

Regulation 61-34.1

Pasteurized Milk and Milk Products

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Statutory Authority:

S.C. Code Sections 44-1-140 and 44-1-150

Regulation History as Published in State Register			
Date	Document Number	Volume	Issue
May 27, 1983	208	7	5
June 27, 1986	627	10	6
January 22, 1993	1567	17	1
May 27, 2005	2926	29	5
June 26, 2015	4497	39	6
April 22, 2022	5033	46	4

SECTION I. Applicability of the Grade “A” Pasteurized Milk Ordinance, 2019 Revision

A. The following sections, appendices, and footnotes of the Grade “A” Pasteurized Milk Ordinance (PMO or Ordinance), 2019 Revision, apply in their entirety:

1. Section 4, Labeling;
2. Section 6, The Examination of Milk and/or Milk Products;
3. Section 7, Standards for Grade “A” Milk and/or Milk Products (including Items 1r through 19r, and 1p through 22p);
4. Section 8, Animal Health;
5. Section 9, Milk and/or Milk Products Which May Be Sold;
6. Section 10, Transferring; Delivery Containers; Cooling;
7. Section 11, Milk and/or Milk Products from Points Beyond the Limits of Routine Inspection;
8. Section 12, Plans for Construction and Reconstruction;
9. Section 13, Personnel Health;
10. Section 14, Procedures When Infection or High Risk of Infection Is Discovered;
11. Section 18, Separability Clause;
12. Footnotes; and
13. Appendices A through S.

B. The following associated documents of the Grade “A” Pasteurized Milk Ordinance, 2019 Revision, apply in their entirety:

1. Procedures Governing the Cooperative State - Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2019 Revision (Procedures);
2. Methods of Making Sanitation Ratings of Milk Shippers, 2019 Revision (Methods); and
3. Evaluation of Milk Laboratories, 2019 Revision.

C. The following provisions of the Grade “A” Pasteurized Milk Ordinance, 2019 Revision, apply with the additions, exceptions, and superseding amendments specified below:

1. Section 1, Definitions applies with the following exceptions:

- a. Definition YY, Regulatory Agency, shall be stricken, and the term “Regulatory Agency,” where used in the Pasteurized Milk Ordinance, 2019 Revision, shall be replaced with the term “Department.” The Department shall mean the South Carolina Department of Health and Environmental Control or its authorized representative.

b. Ordinance, as used in the Pasteurized Milk Ordinance, 2019 Revision, shall mean the provisions and appendices of the Pasteurized Milk Ordinance, 2019 Revision, as adopted by the South Carolina Department of Health and Environmental Control (“the Department”).

c. “... of ...”, as used in the Pasteurized Milk Ordinance, 2019 Revision, shall mean the state of South Carolina.

d. Cross-references to “Section 3. of this *Ordinance*” appearing in Section 5, Section 6, and Appendix N shall mean Section C.3 of this Regulation together with applicable portions of Section 3 of the Ordinance.

2. Section 2, Adulterated or Misbranded Milk and/or Milk Products, applies in its entirety with the following additions:

a. The following applies in addition to Section 2:

Milk and milk products shall be examined by the Department as often as may be necessary to determine freedom from adulteration or misbranding. The Department may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product which it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk or milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on milk or milk products by the Department, and neither such milk or milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department, except on order by a court of competent jurisdiction.

Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of milk and milk products, other than cultured products, is greater than 32.945°F (-0.525°C), the farm or plant owner or manager shall be notified that the milk or milk product apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, milking or processing operations may be observed, and samples will be collected and analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point standard from the individual farm or plant. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm or plant shall call for a two (2) calendar day permit suspension or equivalent.

When milk or milk products are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, they shall be placed under a hold order and additional samples analyzed. Milk or milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk or milk products are positive for drug residues, the milk or milk products shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Department shall determine the producer(s) responsible for the drug residue violation and immediately suspend the producer’s Grade “A” permit or equally effective measures shall be taken to prevent the sale or distribution of milk or milk products containing drug residues, and a penalty shall be imposed. Future pick-ups, sales, or distribution are prohibited until subsequent testing reveals the milk or milk product is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The Department may accept certification from the violative producer’s milk marketing cooperative or purchaser of milk as satisfying the penalty requirements. The

Grade “A” producer’s permit may be reinstated, or other action taken, to allow the sale of milk or milk products for human food, when a representative sample taken from the producer’s milk or milk products, prior to commingling with any other milk or milk product, is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection must be completed by the Department to determine the cause of the residue and actions that must be taken to prevent future violations including:

i. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Department.

ii. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C of the PMO.

When pasteurized milk or milk products are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis proves the product to be free from adulteration.

b. The following applies in addition to the Administrative Procedures part of Section 2:

When two (2) of the last four (4) samples of a pasteurized product are in violation of the milkfat or milk solids not fat standard for that product a warning letter shall be issued by the Department. When three (3) of the last five (5) samples are in violation, the Department shall suspend the permit.

3. Section 3, Permits applies with the following exceptions:

a. The second paragraph on page 17 of the PMO, 2019 Revision (paragraph beginning with “Upon notification”) shall not apply.

b. The following replaces the entire Administrative Procedures part of Section 3:

ISSUANCE OF PERMITS: Every milk producer, milk product producer, milk distributor, milk products distributor, bulk milk hauler/sampler, milk tank truck, milk transportation company, milk plant, receiving station, transfer station, and milk tank truck cleaning facility operator shall hold a valid permit prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this regulation. Permits shall not be transferable to other persons/locations or used by a person other than the permit holder. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler’s permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

While compliance with the requirements for Grade “A” condensed and dry milk products is necessary to receive and retain a permit for these products, it is not the intent of this Regulation to limit the production of a milk plant that condenses and/or dries milk or milk products to Grade “A” products.

The manufacture of ungraded products for other uses in milk plants operating under a permit for the manufacture of Grade “A” condensed and dry milk products is allowed under conditions specified in Section 7 of the Ordinance and whereby such products are processed, packaged, and stored separately. In

such cases, a second permit is required, which is issued with the understanding that ungraded products shall be handled in such a manner so as to avoid confusion with the Grade “A” production.

Either or both permits may be temporarily suspended for the violation of any applicable provision of this Regulation or the Ordinance, or revoked for a serious or repeated violation. Suspension of permits for violation of the sanitation Items of Section 7 is provided for in Section 5 of the Ordinance. In addition, the Department may, at any time, institute court action under the provisions of Section 6 of the Ordinance. There is no specific frequency for the issuance of permits. This should be in accordance with the policies of the Department and in agreement with those employed for the issuance of permits under this Regulation.

SUSPENSION OF PERMIT: The Department may temporarily suspend a permit whenever: it has reason to believe that a public health hazard exists; the permit holder has violated any of the applicable requirements of this Regulation or the Ordinance; the permit holder has violated its permit or an order of the Department, including but not limited to a hold order; the permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or the permit holder exhibits hostile behavior toward a representative of the Department during the performance of its duties. A permit suspension shall remain in effect until any violation has been corrected to the satisfaction of the Department.

The Department may, without warning, notice, or hearing, immediately suspend a permit when, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, cooling temperature standards, violation of drug residue test standards, or the presence of pathogenic organisms.

Following permit suspension, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased while the permit is suspended. A suspension of the permit shall remain in effect until the violation(s) and any imminent health hazard have been corrected to the satisfaction of the Department.

REVOCAION OF PERMIT: The Department may revoke a permit whenever the permit holder: has committed serious or repeated violations of any of the applicable requirements of this regulation, the Ordinance, a permit, or an order of the Department, including but not limited to a hold order; or has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this regulation, the permit may be revoked if any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.

Following permit revocation, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased.

REINSTATEMENT OF PERMITS: Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

When the permit suspension has been due to a violation of any of the bacterial, coliform, or cooling temperature standards, the Department, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the Department may issue a

temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7 of the Ordinance. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform, somatic cell count, and temperature. The Department shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of the Ordinance.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test, or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification, the Department shall make an inspection/audit of the applicant's facility, and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements. When the findings justify, the permit shall be reinstated.

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

When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, the Department may deny a new permit based upon past history, including previous enforcement, suspension, or revocation history. Any person whose permit is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this regulation, resulting in revocation of the permit for a second time, shall not be granted another permit for a period of five (5) years.

4. Section 5, Inspection of Dairy Farms and Milk Plants, applies in its entirety with the exception of:

a. Paragraph 3.c on page 22 in the PMO, 2019 Revision, applies in its entirety with the exception that it shall not apply to milk plants that are not Interstate Milk Shippers (IMS) listed.

b. The fifth paragraph on page 23 in the PMO, 2019 Revision (paragraph beginning with "One (1) copy") is replaced by the following: A copy of the inspection report will be provided, either electronically or in paper form, to the permit holder, manager, or other duly authorized representative.

c. The last sentence of the first paragraph on page 25 in the PMO, 2019 Revision (sentence beginning with "After receipt of a notice of violation") is replaced by the following: After receipt of an inspection report identifying a violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor shall have an opportunity to request extension of the time allowed for correction.

5. Section 7, Item 7p, Water Supply, applies in its entirety with the addition of the following:

At a minimum, the water system must meet the state requirements for a category 3 small water system.

6. The following replaces the language of Section 15, Enforcement, in its entirety:

a. This Regulation is adopted and enforced under the authority of S.C. Code Section 44-1-140 and Section 44-1-150. All applicable provisions of the Ordinance shall be enforced by the Department in

accordance with this Regulation and the *Grade "A" PMO*, with Administrative Procedures, current edition, as applicable.

b. Compliance with all provisions of the Appendices adopted in this Regulation shall be deemed a requirement of the Ordinance and this Regulation.

c. Any person found to be in violation of this Regulation or an applicable requirement of the Ordinance, in noncompliance with an issued permit, or in violation of an order issued by the Department shall be subject to civil monetary penalties, permit suspension, and/or permit revocation.

7. The following replaces the language of Section 16, Penalty, in its entirety:

Violations shall be punishable in accordance with S.C. Code Section 44-1-150. Each day of continued violation shall be a separate offense.

8. Section 17, Repeal and Date of Effect of the PMO, 2019 Revision, shall not apply.

9. Appendix T applies in its entirety with the exception that it shall not apply to milk plants that are not IMS listed.

10. The following additional language applies in accordance with the Footnotes in the Ordinance:

The Department regulates cottage cheese, dry curd cottage cheese, and reduced fat or low-fat cottage cheese under the terms of the Ordinance. The additional provisions specified in Footnotes 7 through 13 for regulatory agencies that regulate such products are hereby adopted and incorporated by reference into the relevant portions of the Ordinance and this Regulation.