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Exempt Action Final Regulation Agency Background Document

Agency name	Board of Agriculture and Consumer Services
Virginia Administrative Code (VAC) citation(s)	2 VAC 5-490
Regulation title(s)	Regulations Governing Grade "A" Milk
Action title	Amendments to adopt the U.S. Food and Drug Administration's 2017 Pasteurized Milk Ordinance (PMO) by reference and revise state-specific provisions to clarify requirements.
Final agency action date	December 12, 2019
Date this document prepared	December 13, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, 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.

2 VAC 5-490, Regulations Governing Grade "A" Milk, details the standards that must be met and the processing requirements necessary for milk to be considered grade A in Virginia. Much of the language in the existing regulation originated from the requirements and guidelines set out in the 2013 Pasteurized Milk Ordinance (PMO), which is promulgated and periodically amended by the U.S. Food and Drug Administration (FDA). The FDA last revised the PMO in 2017, and Virginia's milk-related regulations must reflect the requirements of the most recent edition of the PMO in order for the Virginia dairy industry to ship milk interstate. This regulatory action proposes the adoption of the 2017 PMO by reference, the

repeal of text that is duplicative of the language in the PMO, and the revision of state-specific regulatory requirements to ensure clarity among regulants.

The PMO sets guidelines for minimum regulatory standards with which state dairy inspection programs must comply. The formal adoption of the 2017 PMO by reference will bring Virginia in line with most other states. The primary amendments made to the 2013 PMO, on which 2 VAC 5-490 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).
- Additional requirements established and clarification provided regarding the operation of Automatic Milking Installations and their computer systems' verification and functions (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).
- Establishment of requirements for the frequency of taking regulatory milk samples from grade A dairies that operate seasonally as opposed to year-round (revision made in 2017 PMO).

In addition to the minimum requirements established in the PMO, 2 VAC 5-490 also includes provisions that establish certain additional regulatory requirements. These state-specific provisions address Virginia's regulatory authority over adulterated or misbranded milk or milk products, permits, labeling requirements, standards, milk or milk products that may be sold, construction plans for dairy farms and milk plants, personnel health, the voluntary Hazard Analysis and Critical Control Point (HACCP) program, and interpretation and enforcement. The proposed amendments to such state-specific provisions are intended to clarify these requirements, ensure consistency, and eliminate duplicative language and are as follows:

- The addition of a definition for "summarily suspend" to clarify the enforcement process.
- The addition of language to clarify when producers that operate multiple milking herds or operate milking herds at separate locations must obtain multiple grade A permits.
- The addition of language establishing the agency's ability to administratively cancel any permit that has been under voluntary suspension for more than 24 months in order to ensure the accuracy of the list of Virginia dairy farms.
- The addition of a specific date by which dairy plants must submit all results of tests on samples of raw milk so that the Virginia Department of Agriculture and Consumer Services (VDACS) can submit required reports to the FDA in a timely manner.
- The addition of language to clarify the existing requirement that all bulk tanks shall be equipped with a temperature recording device.
- The addition of language to clarify that, in the event that the 2017 PMO conflicts with the requirements of Title 32.1 of the Code of Virginia regarding waterworks, private wells, and onsite sewage systems, Title 32.1 shall control to the extent of the conflict.

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, internal staff review, petition for rulemaking, periodic review, board decision, etc.). "Mandate" is defined as "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."

There is no mandate for the proposed regulatory change. The current regulation is based on the provisions of the 2013 PMO, and FDA last revised the PMO in 2017. Virginia's milk-related regulations must reflect the requirements of the most recent edition of the PMO in order for the Virginia dairy industry to ship milk interstate. As such, the proposed amendments adopt by reference the 2017 PMO.

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 December 12, 2019, the Board of Agriculture and Consumer Services adopted as final amendments to 2 VAC 5-490, Regulations Covering Grade "A" milk.

Periodic Review Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the proposed stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

This agency background document is not being used to report the result of a periodic review or a small business impact review.

Section 2.2-4007.1 E and F of the Code of Virginia:

1. There is a continued need for this regulation in order to ensure that Virginia milk producers and shippers comply with federal milk standards and with the standards established by the National Conference on Interstate Milk Shippers. Compliance with this regulation is required in order for VDACS to permit dairy farmers to sell milk to intra- and interstate markets and dairy processors to sell finished product grade A fluid milk and dairy products into intra- and interstate commerce.
2. The agency received the following public comments on the proposed revisions to the regulation.:

Commenter	Comment	Agency response
Eric Paulson, Executive Secretary, VA State Dairymen's Association (via mail)	Supports adoption of the 2017 Pasteurized Milk Ordinance (PMO)	This comment is relevant to the issue at hand and will be presented to and taken under consideration by the Board of Agriculture and Consumer Services.
Julie Henderson, Director, Division of Food and General Environmental Services, Virginia Department of Health	Requests additional amendments to 2 VAC 5-490	Section 5 has been amended to address the concerns raised in this comment.

3. The regulation is not overly complex; it is easily understandable and is closely aligned with the federal PMO.
4. This amendment adopts the 2017 PMO by reference and repeals duplicative language in the Virginia Administrative Code. A potential conflict was identified between the 2017 PMO and sections 164, 170, and 176.4 of Title 32.1 of the Code of Virginia, regarding waterworks, private wells, and onsite sewage systems. This potential conflict was alleviated by amending the proposed 2 VAC 5-490-5 to include language stipulating that, in the event of a conflict, the State Board of Health regulations pertaining to waterworks, private wells, or onsite sewage systems shall control to the extent of the conflict. The regulation, as amended, does not overlap, duplicate, or conflict with federal or state law or regulation.
5. The regulation was last amended on May 27, 2019, in response to a petition for rulemaking. Since that time, the nature of the dairy industry has not fundamentally changed, but the adopted amendments are necessary in order to ensure that Virginia conforms with the minimum regulatory standards for dairy programs, as determined by the FDA.