisdiction, the remainder of these regulations shall not be affected thereby.

Author:

Statutory Authority: Code of Ala. 1975,

History: Original Chapter entitled "Processing, Manufacturing, Handling and Inspection of Frozen Desserts" filed September 1, 1982. Emergency Rule No. 420-3-16-.04 filed February 11, 1983. Chapter Repealed and new Chapter entitled "Production,

Chapter 420-3-16

Health

Processing, Handling or Distribution of Milk, Milk Products and Frozen Desserts" adopted in lieu thereof: Filed March 23, 1984.

Note: Chapter 420-3-1-7 (Production, Processing, Handling or Distribution of Milk and Certain Milk Products) was subsumed by Chapter 420-3-16 (filed March 23, 1984.)

Rule Nos. 420-3-16-.05; 420-3-16-.07; 420-3-16-.08 (Table I); 420-3-16-.09; 420-3-16-.10; Appendix G; Appendix J amended: Filed June 23, 1986.

Rule Nos. 420-3-16-.02; 420-3-16-.06; 420-3-16-.07; 420-3-16-.08 (Table 1); 420-3-16.09; 420-3-16-.10. All Appendices have been realigned to correspond with the Food and Drug Administration Grade "A" Pasteurized Milk Ordinance (PMO) 420-3-16 Appendices A, B, C, D, H, I, J, L, and N. Appendices L and N are new additions. Filed May 19, 1993.