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Fast-Track Regulation Agency Background Document

Agency name	Board of Agriculture and Consumer Services
Virginia Administrative Code (VAC) citation(s)	2 VAC 5-501
Regulation title(s)	Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk
Action title	Amendments to adopt the U.S. Food and Drug Administration's 2017 Pasteurized Milk Ordinance (PMO) by reference and update Virginia-specific provisions.
Date this document prepared	May 31, 2019 Revised Statement of Final Agency Action and Detail of Changes Sections on December 12, 2019

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The *Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk* establishes storage and cooling standards for Grade A dairy farms and for milk transported from dairy farms. The standards address requirements relating to: milk cooling, milk storage tanks, pay purpose laboratories, dairy farms and plants, permits, milk house and associated facilities, milk facility construction, and milk cooling and storage tanks; cooling and storage requirements for milk in transport; and the sampling and measuring of milk produced and sold from dairy farms and facilities. The proposed changes are consistent with current relevant federal standards and the U.S. Food and Drug Administration's (FDA) 2017 revision of the Pasteurized Milk Ordinance (PMO).

The PMO serves as a guideline of minimum standards for all state regulatory programs. In certain instances, 2 VAC 5-501 provides additional guidance or establishes requirements that are not included in the PMO. The proposed changes include the formal adoption by reference of the 2017 PMO, the repeal of sections that are duplicative of the PMO, and amendments to certain requirements to ensure consistency with the PMO. The proposed changes also include the addition of a requirement that each bulk milk sampler contact the agency if he or she has not been evaluated within the last 18 months.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

"VDACS" means Virginia Department of Agriculture and Consumer Services.

"PMO" means the Grade "A" Pasteurized Milk Ordinance, 2017 Revision.

"State regulatory agency" means VDACS, the agency having jurisdiction and control over the matters embraced within this chapter.

"Dairy farm" means any place or premises where any cow, goat, sheep, water buffalo, or other mammal (except humans) is kept, from which cow, goat, sheep, water buffalo, or other mammal (except humans) any milk, dairy product, or milk product is sold or offered for sale for human consumption.

"Milk" means the whole, fresh, clean lacteal secretion obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo, or other mammal (except humans) intended for human consumption excluding that obtained before and after birthing, for such a period as may be necessary to render the milk practically colostrum free.

"Milk producer" means any person who operates a dairy farm and provides, sells, or offers any milk for human consumption.

"Bulk milk sampler" means any person who holds a permit issued by VDACS to collect, store, or transport official milk samples.

"Farm bulk cooling or holding tank" means any tank installed on a dairy farm for the purpose of cooling or storing raw milk.

"3-A Sanitary Standards" means the standards for dairy equipment and accepted practices formulated by the 3-A Sanitary Standards Committees representing the International Association for Food Protection, the U.S. Public Health Service, and the Dairy Industry Committee and published by the International Association for Food Protection.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On May 23, 2019, the Board of Agriculture and Consumer Services adopted amendments to 2 VAC 5-501, Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk and authorized staff to take any and all steps necessary to amend this regulation through a fast-track regulatory action.

On December 12, 2019, the Board of Agriculture and Consumer Services adopted an amendment to Section 50 of 2 VAC 5-501, Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk and authorized staff to take any and all steps necessary to amend this regulation through a fast-track regulatory action. The amendment adopted on December 12, 2019, results in the retention of Subsection A of 2 VAC 5-501, which was proposed for repeal in May 2019, as Va. Code § 3.2-5206(B)(2) directs the Board, if it adopts a PMO, to amend its regulation to require milk on a dairy farm to be cooled and stored at a temperature of 40 degrees Fahrenheit or less, but not frozen. The 2017 PMO requires milk on a dairy farm to be cooled to 45 degrees Fahrenheit.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Periodically, the FDA updates the PMO to ensure uniformity, the continued economic viability of the milk industry, and efficient and effective interstate milk transport. Virginia's milk-related regulations must reflect the requirements of the most recent edition of the PMO in order for Virginia dairies to ship milk interstate. The FDA audits states on a regular basis regarding the effectiveness of their enforcement and established policies and procedures. The FDA uses the PMO as a standard during its evaluation. If a state has not adopted the PMO or regulations similar to the PMO, it will not be able to achieve conformance with the audit. Failure to pass the audit could have serious consequences for both the regulatory program and the Virginia dairy industry.

The agency expects the proposed changes to be noncontroversial because they will bring the regulation in line with current federal standards, which were reviewed and commented on by industry at the time they were last updated, and regulations adopted by surrounding states.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

The Board of Agriculture and Consumer Services (Board) serves as the promulgating entity for this regulation. Section 3.2-109 of the Code of Virginia establishes the Board as a policy board and authorizes the Board to adopt regulations in accordance with the provisions of Title 3.2 of the Code.

Section 3.2-5206 of the Code of Virginia authorizes the Board to establish definitions and standards of quality and identity and to adopt and enforce regulations dealing with the issuance of permits, production,

importation, processing, grading, labeling, and sanitary standards for milk, milk products, market milk, market milk products, and those products manufactured or sold in semblance to or as substitutes for milk, milk products, market milk, or market milk products.

This section also authorizes the Board to adopt (i) any regulation or part thereof under federal law that pertains to milk or milk products, amending the federal regulation as necessary for intrastate application and (ii) any model ordinance or regulation issued under federal law, including the PMO and the U.S. Department of Agriculture's Milk for Manufacturing Purposes.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The proposed amendments will bring the regulation in line with current federal standards as established by the 2017 revision of the PMO. In addition to providing for consistency with current federal standards and existing Virginia regulations, these amendments will also ensure that Virginia maintains its own authority to oversee its state-level regulatory program. This will allow the regulatory program to continue to provide sufficient flexibility for the Virginia dairy industry while protecting the public's health, safety, and welfare by ensuring the safety and wholesomeness of all milk shipped from Virginia dairy farms.

Surrounding states have already updated their regulations to be consistent with the requirements governing the storage and transportation of milk established in the 2017 PMO. The proposed changes will facilitate interstate sales by Virginia milk producers by providing a level playing field with surrounding states with regard to the storage and transportation of milk.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The substantive changes are as follows:

1. The adoption by reference of the 2017 PMO as regulations applicable in the enforcement of the milk sanitation program of the U.S. Public Health Service, administered by the VDACS Dairy Program.

The primary amendments made to the 2013 PMO, on which 2 VAC 5-501 is currently based, that are included in the 2017 PMO are as follows:

- Extension of the time that tankers must be evaluated from 24 months to 24 months plus the remaining days in the month in which the inspection is due (revision made in 2015 PMO and retained in 2017 PMO).
- Clarification provided regarding electronic record keeping on farm bulk tanks (revision made in 2015 PMO and retained in 2017 PMO).
- Establishment of a definition for "universal" sample (i.e., any sample taken by any permitted sampler or regulatory personnel) and provisions regarding the evaluation of the collection of a universal sample (revision made in 2017 PMO).

- Clarification provided regarding the term "first use" and how long a tanker can remain washed and empty before being filled with milk again (revision made in 2017 PMO).
- 2. The repeal of provisions of the regulation that are duplicative of the requirements set forth in the 2017 PMO.
- 3. All instances of the phrase "state regulatory authority" were changed to "state regulatory agency."
- 4. The addition of a requirement that each bulk milk sampler contact the state regulatory agency if he has not been evaluated by the state regulatory agency within the last 18 months.
- 5. Revises the wording in 2 VAC 5-501-40 to align the regulations with the PMO and reflect current industry standards with regard to adequate lighting fixtures and the maintenance of weighing and sampling records.
- 6. Updates references to the "3-A Sanitary Standards for Farm Milk Storage Tanks, Document No. 30-01 (Sept. 1984)" with "3-A Sanitary Standards for Farm Milk Storage Tanks, Document No. 30-02 (July 2018)."
- 7. The addition of the requirement that each farm bulk cooling or holding tank shall be capable of registering the temperature of the milk in the tank before it reaches 20 percent of the tank's volume. The current regulation requires that such tanks be capable of registering the temperature of milk in the tank before it reaches 10 percent of the tank's volume. This change will align the regulation with the current minimum requirement in the 2017 PMO.
- 8. The addition of the requirement that each person who operates a dairy farm and installs a recording thermometer on the farm bulk cooling or holding tank shall maintain a minimum of a 30-day supply of unused recorder charts designed for the specific recording thermometer installed and shall maintain a minimum of the past six months of used charts for purposes of inspection. The current regulation requires that such charts be maintained for 60 days. This change will align the regulation with the current minimum requirement in the 2017 PMO.
- 9. Removes the requirement that milk must be delivered to a milk plant, transfer station, or receiving station within 24 hours of last pickup.

Issues

Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1. The primary advantage to the public is that the proposed regulatory change will allow for the safe storage and cooling of milk produced on dairy farms in Virginia and sold in intrastate and interstate commerce and will eliminate the confusion that could result from inconsistencies between state and federal standards. This ensures that the public is afforded the opportunity to consume a safe product and further ensures that the dairy industry is afforded additional flexibility regarding the storage of milk.
2. The primary advantage to the agency and Commonwealth is that the proposed regulatory change will ensure that the Commonwealth can adequately protect the public from milk cooled, stored, or

transported in an unsafe manner. The amendments that will bring Virginia’s regulation in line with the PMO will support the continued intrastate and interstate sales of milk on a more competitive basis, which will ultimately benefit Virginia’s economy.

This proposed regulatory action poses no disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

The proposed amendments adopt the 2017 PMO, which serves as a set of minimum standards and guidelines for state regulatory programs. In addition to the minimum requirements established in the PMO, 2 VAC 5-501 includes provisions that establish more detailed requirements in order to clarify areas of the PMO that are open to broad interpretation. This ensures more standardized parameters for inspectors to follow when conducting inspections and more consistency for Virginia farms.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

The proposed regulation will not particularly affect any other state agency, any specific locality, or any other entity.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources 	<p>There is no projected additional cost to the agency to implement the proposed amendments.</p>
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<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There is no projected additional cost to other state agencies to implement the proposed amendments.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The primary advantage to the agency and Commonwealth is that the regulation ensures that the Commonwealth can adequately protect the public from milk cooled, stored, or transported in an unsafe manner. The requirements will also result in the continued intrastate and interstate sales of milk on a more competitive basis, which will ultimately benefit Virginia's economy.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There are no projected costs, savings, fees, or revenues to localities associated with the proposed amendments.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The primary advantage to localities of the regulation is that it allows for the safe storage and cooling of milk produced on dairy farms in Virginia and sold in intrastate and interstate commerce. This ensures that the public is afforded the opportunity to consume a safe product and further ensures that the dairy industry is afforded additional flexibility regarding the storage of milk.</p>

Impact on Other Entities

<p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p>	<p>Milk haulers, which employ bulk milk samplers, are subject to the provisions of this regulation will be affected by the proposed amendments.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 10 permitted contract milk haulers, all of which the agency estimates are small businesses. These haulers employ a total of approximately 260 bulk milk samplers.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees;</p>	<p>Affected businesses will incur not additional costs as a result of the proposed amendments.</p>

<p>d) purchases of equipment or services; and e) time required to comply with the requirements.</p>	
<p>Benefits the regulatory change is designed to produce.</p>	<p>Economic benefits include consistent regulation with surrounding states, thus facilitating more effective and efficient integration into interstate commerce by Virginia’s dairy industry. Benefits also include the continued availability of safe and wholesome milk for intrastate and interstate sale.</p>

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no viable alternatives to the proposed regulatory action. This regulation must reflect the most recent version of the PMO in order to ensure that Virginia’s regulations are consistent with those adopted by surrounding states so that Virginia milk producers maintain the ability to compete with surrounding states with regard to interstate milk shipments. The agency considered the repeal and replacement of this regulation with a new regulation that simply adopts the 2017 PMO in its entirety. This alternative was rejected because Virginia maintains some state-level regulatory authorities that are more stringent than the federal standards outlined in the PMO. In such cases, the agency anticipates that the PMO will eventually include similar requirements, and the agency believes it would cause confusion to eliminate these provisions.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

Alternative regulatory methods were analyzed, and the agency feels that establishing less stringent requirements than those being currently proposed will result in Virginia regulations being inconsistent with current federal requirements and those of surrounding states, thus hindering the ability of Virginia to ship milk interstate. The PMO serves as a set of minimum required guidelines; thus Virginia is unable to adopt anything less stringent than the current PMO.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of

the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

Throughout the regulation, all instances of the phrase “state regulatory authority” are proposed to be replaced with “state regulatory agency” for consistency with the 2017 PMO, as the PMO uses the phrase “state regulatory agency.”

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
N/A	5	N/A	Adoption by reference of the 2017 revision of the federal Pasteurized Milk Ordinance. Virginia’s milk-related regulations must reflect the requirements of the most recent edition of the PMO in order for Virginia dairies to ship milk interstate.
10	N/A	Definitions	Definitions that are duplicative of those within the 2017 PMO were removed in order to prevent confusion.
30 A	N/A	Each bulk milk sampler shall be evaluated by the state regulatory authority every two years following the year after he receives a bulk milk sampler permit.	Decreased interval between state regulatory authority evaluations from two years to 18 months. Added requirement that each bulk milk sampler contact the regulatory agency if he has not been evaluated within the last 18 months. These proposed amendments are intended to help ensure a safe, wholesome milk supply.
30 I	N/A	Each person who holds a permit to produce milk shall store a minimum of the past 30 days bulk milk pickup tickets in his milkroom for use by the state regulatory authority if he ships his milk by bulk shipment.	Removed this section as the 2017 PMO does not establish a length of time bulk milk pickup tickets must before stored.
40 1	N/A	Requires that each person who operates a dairy farm shall provide (i) incandescent lighting fixtures of 100 watts or more capacity; or (ii) fluorescence lighting	Replaced existing requirement with requirement that each person who operates a dairy farm shall provide adequate lighting fixtures that produce at least 20 foot-candles of light and are located near, but not directly above, any farm bulk milk tank if one is installed.

		fixtures of 40 watts or more capacity in his milkhouse or milkroom; and (iii) lighting fixtures that are located near, but not directly above, any farm bulk milk tank if one is installed	Proposed amendment is intended to align the requirements with those of the 2017 PMO.
40 9	N/A	Requires that each person who operates a dairy farm store in his milk house or milk room the weighing and sampling receipt from each milk pickup for a minimum of the past 60 days if his milk is picked up by a bulk milk hauler	Replaced existing requirement with requirement that each person who operates a dairy farm maintain all records in compliance with Appendix H of the 2017 PMO. Amendments adopting the 2017 PMO are intended to ensure Virginia’s regulations are consistent with those adopted by surrounding states so that Virginia milk producers maintain the ability to compete with surrounding states with regard to interstate milk shipments.
40 10		Requirement that each person who operates a dairy farm shall sell his milk production only to a person who holds a milk plant permit issued by the state regulatory authority of Virginia or another state.	Replaced phrase “milk plant permit” with “permitted to process or manufacture milk or milk products” to clarify the existing requirement.
50	N/A	Requirements regarding temperatures to which milk must be cooled and limits to the length of time milk may be stored before it is sold.	Repealed the subsection regarding length of time a permitted grade A dairy farm may store milk that it sells as grade A milk as this requirement is included in the 2017 PMO, specifically, in Section 7, Item 10r.
60 B 1	N/A	Each farm bulk cooling or holding tank shall comply with the requirements contained in 3-A Sanitary Standards for Farm Milk Cooling and Holding Tanks, Document No. 12-11 (July 2012); or 3-A Sanitary Standards for Farm Milk Storage Tanks, Document No. 30-01 (Sept. 1984)	Reference to the 1984 revision of “3-A Sanitary Standards for Farm Milk Storage Tanks” has been updated to reference the 2018 revision of “3-A Sanitary Standards for Farm Milk Storage Tanks.”
60 B 2	N/A	Each farm bulk cooling or holding tank shall be equipped with an indicating thermometer capable of registering the temperature of the milk in the tank before it reaches 10 percent of the tank’s volume	Increased from 10 to 20 percent the allowed volume of milk in a tank before the required thermometer must be able to register the milk’s temperature in order to reflect Section 7, Item 18r of the 2017 PMO.

60 C 2 d	N/A	Each farm bulk cooling or holding tank shall be equipped with a recording thermometer that shall be installed on the farm bulk cooling or holding tank to record the temperature of the milk in the tank before the milk reaches 10 percent of the tank's volume	Increased from 10 to 20 percent the allowed volume of milk in a tank before the required thermometer must be able to register the milk's temperature to reflect Section 7, Item 18r of the 2017 PMO
60 C 5	N/A	Each person that operates a dairy farm and installs a recording thermometer on the farm bulk cooling or holding tank shall maintain a minimum of a 30-day supply of unused recorder charts designed for the specific recording thermometer installed and shall maintain a minimum of the past 60 days of used charts for purposes of inspection	Increased the timeframe for which a dairy farm operator with a recording thermometer maintains used recorder charts from 60 days to six months to reflect Section 7, Item 18r of the 2017 PMO
80 A	N/A	Section details requirements for contract or subcontract haulers	Removed subsection A as it is duplicative of Appendix B of the 2017 PMO.
80 B 32	N/A	Section details requirements for picking up and transporting of milk in a bulk milk pickup tanker	Removed subsection that requires that milk be delivered to a milk plant, transfer station, or receiving station within 24 hours of last pickup as the 2017 PMO does not prescribe a time within which milk must be delivered.
90	N/A	Section details requirements for a milk tank truck cleaning facility	Section repealed, as it is duplicative of various subsections of Section 7 and Appendix B of the 2017 PMO.