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Document No. 4497

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑1‑140 and 44‑1‑150

61‑34.1. Pasteurized Milk and Milk Products

**Synopsis:**

The intent of R.61‑34.1, *Pasteurized Milk and Milk Product,* is to ensure consumers are receiving safe, high quality Grade “A” milk and milk products and to assure consumers the latest sanitation requirements are being met by the dairy industry. The regulation governs the manufacturing of pasteurized milk and milk products in South Carolina. The current R.61‑34.1 was derived from the U.S. Food and Drug Administration (FDA) Grade "A" Pasteurized Milk Ordinance, 2003 Revision.

R.61‑34.1 was last amended in 2005. Since that amendment, there have been changes in the milk and milk products industry, and updates to the FDA *Grade "A" Pasteurized Milk Ordinance (PMO)*, on which R.61‑34.1 is based. In the most recent FDA Grade "A" Interstate Milk Shippers (IMS) Program Triennial State Evaluation (FY 2011‑2013) report on the South Carolina Dairy Program, the current version of R.61‑34.1 was determined to be out of date and to not meet the minimum Grade "A" IMS Program requirements. FDA Memorandum of Information (M‑I‑03‑2012 ‑ Supplement 1), requires a state to adopt the *Grade "A" Pasteurized Milk Ordinance (PMO)* or have an equivalent regulation no more than six (6) years behind the current National Conference on Interstate Milk Shipments (NCIMS) and the PMO.

The South Carolina Dairy Program’s continued participation at the NCIMS depends on compliance with the PMO. The amendment will bring R.61‑34.1 into compliance with the most updated procedures of the NCIMS; specifically, in accordance with Sections VI and VII of the *Procedures Governing the Cooperative State ‑ Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments and the FDA Pasteurized Milk Ordinance, 2013 Revision*.

Through the FDA Cooperative Milk Safety Program and a Memorandum of Understanding (MOU) established on August 5, 1977 between the FDA and the NCIMS, the FDA requires a state’s dairy regulation be at least as stringent as the FDA *Grade "A" Pasteurized Milk Ordinance*.

In order for South Carolina milk producers and processors to continue the shipment of milk and milk products in interstate commerce and market their milk products as Grade “A,” it is essential to keep R.61‑34.1 updated with respect to the current edition of the FDA *Grade "A" PMO* and its associated documents. This overall amendment incorporates into R.61‑34.1 statutory changes so as to match the administrative appeals process pursuant to S.C. Code Ann. Section 44‑1‑60 (Supp. 2013).

A Notice of Drafting for this amendment was published in the *State Register* on March 28, 2014.

See the Section‑by‑Section Discussion of Amendment below and the Statements of Need and Reasonableness and Rationale herein.

Section‑by‑Section Discussion of Amendment

The Department of Health and Environmental Control, through statutory authority, may make, adopt, promulgate and enforce reasonable rules and regulations from time to time.

The Department has revised R.61‑34.1 in its entirety through adoption by reference with exceptions, information included in the most recent edition of the FDA *Grade "A" Pasteurized Milk Ordinance (PMO), 2013 Revision* and its associated documents. The Section‑by‑Section Discussion of Amendment of Regulation 61‑34.1 is provided to highlight the exceptions for South Carolina State Law and South Carolina specific regulatory requirements to meet these laws and regulation requirements, and the sections from the PMO being adopted by reference.

The FDA *Grade "A" Pasteurized Milk Ordinance, 2013 Revision*, may be accessed from the Internet at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm389905.htm, or a copy can be obtained by contacting the U.S. Food and Drug Administration, Milk Safety Branch, Division of Cooperative Programs, 5100 Paint Branch Parkway, College Park, MD 207403‑3835, and is also available for inspection at the DHEC, Environmental Quality Control, Bureau of Environmental Health Services, Division of Food Protection and Rabies Prevention.

This section‑by‑section information provides relevant details of the adoption by reference of the PMO, 2013 Revision, associated Procedures and Methods documents and the necessary exceptions by sections to the PMO where amendments for South Carolina specific law and regulatory requirements apply.

Correct Statutory Authority to: 1976 S.C. Code Section 44‑1‑140 and 44‑1‑150

**Adoption of the Grade “A” Pasteurized Milk Ordinance, 2013 Revision and Associated Documents**

**As published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, all sections, appendices and footnotes of the Grade "A" Pasteurized Milk Ordinance (PMO), 2013 Revision, along with the PMO associated documents are being adopted by reference with exceptions, and as written the PMO shall become R.61‑34.1 by this amendment.**

**The following sections, appendices, and footnotes of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision apply in their entirety:**

Section 4. Labeling, of the PMO, 2013 Revision, replaces Section IV. Labeling, of R.61‑34.1. Changes reflect bringing the regulation current and in accordance with applicable requirements of the Federal Food, Drug and Cosmetic Act (FFD&CA) and the Nutrition Labeling and Education Act through the PMO language updates.

Section 6. The Examination Of Milk And/Or Milk Products, of the PMO, 2013 Revision, replaces Section VI. The Examination Of Milk And Milk Products, of R.61‑34.1 to update to current language of the PMO.

Section 7. Standards For Grade "A" Milk And/Or Milk Products, of the PMO, 2013 Revision, replaces Section VII. Standards For Milk And Milk Products, of R.61‑34.1 with updates in Table 1 to include goat somatic cell counts numbers and also to include adding public health reasons related to Section 7.

Section 8. Animal Health, of the PMO, 2013 Revision, replaces Section VIII. Animal Health, of R.61‑34.1 to update to current PMO language and added language on determination that herd or stock are free of brucellosis by the development and implementation of a State administered brucellosis free herd certification program. It also includes adding public health reasons related to Section 8.

Section 9. Milk And/Or Milk Products Which May Be Sold, of the PMO, 2013 Revision, replaces Section IX. Milk And Milk Products Which May Be Sold, of R.61‑34.1 to update to current PMO language.

Section 10. Transferring; Delivery Containers; Cooling, of the PMO, 2013 Revision, replaces Section X. Transferring; Delivery Containers; Cooling, of R.61‑34.1 to update to current PMO language.

Section 11. Milk And/Or Milk Products From Points Beyond The Limits Of Routine Inspection, of the PMO, 2013 Revision, replaces Section XI. Milk And Milk Products From Points Beyond The Limits Of Routine Inspections, of R.61‑34.1 for language added to define acceptance of milk and milk products from outside the United States from foreign suppliers required to meet standards of the PMO on milk and/or milk products.

Section 12. Plans For Construction And Reconstruction, of the PMO, 2013 Revision, replaces Section XII. Future Dairy Farms, Milk Plants, Construction, Remodeling, Additions And Equipment Changes, of R.61‑34.1 to update to current PMO language for title change.

Section 13. Personnel Health, of the PMO, 2013 Revision, replaces Section XIII. Personnel Health, of R.61‑34.1 to update to current PMO language.

Section 14. Procedures When Infection Or High Risk Of Infection Is Discovered, of the PMO, 2013 Revision, replaces Section XIV. Procedures When Infection Or High Risk Of Infection Is Discovered, of R.61‑34.1.

Section 18. Separability Clause, of the PMO, 2013 Revision replaces Section XIX. Unconstitutionality Clause of R.61‑34.1.

Footnotes are adopted as written in the PMO, 2013 Revision without exception.

Appendices A through S are adopted as written in the PMO, 2013 Revision without exception.

**The following associated documents of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision apply in their entirety:**

Procedures Governing the Cooperative State ‑ Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2013 Revision (Procedures).

Methods of Making Sanitation Ratings of Milk Shippers, 2013 Revision (Methods).

Evaluation of Milk Laboratories, 2013 Revision.

**The following provisions of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision apply with the additions, exceptions, and superseding amendments specified below:**

**Section 1. Definitions**

Section 1. Definitions, of the PMO 2013 Revision replaces Section I. Definitions and Standards, of R.61‑34.1. Some definitions were amended for South Carolina specific regulatory identification in the PMO.

Amend definition: RR. Regulatory Agency: as defined in the PMO, to read:

 RR. REGULATORY AGENCY: The Regulatory Agency shall mean the State of South Carolina’s Department of Health and Environmental Control (“the Department”) or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*.

 Ordinance, as used in the Pasteurized Milk Ordinance, 2013 Revision, shall mean the provisions and appendices of the Pasteurized Milk Ordinance, 2013 Revision as adopted by the South Carolina Department of Health and Environmental Control (“the Department”).

**Section 2. Adulterated Or Misbranded Milk And/Or Milk Products**

Amend Section 2. with the addition of language from R.61‑34.1 (2005), to PMO, 2013 Revision, for South Carolina specific regulatory compliance and testing equipment use, as quoted below:

 “Milk and milk products shall be examined by the Regulatory Agency as often as may be necessary to determine freedom from adulteration or misbranding. The Regulatory Agency 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 Regulatory Agency, 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 Regulatory Agency, except on order by a court of competent jurisdiction.

 When the freezing point of milk and milk products, other than cultured products, is greater than ‑0.525oH (‑0.507oC), the farm or plant owner or manager shall be notified that apparently the milk or milk product contains added water. If a second violation of this freezing point standard occurs within two (2) years, an observed milking or operation of processing shall be conducted and samples analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point from the individual farm or plant. A violation of the determined freezing point for a specific operation by over three (3) percent within two (2) years of setting the standard shall call for a two (2) day permit suspension or equivalent.

 When milk is found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, it shall be impounded and additional samples analyzed. Milk found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk positive for drug residues, the milk 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 Regulatory Agency 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 of milk containing drug residues and a penalty shall be imposed. Future pick‑ups are prohibited until subsequent testing reveals the milk 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 Regulatory Agency 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 for human food, when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by The Regulatory Agency to determine the cause of the residue and actions taken to prevent future violations including:

 On‑farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.

 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.”

Amend Section 2. by adding language from R.61‑34.1 (2005), to PMO, 2013 Revision, for South Carolina specific regulatory compliance, under administrative procedures, as quoted below:

 “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 Regulatory Agency. When three (3) of the last five (5) samples are in violation, the Regulatory Agency shall suspend the permit.”

**Section 3. Permits**

Amend Section 3. – PMO, 2013 Revision, with deletion of second paragraph on page 16 of the 2013 PMO. The language, as quoted below, is not in compliance for South Carolina specific law and shall not apply as shown:

 “Upon notification, acceptable to the Regulatory Agency, by any person whose permit has been suspended, or upon application within forty‑eight (48) hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the Regulatory Agency shall within seventy‑two (72) hours proceed to a hearing to ascertain the facts of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.”

Amend Section 3. – PMO, 2013 Revision, under Administrative Procedures, Suspension of Permit on page 17 of the 2013 PMO with language from R.61‑34.1 (2005), that complies with South Carolina specific law.

The following part under **SUSPENSION OF PERMIT** as written in the PMO, 2013 Revision shall not apply, and as quoted below, was deleted:

 “The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided:

 1. If the monetary penalty is due to a violation of the bacterial or cooling temperature standards, the Regulatory Agency shall conduct an inspection of the facility and operating methods and make the determination that the conditions responsible for the violation have been corrected. 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 in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this Ordinance.

 2. If the monetary penalty is due to a violation of the somatic cell count standard, the Regulatory Agency shall verify that the milk supply is within acceptable limits as prescribed in Section 7 of this 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 in order to determine compliance with the appropriate standard as determined in accordance with Section 6 of this Ordinance.”

The following part was added under **SUSPENSION OF PERMIT**, and as quoted below, shall apply:

 “When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.

 When the permit suspension is due to violations other than bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative is notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with the Department. If no request is made in thirty (30) days, the permits shall be suspended until the violations are corrected.

 The Department may without warning, notice, or hearing suspend a permit when an imminent health hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards. Following permit suspension, all manufacturing operations shall immediately cease.”

**ISSUANCE OF PERMITS**, and **REINSTATEMENT OF PERMITS** remain the same and applies as written in the PMO, 2013 Revision under Administrative Procedures.

**Section 5. Inspection Of Dairy Farms And Milk Plants**

Amend Section 5. – PMO, 2013 Revision, on page 22 of the PMO, fifth paragraph down, reword to read:

 One (1) copy of the inspection/audit report shall be provided to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request.

**Section 15. Enforcement**

Amend Section 15. Language from R.61‑34.1 (2005), to PMO, 2013 Revision, language for South Carolina specific law, with the addition of the following:

 This Regulation is issued and shall be enforced under the authority of Section 44‑1‑140, 1976 S.C. Code of Laws of South Carolina, as amended.

**Section 16. Penalty**

Amend Section 16. – PMO, 2013 Revision, by deletion of PMO language on page 134 under Section 16. The language is not in compliance for South Carolina specific law, and as quoted below, shall not apply:

 “Any person who shall violate any of the provisions of this Ordinance shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine not more than $ ... and/or such persons may be enjoined from continuing such violation(s). Each day upon which such a violation(s) occurs shall constitute a separate violation.”

Amend Section 16. – PMO, 2013 Revision, by addition of language from R.61‑34.1 (2005) that is specific for South Carolina law, and as quoted below, shall apply:

 “Violations of this Regulation shall be punishable in accordance with S.C. Code Section 44‑1‑150. Each day of continued violation shall be a separate offense.”

**Section 17. Repeal And Date Of Effect**

Section 17. – PMO, 2013 Revision, as written shall not apply. Upon approval by the General Assembly and publication in the State Register, the regulation will have the full weight of regulation as R.61‑34.1 and supersede the previous regulation of the same.

**Instructions:** Replace R.61‑34.1 in its entirety with this amendment.

**Text:**

**61‑34.1. PASTEURIZED MILK AND MILK PRODUCTS.**

Statutory Authority: 1976 S.C. Code Section 44‑1‑140 and 44‑1‑150

SECTION I. APPLICABILITY OF THE GRADE "A" PASTEURIZED MILK ORDINANCE, 2013 REVISION

A. The following sections, appendices, and footnotes of the Grade "A" Pasteurized Milk Ordinance (PMO), 2013 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;

 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, 2013 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, 2013 Revision (Procedures);

 2. Methods of Making Sanitation Ratings of Milk Shippers, 2013 Revision (Methods); and

 3. Evaluation of Milk Laboratories, 2013 Revision.

C. The following provisions of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision apply with the additions, exceptions, and superseding amendments specified below:

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

 a. The definition RR. Regulatory Agency applies with the following amendment:

 RR. **REGULATORY AGENCY**: The Regulatory Agency shall mean the State of South Carolina’s Department of Health and Environmental Control (“the Department”) or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*.

 b. Ordinance, as used in the Pasteurized Milk Ordinance, 2013 Revision, shall mean the provisions and appendices of the Pasteurized Milk Ordinance, 2013 Revision as adopted by the South Carolina Department of Health and Environmental Control (“the Department”).

 2. Section 2. Adulterated Or Misbranded Milk And/Or Milk Products applies with the following exceptions:

 a. The following applies in addition to Section 2:

 Milk and milk products shall be examined by the Regulatory Agency as often as may be necessary to determine freedom from adulteration or misbranding. The Regulatory Agency 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 Regulatory Agency, 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 Regulatory Agency, except on order by a court of competent jurisdiction.

 When the freezing point of milk and milk products, other than cultured products, is greater than ‑0.525oH (‑0.507oC), the farm or plant owner or manager shall be notified that apparently the milk or milk product contains added water. If a second violation of this freezing point standard occurs within two (2) years, an observed milking or operation of processing shall be conducted and samples analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point from the individual farm or plant. A violation of the determined freezing point for a specific operation by over three (3) percent within two (2) years of setting the standard shall call for a two (2) day permit suspension or equivalent.

 When milk is found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, it shall be impounded and additional samples analyzed. Milk found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk positive for drug residues, the milk 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 Regulatory Agency 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 of milk containing drug residues and a penalty shall be imposed. Future pick‑ups are prohibited until subsequent testing reveals the milk 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 Regulatory Agency 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 for human food, when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by The Regulatory Agency to determine the cause of the residue and actions taken to prevent future violations including:

 On‑farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.

 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 16 of the PMO, 2013 Revision shall not apply.

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

 **ISSUANCE OF PERMITS:** Every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck5, milk transportation company and each milk plant, receiving station, transfer station, milk tank truck cleaning facility operator shall hold a valid permit. 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 Ordinance 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 this 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 Ordinance, or revoked for a serious or repeated violation. Suspension of permits for violation of sanitation Items of Section 7 is provided for in Section 5. In addition, the Regulatory Agency may, at any time, institute court action under the provisions of Section 6. There is no specific frequency for the issuance of permits. This should be in accordance with the policies of the Regulatory Agency and in agreement with those employed for the issuance of permits under this Ordinance.

 **SUSPENSION OF PERMIT:** When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.

 When the permit suspension is due to violations other than bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative shall be notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with the Regulatory Agency. If no request is made in thirty (30) days, the permits shall be suspended until the violations are corrected.

 The Department may without warning, notice, or hearing suspend a permit when an imminent health hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards. Following permit suspension, all manufacturing operations shall immediately cease.

 **REINSTATEMENT OF PERMITS:** Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit.

 When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, 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 Regulatory Agency 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. 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 Regulatory Agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of this 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 Regulatory Agency 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.

 4. Section 5. Inspection Of Dairy Farms And Milk Plants applies with the replacement of language in the fifth paragraph on page 22 in the PMO, 2013 Revision with:

 One (1) copy of the inspection/audit report shall be provided to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request.

 5. Section 15. Enforcement applies with the addition of the following:

 This Regulation is adopted and enforced under the authority of S.C. Code Section 44‑1‑140.

 6. 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.

 7. Section 17. Repeal And Date Of Effect of the PMO, 2013 Revision shall not apply.

**Fiscal Impact Statement**:

There are no anticipated new costs associated with the implementation of this regulation to the State or its political subdivisions.

**Statement of Need and Reasonableness:**

The Statement of Need and Reasonableness was determined by staff analysis pursuant to 1976 S.C. Code Section 1‑23‑115(C) (1)‑(3) and (9)‑(11):

DESCRIPTION OF REGULATION:

Purpose: The intent of R.61‑34.1, *Pasteurized Milk and Milk Products,* is to ensure consumers are receiving safe, high quality Grade “A” milk and milk products and proper sanitation requirements are being met by the dairy industry. The regulation governs the manufacturing of pasteurized milk and milk products in South Carolina. The amendment of R.61‑34.1 will meet the current standards of the most recent edition of the United States Public Health Service, United States Food and Drug Administration (FDA) *Grade "A" Pasteurized Milk Ordinance (PMO), 2013 Revision*, inclusive of its associated documents.

In accordance with the FDA Cooperative Milk Safety Program and a Memorandum of Understanding (MOU) established on August 5, 1977 between the FDA and the National Conference on Interstate Milk Shipments (NCIMS), a state’s dairy regulation must be at least as stringent as the FDA *Grade "A" Pasteurized Milk Ordinance* to meet requirements for interstate commerce of pasteurized milk and milk products. South Carolina is a participant in the NCIMS. The amendment will bring R.61‑34.1 into compliance with the most up to date procedures of the NCIMS, specifically Sections VI and VII of the *Procedures Governing the Cooperative State ‑ Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* and the *Grade "A" Pasteurized Milk Ordinance,* 2013 Revision.

Legal Authority: The legal authority for R.61‑34.1 is 1976 S.C. Code Section 44‑1‑140.

Plan for Implementation: This amendment will take effect upon approval of the S.C. General Assembly and publication as a final regulation in the South Carolina State Register. A copy of the amended regulation will be available electronically on the Department’s website under the Environmental Health Services Category at http://www.scdhec.gov/Agency/RegulationsAndUpdates/ LawsAndRegulations/ and subsequently in the Code of Regulations of the South Carolina Code of Laws. As these are federal amendments, both the regulated industry and the regulatory community are already familiar with and are implementing the requirements.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

R.61‑34.1, *Pasteurized Milk and Milk Products,* was last amended in 2005. Since that amendment, there have been changes in the milk and milk products industry, and numerous revisions to the FDA *Grade "A" Pasteurized Milk Ordinance (PMO),* on which R.61‑34.1 is based. The revision of R.61‑34.1 represents an update and recognition of technological advances, milk plant environment changes, drug residue controls for food processing animals, and changes in production and processing equipment.

The revision of R.61‑34.1 will bring South Carolina into conformance with the PMO requirement adopted by other states, thereby permitting the movement of milk and milk products across state lines and to federal institutions. The incorporation and adoption of the PMO, 2013 Revision, into R.61‑34.1 translates new knowledge, technology and methodologies into effective and practicable public health practices.

In the most recent FDA Grade "A" Interstate Milk Shippers (IMS) Program Triennial State Evaluation (FY 2011‑2013) report on the South Carolina Dairy Program, the current version of R.61‑34.1 was determined to be out of date and to not meet the minimum Grade "A" IMS Program requirements. FDA Memorandum of Information (M‑I‑03‑2012 ‑ Supplement 1), requires that a State must have adopted the *Grade "A" Pasteurized Milk Ordinance (PMO)* or have an equivalent regulation no more than six (6) years behind the current National Conference on Interstate Milk Shipments and the PMO. In order for South Carolina milk producers and processors to continue the shipment of milk and milk products in interstate commerce and market their milk and milk products as Grade “A,” it is essential to keep R.61‑34.1 updated to comply with the current edition of the FDA *Grade "A" Pasteurized Milk Ordinance*.

The South Carolina Dairy Program’s continued participation at the NCIMS depends on compliance with the PMO. The amendment will bring R.61‑34.1 into compliance with the most up to date procedures of the NCIMS; specifically, in accordance with Sections VI and VII of the *Procedures Governing the Cooperative State ‑ Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments and the FDA Pasteurized Milk Ordinance, 2013 Revision*.

The Grade "A" PMO, Procedures, and Methods serve as the official documents setting forth the sanitation requirements governing the interstate shipment of milk and milk products to and from other states and to federal institutions. Failure to keep South Carolina’s milk regulation current and in conformance with other states’ requirements could result in South Carolina milk processors and producers not being allowed to ship milk and milk products in interstate commerce or to federal institutions.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated new costs associated with the implementation of this regulation. There is anticipated benefit to South Carolina’s environment and the health of its citizens as the intent of this regulation is to ensure consumers continue to receive safe, high quality Grade "A" milk and milk products based on the latest science. The amendment of Regulation 61‑34.1 to the most recent edition of the FDA *Grade "A" Pasteurized Milk Ordinance* will allow the regulation to conform to the current national standard. For the milk and dairy industry, the current edition of the FDA *Grade "A" Pasteurized Milk Ordinance* provides uniformity and consistency with pasteurized milk and milk products regulations nationally for interstate commerce.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

Implementation of the regulation should not compromise the protection of the environment or the public health. The regulation seeks to help ensure consumers are receiving safe, high quality Grade "A" pasteurized milk and milk products. The amendment of R.61‑34.1 to conform to the most recent edition of the FDA *Grade "A" Pasteurized Milk Ordinance* also seeks to provide effective means of reducing the risks of foodborne illnesses, thus protecting consumers and industry from potentially devastating public health consequences and financial losses.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated adverse effect on the environment if the regulation is not implemented. Not implementing the amendment to R.61‑34.1 will prevent the implementation of the latest sanitary standards for Grade "A" pasteurized milk and milk products in manufacturing and processing facilities, and will not provide the comprehensive approach to pasteurized milk and milk products safety required by the most recent edition of the FDA *Grade "A" Pasteurized Milk Ordinance*. Any decrease in sanitary standards may have a detrimental effect on the health of South Carolina’s citizens and visitors. Any delays in revising South Carolina’s regulation governing pasteurized milk and milk products will also likely result in penalties imposed on the program by FDA and NCIMS. These penalties would include removal of South Carolina’s milk and milk product producers and processors from the Interstate Milk Shipments (IMS) listing and the exclusion of South Carolina’s regulatory dairy program from participation and voting at the National Conference on Interstate Milk Shipments. This could have a negative economic impact on South Carolina’s milk producers and manufacturers.

**Statement of Rationale:**

The determination to amend this regulation was in response to FDA’s FY2011‑2013 Triennial State Evaluation report of South Carolina’s Grade "A" Interstate Milk Shipments Program dated January 15, 2014. In FDA’s FY2011‑2013 report as well as in the previous FY2008‑2010 report it was noted that South Carolina should adopt into law or by reference the most current edition of the FDA *Grade "A" Pasteurized Milk Ordinance (PMO)* and associated documents. The FDA *Grade "A" Pasteurized Milk Ordinance* is used as the sanitary regulation for pasteurized milk and milk products served on interstate carriers and is recognized by the Public Health Agencies, the milk industry, and many others as the national standard for milk sanitation. The FDA *Grade "A" Pasteurized Milk Ordinance* and its associated guidance documents for *Procedures and Methods*, adopted and uniformly applied, will continue to provide effective public health protection without being unduly burdensome to either the Department or the dairy industry. It represents a consensus of current knowledge and experience and thus represents a practical and equitable milk sanitation standard for the nation.