

CHAPTER 59. MILK SANITATION

Subchap.	Sec.
A. PRELIMINARY PROVISIONS	59.1
B. STANDARDS FOR MILK AND MILK PRODUCTS	59.51
C. MISCELLANEOUS PROVISIONS	59.301
D. ADMINISTRATIVE PROCEDURES	59.401
E. MILK FOR MANUFACTURING	59.501
F. FARMS PRODUCING MILK FOR MANUFACTURING	59.601
G. MANUFACTURING PLANTS	59.701

Authority

The provisions of this Chapter 59 issued under section 19 of the act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. § 660c), unless otherwise noted.

Source

The provisions of this Chapter 59 adopted March 12, 1970; amended August 6, 1982, effective August 7, 1982, 12 Pa.B. 2584, unless otherwise noted. Immediately preceding text appears at serial pages (32379) to (32381), (24363), (26027), (27106), (24366) to (24372), (1608) to (1613), (26028) to (26029), (24375) to (24376), (1618) to (1620), (7332), (26030), (24378), (16799), (7334), (1624), (24379), (26031), (24381), (27107) to (27108), (24384) to (24386), (1633) to (1637), (24387) to (24392), (16801) to (16802), and (24393) to (24394).

Cross References

This chapter cited in 7 Pa. Code § 39.1 (relating to scope); 7 Pa. Code § 57.42 (relating to specific labeling requirements); and 7 Pa. Code § 61.72 (relating to applicable standards).

Subchapter A. PRELIMINARY PROVISIONS

TERMS AND APPLICATION

- Sec. 59.1. Definitions.
- 59.2. Context.

SPECIFIC PROVISIONS

- 59.11. Contents.
- 59.12. [Reserved].
- 59.13. Approved.
- 59.14. Sanitization.
- 59.15. 3A Sanitary Standards.
- 59.16. Adulterated milk or milk products.
- 59.17. Permits.

LABELING

- 59.21. General labeling requirements.
- 59.22. Milk dating.

QUALITY CONTROL

- 59.31. Inspection of dairy farms.
- 59.32. Sampling and examination.
- 59.33. Problems.
- 59.34. Analysis.

Notes of Decisions

Although milk cooperative had duty under the statutory and regulatory provisions to inspect dairy farms for sanitation of milk production facilities, the cooperative had no duty to assure the safety of person removing raw milk from a bulk tank on dairy farm. *Johnson v. Baker*, 499 A.2d 372 (Pa. Super. 1985).

TERMS AND APPLICATION

§ 59.1. Definitions.

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

Abnormal milk—Milk secreted from cows immediately after parturition, curdled, ropy, bloody or mastitic condition or 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 Department may be deleterious to human health.

Acceptable milk—Milk that qualified under § 59.502 (relating to sight and odor) as to sight and odor, and that is classified No. 1 or No. 2 for sediment content—§ 59.503 (relating to sediment content classification)—and No. 1 or No. 2 for bacterial estimate—§ 59.504 (relating to bacterial estimate classification).

Approved dairy ingredients—Milk and dairy products approved by the Department.

Approved milkgrader—A person approved by the Department for the grading of raw milk for manufacturing in accordance with the quality standards and procedures of this subchapter using sight, odor and sediment grading.

Approved sampler—A person certified by the Department to obtain samples of milk or milk products for analysis by a Pennsylvania approved laboratory.

Aseptically processed dairy products—Milk and milk products which are packaged in hermetically sealed containers allowing storage for long periods of time without refrigeration.

Aseptically processed and packaged milk or milk product—Milk or milk product thermally processed, either before or after sealing in a hermetically sealed container, so as to render the product free of microorganisms capable of reproducing in the product under normal nonrefrigerated conditions of storage and distribution, and shall be free of viable microorganisms (including spores) of public health significance. The product shall conform with applicable provisions of the 1978 Grade A Pasteurized Milk Ordinance.

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

Bulk tank unit (BTU)—A specified group of dairy farms from which milk for pasteurization or for manufacturing purposes is collected by a milk tank truck.

Certified milk—Milk from dairy farms operated in accordance with “Methods and Standards for the Production and Distribution of Certified Milk,” last adopted by the American Association of Medical Milk Commissioners, Inc., the production and handling of which shall be certified by a commission instituted in compliance herewith.

Classification of farm sanitation compliance—

(i) *Passing*—A general compliance with sanitary standards established for the production of milk.

(ii) *Reinspect*—A significant noncompliance with sanitary standards established for the production of milk requiring remedial action and a subsequent review to determine conformity.

(iii) *Suspend*—Major noncompliance with sanitary standards or evidence of conditions that would render the milk unsafe for human consumption, or if on the reinspection it is found that sufficient progress has not been made on the previously recommended corrections.

Cleaned-In-Place (CIP)—The procedure by which sanitary pipelines or pieces of dairy equipment are mechanically cleaned in place by circulation.

Commingled milk—Milk from two or more producers; in a milk plant, a representative sample of all daily sources of milk prior to pasteurization.

Cowyard—The enclosed or unenclosed area adjacent to the milking barn in which cows may congregate.

Dairy farm—Any place where cows or goats are kept and from which a part or all of the milk is sold.

Department—The Pennsylvania Department of Agriculture.

Designated inspector—A Pennsylvania Approved Inspector who has been certified to inspect dairy farms on which milk is produced for an interstate milk shipper.

Dry milk and whey products—Products which have been produced for use in pasteurized milk or milk products and which have been manufactured under this chapter.

Excluded milk for manufacturing—All of a producer's milk excluded from the market by § 59.507 (relating to inspection and testing of milk).

Food establishment—A retail food store and a room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food. The term includes those portions of public eating and drinking licensees which offer food for sale for off-premises consumption, except those portions of establishments operating exclusively under milk or milk products permits.

Growth inhibitor—Any antimicrobial adulterant, including but not limited to antibiotics.

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

Higher heat shorter time pasteurization—A process through which every particle of a dairy product is heated to between 191°F and 212°F at holding times between 1.0 and 0.1 seconds before packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

Homogenized—Milk or a milk product has been treated to insure breakup of the fat globules to such an extent that, after 48 hours of quiescent storage at 45 F(7°C), no visible cream separation occurs on the milk and that the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10% from the fat percentage of the remaining milk as determined after thorough mixing.

Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk—The product resulting from the treatment of milk, lowfat milk or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of lactose to glucose or galactose, or both, so that the remaining lactose is less than 30% of the lactose in milk, lowfat milk or skim milk.

Manufactured dairy products—Butter, cheese (natural or processed), dry whole milk, nonfat dry milk, dry buttermilk, dry whey and dry whey products, evaporated milk (whole or skim), condensed whole and condensed skim milk (plain or sweetened), and other products for human consumption designated by the Secretary.

Milk—The natural lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats.

Milk distributor—Any person who offers for sale or sells any milk or milk product.

Milk for manufacturing purposes—Milk produced for processing and manufacturing into products for human consumption, not subject to requirements of milk for pasteurization, except for applicable provisions in this chapter.

Milk for pasteurization—Milk which conforms with relevant provisions of this chapter and is used in the preparation of pasteurized milk and milk products.

Milk plant—Any place where milk or milk products are collected, handled, processed, stored, pasteurized, packaged, or prepared for distribution.

Milk processor—Any person who operates a plant where milk is received or processed.

Milk producer—Any person who operates a dairy farm.

Milk products—Ice cream, ice cream mix, custard ice cream, French ice cream, frozen custard, ice milk, sherbet, and other similar frozen and semifrozen products and all dairy products used in the manufacture thereof.

Milk tank truck—A bulk milk pick-up tanker or a milk transport tank.

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

Milking parlor—The area of a dairy barn which is used exclusively for the milking of cows and in which no bedding is used.

New producer—A producer who has not produced milk or cream for pasteurization or for manufacturing purposes.

Official laboratory—A biological, chemical, or physical laboratory which is under the direct supervision of the Department.

Pasteurized concentrated dairy products—Includes homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section.

Pasteurized frozen milk concentrate—A frozen dairy product with a composition of milkfat and milk solids not fat in proportions so 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.

Pasteurized low-sodium milk or low-sodium lowfat milk or low-sodium skim milk—The product resulting from the treatment of milk, lowfat milk or skim milk by a process of passing the milk, lowfat milk or skim milk through an ion exchange resin process or by any process which has been recognized by the

Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

Pasteurized product—Every particle of such product shall have been heated in properly operated equipment approved by the Secretary, to one of the temperatures specified in the following table and held continuously at or above that temperature for the specified time (or other time/temperature relationship equivalent thereto in microbial destruction):

<i>Temperature</i>	<i>Time</i>
*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

*If the fat content of the dairy product is 10% 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 containing dairy products shall be heated to at least the following temperature and time specifications:

<i>Temperature</i>	<i>Time</i>
155°F(69°C)	30 minutes
175°F(80°C)	25 seconds
180°F(83°C)	15 seconds

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 Secretary.

Pennsylvania approved dairy laboratory—

(i) A commercial or regulatory laboratory authorized by the Department to do official analyses of milk and milk products.

(ii) A milk industry laboratory officially designated by the Department for the examination of producer samples of raw milk for pasteurization or of commingled raw milk for pasteurization for the detection of growth inhibitor residues and bacterial limits. Such laboratories may also be designated for the examination of milk products—frozen desserts and frozen desserts mixes—processed under their direct control.

Pennsylvania approved inspector—A person who has demonstrated, by examination and field evaluation, his proficiency in inspecting dairy farms and has been issued a license by the Secretary to enforce this part.

PMO—The 1978 Grade A Pasteurized Milk Ordinance, which is a document published periodically by the United States Department of Health and Human

Services covering the recommendations of the United States Public Health Service/Food and Drug Administration giving procedures governing the Cooperative State—Public Health Service/Food and Drug Administration Program for certification of interstate milk shippers.

Permit holder—A person holding a permit issued by the Department to sell milk or milk products.

Probational milk—Milk classified No. 3 for sediment content—§ 59.503 or milk classified undergrade for bacterial estimate—§ 59.504 that may be accepted by plants for specific time periods.

Raw milk—Raw milk is milk which conforms with the relevant provisions of this chapter and may be sold to consumers without further treatment or processing.

Receiving station—Any place where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

Reject milk—Milk that does not qualify under § 59.502 or that is classified No. 4 for sediment content—§ 59.503, which is rejected by the plant under § 59.505 (relating to rejected milk).

Retail food store—An establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premises consumption.

Sanitization—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.

Secretary—The Secretary of Agriculture of the Commonwealth or his authorized representative.

3A Sanitary Standards—Standards 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 and Food Branch, Division of Environmental Engineering and Food Protection, Public Health Service, Department of Health and Human Services.

Standard Methods—*Standard Methods for the Examination of Dairy Products*, published by the American Public Health Association.

Transfer producer—A producer who has sold milk or cream, or both, to a milk plant and who changes his sales to another milk plant.

Transfer station—Any place where milk or milk products are transferred directly from one milk tank truck to another.

Ultra-pasteurized product—A product 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.

Weigher/sampler—A bulk milk pick-up driver or a milk plant person certified by the Department to take samples of producers' milk for chemical and bacteriological analyses.

Authority

The provisions of this § 59.1 issued under the act of July 2, 1935 (P. L. 558, No. 163) (31 P. S. §§ 645—660f).

Source

The provisions of this § 59.1 amended October 11, 1985, effective October 12, 1985, 15 Pa.B. 3642; amended July 5, 1996, effective July 6, 1996, 26 Pa.B. 3129; amended December 13, 1996, effective December 14, 1996, 26 Pa.B. 5950; amended September 5, 2003, effective September 6, 2003, 33 Pa.B. 4445. Immediately preceding text appears at serial pages (223210) to (223216).

Cross References

This section cited in 7 Pa. Code § 59.216b (relating to high temperature short-time (HTST) continuous flow pasteurization requirements); and 7 Pa. Code § 59.709 (relating to pasteurized, ultra-pasteurized or aseptically processed and packaged products).

§ 59.2. Context.

This chapter will be applied in conjunction with Chapter 57 (relating to milk and dairy products—general provisions) concerning identity of milk and milk products.

SPECIFIC PROVISIONS**§ 59.11. Contents.**

Milk that is in final package form for beverage use shall contain not less than 8.25% milk solids not fat and not less than 3.25% milkfat.

Cross References

This section cited in 7 Pa. Code § 59.32 (relating to sampling and examination).

§ 59.12. [Reserved].**Source**

The provisions of this § 59.12 reserved December 13, 1996, effective December 14, 1996, 26 Pa.B. 5950. Immediately preceding text appears at serial page (217604).

§ 59.13. Approved.

All milk and dairy products shall be approved by the Department before use in pasteurized products.

§ 59.14. Sanitization.

Sanitization shall not adversely affect the equipment, milk or milk product or the health of consumers. Sanitization shall be acceptable to the Department.

§ 59.15. 3A Sanitary Standards.

Equipment manufactured in conformity with 3A Sanitary Standards complies with the sanitary design and constructions standards of this chapter.

§ 59.16. Adulterated milk or milk products.

(a) Milk or milk products produced and distributed for sale shall not be adulterated in any manner by the addition of substances not normally found therein, except those substances approved by the Secretary in this chapter.

(b) The Secretary may seize, condemn, denature, or destroy any milk or milk product without compensation to the owner or owners thereof if he considers the milk or milk product unsafe or a menace to public health.

Cross References

This section cited in 7 Pa. Code § 59.32 (relating to sampling and examination).

§ 59.17. Permits.

(a) Permits will be required for the sale of milk and milk products and will be issued only upon application.

(b) Separate permit shall be obtained for each milk plant, milk distributor, receiving station, transfer station, and bulk tank unit and by every producer of raw milk.

(c) The permit year shall begin September 1 of each year and end on August 31 of the following year.

Cross References

This section cited in 7 Pa. Code § 59.716 (relating to permits).

LABELING**§ 59.21. General labeling requirements.**

(a) The term, "milk," unqualified, means cow's milk. Milk derived from goats shall be labeled as such.

(b) All bottles, containers and packages enclosing milk and milk products shall be labeled in accordance with §§ 57.41 and 57.42 (relating to labeling) and, where specific labeling requirements are not prescribed in this section or § 59.22 (relating to milk dating), Federal labeling requirements shall be followed.

(c) All bottles, containers, and packages enclosing milk or milk products offered for sale, except milk tank trucks, storage tanks, and cans of raw milk from dairy farms shall be marked with the following information:

- (1) Name of the food, raw, pasteurized, certified, or other such designations as approved by the Department.
- (2) Name and address of the processor or distributor, as appropriate.
- (3) Identity of plant where processed.

- (4) The word “reconstituted” or “recombined” if the product is made by reconstitution or recombination.
- (5) The volume or proportion of water to be added for reconstitution or recombination, in the case of concentrated milk or milk products.
- (d) Proposed labeling of all containers and closures shall be submitted to the Department for approval.
- (e) All vehicles containing milk or dairy products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. Milk transport tank trucks transporting bulk milk and dairy products shall be sealed and shall be accompanied by a legible shipping statement containing the following information:
- (1) Shipper’s name, address, and plant identification number.
 - (2) Identification of hauler.
 - (3) Point of origin of shipment.
 - (4) Tanker identification number.
 - (5) Name of product.
 - (6) Weight of product.
 - (7) Grade of product.
 - (8) Temperature of product.
 - (9) Date of shipment.
 - (10) Name of supervisory regulatory agency at point of origin.
 - (11) Whether the product is raw, pasteurized or heat-treated.
- (f) All cans of raw milk from individual dairy farms shall be identified by name or number of the producer.
- (g) Misleading marks, words or endorsements upon the label are prohibited. Registered trade designs or terms may be permitted on the container cap or label provided they are not misleading and do not obscure the required labeling.

Cross References

This section cited in 7 Pa. Code § 59.32 (relating to sampling and examination).

§ 59.22. Milk dating.

- (a) *Label requirement.* The cap or nonglass container of pasteurized milk held in retail food stores, restaurants, schools or similar food establishments for resale shall be conspicuously and legibly marked in a contrasting color with the designation of the “sell-by” date—the month and day of the month after which the product may not be sold or offered for sale. The designation may be numerical—such as “8-15”—or with the use of an abbreviation for the month, such as “AUG 15 or AU 15.” The words “Sell by” or “Not to be sold after” shall precede the designation of the date, or the statement “Not to be sold after the date stamped above” shall appear legibly on the container. This designation of the date may not exceed 17 days beginning after midnight on the day on which the milk was pasteurized.

(b) *Prominence of sell-by date on label.* The sell-by date shall be separate and distinct from any other number, letter or intervening material on the cap or non-glass container.

(c) *Prohibition.* Pasteurized milk may not be sold or offered for sale if either of the following occurs:

(1) The milk is sold or offered for sale after the sell-by date designated on the container.

(2) Without regard to the sell-by date designated on the container, the milk exceeds the bacterial limits for pasteurized milk described in § 59.52 (relating to table).

(d) *Exemption.* The following pasteurized dairy products are exempt from the requirements of this section:

(1) Ultra-pasteurized dairy products.

(2) Cultured dairy products.

(3) Aseptically processed dairy products.

(4) Dairy products that have undergone higher heat shorter time pasteurization.

(5) Milk sold or offered for retail sale on the same premises at which it was processed.

(e) *Monitoring by the Department.*

(1) The Department will periodically sample containers of pasteurized milk in the possession of the processor or distributor. This sampling may occur at any time before the pasteurized milk is delivered to the store or the customer. The Department will sample at least one milk product from each processor each calendar year.

(2) The samples described in paragraph (1) shall be analyzed by a Pennsylvania-approved dairy laboratory, applying a methodology set forth in the most current edition of Dairy Practices Council Guideline No. 10, entitled "Guidelines for Maintaining and Testing Fluid Milk Shelf Life," to determine whether the bacterial test results exceed the bacterial limits for pasteurized milk described in § 59.52 prior to the expiration of the sell-by date designated on the retail container.

(3) When two or more samples demonstrate a processor cannot produce pasteurized milk that remains consistently within the bacterial limits referenced in paragraph (2) during a 17-day sell-by period, the Department will require a processor to use a sell-by date of something less than the 17-day period described in subsection (a). The Department will calculate this revised sell-by date so that bacterial growth in the milk will not exceed the referenced bacterial limits within that sell-by period if the milk is maintained in accordance with the temperature standards for pasteurized milk in § 59.52.

(4) A processor may submit samples to the Department for analysis to obtain approval to resume a 17-day sell-by period for the product sampled. The Department will approve resumption of a 17-day sell-by period when analysis

of a sample demonstrates that bacterial growth in the milk will not exceed the referenced bacterial limits within that sell-by period if the milk is maintained in accordance with the temperature standards for pasteurized milk in § 59.52.

Authority

The provisions of this § 59.22 amended under the act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645—660g).

Source

The provisions of this § 59.22 amended September 4, 1987, effective September 5, 1988, 17 Pa.B. 3599; amended August 9, 1991, effective August 10, 1991, 21 Pa.B. 3508; amended July 5, 1996, effective July 6, 1996, 26 Pa.B. 3129; amended September 5, 2003, effective September 6, 2003, 33 Pa.B. 4445. Immediately preceding text appears at serial pages (217606) to (217607).

Cross References

This section cited in 7 Pa. Code § 46.385 (relating to potentially hazardous food: hot and cold holding); 7 Pa. Code § 59.21 (relating to general labeling requirements); and 7 Pa. Code § 59.32 (relating to sampling and examination).

QUALITY CONTROL

§ 59.31. Inspection of dairy farms.

(a) Each producer of milk for pasteurization will be inspected initially and on any change of market by a Pennsylvania approved inspector and shall have a passing score before the first milk is shipped. All producers shall be inspected no less than once in each 6-month period by a Pennsylvania approved inspector, and an accurate record of farm inspections shall be maintained on forms acceptable to the Secretary.

(b) Producers who cannot produce milk of a wholesome, sanitary quality are to be excluded. Producers who are not in substantial compliance with §§ 59.101—59.121 (relating to sanitation requirements applicable to production of milk for pasteurization) will be reinspected after an appropriate time for correction of deficiencies.

(c) Inspectors of farms producing milk for interstate shipment will be designated as an agent of the Secretary and certified in accordance with provisions of the PMO.

(d) A permit holder shall promptly notify the Department of initial instatement, suspension or reinstatement of any producer from which milk for pasteurization is or was received. Identification of the producer, including name and address, shall be provided orally or by mail within 24 hours of such action.

§ 59.32. Sampling and examination.

(a) The sampling and testing required in this section shall be the responsibility of the permit holder.

(b) Raw milk and raw cream shall be tested at least semimonthly for the standard plate count and coliform group and monthly for somatic cell count and growth inhibitor.

(c) It shall be the responsibility of the weigher/sampler 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, laboratory or other location approved by the Department.

(d) At least monthly, one sample of milk for pasteurization shall be obtained from each producer by an approved sampler. At least monthly, one sample of commingled milk shall be taken by an approved sampler from each milk plant after receipt of the milk by the plant and prior to pasteurization. In addition, at least monthly, one sample of pasteurized milk and each milk product shall be taken from each milk plant. Frozen desserts—vanilla, chocolate, and one other flavor where applicable—shall be tested at least monthly for the standard plate count and coliform group. Milk products mix shall be tested at least monthly for the standard plate count, coliform group, and phosphatase activity. Samples of milk and milk products shall be taken while in possession of the processor or distributor at any time prior to delivery to the store or customer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores, and other places where milk and milk products are sold shall be examined periodically as determined by the Department; and the results of such examination will be used to determine compliance with § 59.11 (relating to contents), § 59.16 (relating to adulterated milk or milk products), and §§ 59.21 and 59.22 (relating to labeling). Proprietors of such establishments shall furnish the Department, upon request, with the names of all distributors from whom milk or milk products are obtained.

(e) Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on milk for pasteurization. In addition, growth-inhibitor tests on each producer's milk or on commingled raw milk from tank trucks shall be conducted at least monthly. 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, growth-inhibitor tests, coliform determinations, phosphatase tests, and cooling temperature checks shall be performed on pasteurized milk and dairy products.

Cross References

This section cited in 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.304 (relating to milk and milk products from beyond the limits of routine inspection).

§ 59.33. Problems.

(a) Whenever two of the last four consecutive bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures—taken on separate days—exceed the limit of the standard for the milk or dairy products, the Department will send a written notice thereof to the permit holder concerned. In the case of individual producers, the permit holder shall send the written notice. This notice shall be in effect so long as two of the last four consecutive samples exceed the limit of the standard. In the case of an individual milk producer, whenever test standards are exceeded by three of the last five bacteria, temperature, or somatic cell counts, the plant purchasing the milk shall immediately exclude such milk from the supply for a period of at least two days or until such time as conformance can reasonably be assured. In the case of a permit holder, whenever the standard of the product is exceeded by three of the last five bacteria counts, coliform determinations or temperature determinations, the permit holder shall be subject to the punitive clause of the Milk Sanitation Law, section 20 of the act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. § 660d).

(b) Whenever a phosphatase test is positive, the cause shall be determined. When the cause is improper pasteurization, it shall be corrected, and any milk or milk product involved shall not be offered for sale. Reference should be made to § 59.309 (relating to approved laboratory reports).

(c) Whenever a growth-inhibitor or 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 growth-inhibitor or pesticide residues, and no milk shall be offered for sale until it is shown by a subsequent sample to be free of growth-inhibitor or pesticide residue or below the actionable levels established for such residues.

(d) When a test conducted by an approved laboratory indicates that milk from a producer is unsafe due to a growth inhibitor, the permit holder shall immediately notify and suspend the producer for 2 days. A test shall be made of the subsequent milking after suspension, and it must be free of growth inhibitor before offering that milk for sale.

Cross References

This section cited in 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.304 (relating to milk and milk products from beyond the limits of routine inspection).

§ 59.34. Analysis.

(a) Samples analyzed for added water and found to have a freezing point above -0.525°H (-0.508°C) shall be considered adulterated unless proven free of added water.

(b) Samples shall be analyzed at an official or a Pennsylvania approved dairy laboratory. All sampling procedures and required laboratory examinations with the current edition of the *Standard Methods for the Examination of Dairy Prod-*

ucts of the American Public Health Association and the current edition of the *Official Methods of Analysis of the Association of Official Analytical Chemists* or other methods approved by the Secretary. Such procedures, including the certification of sample collectors and examination, shall be evaluated in accordance with the *Evaluation of Milk Laboratories, 1978 Recommendations of the United States Public Health Service/Food and Drug Administration*. Examinations and tests to detect adulterants, including pesticides, shall be conducted as the Department requires.

(c) Assays of milk and dairy products to which vitamins or minerals have been added shall be made at least annually in a laboratory acceptable to the Department, and a copy of the results shall be sent to the Department. If, in the opinion of the Department, there is reason to doubt that fortification is being carried out properly, the Department may require additional samples to be tested at the expense of the permit holder.

Cross References

This section cited in 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.304 (relating to milk and milk products from beyond the limits of routine inspection).

Subchapter B. STANDARDS FOR MILK AND MILK PRODUCTS

GENERAL PROVISIONS

Sec.	
59.51.	Rule.
59.52.	Table.

SANITATION REQUIREMENTS APPLICABLE TO PRODUCTION OF MILK FOR PASTEURIZATION

59.101.	Abnormal milk.
59.102.	Milking barn, stable or parlor—construction and maintenance.
59.103.	Milking barn, stable or parlor—cleanliness.
59.104.	Cowyard.
59.105.	Milkhouse or room—construction and facilities.
59.106.	Milkhouse or room—cleanliness.
59.107.	Toilet.
59.108.	Water supply.
59.109.	Utensils and equipment—construction.
59.110.	Utensils and equipment—cleaning.
59.111.	Utensils and equipment—sanitation.
59.112.	Utensils and equipment—storage.
59.113.	Utensils and equipment—handling.
59.114.	Milking—flanks, udders and teats.

- 59.115. Milking—surcingles, milk stools and antikickers.
- 59.116. Protection from contamination.
- 59.117. Personnel—hand-washing facilities.
- 59.118. Personnel—cleanliness.
- 59.119. Cooling.
- 59.120. Vehicles.
- 59.121. Insect and rodent control.

**SANITATION AND PROCEDURE REQUIREMENTS APPLICABLE
TO THE HANDLING AND PROCESSING OF PASTEURIZED MILK
AND MILK PRODUCTS (MILK PLANT)**

- 59.201. Floors—construction.
- 59.202. Walls and ceilings—construction.
- 59.203. Doors and windows.
- 59.204. Lighting and ventilation.
- 59.205. Separate rooms.
- 59.206. Toilet-sewage disposal facilities.
- 59.207. Water supply.
- 59.208. Hand-washing facilities.
- 59.209. Milk plant cleanliness.
- 59.210. Sanitary piping.
- 59.211. Construction and repair of containers and equipment.
- 59.212. Cleaning and sanitizing containers and equipment.
- 59.213. Storage of cleaned containers and equipment.
- 59.214. Storage of single-service containers, utensils and materials.
- 59.215. Protection from contamination.
- 59.216. Pasteurization.
- 59.216a. Batch pasteurization requirements.
- 59.216b. High temperature short-time (HTST) continuous flow pasteurization requirements.
- 59.216c. Pasteurizers employing regenerative heating.
- 59.216d. Temperature-recording charts, equipment tests and examinations.
- 59.217. Cooling of milk.
- 59.218. Bottling and packaging.
- 59.219. Capping.
- 59.220. Personnel—cleanliness.
- 59.221. Vehicles.
- 59.222. Surroundings.

HANDLING

- 59.251. Receiving station requirements.
- 59.252. Transfer station requirements.
- 59.253. Tank truck cleaning and sanitation facilities requirements.

Cross References

This subchapter cited in 7 Pa. Code § 39.5 (relating to standards for frozen dessert mix); 7 Pa. Code § 39.6 (relating to wholesale manufacturers of frozen desserts); 7 Pa. Code § 59.302 (relating to raw milk); 7 Pa. Code § 59.303 (relating to transferring; delivery containers; cooling; retail establishment handling practices); and 7 Pa. Code § 59.304 (relating to milk and milk products from beyond the limits of routine inspection).

GENERAL PROVISIONS**§ 59.51. Rule.**

(a) All raw milk for pasteurization and all pasteurized milk and milk products shall be produced, processed, and pasteurized to conform with the chemical, bacteriological, and temperature standards and the sanitation requirements of this chapter.

(b) No process or manipulation other than pasteurization, processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms; provided, that, in the bulk shipment of raw cream, skim milk, or lowfat milk, the heating of the raw milk to temperatures no greater than 125°F (52°C) for separation purposes is permitted when the resulting bulk shipments of cream, skim milk and lowfat milk are labeled heat-treated.

§ 59.52. Table.

The following table sets forth the chemical, bacteriological and temperature standards for milk and milk products:

Milk for pasteurization	Temperature—	Bulk milk cooled to 40°F (4°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F (10°C).
	Bacterial limits—	Individual producer milk not to exceed 100,000 per ml. prior to commingling with other producer milk.
	Growth inhibitors—	No growth inhibitor residue in excess of actionable level as determined by the <i>B. stearothersophilus</i> Disc Assay Method or equivalent.
	Somatic cell count—	Samples exceeding 18 mm WMT to be confirmed by DMSCC or acceptable tests. Not to exceed 1 million per ml.
Commingled milk	Temperature—	Maintained at 45°F or less.
	Bacterial limits—	Not to exceed 300,000 per ml.
	Growth inhibitors—	No growth inhibitor residue in excess of actionable levels as determined by the <i>B. stearothersophilus</i> Disc Assay Method or equivalent.

Pasteurized milk	Temperature—	Cooled to 45°F (7°C) or less and maintained thereat.
	*Bacterial limits—	20,000 per ml.
	Coliform—	Not to exceed 10 per ml., provided that, in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.
	Phosphatase—	Less than 1 microgram per ml. by the Scharer Rapid Method or equivalent.
Milk products	Growth inhibitors—	No growth inhibitor residue in excess of actionable level as determined by the <i>B. stearothermophilus</i> Disc Assay Method or equivalent.
	Temperature—	Cooled to 45°F (7°C) or less and maintained thereat.
	*Bacterial limits—	50,000 per gram.
	Coliform—	Not to exceed 10 per gram. When fruit or nuts and flavoring is added after pasteurization, the count shall not exceed 20 per gram.
Raw milk	Phosphatase—	Less than 1 microgram per ml. by the Scharer Rapid Method or equivalent. *Tests to be on plain frozen dessert mix prior to addition of flavoring material.
	Growth inhibitors—	No growth inhibitor residue in excess of actionable level as determined by the <i>B. stearothermophilus</i> Disc Assay Method or equivalent. *Milk ingredients used in frozen dessert mixes shall be tested for growth inhibitor.
	Temperature—	Cooled at 40°F (4°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F (10°C).
	Bacterial limits—	20,000 per ml.
	Coliform—	Not to exceed 10 per ml.
	Growth inhibitors—	No growth inhibitor residue in excess of actionable level as determined by the <i>B. stearothermophilus</i> Disc Assay Method or equivalent.
	Somatic cell count—	Samples exceeding 18 mm WMT to be confirmed by DMSCC or acceptable tests. Not to exceed 1,000,000 per ml.

*Not applicable to cultured products.

Authority

The provisions of this § 59.52 amended under the act of July 2, 1935 (P. L. 589, No. 12) (31 P. S. §§ 645—660f).

Source

The provisions of this § 59.52 amended September 5, 1986, effective September 6, 1986, 16 Pa.B. 3285; amended December 13, 1996, effective December 14, 1996, 26 Pa.B. 5950. Immediately preceding text appears at serial pages (217612) to (217614).

Cross References

This section cited in 7 Pa. Code § 59.22 (relating to milk dating).

SANITATION REQUIREMENTS APPLICABLE TO PRODUCTION OF MILK FOR PASTEURIZATION

§ 59.101. Abnormal milk.

(a) Cows which show evidence of the secretion of abnormal milk in one or more quarters based on bacteriological, chemical or physical examination and cows which have been treated with or have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which in the judgment of the Secretary may be deleterious to human health shall be milked last or with separate equipment. The milk may not be offered for sale for human consumption.

(b) Milk from cows being treated with medicinal agents may not be offered for sale for periods recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

(c) Milk from cows treated with or exposed to insecticides not approved for use on dairy cattle by the United States Environmental Protection Agency may not be offered for sale until the milk has been tested and found acceptable by the Secretary.

(d) Bloody, stringy, off-color milk or milk abnormal to the sight or odor shall be so handled and disposed of as to preclude the infection of other cows and the contamination of the utensils.

(e) Cows secreting abnormal milk shall be milked last or with separate equipment which effectively prevents contamination of the wholesome supply.

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

(g) The Wisconsin Mastitis Test may be used as a screening test. A test of 18mm or higher shall be considered to indicate abnormal milk and shall require confirmation by the Direct Microscopic Somatic Cell Count Method or an equivalent method according to the current edition of *Standard Methods for the Examination of Dairy Products*.

(h) Poultry litter and recycled animal body discharges may not be fed to lactating dairy animals.

Source

The provisions of this § 59.101 amended September 5, 1986, effective September 6, 1986, 16 Pa.B. 3285. Immediately preceding text appears at serial page (103217).

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.102. Milking barn, stable or parlor—construction and maintenance.

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd is housed during milking time operations. The areas used for milking purposes shall meet the following requirements:

(1) Floors, feed troughs and gutters, if present, shall be constructed of good quality concrete or equally impervious material. Floors shall be constructed so as to be easily cleaned—brushed surfaces are permitted—and shall be graded to drain.

(2) Walls and ceilings shall be finished with wood, tile, smooth-surfaced concrete, cement plaster, brick or other equivalent materials with light-colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair, and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable, or parlor. If a hay opening is provided from the loft into the milking portion of the barn,

each opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

(3) Separate pens shall be provided for bulls, horses, and calves. These areas shall be separated by tight partitions, from the milking area. Such portion of the barn not so separated shall comply with this section.

(4) The milking barn shall be provided with natural or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least 10 foot-candles of light in all working areas shall be provided.

(5) Air circulation shall be sufficient to minimize odors and to prevent condensation upon walls and ceilings.

(6) There shall be no overcrowding 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.

(7) 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 feed, but not storing feed, in the milking barn.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.103. Milking barn, stable or parlor—cleanliness.

The interior of the milking barn, stable, or parlor shall meet the following standards of cleanliness:

- (1) The interior of such facilities shall be kept clean.
- (2) Leftover feed in feed mangers shall appear fresh and shall not be wet or soggy.
- (3) The bedding material, if used, shall not contain more manure than has accumulated since the previous milking.
- (4) Outside surfaces of pipeline systems located in the milking barn, stable, or parlor shall be reasonably clean.
- (5) Gutter cleaners shall be reasonably clean.
- (6) All pens, calf stalls, and bull pens—if not separated from the milking barn, stable, or parlor—shall be clean.
- (7) Swine and fowl shall be kept out of the milking barn.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.104. Cowyard.

Cowyards shall meet the following requirements:

(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, shall be graded and drained; depressions and soggy areas shall be filled; cow lanes shall be reasonably dry.

(2) Approaches to the barn door and surroundings of stock watering and feeding stations shall be solid to the footing of the animal.

(3) Wastes from the barn or milkhouse shall not be allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered in violation of this paragraph.

(4) Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in cowyards in such a manner as to permit the soiling of cows' udders and flanks. Cattlehousing areas—stables without stanchions such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, and free-stall housing—will be considered a part of the cowyard. Manure packs shall be solid to the footing of the animal.

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

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.105. Milkhouse or room—construction and facilities.

The milkhouse or room shall meet the following construction requirements:

(1) A separate milkhouse of sufficient size and conveniently located shall be provided for the cooling, handling, and storing of milk containers and utensils except as provided for in § 59.112 (relating to utensils and equipment—storage).

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

(3) The floor shall slope to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.

(4) The liquid wastes shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer.

(5) Walls and ceilings shall be constructed of smooth dressed lumber or similar material, well painted with a light-colored washable paint, and shall be in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color may be used; the surfaces and joints shall be smooth. Impervious materials shall be used to a height of at least 18 inches above the floor.

(6) A minimum of 20 foot-candles of light shall be provided at all working areas from natural or artificial light, or both, for milkhous operations.

(7) Windows and solid doors shall be closed during dusty weather.

(8) The milkhous shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

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

(10) The milkhous shall be used for no other purpose than milkhous operations.

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

(12) A vestibule, if used, shall comply with the applicable milkhous construction requirements.

(13) The transfer of milk from a bulk-holding/cooling tank to a transport tank shall be through a hose port located in the milkhous 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 shall be piped into the milkhous.

(15) Each milkhous shall be provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

(16) The milkhous shall be equipped with a wash-and-rinse vat having at least two compartments. Each compartment shall 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 that 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 sanitizing of other utensils and equipment.

(17) A suitable shelter shall be 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.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.106. Milkhouse or room—cleanliness.

The milkhouse or room shall meet the following cleanliness requirements:

- (1) The milkroom structure, equipment, and other milkroom facilities used in its operation or maintenance shall be clean at all times.
- (2) Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkroom; provided that they are kept clean, that ample space is available to conduct the normal operations in the milkroom, and that they will not cause contamination of the milk.
- (3) Vestibules, if provided, shall be kept clean.
- (4) Animals and fowl shall be kept out of the milkroom.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.107. Toilet.

The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply. Toilet facilities shall meet the following standards:

- (1) There shall be 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 of privy. Such sewage systems shall be constructed and operated in accordance with the requirements of the State agency responsible for construction and operation thereof.
- (2) A toilet or privy shall be convenient to the milking barn and the milkroom. There shall be no evidence of human defecation or urination about the premises.
- (3) No toilet or privy shall open directly into the milkroom.
- (4) The toilet room, including all fixtures and facilities, shall be kept clean and free of flies and odors.
- (5) When flush toilets are used, doors to toilet rooms shall be 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 shall be screened.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.108. Water supply.

The water supply shall meet the following requirements:

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

(2) The water supply shall contain a Most Probable Number of Coliform Organisms (MPN) of less than 2.2/100 ml by the multiple tube fermentation method or less than 1/100 ml by the membrane filter technique.

(3) No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply or any other source of pollution.

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

(5) The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage system, privy, or other source of pollution can reach such water supply.

(6) New individual water supplies and water supply systems which have been repaired or which otherwise become contaminated shall be thoroughly 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) All containers and tanks used in the transportation of water shall be 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 groundwater 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 dustproof/enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dustproof and rainproof cover and 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.

(8) Samples for bacteriological examination shall be taken upon the initial approval of the physical structure, when any repair or alteration of the water supply system has been made, and at least every 3 years; provided that water supplies with buried well casing seals installed prior to August 7, 1982, shall be tested at intervals no greater than 6 months apart. Whenever such samples

indicate either the presence of bacteria of the coliform group or whenever the well casing, pump, or seal need 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 section; 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 Secretary.

(9) Current records of water tests shall be retained on file by the permit holder.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); 7 Pa. Code § 59.119 (relating to cooling); 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.606 (relating to water supply).

§ 59.109. Utensils and equipment—construction.

Construction of utensils and equipment shall meet the following requirements:

(1) All multiuse 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 shall be made of smooth impervious, nonabsorbent, safe materials of the following types:

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

(ii) Equally corrosion-resistant, non-toxic metal.

(iii) Heat-resistant glass.

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

(2) Single-service articles shall have been manufactured, packaged, transported, and handled in a sanitary manner and shall comply with the applicable requirements of §§ 59.210 and 59.211 (relating to sanitary piping; and construction and repair of containers and equipment).

(3) Articles intended for single-service use shall not be reused.

(4) All containers, equipment, and utensils shall be free of breaks and corrosion.

(5) All joints in such containers, equipment, and utensils shall be smooth and free from pits, cracks, or inclusions.

(6) Cleaned-in-place milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material

meeting specifications described in paragraph (1)(iv) 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 shall be submitted to the Secretary for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Secretary.

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

(9) All milking machines including heads, milk claws, milk tubing, and other milk-contact surfaces shall be able to be cleaned and inspected easily.

(10) Milk cans shall have umbrella-type lids.

(11) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of §§ 59.210 and 59.211. Milk handling equipment shall be constructed and installed to conform with 3A Standards.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.707 (relating to protection and transport of raw milk and cream).

§ 59.110. Utensils and equipment—cleaning.

Utensils and equipment shall meet the following cleaning requirements: the product contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.111. Utensils and equipment—sanitation.

All product contact surfaces of multiuse 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 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 5 minutes.

(2) Complete immersion for at least 1 minute in or exposure for at least one minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces shall be wetted by the sanitizing solution, and piping so treated shall be filled. Sanitizing sprays may be used.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); 7 Pa. Code § 59.212 (relating to cleaning and sanitizing containers and equipment); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.112. Utensils and equipment—storage.

Utensils and equipment shall meet the following storage requirements:

(1) All milk containers, utensils, and equipment—including milking machine vacuum hoses—shall be stored in the milkhouse on racks until used. Pipeline milking equipment—such as milker claw, inflations, weigh jars, meters, milk hoses, milk receivers, and milk pumps which are designed for mechanical cleaning—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 stable or parlor must be used only for milking. Concentrates may be fed in the stable during milking, but the stable may not be used for housing cattle. When manual cleaning of product contact surfaces is necessary, the cleaning shall be done in the milkhouse.

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

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

(4) Strainer pads, gaskets, and similar single service articles shall be stored in a suitable container or cabinet in original container and protected against contamination.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); 7 Pa. Code § 59.105 (relating to milkhouse or room—construction and facilities); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.113. Utensils and equipment—handling.

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

(1) Sanitized product-contact surfaces, including farm cooling tank openings and outlets, shall be 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 shall be cleaned and sanitized before being used.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.114. Milking—flanks, udders and teats.

Milking practices shall meet the following requirements:

- (1) Milking shall be done in a milking barn, stable, or parlor.
- (2) Brushing shall be completed prior to milking.
- (3) Flanks, bellies, tails, and udders shall be clipped as often as necessary to facilitate cleaning of these areas and shall be 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 shall be cleaned and treated with a sanitizing solution and shall be relatively dry just prior to milking.
- (5) Wet hand milking is prohibited.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.115. Milking—surcingles, milk stools and antikickers.

Surcingles, milk stools, and antikickers shall meet these requirements:

- (1) Milk stools shall not be padded and shall be constructed to be easily cleaned.
- (2) Milk stools, surcingles, and antikickers shall be kept clean and shall be stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse when not in use.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.116. Protection from contamination.

Protection from contamination requires compliance with the following:

(1) Equipment and operations shall be 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 milking, pipelines and equipment used to contain or conduct milk shall be effectively separated from tanks or circuits containing cleaning or sanitizing solutions.

(3) All milk which has overflowed, leaked, been spilled, or been improperly handled shall be discarded.

(4) All product-contact surfaces of containers, equipment, and utensils shall be 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.

(5) The receiving receptacle shall be 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 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 shall be transferred immediately from the milking barn, stable, or parlor to the milkhouse.

(7) Pails, cans, and other equipment containing milk shall be 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 shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor.

(9) Antibiotics and medicinals shall be stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the equipment, containers, or utensils.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.117. Personnel—hand-washing facilities.

The following hand-washing facilities are required:

(1) Hand-washing facilities shall be located in the milkhouse and in or convenient to the milking barn, stable, parlor or flush toilet.

(2) Hand-washing facilities include soap or detergent, hot and cold or warm running water, individual sanitary towels and a readily accessible lavatory fixture. Utensil wash and rinse vats shall not be considered as hand-washing facilities.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.118. Personnel—cleanliness.

All persons shall meet the following requirements:

- (1) Hands shall be clean and dried with an individual sanitary towel immediately before milking, before performing any milkhous function, and immediately after the interruption of any of these activities.
- (2) Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.119. Cooling.

Milk shall be cooled in accordance with the following requirements:

- (1) Can milk shall be promptly cooled to 50°F or lower and maintained at that temperature or less until delivery to the milk plant within 30 hours of initial milking.
- (2) Milk, if not cooled, shall be delivered to the milk plant within 2 hours after milking.
- (3) Bulk milk shall be cooled to 40°F within 2 hours after milking. Cooled milk shall not be allowed to rise above a temperature of 50°F by subsequent addition of milk to bulk tank and shall be delivered to milk plant within 66 hours of the initial milking.
- (4) Bulk tank milk shall be cooled to 40°F or lower at time of pick-up.
- (5) Transshipment of milk from plant to plant shall be acceptable only if received at a temperature of 45°F or less.
- (6) Agitation and refrigeration on all farm bulk milk cooling and holding tanks shall be automatically controlled, except as provided for in paragraph (7). Automatic controls shall consist of an interval timer to require agitation of the milk for a minimum period of two minutes in every 60-minute interval and refrigeration to maintain mixed milk temperature between 32°F and 40°F.
- (7) In lieu of automatic refrigeration controls, as provided for in paragraph (6), an accurate 48-hour recording thermometer shall be installed to provide a continuous and true record of milk temperature. Each temperature recording chart shall be dated and signed by the approved sampler, filed chronologically in the milkhous for not less than 6 months, and readily accessible for regulatory review.
- (8) Recirculated cold water which is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Such

water shall be tested semiannually and shall comply with the bacteriological standards cited in § 59.108 (relating to water supply).

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

§ 59.120. Vehicles.

Vehicles used to transport milk shall meet the following requirements:

- (1) Vehicles used to transport milk from the dairy farm to the milk plant or receiving station shall be constructed and operated to protect their contents from sun, freezing and contamination.
- (2) Vehicles shall have bodies with solid enclosures and tight, solid doors.
- (3) Vehicles shall be kept clean, inside and out.
- (4) No substance capable of contaminating the milk shall be transported with the milk.

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); 7 Pa. Code § 59.302 (relating to raw milk); and 7 Pa. Code § 59.707 (relating to protection and transport of raw milk and cream).

§ 59.121. Insect and rodent control.

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. This section will be deemed to be satisfied when the following provisions are met:

- (1) Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be:
 - (i) Spread directly on the fields;
 - (ii) Stored for not more than 4 days in a pile on the ground surface and then spread on the fields;
 - (iii) Stored for not more than 7 days in an impervious-floored bin or on an impervious-curbed platform and then spread;
 - (iv) Stored in a tight-screened and trapped manure shed;
 - (v) Effectively treated with larvicides; or
 - (vi) 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 shall be properly bedded and managed to prevent fly breeding.
- (3) Milk rooms shall be free of insects and rodents.
- (4) Milk rooms shall be effectively screened or otherwise protected against the entrance of vermin.

(5) Outer milkhouse doors shall be tight and self-closing. Screen doors shall open outward.

(6) Effective measures shall be 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 Secretary or registered with the United States Environmental Protection Agency shall be used for insect and rodent control.

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

Cross References

This section cited in 7 Pa. Code § 59.31 (relating to inspection of dairy farms); and 7 Pa. Code § 59.302 (relating to raw milk).

SANITATION AND PROCEDURE REQUIREMENTS APPLICABLE TO THE HANDLING AND PROCESSING OF PASTEURIZED MILK AND MILK PRODUCTS (MILK PLANT)

§ 59.201. Floors—construction.

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

(b) The floor surface shall be smooth and sloped, so that there are no pools of standing water after flushing; and the joints between the floor and the walls shall be impervious.

(c) The floors shall be 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 or packaging materials need not be provided with drains.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.702 (relating to buildings).

§ 59.202. Walls and ceilings—construction.

(a) Walls and ceilings shall be finished with smooth, washable, light-colored painted wood, tile, smooth-surface concrete, cement plaster, brick or equivalent materials.

(b) Walls, partitions, windows, and ceilings shall be kept in good repair and refinished as often as the finish wears off or becomes discolored.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.702 (relating to buildings).

§ 59.203. Doors and windows.

(a) All openings to the outer air shall be effectively protected by:

- (1) Screening;
- (2) Effective electric screen panels;
- (3) Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of flies;
- (4) Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or
- (5) Any effective combination of methods listed in paragraphs (1)—(4) or by any other method which prevents the entrance of flies.

(b) All outer doors shall be tight and self-closing. Screen doors shall open outward.

(c) All outer openings shall be rat-proofed to the extent necessary to prevent the entry of rodents.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.702 (relating to buildings).

§ 59.204. Lighting and ventilation.

(a) Adequate light sources shall be provided—natural or artificial, or 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, or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five foot-candles of light.

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

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

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); and 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements).

§ 59.205. Separate rooms.

(a) Pasteurizing, processing, cooling and packaging shall be conducted in a single room, but not in the same room used for the cleaning of milk cans, bottles, and cases or the unloading or cleaning and sanitizing of milk tank trucks; provided that, in a receiving station, cooling may be done in the room where milk tank trucks are unloaded or cleaned and sanitized.

(b) All bulk milk storage tanks shall be 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.

(c) Solid doors installed in required partitions shall be self-closing.

(d) Facilities for the cleaning and sanitizing of milk tank trucks shall be properly equipped for manual 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.

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

(f) All rooms shall be of sufficient size for their intended purposes.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements).

§ 59.206. Toilet-sewage disposal facilities.

(a) Suitable toilet facilities shall be provided.

(b) Toilet rooms shall not open directly into any room in which milk or milk products are processed.

(c) Toilet rooms shall be completely enclosed and have tight-fitting self-closing doors.

(d) Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair, and well ventilated and well lighted.

(e) Toilet tissue and easily cleanable covered waste receptacles shall be provided in toilet rooms.

(f) All plumbing shall be installed to meet the applicable provisions of the State or local plumbing code.

(g) Sewage and other liquid wastes shall be disposed of in a sanitary manner.

(h) Non-water-carried sewage disposal facilities shall not be used.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); and 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements).

§ 59.207. Water supply.

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

(b) The water supply shall be approved as safe by the State Water Control Authority and, in the case of individual water systems, it shall contain a Most Probable Number of Coliform Organisms (MPN) of less than 2.2/100 ml by the multiple tube fermentation technique or less than 1/100 ml by the membrane filter technique.

(c) There shall be no cross-connection between the safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank such as for cooling or condensing, unless protected by an air gap or effective backflow preventer, constitutes a violation of this subsection.

(d) Condensing water for milk evaporators, and water used to produce a vacuum or to condense vapors in vacuum heat processing equipment shall be from a source complying with subsection (b); provided that, when approved by the Secretary, water from sources not complying with subsection (b) 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 a vacuum. Means of preventing such contamination are either of the following:

(1) Use of a surface type condenser in which the condensing water is physically separated from the vapors and condensates.

(2) 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 inflowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air, or electricity and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

(e) Condensing water for all milk evaporators complying with subsection (b) and water reclaimed from milk or milk products may be reused when all necessary means of protecting are afforded and it has been inspected and approved by the Secretary's representative.

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

(g) Samples for bacteriological testing of individual water supplies shall be taken upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Bacteriological examinations shall be conducted in a laboratory acceptable to the Secretary.

(h) Current records of water tests shall be kept on file by the permittee.

Cross References

This section cited in 7 Pa. Code § 59.217 (relating to cooling of milk); 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.703 (relating to facilities).

§ 59.208. Hand-washing facilities.

(a) Convenient hand-washing facilities shall be provided, including hot and cold or warm running water, soap and individual sanitary towels or other approved hand-drying devices.

(b) Hand-washing facilities shall be convenient to all toilets and to all rooms in which milk plant operations are conducted.

(c) Hand-washing facilities shall be kept in a clean condition and in good repair.

(d) Steam-water mixing valves and vats for washing bottles, cans and similar equipment shall not be used as hand-washing facilities.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.703 (relating to facilities).

§ 59.209. Milk plant cleanliness.

(a) 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.

(b) All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment shall be clean.

(c) No trash or solid waste shall be 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.

(d) All rooms in which milk and milk products are handled, processed, or stored or in which containers, utensils, or equipment are washed or stored shall be kept clean, neat, and free of evidence of insects and rodents.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); 7 Pa. Code § 59.711 (relating to cleaning and sanitizing treatment); and 7 Pa. Code § 59.712 (relating to insect and rodent control program).

§ 59.210. Sanitary piping.

(a) 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, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.

(b) All sanitary piping, connections and fittings shall consist of any of the following:

(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series.

(2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent.

(3) Heat-resistant glass. *Provided:* that plastic or rubber and rubberlike materials which are relatively inert and resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant and 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 short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

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

(d) All interior surfaces of demountable piping—including valves, fittings and connections—shall be designed, constructed, and installed to permit inspection and drainage.

(e) All cleaned-in-place milk pipelines and return-solution lines shall be rigid, self-draining, and so supported to maintain uniform slope and alignment.

(1) Return solution lines shall be constructed of material meeting the specifications of subsection (b). If gaskets are used, they shall be self-positioning; of material meeting the specifications outlined in subsection (b); 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.

- (2) 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 Secretary.
- (3) 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 or 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.
- (4) Detailed plans for welded pipeline systems shall be submitted to the Secretary 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 Secretary.
- (f) Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary milk piping.

Cross References

This section cited in 7 Pa. Code § 59.109 (relating to utensils and equipment—construction); 7 Pa. Code § 59.216a (relating to batch pasteurization requirements); 7 Pa. Code § 59.218 (relating to bottling and packaging); 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.704 (relating to equipment and utensils).

§ 59.211. Construction and repair of containers and equipment.

- (a) All multiuse containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant and non-toxic material.
- (b) All milk contact surfaces of multiuse containers and equipment shall consist of any of the following:
- (1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series.
 - (2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent.
 - (3) Heat-resistant glass.
 - (4) Plastic or rubber and rubberlike materials which are relatively inert, and resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat-resistant and relatively nonabsorbent; which do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.
- (c) All joints in containers, equipment, and utensils shall be flush and finished as smooth as adjoining surfaces. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Where a thermometer or

temperature-sensing element is inserted through a surface with which milk or milk products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

(d) All openings in covers of tanks, vats, separators and the like shall be 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 watertight joint is provided.

(e) All surfaces with which milk or milk products come into contact shall be easily accessible or demountable for manual cleaning or shall be 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.

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

(g) All multiuse containers and other equipment shall have rounded corners and shall be in good repair and free from breaks, crevices and corrosion. Milk cans shall have umbrella-type covers.

(h) Strainers, if used, shall be 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 that, 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.

(i) All single-service containers, closures, gaskets and other articles with which milk or milk products come in contact shall be nontoxic.

(j) The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles shall be approved by the Secretary. Inspections and tests will be made by the Secretary or any agency authorized by him. Milk handling equipment shall be constructed and installed to conform with 3A Standards.

Cross References

This section cited in 7 Pa. Code § 59.109 (relating to utensils and equipment—construction); 7 Pa. Code § 59.212 (relating to cleaning and sanitizing containers and equipment); 7 Pa. Code § 59.218 (relating to bottling and packaging); 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.704 (relating equipment and utensils).

§ 59.212. Cleaning and sanitizing containers and equipment.

(a) All multiuse containers and utensils shall be thoroughly cleaned and sanitized after each use, and all equipment shall be thoroughly cleaned and sanitized at least once each day used; provided that the 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 longer than 24 hours and silo tanks used for the storage of raw milk which are installed after August 7, 1982, shall be equipped with a 7-day circular chart temperature recording device or a strip chart which moves not less than 1 inch per hour. Such recording device shall meet all the requirements for storage tank recording thermometers in Appendix H of the PMO.

(1) All milk tank trucks shall be thoroughly cleaned and sanitized at least once each day of use.

(2) Whenever a milk tank truck has been cleaned and sanitized, there shall be attached to the manhole lid and under the dust cover, a tag showing the tank identity, date, time, place and signature of the employe 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 at least 15 days for review by the Department.

(b) Pipelines and equipment designed for mechanical cleaning shall meet the following requirements:

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

(2) A temperature-recording device shall be installed in the return solution line to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing.

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

(c) Plants in which containers are washed manually shall be 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.

(d) In plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment by means of steam, hot water or chemical treatment.

(1) In 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 or soaker-type bottle washers.

COMBINATIONS OF CAUSTICITY, TIME AND TEMPERATURES OF EQUAL BACTERICIDAL VALUE, FOR SOAKER TANK OR SOAKER-TYPE BOTTLE WASHERS
(Based on NSDA specifications for beverage bottles)

<i>Time in minutes</i>	<i>Temperature, degrees</i>						
	F170	160	150	140	130	120	110
	C 77	71	66	60	54	49	43
Concentration of NaOH, 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	2.66	3.98

(2) 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 contamination of the treated bottle during the rinsing operation.

(e) All multiuse containers, equipment, and utensils shall be sanitized before use, employing one or a combination of the methods prescribed under § 59.111 (relating to utensils and equipment—sanitization). Assembled equipment shall be sanitized prior to each day's run. Plants using chemical sanitizing methods shall possess appropriate testing equipment.

(f) The residual bacteria count of multiuse and single-service containers used for packaging pasteurized milk and milk products shall not exceed 1/ml of capacity when the rinse test is used or 50 colonies per 8 square inches (one per square centimeter) of product-contact surface when the swab test is used in three out of four samples taken at random on a given day. All multiuse and single-service containers shall be free of coliform organisms.

(g) Plants which utilize multiuse plastic containers for pasteurized milk and milk products shall comply with the following criteria:

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

(2) The plastic material shall comply with the material specifications of § 59.211 (relating to construction and repair of containers and equipment).

(3) 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 that the code is revealed to the Department.

(4) 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 Secretary 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 must 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 shall 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 to provide equal assurance of freedom from contamination and recognized by the Department to be equally efficient may be accepted.

(5) A standard shall be available for the use by the Department for testing the proper sensitivity functioning levels of the detection device.

(6) The containers shall comply with the applicable construction requirements of § 59.211. The closure for the container shall be single-service. Screw-type closures shall not be used.

(7) 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 and regulations issued thereunder.

(8) The phrase "Use Only for Food" shall appear on all containers.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); and 7 Pa. Code § 59.711 (relating to cleaning and sanitizing treatment).

§ 59.213. Storage of cleaned containers and equipment.

(a) After cleaning, all multiuse containers, equipment, and utensils shall be transported 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.

(b) Floors shall not be flushed or washed when crates of clean bottles are stacked on them.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements).

§ 59.214. 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 and milk products shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept in a clean, dry place until used; and shall be handled in a sanitary manner.

(b) Paperboard shipping containers used to enclose plastic bags or unfilled containers shall be used only once unless other methods are employed to protect the containers from contamination.

(c) Tubes or cartons shall not be refilled with spilled caps, gaskets or parchment papers.

(d) Cartons or boxes from which contents have been partially removed shall be kept closed.

(e) Suitable cabinets shall be provided for storage of tubes after removal from the larger outer box and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures or containers.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); and 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements).

§ 59.215. Protection from contamination.

(a) Equipment and operations shall be 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.

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

(c) All milk and milk products which have overflowed, leaked, been spilled, or been improperly handled shall be discarded. Milk and milk products drained from processing equipment at the end of a run or collected from a defoamer system which does not continuously return such product to the filler bowl—or milk solids rinsed from equipment, containers, or pipelines—shall be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 45°F (7°C) or less. When the handling or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be discarded. Returned packaged milk and milk products shall not be repasteurized for fluid milk; provided that the repasteurization of milk and milk products shipped in transport tankers which have been pasteurized at another plant and have been handled in a sanitary manner and maintained at 45°F (7°C) or less is permitted.

(d) All product-contact surfaces of containers, equipment, and utensils shall be 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, pump, vats, and the like—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:

(1) If the area is completely enclosed—walls and ceiling, with doors closed—during the unloading process and the dustcover 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 dustcover or manhole cover are opened in excess of that provided by the metal clamps or if the covers have been removed, then a suitable filter shall be required for the manhole.

(2) If the area is not completely enclosed or if doors of the unloading area are open during unloading, then a suitable filter shall be required for the manhole or air inlet vent and suitable protection shall 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 shall be made from valve to valve and not from manhole to manhole, and the dustcover—dome—of the milk tank truck being filled shall be closed.

(3) 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 a strainer in place.

(e) Whenever air under pressure is used for the agitation or movement of milk or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor. Reference should be made to Appendix H of the PMO. The use of steam containing toxic substances is 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 quality.

(f) Standardization shall be done before the pasteurization process is started unless pasteurized milk or milk products are used for standardization. Such pasteurized 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 milk and dairy products with other than approved milk and dairy products is prohibited.

(g) The processing of foods and drinks other than milk and milk products approved by the Secretary shall be performed to preclude the contamination of such milk and milk products. Such approved products shall be from a source acceptable to the Secretary with respect to sanitation and protection of public health.

(h) Means shall be provided to prevent contamination of milk containers, utensils, and equipment by drippings, spillage and splash from overhead piping, platforms, or mezzanines.

(i) All ingredients and nonproduct-contact materials used in the preparation or packaging of milk and milk products shall be stored in a clean place and shall be so handled as to prevent their contamination.

(j) Pasteurized milk shall not be strained or filtered except through a perforated metal strainer.

(k) 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 shall be present in the dairy plant.

(l) Those poisonous or toxic materials that are necessary shall not be stored in any room where milk or milk products are received, processed, pasteurized, or stored where equipment, containers, or utensils are washed; or where single-service containers, closures or caps are stored.

(m) Those poisonous or toxic materials that are necessary shall be 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.

(n) Only insecticides and rodenticides approved by the Department or registered with the United States 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.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); 7 Pa. Code § 59.703 (relating to facilities); and 7 Pa. Code § 59.704 (relating to equipment and utensils).

§ 59.216. Pasteurization.

Every particle of milk or milk product shall be 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:

<i>Temperature</i>	<i>Time</i>
*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

*If the fat content of the milk product is 10% or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C).

(1) Provided that eggnog and frozen dessert mix containing dairy products shall be heated to at least the following temperature and time specifications:

<i>Temperature</i>	<i>Time</i>
155°F (69°C)	30 minutes
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds

(2) Provided further, that 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 Secretary.

Cross References

This section cited in 7 Pa. Code § 59.216c (relating to pasteurizers employing regenerative heating).

§ 59.216a. Batch pasteurization requirements.

All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H of the PMO.

(1) *Time and temperature controls.*

(i) *Temperature difference.*

(A) The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product at the center and the coldest milk or milk product in the vat will not exceed 1°F (0.5°C) at any time during the holding period.

(B) The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

(ii) *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 or milk products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometers.

(iii) *Assurance of minimum holding periods.* Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least 30

minutes. When milk or milk products 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 or milk products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30 minutes or 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.

(A) When the recorder time interval on the recorder chart at the pasteurization temperature includes filling or emptying time, such intervals shall be indicated on the recorder chart by the operator by removing the recording thermometer bulb from the milk for a sufficient time to depress the pen, 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 will be determined by the Secretary, initially and after any change which may affect these times.

(B) No milk shall be added to the holder after the start of the holding period.

(2) *Airspace heating.*

(i) Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and milk products at a temperature not less than 5°F (3°C) higher than the minimum required temperature of pasteurization during the holding period.

(ii) Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least 1 inch below the bottom of the thermometer bulb when the vat is in operation.

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

(3) *Inlet and outlet valve and connections.* The following definitions shall apply to inlet and outlet valves and connections:

(i) “Valve stop” shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

(ii) “90° stop” shall mean a stop so designed as to prevent turning the plug more than 90°.

(iii) “120° stop” shall mean a stop which prevents turning the plug more than 120°.

(iv) "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.

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

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

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

(viii) "The closed position" shall mean any position of the valve seat which stops the flow of milk into or out of the pasteurizer.

(ix) "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.

(x) "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.

(xi) "Leakage" shall mean the entrance of unpasteurized milk into a batch pasteurizer during the holding or emptying period or the entrance of unpasteurized milk into any pasteurized milk line at any time.

(xii) "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 milk past the valve or, in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage of milk past the valve or the leakage of milk due to the leakage of air past the suction valve or the compressed air valve, as the case may be.

(xiii) "Close-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 milk in the valve inlet is more than 1°F (0.5°C) colder than the milk at the center of the pasteurizer at any time during the holding period. A close-coupled valve which is not truly flush shall be considered as satisfying this requirement when:

(A) 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;

(B) 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

(C) in the case of batch pasteurizers, the outlet and the agitator are so placed as to insure that milk currents will be swept into the outlet.

(4) *Design and installation of valves and connections.* All valves and connections shall comply with the following requirements:

(i) Valves and pipeline connections shall meet the requirements of § 59.210 (relating to sanitary piping).

(ii) 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.

(iii) To prevent clogging and to promote drainage, all leak-protection grooves shall be at least 0.187 inches wide, and at least 0.094 inches 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.

(iv) 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 milk 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; however, the plug need not be irreversible if duplicate, diametrically opposite grooves are also provided. In the case of two-way, plug-type valves—that is, 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.

(v) Outlet valves shall be so designed as to prevent the accumulation of unpasteurized milk in the milk passages of the valve when the valve is in any closed position.

(vi) All inlet pipelines and outlets from vat pasteurizers shall be equipped with leak-protector valves; provided that installations not equipped with leak-protector inlet valves will be acceptable 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.

(vii) Inlet and outlet connections other than through closed-coupled valves shall not enter or leave the pasteurizer below the level of the milk therein.

(viii) In cases where the inlet enters the holder above the milk level and in which the inlet line may be submerged preventing 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 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 inches in diameter in the vat pipe, below the vat cover but above the maximum milk level.

(ix) All leak-protector valves shall be installed in the proper position to insure 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.

(x) 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.

(5) *Recording charts.* All recording thermometer charts shall comply with the applicable requirements of § 59.216d (relating to temperature-recording charts, equipment tests and examinations).

Cross References

This section cited in 7 Pa. Code § 59.216c (relating to pasteurizers employing regenerative heating); and 7 Pa. Code § 59.704 (relating to equipment and utensils).

§ 59.216b. High temperature short-time (HTST) continuous flow pasteurization requirements.

(a) *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 or milk products shall comply with the applicable specifications set forth in Appendix H of the PMO.

(b) *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 paragraphs (1) and (2).

(1) "Automatic milkflow controls" shall mean those safety devices which control the flow of milk in relation to the temperature of the milk, heating medium, 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 causes the diversion of the milk in response to a sublegal pasteurization temperature. At sublegal temperatures, flow-diversion devices return the milk to the raw milk side of the heating system continuously until legal pasteurization temperatures are obtained; at which time, the device restores forward flow through the pasteurizer.

(2) All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(i) Forward flow of subtemperature milk due to the omission or looseness of the connecting clip shall be prevented by:

- (A) Making the valve and its actuating mechanism integral;
 - (B) Where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism except in such a manner that it will function properly;
 - (C) 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;
 - (D) By providing that the pump will shut down when the milk is below the pasteurization temperature and the valve is not in the fully-diverted position; or
 - (E) By any other equally satisfactory means.
- (ii) 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.
 - (iii) 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 milkflow is being diverted, the leak escape should lie between two valve seats or 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 that when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line in a vertical position to provide a visual means of leak detection.
 - (iv) 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.
 - (v) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.
 - (vi) The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk line not more than 18 inches upstream from the flow-control device.
 - (vii) In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperature 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 or cooler section; provided that when the flow-diversion device is located downstream from the regenerator 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 § 59.1 (relating to definitions).

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

(ix) When it is used, the pipeline from the leak detection 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 leak detector line cannot occur.

(c) *Milk-flow controller instrumentation.* The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(1) 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 nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the regulatory agency after testing and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no milk 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 day's operation and entered upon the recorder chart daily by the plant operator.

(2) 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 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. 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 regulatory agency after test and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be by-passed 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 temperature is not required.

(3) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder shall be wired so that the cir-

cuit is completed only when the milk is above the required pasteurization temperature or when the diversion device is in the fully-diverted position.

(d) *Holding tube.*

(1) Holders shall be designed to provide for the holding of every particle of milk or milk product for at least the time required for pasteurization.

(2) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest milk 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 fittings through which the milk may not be thoroughly swept.

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

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

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

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

(7) The holding time for the HHST processes shall be determined from the pumping rate rather than by the salt conductivity test because of the short holding tube. The holding tube length shall 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 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 standard time.

(8) 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 falls below a prescribed value. For operating temperatures between 191°F (89°C) and 212°F (100°C), the pressure switch shall be set at ten pounds per square inch (psi). For units which have operating temperatures above 212°F (100°C), the pressure switch shall be set at a pressure ten psi the boiling pressure of the product at its maximum temperature in the holding tube.

(9) 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 differential across the injector falls below ten psi.

(e) *Indicating and recording thermometers.*

(1) All indicating thermometers shall be located as near as possible to the temperature sensor of the recorder/controller but may be located a short distance upstream from the latter where milk between the two thermometers does not differ significantly in temperature.

(2) 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.

(3) The recorder/controller charts shall comply with the applicable provisions of § 59.216d (relating to temperature-recording charts equipment tests and examinations).

(f) *Flow-promoting devices.*

(1) The pump or pumps and other equipment which may produce flow through the holder shall be located up-stream 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 negative pressure in the line between the flow-diversion device and the vacuum chamber will be acceptable.

(2) The speed of pumps or other flow-promoting devices governing the rate of flow through the holder shall be so controlled as to insure the holding of every particle of milk for at least the time required as defined in § 59.1 for the milk or milk products and the process used. In all cases, the motor shall be connected to the metering pump by means of 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 holding time cannot be shortened without detection by the Department. This shall be accomplished by the application of a suitable seal after tests by the Department and such seal shall not be broken without immediately notifying the Department. This paragraph applies 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.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization throughout the holder section. 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. The holding time shall be tested during both forward and diverted flow. If 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 Department.

(g) *Heating by direct addition of steam.* 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:

(1) The product and steam flows shall be isolated from pressure fluctuations inside the injection chamber.

(2) The product pressure in the holding tube shall be of sufficient magnitude to condense the steam and keep the product in the liquid phase. A minimum product pressure in the holding tube of ten psi for operating temperatures from 191°F (89°C) to 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 ten psi above the boiling pressure of the product at its maximum temperature in the holding tube.

(3) The process should be as free as possible for noncondensable gases that may evolve from the product or be carried in the steam supply. The steam boiler shall be provided with a deaerator.

(h) *Prevention of product adulteration with added water.*

(1) 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. The requirements of this paragraph 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.

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

(3) When 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 paragraph 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. 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.

Cross References

This section cited in 7 Pa. Code § 59.216c (relating to pasteurizers employing regenerative heating).

§ 59.216c. Pasteurizers employing regenerative heating.

(a) *Milk-to-milk regenerative heating.* Pasteurizers employing milk-to-milk regenerating heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

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

(2) The pasteurized milk, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 12 inches above the highest raw milk level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation. A vacuum breaker shall be considered open to the atmosphere.

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

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

(5) No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank unless it is designed and installed to operate only when milk is flowing through the pasteurized milk side of the regenerator and when the pressure of the pasteurized milk 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:

(i) the metering pump is in operation;

(ii) the flow-diversion device is in forward-flow position; and

(iii) the pasteurized milk pressure exceeds by at least one psi the maximum pressure developed by the booster pump; pressure gauges shall be installed at the raw milk inlet to the regenerator and the pasteurized milk outlet of the regenerator or the outlet of the cooler. The accuracy of required pressure gauges will be checked by the Department.

(6) The motor, casing, and impeller of the booster pump shall be identified and such records thereof maintained as directed by the Department. 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 this section, §§ 59.216, 59.216a, 59.216b and 59.216d.

(7) All raw milk in the regenerator shall drain freely back into the constant-level raw milk tank when the raw milk pumps are shut down and the raw milk outlet from the regenerator is disconnected.

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

(9) 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, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to 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 that 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 provided that 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.

(10) 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 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 paragraph (9).

(11) When the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph (9), the raw product booster pump may be permitted to run at all times, provided the metering pump is in operation.

(b) *Milk-to-water-to-milk regenerative heating.* Milk-to-water-to-milk regenerators with both the milk and the heat-transfer water in the raw milk section closed to the atmosphere shall comply with the following or equally satisfactory specifications:

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

(2) The heat-transfer water shall be safe 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, than any raw milk 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 above any raw milk in the system and shall be open to the atmosphere at this or a higher elevation.

(3) 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 automatically and immediately replenish whenever raw milk is present in the regenerator.

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

(5) No pump shall be located between the raw milk inlet to the regenerator and the raw milk 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 milk. This may be accomplished by wiring the booster pump so that it cannot operate unless:

(i) The heat-transfer water pump is in operation.

(ii) The heat-transfer water pressure exceeds, by at least one pound per square inch, the raw milk pressure in the regenerator; pressure gauges shall be installed at the raw milk inlet and the heat-transfer water outlet of the regenerator.

§ 59.216d. Temperature-recording charts, equipment tests and examinations.

(a) *Temperature recording charts.* All temperature recording charts shall be preserved for a period of 3 months. 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 subsection. The following information shall be entered on the chart as applicable.

(1) *Batch pasteurizers.* Information for batch pasteurizers shall be as follows:

(i) Date.

(ii) Number or location of recorder when more than one is used.

(iii) Extent of holding period, including filling and emptying times, when required.

(iv) Reading of airspace thermometer within the holding period at a given time or reference point as indicated on the chart.

(v) Reading of indicating thermometer within the holding period at a given time or reference point as indicated on the chart.

(vi) Quarterly, the initials of the regulatory agency opposite the required readings of the indicating thermometer and airspace thermometer.

(vii) Quarterly, the time accuracy of the recorder, as determined by the Department.

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

(ix) Record of unusual occurrences.

(x) Signature or initials of operator.

(xi) Name of milk plant.

(2) *High-temperature, short-time pasteurizers.* Recording thermometer charts shall contain all the information specified in paragraph (1) except paragraph (1)(iii) and (iv), and reference to airspace thermometers in paragraph (1)(vi) shall include the following:

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

(ii) The cut-in and cut-out milk temperatures recorded daily by the operator at the beginning of the run and initialed quarterly by the Department.

(b) *Equipment tests and examinations.* The Department will perform the indicated tests on the following instruments and devices in accordance with Appendix I of the PMO.

TEST TABLE

<i>Instrument or device</i>	<i>Test#</i>	<i>Test objective</i>
Batch pasteurizer indicating thermometer	1	Accuracy
Batch pasteurizer recording thermometer	2	Temperature accuracy
Batch pasteurizer recording thermometer	3	Time accuracy
Batch pasteurizer 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 indicating thermometer	1	Accuracy

<i>Instrument or device</i>	<i>Test#</i>	<i>Test objective</i>
HTST indicating thermometer	7	Thermometric response
HTST recording thermometer	2	Temperature accuracy
HTST recording thermometer	3	Time accuracy
HTST recorder controller	2	Temperature accuracy
HTST recorder controller	4	Check reading of recorder controller against indicating thermometer
HTST recorder controller	8	Thermometric response
HTST recorder controller	10	Confirm cut-in and cut-out temperatures
HTST flow diversion device	5	Assembly and function
HTST auxiliary (booster) pump	9	Function of automatic control devices
HTST auxiliary (booster) pump	9	Accuracy of pressure gauges
HTST system	11	Check holding time
HHST system	12	Thermal limit control for sequence logic
HHST system	13	Setting of control switches for product pressure in the holding tube
HHST system	14	Setting of control switches for differential pressure across the injector

Cross References

This section cited in 7 Pa. Code § 59.216a (relating to batch pasteurization requirements); 7 Pa. Code § 59.216b (relating to high temperature short-time (HTST) continuous flow pasteurization requirements); and 7 Pa. Code § 59.216c (relating to pasteurizers employing regenerative heating).

§ 59.217. Cooling of milk.

(a) All raw milk and milk products be maintained at 45°F (7°C) or less until processed.

(b) All pasteurized milk and milk products except those to be cultured shall be 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.

(c) Each refrigerator room in which milk or milk products are stored shall be equipped with an indicating thermometer. 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% of its calibrated capacity. Such thermometers shall comply with the applicable specifications of Appendix H of the PMO.

(d) All surface coolers comply with the following specifications:

(1) The sections of open-surface coolers shall be so installed as to leave a gap of at least 0.25 inches between the header sections to permit easy cleaning.

(2) Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk products 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, by shortening the bottom trough, or by some other approved method.

(3) The location of supports of cooler sections shall prevent drip from entering the milk or milk products.

(4) All open-surface coolers shall be provided with tight-fitting shields which protect the milk and milk products from contamination by flies, dust, drip, splash, or manual contact.

(e) Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, shall be from a safe source and shall be protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards as cited in § 59.207 (relating to water supply). 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.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); and 7 Pa. Code § 59.704 (relating to equipment and utensils).

§ 59.218. Bottling and packaging.

(a) All milk and milk products, including concentrated milk and milk products, shall be bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

(b) All bottling or packaging shall be done on mechanical equipment. The term “mechanical equipment” shall not be meant to exclude manually operated

machinery but is meant to exclude methods in which the bottling and capping devices are not integral in one system. Such equipment is subject to the approval of the Department.

(c) Bottling or packaging machines shall be designed to minimize the need for adjustment during operation. All pipes, connections, defoaming devices, and similar appurtenances shall comply with § 59.210 (relating to sanitary piping) and § 59.211 (relating to construction and repair of containers and equipment).

(d) Bottling or packaging machines supply tanks and bowls shall 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.

(e) A drip reflector shall be installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container.

(f) Container in-feed conveyors to automatic bottling or packaging machines shall 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 infeed conveyors when the cans are fed to the filler with covers off.

(g) Container fabricating materials such as paper stock, foil, wax, and plastic, shall be handled in a sanitary manner and protected against undue exposure during the package assembly operation.

(h) Bottling and packaging machine floats shall be designed to be adjustable without removing the cover.

(i) The filler pipe of all bottling and packaging machines shall 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.

(j) Filling cylinders on packaging machines shall be 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 and sterile and shall be sparingly applied in a sanitary manner.

§ 59.219. Capping.

(a) The capping or closing of milk and milk product containers shall be done in a sanitary manner on mechanical capping/closing equipment. The term "mechanical capping/closing equipment" shall not exclude manually operated machinery. Such equipment shall be subject to the approval of the Department. Hand-capping shall be prohibited; provided that, if suitable mechanical equipment for the capping or closing of specific containers of three gallons or more is not available, other methods which eliminate all possibility of contamination may be approved by the Department.

(b) All mechanical capping or closing mechanisms shall be designed to minimize the need for adjustment during operation.

(c) Bottles and packages which have been imperfectly capped or closed shall be emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 45°F (7°C) or less, and subsequently repasteurized or discarded.

(d) All caps and closures shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and that, with respect to fluid product containers, removal cannot be made without detection if sold off premises where processed. Single-service containers shall be so constructed that the product and the pouring and opening areas are protected from contamination during handling and storage and when the containers are initially opened.

(e) Caps and closures shall be handled in a sanitary manner. The first cap from each tube, the first lap 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 capper at the end of an operating period after removal from the cap tubes shall be a violation of this subsection.

§ 59.220. Personnel—cleanliness.

(a) Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination.

(b) Each employe shall wash his hands following a visit to the toilet room and prior to resuming work.

(c) All persons while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils shall wear clean outer garments.

(d) Persons while engaged in the processing of milk or milk products shall not use tobacco and shall wear adequate head covering.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); and 7 Pa. Code § 59.705 (relating to personnel cleanliness).

§ 59.221. Vehicles.

All vehicles used for transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 45°F (7°C) or less and are protected from sun, from freezing, and from contamination.

(1) All vehicles shall be kept clean.

(2) Material which is capable of contaminating milk or milk products shall not be transported with milk or milk products.

(3) Vehicles shall have fully enclosed bodies with well-fitted solid doors.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements).

§ 59.222. Surroundings.

Milk 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.

(1) There shall be no accumulation of trash, garbage, or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance.

(2) Driveways, lanes, and areas serving milk plant vehicular traffic shall be graded, drained, and free from pools of standing water.

(3) Outdoor areas for milk tank truck unloading shall be 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 Department or registered with the United States Environmental Protection Agency shall be used for insect and rodent control.

Cross References

This section cited in 7 Pa. Code § 59.251 (relating to receiving station requirements); 7 Pa. Code § 59.252 (relating to transfer station requirements); 7 Pa. Code § 59.253 (relating to tank truck cleaning and sanitizing facilities requirements); 7 Pa. Code § 59.701 (relating to surroundings); and 7 Pa. Code § 59.712 (relating to insect and rodent control program).

HANDLING**§ 59.251. Receiving station requirements.**

All receiving stations shall comply with §§ 59.201—59.215, 59.217 and 59.220—59.222.

§ 59.252. Transfer station requirements.

A transfer station shall comply with §§ 59.201—59.204, 59.206—59.212, 59.214, 59.215 and 59.222.

§ 59.253. Tank truck cleaning and sanitation facilities requirements.

Facilities for cleaning and sanitizing milk tank trucks shall comply with §§ 59.201—59.204, 59.206—59.212, 59.214, 59.215 and 59.222.

Cross References

This section cited in 7 Pa. Code § 59.707 (relating to protection and transport of raw milk and cream); and 7 Pa. Code § 59.711 (relating to cleaning and sanitizing treatment).

Subchapter C. MISCELLANEOUS PROVISIONS

- Sec.
59.301. Animal health.
59.302. Raw milk.
59.303. Transferring; delivery containers; cooling; retail establishment handling practices.
59.304. Milk and milk products from beyond the limits of routine inspection.
59.305. Dairy building and equipment plans approval.
59.306. Personnel health.
59.307. Procedure when infection is suspected.
59.308. Recordkeeping.
59.309. Approved laboratory reports.
59.310. Frequency of analyses.

§ 59.301. Animal health.

(a) *T. B. accreditation.* All milk for pasteurization shall be from herds which are located in a Modified Accredited Tuberculosis Area or Accredited Free State as defined by the United States Department of Agriculture, 9 CFR Part 77 and the *Tuberculosis Uniform Methods and Rules*. Herds located in an area that fails to maintain such accredited status shall have passed an annual tuberculosis test.

(b) *Brucellosis certification.* All milk for pasteurization shall be from herds under a brucellosis eradication program which conforms with United States Department of Agriculture requirements, 9 CFR Part 78 and the *Brucellosis Uniform Methods and Rules*.

(c) *Prohibition.* All brucellosis and tuberculosis reactors disclosed shall be separated immediately from the milking herd. Milk from brucellosis or tuberculosis reactors may not be sold.

§ 59.302. Raw milk.

(a) *Herd health.* Raw milk shall be milk from cows or goats that have been determined to be free from brucellosis and tuberculosis by annual tests conducted in accordance with the Individual Certified and Accredited Herd Plan set forth in Chapters 7 and 9 (relating to brucellosis regulations; and control and eradication of tuberculosis of livestock). An annual physical examination of the animals shall be made by a licensed veterinarian and report of the examination shall be filed with the producer.

(b) *General requirements.* Raw milk shall meet all the requirements of §§ 59.101—59.121 (relating to sanitation requirements applicable to production of milk for pasteurization) with the following exceptions:

- (1) Permits shall be issued for sale of raw milk only upon submission of the required application.
- (2) Labeling on all containers and caps except those owned by customers shall be approved by the Department.
- (3) Water supplies shall meet the requirements of § 59.108 (relating to water supply), except that samples for bacteriological testing of individual water supplies shall be taken upon the initial approval of the physical structure, each 6 months thereafter, and when any repair or alteration of the water supply system has been made. Bacteriological examinations shall be conducted in a laboratory acceptable to the Department.
- (4) One-room milk houses shall be sufficient if the milk is to be sold in containers owned by the customers. If the containers of the producers are to be used, an additional room shall be provided for bottle washing.
- (5) Milk houses or milk plants in which raw milk is handled shall not be constructed or altered until the Department has approved the plans and specifications.
- (6) Raw milk shall be delivered to the consumer only in containers that have been filled in the milk house or milk room.
- (7) For prepackaging, a mechanical means of filling and capping bottles shall be used. The cap or closure shall protect the pouring lip to its largest diameter.
- (8) Raw milk shall be tested in conformance with requirements of §§ 59.32—59.34 (relating to sampling and examination; problems; analysis) and Subchapter B (relating to standards for milk and milk products).

§ 59.303. Transferring; delivery containers; cooling; retail establishment handling practices.

- (a) No 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 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.
- (b) It shall be unlawful to sell or serve any milk or fluid milk product except in the 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 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 gallon capacity or from a bulk dispenser approved for such service by the Department.
- (c) It shall be unlawful to sell or serve any pasteurized milk or milk product which has not been maintained at the temperature set forth in Subchapter B

(relating to standards for milk and milk products). If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

(d) Unreasonable exposure of milk and dairy products to possible contamination shall be prevented at all times. To preserve nutrient and flavor qualities of milk, exposure to sunlight or fluorescent light should be minimized. It is recommended that fluorescent intensity in a dairy case be limited to less than 100 foot candles. Milk shall not be sold by a retail establishment after date designated on container.

Cross References

This section cited in § 59.707 (relating to protection and transport of raw milk and cream).

§ 59.304. Milk and milk products from beyond the limits of routine inspection.

Shippers of milk or milk products located outside this Commonwealth but in a reciprocal state shall be entitled to a permit to ship such milk or milk products into this Commonwealth provided it has been produced and pasteurized under regulations which are substantially equivalent to Pennsylvania requirements and has 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. Such milk or milk products must have been awarded an Interstate Milk Shippers rating of at least 90% and shall meet the bacteriological, chemical, temperature, and cooling standards of Subchapter B (relating to standards for milk and milk products) and the testing requirements of §§ 59.32—59.34 (relating to sampling and examination; problems; analysis).

§ 59.305. Dairy building and equipment plans approval.

Properly prepared plans for all transfer stations, receiving stations, and milk plants regulated under this chapter which are constructed, reconstructed, or extensively altered, after August 7, 1982, shall be submitted to the Secretary for written approval before work is begun. Plans must likewise be approved before construction or extensive modification of manure storage system; installation of a bulk milk storage tank; installation of a milk transfer system on a dairy farm; or installation of milk handling equipment in a transfer station, receiving station, or milk plant.

Cross References

This section cited in 7 Pa. Code § 59.605 (relating to utensils and equipment).

§ 59.306. 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 or milk plant in any capacity which

brings him into contact with the production, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils; and no dairy farm or milk plant operator shall employ in any such capacity any person suspected of having a disease in a communicable form, or any person suspected of being a carrier of such disease. Any producer or distributor of milk or milk products upon whose dairy farm or in whose milk plant any communicable disease occurs or who suspects that any employe has contracted any disease in a communicable form or has become a carrier of such disease shall notify the Department immediately.

Cross References

This section cited in 7 Pa. Code § 59.706 (relating to personnel health).

§ 59.307. 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 or milk products, the Department is authorized to require any or all of the following measures:

- (1) The immediate exclusion of that person from milk handling.
- (2) The immediate exclusion of the milk supply concerned from distribution and use.
- (3) Adequate medical and bacteriological examination of the person and his associates and of their body discharges.

§ 59.308. Recordkeeping.

All bacteriological and chemical tests required under this chapter shall be kept on file by the permit holder, in chronological order, for at least 1 year, on forms approved by the Department. The following records must be kept:

- (1) *Raw milk permit holder.*
 - (i) Chemical and bacteriological tests, including SPC, GI, coliform group and somatic cell count.
 - (ii) Individual water and recirculated cooling water test.
 - (iii) Annual herd physical, brucellosis, and tuberculosis test.
- (2) *Milk plant, receiving station, or BTU permit holder.*
 - (i) A list of producers and their quality control records, which shall include SPC or PLC, growth inhibitor, temperature, somatic cell counts, and inspection reports.
 - (ii) Tests of individual water supplies of producers and plants and plants' recirculated cooling water.
 - (iii) Pasteurization, CIP, and sanitization records of plants and SPC, coliform group, and phosphatase tests on all finished products.
 - (iv) A record of vitamin and mineral assays where applicable.
 - (v) A list of weighers/samplers who deliver milk on a regular or intermittent schedule, and their current certification date.

(vi) A list of tankers, farm pick-up, and milk transport servicing the plant or BTU, with the date of inspection.

§ 59.309. Approved laboratory reports.

(a) Pennsylvania approved dairy laboratories shall send to the Department, at least weekly, the report of all permit holders official analytical test results.

(b) Pennsylvania approved dairy laboratories shall immediately notify the Department of nonconforming phosphatase, growth-inhibitor and pesticide residue test results.

(c) All reports shall be signed by a Pennsylvania approved dairy laboratory director.

Cross References

This section cited in 7 Pa. Code § 59.33 (relating to problems).

§ 59.310. Frequency of analyses.

Required bacteriological, chemical and physical analyses shall be made in Pennsylvania approved dairy laboratories at the following minimum frequencies:

(1) *Raw milk and raw cream.* Raw milk and raw cream shall be tested at least semi-monthly for the SPC and coliform group and monthly for growth inhibitor and somatic cell count.

(2) *Milk for pasteurization.*

(i) Milk for pasteurization shall be tested at least monthly for SPC or PLC, growth inhibitors, temperature and somatic cell count.

(ii) Condensed milk, dry milk powder and whey powder shall be tested at least monthly for SPC, coliform group and growth inhibitors.

(3) *Pasteurized milk, cultured and acidulated products.* All types of pasteurized milk shall be tested at least monthly for standard plate count, coliform group, growth inhibitors and phosphatase activity. Cultured or acidulated products shall be tested at least monthly for coliform group. Milk and cream used in processing of cultured or acidulated products shall be tested at least monthly for phosphatase activity prior to culturing or acidulating.

(4) *Milk products.* Milk products shall be tested at least monthly for standard plate count, coliform group and phosphatase activity. Frozen dessert mixes shall be tested for phosphatase activity prior to the addition of flavoring material.

(5) *New producers and new products.* In the case of the new producers and new or seasonal products, bacteriological tests shall be made at least weekly until three samples are analyzed, followed by monthly testing as applicable.

(6) *Individual water supply.*

(i) Permit holder's water supply shall be tested every 6 months.

(ii) Producer's water supply shall be tested every 3 years.

(iii) Water from a drilled well with buried casing seal shall be tested every 6 months.

(7) *Cooling water.* Recirculating cooling water shall be tested every 6 months.

Authority

The provisions of this § 59.310 amended under the act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645—660f).

Source

The provisions of this § 59.310 amended December 13, 1996, effective December 14, 1996, 26 Pa.B. 5950. Immediately preceding text appears at serial pages (217665) to (217666).

Subchapter D. ADMINISTRATIVE PROCEDURES

Sec.

- 59.401. Farm inspection.
- 59.402. Milk permits.
- 59.403. Plant inspection.
- 59.404. Certification of bulk milk collectors—weighers/samplers.
- 59.405. Approved milk graders.
- 59.406. Delayed effective date.

Authority

The provisions of this Subchapter D issued under the act of July 2, 1935 (P. L. 558, No. 163) (31 P. S. §§ 645—660f), unless otherwise noted.

Source

The provisions of this Subchapter D adopted October 11, 1985, effective October 12, 1985, 15 Pa.B. 3642, unless otherwise noted.

§ 59.401. Farm inspection.

By October 12, 1986, farms producing and selling milk for manufacturing purposes shall comply with the following inspection provisions:

(1) Each dairy farm operated by a producer of milk for manufacturing purposes shall be inspected initially and on any change of market by a Pennsylvania approved inspector and shall have a passing score before the first milk is shipped. All dairy farms producing milk for manufacturing purposes shall be inspected no less than once in each 6 month period by a Pennsylvania approved inspector, and an accurate record of inspections shall be maintained by each permit holder on forms acceptable to the Secretary.

(2) Producers who cannot produce milk of a wholesome sanitary quality will be suspended. Producers who are not in substantial compliance with §§ 59.509 and 59.601—59.607 will be reinspected after an appropriate time for correction of deficiencies.

(3) A permit holder shall promptly notify the Department of initial instatement, suspension or reinstatement of a producer from which milk for manufacturing is or was received. Identification of the producer, including name and address, shall be provided orally or by mail within 24 hours of the action.

§ 59.402. Milk permits.

By April 12, 1986, plants receiving or processing milk for manufacturing of dairy products shall apply for a permit.

(1) Permits shall be required for the sale of milk for manufacturing purposes and manufactured dairy products. Application shall be made annually on a form secured from the Secretary.

(2) A separate permit shall be obtained for each plant, receiving station, transfer station, and bulk tank unit.

(3) The permit year shall begin September 1 of each year and end on August 31 of the following year.

§ 59.403. Plant inspection.

After October 12, 1985, plants receiving milk or dairy products, for manufacturing or further processing, shall be subject to inspection by the Secretary or his agent.

§ 59.404. Certification of bulk milk collectors—weighers/samplers.

All weighers/samplers will be evaluated and approved by the Department.

§ 59.405. Approved milk graders.

Milk graders will be approved by the Department.

§ 59.406. Delayed effective date.

Section 59.601 (relating to milking facilities and housing) is effective October 12, 1986.

Subchapter E. MILK FOR MANUFACTURING

Sec.	
59.501.	Basis.
59.502.	Sight and odor.
59.503.	Sediment content classification.
59.504.	Bacterial estimate classification.
59.505.	Rejected milk.
59.506.	Suspended milk for manufacturing.
59.507.	Inspection and testing of milk.
59.508.	Record of tests.
59.509.	Abnormal milk.
59.510.	Animal health.

Authority

The provisions of this Subchapter E issued under the act of July 2, 1935 (P. L. 558, No. 163) (31 P. S. §§ 645—660f), unless otherwise noted.

Source

The provisions of this Subchapter E adopted October 11, 1985, effective October 12, 1985, 15 Pa.B. 3642, unless otherwise noted.

§ 59.501. Basis.

The classification of raw milk for manufacturing purposes shall be based on sight, odor and quality control tests for sediment content, bacterial estimate, and somatic cell count.

§ 59.502. Sight and odor.

The odor of acceptable raw milk shall be fresh and sweet. The milk shall be free from objectionable off-odors that would adversely affect the finished product, and it shall not show abnormal conditions such as a curdled, ropy, bloody, or mastitic condition as determined by an approved milk grader.

Cross References

This section cited in 7 Pa. Code § 59.1 (relating to definitions); and 7 Pa. Code § 59.505 (relating to rejected milk).

§ 59.503. Sediment content classification.

Milk in cans and in farm bulk tanks shall be classified for sediment content as follows:

TABLE 1
Sediment Content

<i>Sediment content classification</i>	<i>Milk in cans (off the bottom method, 1-1/8 inch diameter disc)</i>	<i>Milk in farm bulk tanks (mixed sample, 0.40 inch diameter disc or equivalent)</i>
No. 1 (acceptable)	Not to exceed 0.50 mg.	Not to exceed 0.50 mg. equivalent
No. 2 (acceptable)	Not to exceed 1.50 mg.	Not to exceed 1.50 mg. equivalent
No. 3 (probational)	Not to exceed 2.50 mg.	Not to exceed 2.50 mg. equivalent
No. 4 (reject)	Over 2.50 mg.	Over 2.50 mg. equivalent

Sediment content classification is based on comparison with applicable charts of sediment standards prepared by the United States Department of Agriculture (USDA) 7 CFR §§ 58.2728—58.2732 (relating to United States sediment standards for milk and milk products).

(1) *Method of testing.* Methods for determining sediment content of milk shall be those described in the current edition of *Standard Methods* and the current edition of the *Official Methods of Analysis of the Association of Official Analytical Chemists* (AOAC) or other methods approved by the Secretary. For the testing of milk in cans, the off-the-bottom method shall be used. For

testing bulk milk, a mixed 1 pint sample or equivalent shall be tested. Sediment content shall be based on comparison with official USDA sediment standards, 7 CFR 58.2728—58.2732 (relating to United States sediment standards for milk and milk products).

(2) *Frequency of tests.* At least once each month, at irregular intervals, the milk from each producer shall be tested as follows:

(i) *Milk in cans.* A sample shall be taken from one or more cans of milk selected at random from each producer.

(ii) *Milk in farm bulk tanks.* A sample shall be taken from each farm bulk tank.

(3) *Acceptance or rejection of milk.* If the sediment disc is classified as No. 1, No. 2 or No. 3, the producer's milk may be accepted. If the sediment disc is classified as No. 4, the milk shall be rejected. If the shipment of milk is commingled with other milk in a transport tank, the next shipment shall not be accepted until its quality has been determined at the farm before being picked up; however, if the person making the test is unable to get to the farm before the next shipment, it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, if in cans, all cans shall be tested. Producers of No. 3 or No. 4 milk—cans or bulk—shall be notified immediately and shall be furnished applicable sediment discs, and the next shipment shall be tested.

(4) *Retests.* On tests of the next shipment (if in cans, all cans shall be tested) milk classified as No. 1, No. 2 or No. 3, may be accepted, but No. 4 milk shall be rejected. Retests of bulk milk classified as No. 4 shall be made at the farm before pickup. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment shall be tested. This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for a period not to exceed 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be excluded from market.

Cross References

This section cited in 7 Pa. Code § 59.1 (relating to definitions); 7 Pa. Code § 59.506 (relating to suspended milk for manufacturing); and 7 Pa. Code § 59.507 (relating to inspection and testing of milk).

§ 59.504. Bacterial estimate classification.

Milk shall be classified for bacterial estimate as follows by one of the listed methods:

TABLE 2

<i>Bacterial estimate classification</i>	<i>Direct microscopic clump count, standard plate count or plate loop count</i>
No. 1 (acceptable)	Not over 500,000 per ml.
No. 2 (acceptable)	Not over 1,000,000 per ml.
Undergrade (probation 4 weeks)	Over 1,000,000 per ml.

(1) *Method of testing.* Methods for determining the bacterial estimate of milk shall be those described in the current edition of *Standard Methods* and the current edition of the *Official Methods of Analysis of the Association of Official Analytical Chemists* or other methods approved by the Secretary.

(2) *Frequency of tests.* At least once a month at irregular intervals, a mixed sample of each producer's milk shall be tested.

(3) *Acceptance of milk.* If the sample of milk is classified as No. 1 or No. 2, the producer's milk may be accepted without qualification. If the sample is classified as undergrade—probational—the producer's milk may be accepted for a temporary period of 4 weeks. The producer of undergrade milk shall be notified immediately by the permit holder.

(4) *Retests.* Additional samples shall be tested and classified at least weekly, and the producer shall be notified immediately of the results. This procedure of testing at least weekly and accepting undergrade milk may be continued for a period not exceeding 4 weeks. If at the end of this time the producer's milk does not meet the acceptable bacterial estimate requirements (No. 1 or No. 2), it shall be suspended from market.

Cross References

This section cited in 7 Pa. Code § 59.1 (relating to definitions); 7 Pa. Code § 59.506 (relating to suspended milk for manufacturing); and 7 Pa. Code § 59.507 (relating to inspection and testing of milk).

§ 59.505. Rejected milk.

(a) A plant shall reject specific milk from a producer if it fails to meet the requirements of § 59.502 (relating to sight and odor), if it is classified No. 4 for sediment content, or if it fails to meet the provisions of § 59.509 (relating to abnormal milk).

(b) Reject milk shall be identified with a reject tag, and harmless food coloring may be added.

Cross References

This section cited in 7 Pa. Code § 59.1 (relating to definitions).

§ 59.506. Suspended milk for manufacturing.

A plant may not accept milk from a producer for use in products if one of the following occurs:

(1) A new producer’s milk does not meet the requirements for acceptable milk—§§ 59.503 and 59.504 (relating to sediment content classification; and bacterial estimate classification).

(2) The milk has been in a probational (No. 3) sediment content classification for more than 10 calendar days—§ 59.503.

(3) The milk has been classified undergrade for bacterial estimate for more than 4 successive weeks—§ 59.504.

(4) A growth inhibitor or pesticide residue exceeds actionable level. If a growth inhibitor or 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 growth inhibitor or pesticide residues, and no milk may be offered for sale until it is shown by a subsequent sample to be free of growth inhibitor or pesticide residue or below the actionable levels as determined by the Department. When a test conducted in a Pennsylvania Approved Dairy Laboratory indicates that milk from a producer is unacceptable due to a growth inhibitor, the permit holder shall immediately notify and suspend the producer for 2 days. A test shall be made of the subsequent milking after suspension, and it must be free of growth inhibitor before offering that milk for sale.

TABLE 3

Excluded milk classification

Growth Inhibitor	No growth inhibitor residue in excess of actionable level as determined by the B. stearothermophilus Disc Assay Method or equivalent.
Pesticide or similar adulterants	When a pesticide test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. Milk containing residues in excess of actionable levels shall not be offered for sale.

(5) The milk contains added water. Samples analyzed for added water and found to have a freezing point above -0.525°H (-0.508°C) shall be considered adulterated unless proven free of added water.

§ 59.507. Inspection and testing of milk.

(a) *Inspections.* Inspections shall be as follows:

(1) A dairy farm on which milk is produced for manufacturing purposes shall be inspected initially and shall have a passing score before the first milk is shipped.

(2) The dairy farm of a producer, on a change of market shall be inspected by a Pennsylvania approved inspector and shall have a passing score before the first milk is shipped.

(3) Dairy farms shall be inspected no less than once in each 6 month period by a Pennsylvania approved inspector.

(b) *Testing.* An examination shall be made on the first shipment of milk from producers shipping milk to a plant for the first time or after a period of nonshipment. The milk shall meet the requirements for acceptable milk—§§ 59.503 and 59.504 (relating to sediment content classification; and bacterial estimate classification). Thereafter, testing shall be done under §§ 59.503 and 59.504.

(c) *Transfer producers.* Transfers shall be as follows:

(1) When a producer discontinues milk delivery to one plant and begins delivery to a different plant, the dairy farm shall be inspected by a Pennsylvania approved inspector and shall have a passing score before milk is shipped.

(2) Quality control records may be obtained from the previous buyer for the previous 6 month period; otherwise, the new buyer shall examine and classify each transfer producer's first shipment of milk and shall subsequently examine shipments under §§ 59.503 and 59.504.

Cross References

This section cited in 7 Pa. Code § 59.1 (relating to definitions).

§ 59.508. Record of tests.

Accurate records, listing the results of quality tests of a producer, shall be kept on file at the receiving plant for not less than 12 months and shall be available for examination by the Department.

§ 59.509. Abnormal milk.

(a) Cows which show evidence of the secretion of abnormal milk in one or more quarters based on bacteriological, chemical, or physical examination and cows which have been treated with or have consumed chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which in the judgment of the Secretary may be deleterious to human health shall be milked last or with separate equipment and the milk may not be offered for sale for human consumption.

(b) Milk from cows being treated with medicinal agents may not be offered for sale for periods recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

(c) Milk from cows treated with or exposed to insecticides not approved for use on dairy cattle by the United States Environmental Protection Agency may not be offered for sale until the milk has been tested and found acceptable by the Secretary.

(d) Bloody, stringy, off-color milk or milk abnormal in sight and odor shall be so handled and disposed of as to preclude the infection of other cows, and the contamination of the utensils.

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

(f) Poultry litter and recycled animal body discharges may not be fed to lactating dairy animals.

(g) The Wisconsin Mastitis Test may be used as a screening test. A test of 22 mm or higher shall be considered to indicate abnormal milk and shall require confirmation by the Direct Microscopic Somatic Cell Count Method or an equivalent method according to the current edition of *Standard Methods*.

TABLE 4

Abnormal milk classification

Somatic cell count	Samples exceeding 18 mm WMT to be confirmed by DMSCC or acceptable tests. Not to exceed 1million per ml.
--------------------	--

Source

The provisions of this § 59.509 amended September 5, 1986, effective September 6, 1986, 16 Pa.B. 3285. Immediately preceding text appears at serial pages (103278) to (103279).

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection); and 7 Pa. Code § 59.505 (relating to rejected milk).

§ 59.510. Animal health.

(a) *Tuberculosis accreditation.* Milk for manufacturing shall be from herds which are located in a Modified Accredited Tuberculosis Area or Accredited Free State as defined by the United States Department of Agriculture, 9 CFR Part 77 (relating to tuberculosis in cattle). Herds located in an area that fails to maintain accredited status shall have passed an annual tuberculosis test.

(b) *Brucellosis certification.* Milk for manufacturing shall be from herds under a brucellosis eradication program which conforms with United States Department of Agriculture requirements, 9 CFR Part 78 (relating to brucellosis in cattle).

(c) *Prohibition.* Brucellosis and tuberculosis reactors disclosed shall be separated immediately from the milking herd. Milk from brucellosis or tuberculosis reactors may not be sold.

Subchapter F. FARMS PRODUCING MILK FOR MANUFACTURING

- Sec.
59.601. Milking facilities and housing.
59.602. Milking procedures.
59.603. Cooling.
59.604. Milkhouse or milkroom.
59.605. Utensils and equipment.
59.606. Water supply.
59.607. Sewage disposal.

Authority

The provisions of this Subchapter F issued under the act of July 2, 1935 (P. L. 558, No. 163) (31 P. S. §§ 645—660f), unless otherwise noted.

Source

The provisions of this Subchapter F adopted October 11, 1985, effective October 12, 1985, 15 Pa.B. 3642, unless otherwise noted.

§ 59.601. Milking facilities and housing.

(a) A milking barn or milking parlor of adequate size and arrangement shall be provided to permit normal sanitary milking operations. It shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material. The facility shall be kept clean, the manure removed daily and stored to prevent access of cows to accumulation thereof. No swine or fowl may be permitted in the milking area. When a milking barn is used and horses are present, they shall be stalled in a separate area a sufficient distance from the milking area or separated by tight partitions.

(b) Concentrates and feed, if stored in the building, shall be stored in a tightly covered box, bin or container.

(c) If milk is exposed during straining or transferring in the milking area it shall be protected from falling particles from areas above the milk facility.

(d) The yard or loafing area shall be of ample size to prevent overcrowding, shall be drained to prevent forming of standing water pools, insofar as practicable, and shall be kept clean.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection); and 7 Pa. Code § 59.406 (relating to delayed effective date).

§ 59.602. Milking procedures.

(a) The udders and flanks of all milking cows shall be kept clean. The udders and teats shall be washed or wiped immediately before milking with a clean, damp cloth or paper towel moistened with a sanitizing solution and wiped dry or by another sanitary method.

(b) The milker's outer clothing shall be clean and his hands clean and dry. No person with an infected cut or open sores on the person's hands or arms shall milk cows, or handle milk or milk containers, utensils or equipment.

(c) Milk stools, surcingles or antikickers shall be kept clean and properly stored. Dusty operations shall not be conducted immediately before or during milking. Strong flavored feeds shall not be fed immediately before or during milking.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

§ 59.603. Cooling.

(a) Milk in cans shall be cooled immediately after milking to 50°F or lower at the farm, and not exceed 55°F upon delivery to the plant, unless delivered to the plant within 2 hours after milking. Until October 12, 1988, the temperature of can milk on the farm may be 55°F or under and 60°F or under when delivered to the plant. The cooler, tank, or refrigerated unit shall be kept clean. Maximum time of delivery of milk to a milk plant shall be within 48 hours of initial milking.

(b) Milk in farm bulk tanks shall be cooled to 40°F within 2 hours after milking. Cooled milk may not be allowed to rise above a temperature of 50°F by subsequent addition of milk to the bulk tank and shall be cooled at 45°F or lower at time of pick-up, and not exceed 50°F upon delivery to the plant. Maximum time of delivery of milk to a milk plant may not exceed 72 hours of initial milking.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

§ 59.604. Milkhouse or milkroom.

(a) A milkhouse or milkroom conveniently located and properly constructed, lighted, and ventilated shall be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment. Other products shall not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public health hazard.

(b) The milkroom shall be equipped with wash and rinse vat, utensil rack, milk cooling facilities and an adequate supply of hot water available for cleaning milking equipment. If a part of the barn or other building, it shall be partitioned,

screened, and sealed to prevent the entrance of dust, flies, or other contamination. The floor of the building shall be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings shall be constructed of smooth easily cleaned material. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies.

(c) If a farm bulk tank is used, it shall be properly located in the milkhouse or milkroom for access to all areas for cleaning and servicing. It may not be located over a floor drain or under a ventilator.

(d) If a farm bulk tank is used, a small platform or slab constructed of concrete or other impervious material shall be provided outside the milkhouse, properly centered under a suitable port opening in the wall of the milkhouse. The opening shall be fitted with a tight, self-closing door. The truck approach to the milkhouse or milkroom shall be properly graded and surfaced to prevent mud or pooling of water at the point of loading.

(e) The milkhouse or milkroom and appurtenances shall be kept clean and free of trash, animals, and fowl. Only approved pesticides applicable to dairy use shall be stored in this room in a protected cabinet and when used shall be used in accordance with label instructions so as to prevent contamination of the milk.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

§ 59.605. Utensils and equipment.

(a) Utensils, milk cans, milking machines—including pipeline systems—rubber and rubber like parts and other equipment used in the handling of milk shall be maintained in good condition, shall be free from rust, open seams, milkstone, or an unsanitary condition, and shall be washed, rinsed, and drained after each milking, stored in suitable facilities, and sanitized immediately before use with at least 100 p.p.m. chlorine solution, 12 p.p.m. iodine, or its equivalent. New or replacement can lids shall be umbrella type. All new utensils and equipment shall comply with applicable *3-A Sanitary Standards*.

(b) Farm bulk tanks shall meet *3-A Sanitary Standards* for construction at the time of installation and shall be installed under § 59.305 (relating to dairy building and equipment plans approval).

(c) Single service articles shall be properly stored and shall not be reused.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

§ 59.606. Water supply.

Water supplies shall comply with § 59.108 (relating to water supply), except that a source that does not conform with the construction requirements of the

Department, but is tested annually by an approved laboratory and found to be safe and of sanitary quality shall be satisfactory. After October 12, 1985, new sources of water supply or farm water supply requiring repairs or reconstruction of a source from which tested samples have been found unsatisfactory shall meet the construction requirements of the Department.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

§ 59.607. Sewage disposal.

House, milkhouse or milkroom and toilet wastes shall be disposed of in a manner that will not pollute the soil surface, contaminate the water supply or be conducive to the breeding of insects.

Cross References

This section cited in 7 Pa. Code § 59.401 (relating to farm inspection).

Subchapter G. MANUFACTURING PLANTS

GENERAL REQUIREMENTS

Sec.	
59.701.	Surroundings.
59.702.	Buildings.
59.703.	Facilities.
59.704.	Equipment and utensils.
59.705.	Personnel cleanliness.
59.706.	Personnel health.
59.707.	Protection and transport of raw milk and cream.
59.708.	Raw product storage.
59.709.	Pasteurized, ultra-pasteurized or aseptically processed and packaged products.
59.710.	Composition and wholesomeness.
59.711.	Cleaning and sanitizing treatment.
59.712.	Insect and rodent control program.
59.713.	Plant records.
59.714.	Packaging and general identification.
59.715.	Storage of finished product.
59.716.	Permits.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING INSTANT
NONFAT DRY MILK, NONFAT DRY MILK, DRY WHOLE MILK,
DRY BUTTERMILK, DRY WHEY AND OTHER DRY MILK
PRODUCTS**

59.721.	Requirements for rooms and compartments.
59.722.	Dry storage.

- 59.723. Packaging room for bulk products.
- 59.724. Hopper or dump room.
- 59.725. Repackaging room.
- 59.726. Equipment and utensils.
- 59.727. Preheaters.
- 59.728. Hotwells.
- 59.729. Evaporators or vacuum pans, or both.
- 59.730. Surge tanks.
- 59.731. High pressure pumps and lines.
- 59.732. Dryers.
- 59.733. Collectors and conveyors.
- 59.734. Dry dairy product cooling equipment.
- 59.735. Special treatment equipment.
- 59.736. Sifters.
- 59.737. Portable and stationary bulk bins.
- 59.738. Automatic sampling device.
- 59.739. Dump hoppers, screen, mixers and conveyors.
- 59.740. Filler and packaging equipment.
- 59.741. Heavy duty vacuum cleaners.
- 59.742. Clothing and shoe covers.
- 59.743. Operations and operating procedures.
- 59.744. Condensed surge supply.
- 59.745. Condensed storage tanks.
- 59.746. Drying.
- 59.747. Cooling dry products.
- 59.748. Packaging, repackaging and storage.
- 59.749. Product adulteration.
- 59.750. Checking quality.
- 59.751. Requirements for instant nonfat dry milk.
- 59.752. Cleaning of dryers, conveyors, sifters and storage bins.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING BUTTER
AND RELATED PRODUCTS**

- 59.761. Rooms and compartments.
- 59.762. Equipment and utensils.
- 59.763. Operations and operating procedures.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING AND PACKAGING CHEESE**

- 59.771. Rooms and compartments.
- 59.772. Equipment and utensils.
- 59.773. Operations and operating procedures.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING
PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS**

- 59.781. Equipment and utensils.
59.782. Operations and operating procedures.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING
EVAPORATED AND CONDENSED MILK**

- 59.791. Equipment and utensils.
59.792. Operations and operating procedures.

Authority

The provisions of this Subchapter G issued under the act of July 2, 1935 (P. L. 558, No. 163) (31 P. S. §§ 645—660f), unless otherwise noted.

Source

The provisions of this Subchapter G adopted October 11, 1985, effective October 12, 1985, 15 Pa.B. 3742, unless otherwise noted.

GENERAL REQUIREMENTS

§ 59.701. Surroundings.

Surroundings shall conform with § 59.222 (relating to surroundings).

§ 59.702. Buildings.

Buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs and cats. Service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

- (1) Outside doors, windows, openings, and the like, shall conform with § 59.203 (relating to doors and windows).
- (2) Walls, ceilings, partitions, and posts shall conform with § 59.202 (relating to walls and ceilings—construction).
- (3) Floors shall conform with § 59.201 (relating to floors—construction).
- (4) Lighting and ventilation shall comply with the following:
 - (i) Light shall be ample, natural or artificial, or both, of good quality and well distributed. Rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 20 foot-candles of light intensity on all working surfaces and at least 50 foot-candles of light intensity in areas where dairy products are graded or examined for condition

and quality. In other rooms, there shall be at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of a product by broken glass is possible, light bulbs, fluorescent tubes, fixtures, skylight or other glass suspended over the product shall be protected against breakage.

(ii) There shall be adequate heating, ventilation or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods or temperature and humidity control facilities shall be provided where and when needed, to minimize or eliminate undesirable room temperatures, objectionable odors, moisture condensation, or mold. Inlet fans shall be provided with an adequate air filtering device to eliminate dirt and dust from the incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. When not in use, exhaust outlets shall be screened or provided with self-closing louvers to prevent the entrance of insects.

(5) Rooms and compartments in which raw material, packaging, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be designed, constructed, and maintained to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from the processing rooms by a partition—partial or complete—by suitable arrangement of equipment or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing rooms shall be kept free from equipment and materials not regularly used. Rooms and compartments shall comply with the following:

(i) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidity to adequately protect the product and minimize the growth of mold. Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

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

(iii) *Boiler rooms, shop room, and service areas.* The boiler rooms, shop room and service areas shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. The rooms shall be kept orderly and reasonably free from dust and dirt.

(iv) *Toilet and dressing rooms.* Adequate toilet and dressing rooms facilities shall be conveniently located.

(A) Toilet rooms may not open directly into a room where milk or dairy products are processed, manufactured, packaged, or stored. Doors shall be self-closing. Ventilation shall be provided by mechanical means or screened openings to the outer air. Fixtures shall be kept clean and in good repair.

(B) All employees shall be furnished with a locker, or other suitable facility, and the lockers and dressing rooms shall be kept clean and orderly. Adequate handwashing facilities shall be provided and durable, legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(v) *Laboratory.* The permit holder may establish its own laboratory to perform required tests on milk received as milk for manufacturing purposes. The laboratory shall be adequately equipped and maintained and be properly staffed with qualified, trained personnel, to meet requirements established by the Department. If the permit holder does not establish its own laboratory, an existing approved laboratory is acceptable if services are conveniently available so that samples and results can be transmitted without delay.

(vi) *Starter facilities.* Adequate sanitary facilities shall be provided for the handling of starter cultures.

(vii) *Lunch rooms and eating areas.* When eating areas are provided, they shall be kept clean and orderly and not open directly into a room in which milk or dairy products are processed, manufactured or packaged. Signs shall be posted directing employees to wash their hands before returning to work.

Cross References

This section cited in 7 Pa. Code § 59.721 (relating to requirements for rooms and compartments); and 7 Pa. Code § 59.723 (relating to packaging room for bulk products).

§ 59.703. Facilities.

- (a) Water supplies shall conform with § 59.207 (relating to water supply).
- (b) Sanitary drinking water facilities shall be provided in the plant and shall be conveniently located.
- (c) Handwashing facilities shall conform with § 59.208 (relating to handwashing facilities).
- (d) Steam shall conform with § 59.215(e) (relating to protection from contamination).

- (e) Air under pressure shall conform with § 59.215(e).
- (f) Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tight fitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches. Waste containers may be kept inside a suitably enclosed, clean and flyproof room. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry wastepaper and cardboard shall be kept to a minimum. The paper shall be burned at the plant in a properly constructed incinerator, or compressed or bagged and hauled away.

§ 59.704. Equipment and utensils.

- (a) General construction, repair, and installation shall conform with §§ 59.210 and 59.211 (relating to sanitary piping; and construction and repair of containers and equipment).
- (b) Weigh cans and receiving tanks shall conform with § 59.215(d)(3) (relating to protection from contamination).
- (c) Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.
- (d) Product storage tanks or vats shall conform with § 59.211.
- (e) Product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals.
- (f) Batch pasteurizers shall conform with § 59.216a (relating to batch pasteurization requirements).
- (g) High-temperature, short-time pasteurizers shall conform with § 59.216b (relating to high temperature short-time (HTST) continuous flow pasteurization requirements).
- (h) Thermometers and recorders shall conform with § 59.216b(e).
- (i) Surface coolers shall conform with § 59.217(d) (relating to cooling of milk).
- (j) Plate-type heat exchangers shall meet the *3-A Sanitary Standards for Construction and Installation*. Gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent

intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen shall be posted to insure proper cleaning procedures between inspection periods.

- (k) Internal return tubular heat exchangers shall conform with § 59.211.
- (l) Pumps shall conform with § 59.211.
- (m) Homogenizers shall conform with § 59.211.
- (n) New equipment and replacements shall conform with § 59.211.
- (o) A vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally noncorrosive metal. The unit shall be constructed to facilitate cleaning and product contact surfaces shall be accessible for inspection. It shall be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow diversion valve of the HTST pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

Cross References

This section cited in 7 Pa. Code § 59.726 (relating to equipment and utensils); 7 Pa. Code § 59.762 (relating to equipment and utensils); 7 Pa. Code § 59.772 (relating to equipment and utensils); 7 Pa. Code § 59.781 (relating to equipment and utensils); 7 Pa. Code § 59.791 (relating to equipment and utensils); and 7 Pa. Code § 59.792 (relating to operations and operating procedures).

§ 59.705. Personnel cleanliness.

Personnel cleanliness shall conform with § 59.220 (relating to personnel—cleanliness).

§ 59.706. Personnel health.

Personnel health shall conform with §§ 59.306 and 59.307 (relating to personnel health; and procedure when infection is suspected).

§ 59.707. Protection and transport of raw milk and cream.

- (a) *Equipment and facilities.*
 - (1) Milk cans shall conform with § 59.109 (relating to utensils and equipment—construction).
 - (2) Farm bulk tanks shall conform with § 59.109.
- (b) *Transporting milk or cream.*
 - (1) Vehicles shall conform with § 59.120 (relating to vehicles).
 - (2) The exterior shell of transport tanks shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and constructed so it will not buckle, sag, or prevent complete drainage. Product contact surfaces shall be smooth, easily

cleaned, and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with dust covers to give adequate protection from road dust. New and replacement transport tanks shall meet *3-A Sanitary Standards for Milk Transport Tanks*.

(c) *Cleaning and sanitizing facilities.* Facilities for cleaning and sanitizing shall be convenient and conform with § 59.253 (relating to tank truck cleaning and sanitation facilities requirements).

(d) *Transfer of milk.* Transfer of milk to transport tanks shall conform with § 59.303(a) (relating to transferring; delivery containers; cooling; retail establishment handling practices).

§ 59.708. Raw product storage.

(a) Milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers or another source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the dairy plant shall be handled to minimize bacterial increase and shall be maintained at 45 F or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(b) The bacteriological quality of commingled milk in storage tanks shall be 3 million/ml or lower.

(c) At least monthly, a representative sample of commingled milk shall be taken by an approved sampler after receipt of milk by the plant and prior to processing.

§ 59.709. Pasteurized, ultra-pasteurized or aseptically processed and packaged products.

Pasteurized, ultra-pasteurized or aseptically processed and packaged products shall conform with § 59.1 (relating to definitions).

§ 59.710. Composition and wholesomeness.

Necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. Substances and ingredients used in the processing or manufacturing of a dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished product shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—392) and applicable Commonwealth statutes as to their composition and wholesomeness.

§ 59.711. Cleaning and sanitizing treatment.

(a) *Equipment and utensils.* Equipment and utensils shall conform with § 59.212 (relating to cleaning and sanitizing containers and equipment).

(b) *Milk cans and can washers.* Milk cans and can washers shall comply with the following:

(1) Milk cans and lids shall be cleaned, sanitized, and dried before they are returned to producers. Inspection, repair, or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or an unsanitary condition.

(2) Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer.

(c) *Transport tanks.* Milk transport tanks shall conform with § 59.212(a) and (b) and § 59.253 (relating to tank truck cleaning and sanitation facilities requirements).

(d) *Buildings.* Buildings shall conform with § 59.209 (relating to milk plant cleanliness).

§ 59.712. Insect and rodent control program.

Insect and rodent control programs shall conform with §§ 59.209 and 59.222 (relating to milk plant cleanliness; and surroundings).

§ 59.713. Plant records.

Adequate plant records shall be maintained of required tests on raw milk receipts. Records shall be available for examination at reasonable times by the Secretary or his agent. The following are the records which shall be maintained for examination at the plant or receiving station where performed:

(1) Sediment and bacterial test results on raw milk from each producer: retain for 12 months.

(i) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(ii) Retests, if initial test places milk in probationary status.

(iii) Rejection of raw milk over No. 3 in quality.

(2) Pasteurization recorder charts: retain for 12 months.

(3) Water test reports: retain copies for 12 months.

§ 59.714. Packaging and general identification.

(a) *Containers.* Containers shall comply with the following:

(1) The size, style and type of packaging used for dairy products shall be commercially acceptable containers and packaging materials which satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling. The weights and shape within each size and style shall be as nearly uniform as is practical.

(2) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. The wrapper shall be resistant to punc-

turing, tearing, cracking, or breaking under normal conditions of handling, shipping and storage. When special type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(b) *Packaging and repackaging.* Packaging dairy products or cutting and repackaging styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and packaging material shall be practically free from mold and bacterial contamination. Method for checking the level of contamination shall be as prescribed by the current edition of *Standard Methods*.

(c) *General identification.* Commercial bulk packages containing dairy products manufactured under this subpart shall be adequately and legibly marked with the name of the product, net weight, name and address of processor or manufacturer or other assigned plant identification, lot number and other identification that may be required. Consumer packaged products shall be legibly marked with the name of the product, net weight, name and address of packer, manufacturer or distributor and other identification required by the Department.

§ 59.715. Storage of finished product.

(a) *Dry storage.* The finished product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, so it is orderly and easily accessible for inspection. Rooms shall be cleaned regularly. Care shall be taken in the storage of products foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

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

Cross References

This section cited in 7 Pa. Code § 59.722 (relating to dry storage).

§ 59.716. Permits.

Permits shall be required as specified in § 59.17 (relating to permits).

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING, AND PACKAGING
INSTANT NONFAT DRY MILK, NONFAT DRY MILK, DRY
WHOLE MILK, DRY BUTTERMILK, DRY WHEY, AND
OTHER DRY MILK PRODUCTS**

§ 59.721. Requirements for rooms and compartments.

Rooms and compartments shall conform with § 59.702(e) (relating to buildings).

§ 59.722. Dry storage.

Dry storage of instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products shall conform with § 59.715 (relating to storage of finished product).

§ 59.723. Packaging room for bulk products.

A separate room or area shall be provided for filling bulk bins, drums, bags or other bulk containers and shall be constructed under § 59.702 (relating to buildings). The number of control panels and switchboxes in this area shall be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or shall be mounted in the wall and provided with tight-fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the accumulation of product dust within the packaging room and, where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least 6 inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, may not be allowed in the packaging room.

§ 59.724. Hopper or dump room.

A separate room shall be provided for the transfer of bulk dry dairy products from bags or drums to the hoppers and conveyors which lead to the fillers. The room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities providing for the transfer of dry dairy products from portable bulk bins shall be acceptable if gasketed surfaces or direct connections are used that essentially eliminate the escape of product into the area.

§ 59.725. Repackaging room.

A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

§ 59.726. Equipment and utensils.

Equipment and utensils shall conform with § 59.704 (relating to equipment and utensils).

§ 59.727. Preheaters.

Preheaters shall be of stainless steel or other equally corrosion-resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

§ 59.728. Hotwells.

Hotwells shall be enclosed or covered and equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell and if used for holding high heat products they shall also have recorders.

§ 59.729. Evaporators or vacuum pans, or both.

Open-type evaporators or vacuum pans, or both, shall be equipped with an automatic condenser water level control, barometric leg, or constructed to prevent water from entering the product, and shall meet the applicable *3-A Sanitary Standards*. When enclosed-type condensers are used, no special controls are needed to prevent water from entering the product.

§ 59.730. Surge tanks.

If surge tanks are used for hot milk and temperatures of products including foam being held in the surge tank during processing is not maintained at a minimum of 150°F, two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

§ 59.731. High pressure pumps and lines.

High pressure lines may be cleaned in place and shall be of construction so that deadends, valves and the high pressure pumps can be disassembled for hand cleaning. New high pressure pumps shall meet the *3-A Sanitary Standard Covering Homogenizers and High Pressure Pumps of the Plunger Type*.

§ 59.732. Dryers.

(a) *Spray dryers.* Spray dryers shall be of a continuous discharge type and all product contact surfaces shall be of stainless steel or other equally corrosion-resistant material. Joints and seams in the product contact surfaces shall be welded and ground smooth. Dryers shall be constructed so as to facilitate ease of cleaning and inspection. Sight glasses or ports of sufficient size shall be located at strategic positions. Dryers shall be equipped with suitable air intake filters and with air intake and exhaust recording thermometers. The filter system shall con-

sist of filtering media or devices that shall effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying chamber. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas-fired dryers, precautions shall be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust, or dirt.

(b) *Roller dryers.* Roller dryers shall comply with the following:

(1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rusts. The knives shall be maintained in a condition so they don't cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. Air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system shall consist of a filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. Dryer adjustments shall be made and the dryer operating normally before food grade powder can be collected from the dryer.

§ 59.733. Collectors and conveyors.

Collectors shall be made of stainless steel or equally noncorrosive material and shall be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall be in good condition and the system shall be of a construction so parts are accessible for cleaning and inspection. Conveyors shall be of stainless steel or equally corrosion-resistant material and shall be constructed to facilitate thorough cleaning and inspection.

§ 59.734. Dry dairy product cooling equipment.

Cooling equipment shall be provided with sufficient capacity to cool the products to 110°F or lower immediately after removal from dryer and prior to packaging. If bulk bins are used, the product shall be cooled to approximately 90°F but may not be more than 110°F. A suitable dry air supply with effective filtering shall be provided where air cooling and conveying is used.

§ 59.735. Special treatment equipment.

Special equipment, such as instantizing systems, flakers, pulverizers or hammer mills used to further process dry milk products shall be of sanitary construction and parts shall be accessible for cleaning and inspection.

§ 59.736. Sifters.

Newly installed sifters used for dry milk and dry milk products shall meet the *3-A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products*. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the *3-A Standard for Sifters*.

§ 59.737. Portable and stationary bulk bins.

Bulk bins shall be constructed of stainless steel, aluminum or other equally corrosion-resistant materials, free from cracks and seams and shall have an interior surface that is relatively smooth and easily cleanable. Product contact surfaces shall be easily accessible for cleaning.

§ 59.738. Automatic sampling device.

If automatic sampling devices are used, they shall be constructed to prevent contamination of the product, and all parts shall be readily accessible for cleaning.

§ 59.739. Dump hoppers, screens, mixers and conveyors.

The product contact surfaces of dump hoppers, screens, mixers and conveyors which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless steel or equally corrosion resistant material and designed to prevent contamination. Parts shall be accessible for cleaning. The dump hoppers shall be of a height above floor level to prevent foreign material or spilled product from entering the hopper.

§ 59.740. Filler and packaging equipment.

Filling and packaging equipment shall be of sanitary construction and parts, including valves and filler heads, accessible for cleaning.

§ 59.741. Heavy duty vacuum cleaners.

Plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. Regular scheduling shall be established for its use in vacuuming applicable areas.

§ 59.742. Clothing and shoe covers.

Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the dryer when it is necessary to enter the dryer to perform the cleaning operation.

§ 59.743. Operations and operating procedures.

(a) Milk, buttermilk, and whey used in the manufacture of dry dairy products shall be pasteurized at the plant where dried, except that condensed whey and acidified buttermilk containing 40% or more solids may be transported to another plant for drying without repasteurization. Milk or skim milk to be used in the manufacture of nonfat dry milk shall be heated prior to condensing to at least the minimum pasteurization temperature of 161°F for at least 15 seconds or its equivalent in bacterial destruction. Condensed skim made from pasteurized skim milk may be transported to a drying plant; however, it shall be effectively repasteurized at the drying plant, prior to drying, at not less than 175°F for 25 seconds or its equivalent in bacterial destruction.

(b) Buttermilk or cream from which it is derived shall be pasteurized prior to condensing at a temperature of 185°F for 15 seconds or its equivalent in bacterial destruction.

(c) Cheese whey or milk from which it is derived shall be pasteurized prior to condensing at a temperature of 161°F for 15 seconds or its equivalent in bacterial destruction.

§ 59.744. Condensed surge supply.

Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold the minimum amount of condensed product necessary for a uniform flow to the dryers. Tanks holding products at temperatures below 150°F shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

§ 59.745. Condensed storage tanks.

(a) Excess production of condensed products over that which the dryer will take continuously from the pans should be by-passed through a cooler into a storage tank at 50°F or lower and held at this temperature until used.

(b) Product cut-off points shall be made at least every 24 hours and the tank completely emptied, washed, and sanitized before reuse.

§ 59.746. Drying.

Each dryer shall be operated at not more than the manufacturer's rated capacity for the highest quality dry product consistent with the most efficient operation. This does not preclude the remodeling or redesignation of dryers after installation

when properly engineered and designed. The dry products shall be removed from the drying chamber continuously during the drying process.

§ 59.747. Cooling dry products.

Prior to packaging and immediately following removal from the drying chamber, the dry product shall be cooled to a temperature not exceeding 110°F.

§ 59.748. Packaging, repackaging and storage.

(a) *Containers.* Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be a clean, sound commercially accepted container or packaging material which shall satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. Containers which have previously been used for nonfood items or food which would be deleterious to the dairy product may not be used for the bulk handling of dairy products.

(b) *Filling.* Empty containers shall be protected from possible contamination and containers which are to be lined may not be prepared more than 1 hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary, a mechanical shaker shall be provided. The tapping or pounding of containers shall be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of product remnants before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. Exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The flow shall be kept free of dust accumulation, waste, cartons, liners or other refuse. Conveyors, packaging and cartonmaking equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials shall be permitted in the repackaging or hopper room. The inlet openings of hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention shall be given to cleaning points of equipment where residues of the dry product may accumulate. A thorough clean-up including windows, doors, walls, light fixtures, and ledges, shall be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers shall be properly identified and disposed of as animal feed.

(d) *Storage.* Storage shall be as follows:

(1) *Product.* The packaged dry milk product shall be stored or arranged in aisles, rows or sections and lots at least 18 inches from a wall and in an orderly, easily accessible manner for inspection or for cleaning of the room. Bags and small containers of products shall be placed on pallets elevated approximately 6 inches from the floor. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* Supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. Supplies shall be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers, they shall be kept in an enclosed metal cabinet, bins, or on shelving, and if not enclosed shall be protected from powder and dust or other contamination. The room shall be vacuumed as often as necessary and kept clean and orderly.

§ 59.749. Product adulteration.

Necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry product with another shall be considered as an adulteration of the product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, if applicable labeling requirements are met.

§ 59.750. Checking quality.

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

§ 59.751. Requirements for instant nonfat dry milk.

(a) *Sampling and testing.* Instant nonfat dry milk offered for sale shall be sampled and tested by an approved laboratory at least once each month for the purpose of assuring that the product meets the requirements of subsection (b). The dry milk plant shall have each subplot of approximately 5,000 pounds tested and analyzed prior to being packaged or offered for sale. Products which do not meet the requirements of subsection (b) may not be offered as extra grade.

(b) *Requirements for extra grade instant nonfat dry milk.* Requirements are as follows:

(1) *Flavor and odor.* The flavor and odor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree: Chalky, cooked, feed, flat.

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

- (3) *Bacterial estimate.* The standard plate count shall not be more than 30,000 per gram.
- (4) *Coliform count.* The coliform count shall not be more than 10 per gram.
- (5) *Milkfat content.* The milkfat shall not be more than 1.25%.
- (6) *Moisture count.* The moisture shall not be more than 4.5%.
- (7) *Scorched particle content.* Scorched particles shall not be more than 15 mg.
- (8) *Solubility index.* The solubility index shall not be more than 1 ml.
- (9) *Titrateable acidity.* The titrateable acidity shall not be more than 0.15%.
- (10) *Dispersibility.* The dispersibility may not be less than 85% by the Modified Moats-Dabbah Method, as recommended by the United States Department of Agriculture.
- (11) *Direct microscopic clump count.* The direct microscopic clump count shall not be more than 75 million per gram.

§ 59.752. Cleaning of dryers, conveyors, sifters and storage bins.

Dryers, conveyors, sifters and storage bins shall be cleaned as often as necessary to maintain the equipment in a clean and sanitary condition. The kind of cleaning procedure, either wet or dry, and the frequency of cleaning shall be based upon observation of actual operating results and conditions.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING
BUTTER AND RELATED PRODUCTS**

§ 59.761. Rooms and compartments.

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

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

(c) *Print and bulk packaging rooms.* Rooms used for packaging print or bulk butter and related products shall, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold—no more than 10 mold colo-

nies per cubic foot of air—dust, or other airborne contamination and be maintained at a reasonable room temperature.

§ 59.762. Equipment and utensils.

(a) *General construction, repair and installation.* Equipment and utensils necessary to the manufacture of butter and related products shall meet requirements of § 59.704 (relating to equipment and utensils). For certain other equipment, the requirements of this section shall be met.

(b) *Continuous churn.* Product contact surfaces shall be of noncorrosive material. Nonmetallic product contact surfaces shall comply with *3-A Standards for Plastic, Rubber, and Rubber-like Materials*. Product contact surfaces shall be readily accessible for cleaning and inspection.

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

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

(e) *Butter, frozen or plastic cream melting machines.* Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, sanitary construction and readily cleanable.

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

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

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

§ 59.763. Operations and operating procedures.

(a) *Pasteurization.* The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product.

(1) *Cream for buttermaking.* Requirements are as follows:

(i) The cream for buttermaking shall be pasteurized at a temperature of not less than 165°F and held continuously in a vat at that temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum temperature of not less than 185°F for not less than 15 seconds; or by another equivalent time and temperature combination. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping quality characteristics.

(ii) Adequate pasteurization control shall be used and the diversion valve shall be set to divert at no less than 185°F with a 15 second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching the minimum temperature before holding time starts. Covers shall also be kept closed during the holding and cooling period.

(2) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in subparagraph (i) except that the temperature for the vat method shall be not less than 170°F for not less than 30 minutes, or not less than 190°F for not less than 15 seconds or by another temperature and holding time which will assure adequate pasteurization and comparable keeping quality characteristics.

(b) *Composition and wholesomeness.* Ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and other necessary precautions shall be taken to prevent contamination of products. Finished products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—392), as to composition and wholesomeness.

(c) *Containers.* Containers shall comply with the following:

(1) Containers used for the packaging of butter and related products shall satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less, to protect the product from contamination during subsequent handling.

(2) Liners and wrappers shall comply with the following:

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

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

(iii) Other liners, such as polyethylene, shall be treated or handled to prevent contamination of the liner prior to filling.

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

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

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

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

(g) *Storage of finished product in freezer.*

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

(2) *Freezer storage.* Freezer storage shall comply with the following:

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

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

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

§ 59.771. Rooms and compartments.

(a) *Starter room.* Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. Necessary precautions shall be taken to prevent contamination of the starter, of the room, equipment and of the air therein.

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

(c) *Drying room.* If cheese is to be paraffined, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Suitable temperature and humidity control facilities shall be provided.

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

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

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

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

§ 59.772. Equipment and utensils.

(a) *General construction, repair, and installation.* Equipment and utensils necessary to the manufacture of cheese and related products shall meet the requirements of § 59.704 (relating to equipment and utensils). For other equipment the requirements in this section shall be met.

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

(c) *Cheese vats.* Requirements shall be as follows:

(1) The vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16-gauge stainless steel or other equally corrosion resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The

liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket, when metal, shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

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

(3) Copper Swiss kettles will be acceptable and need not be equipped with outlet valves.

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

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

(f) *Hoops and followers.* The hoops, forms, and followers shall be constructed of stainless steel or heavy tinned steel. If tinned, they shall be kept tinned and free from rust. Hoops, forms and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

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

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

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

§ 59.773. Operations and operating procedures.

(a) *Cheese from pasteurized milk.*

- (1) If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161 F for not less than 15 seconds, or equivalent pasteurization process approved by the Secretary.
 - (2) HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45°F or lower until time of setting.
- (b) *Cheese from unpasteurized milk.* If the cheese is labeled as “heat treated,” “unpasteurized,” “raw milk,” or “for manufacturing,” the milk may be raw or heated at temperature below pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45°F or lower until time of setting.
- (c) *Whey disposal.* Disposal shall be as follows:
- (1) Adequate sanitary facilities shall be provided for the disposal of whey. If outside, necessary precautions shall be taken to minimize flies, insects, and development of objectionable odors.
 - (2) Whey or whey products intended for human food shall at all times be handled in a sanitary manner under this subpart as specified for handling milk and dairy products.
- (d) *Packaging and repackaging.* Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be practically free from mold and bacterial contamination.
- (e) *General identification.* Each bulk cheese shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number or name and address of manufacturer. Each consumer sized container shall be plainly marked with the name and address of the manufacturer, packer, or distributor, net weight of the contents, name of the product and other information that may be required.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING, AND PACKAGING
PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS**

§ 59.781. Equipment and utensils.

- (a) *General construction, repair, and installation.* The equipment and utensils used for the handling and processing of cheese products shall be as specified in § 59.704 (relating to equipment and utensils). For other equipment, the requirements in this section shall be met.
- (b) *Conveyors.* Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

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

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

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

§ 59.782. Operations and operating procedures.

(a) *Trimming and cleaning.* The natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surfaces, mold or unclean areas of another part which is unwholesome or unappetizing shall be removed.

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

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

(d) *Filling containers.* Hot fluid cheese from the cookers may be held in hot-wells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount

of product into the pouch or container in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

(e) *Closing and sealing containers.* Pouches, liners, or containers having product contact surfaces after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, so as to assure against contamination. Each container in addition to other required labeling shall be coded in a manner that is easily identifiable as to date of manufacture by lot or subplot number.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING, AND PACKAGING
EVAPORATED AND CONDENSED MILK**

§ 59.791. Equipment and utensils.

(a) *General construction, repair, and installation.* The equipment and utensils used for processing and packaging evaporated and condensed milk shall be as specified in § 59.704 (relating to equipment and utensils). All requirements for low acid can food products shall be met. For other equipment, the requirements of this section shall be met.

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

(c) *Fillers.* Both gravity and vacuum type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion resistant material. Certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Nonmetallic product contact surfaces shall meet the requirements for *3-A Sanitary Standards for Rubber and Rubber-Like Materials or for Multiple-Use Plastic Materials*. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

(d) *Batch or continuous incontainer sterilizers.* Batch or continuous incontainer sterilizers shall be equipped with accurate temperature controls and effective valves for regulating the sterilization process. The equipment shall be maintained to assure control of the length of time of processing and to minimize the number of damaged containers.

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

§ 59.792. Operations and operating procedures.

(a) *Preheat, pasteurization.* When pasteurization is intended or required by either the vat method, HTST method, or by the UHT method it shall be accomplished by systems and equipment meeting the requirements of § 59.704 (relating to equipment and utensils).

(b) *Sterilization.* The complete destruction of all living organisms shall be performed in one of the following methods:

(1) The complete in-container method, by heating the container and contents to a range of 212°F to 280°F for a sufficient time.

(2) By a continuous flow UHTST process at high temperature of 280°F and above for a sufficient time, then packaged aseptically.

(3) The product is first sterilized according to UHTST methods as in paragraph (2), then packaged and given further heat treatment to complete the sterilization process.

(c) *Filling containers.*

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

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

(d) *Aseptic filling.* A previously sterilized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The containers prior to being filled shall be sterilized and maintained in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

(e) *Storage.* Proper facilities shall be provided for the storage and handling of finished product.

[Next page is 61-1.]

59-108

(217704) No. 262 Sep. 96

Copyright © 1996 Commonwealth of Pennsylvania