

Virginia Department of Planning and Budget **Economic Impact Analysis**

2 VAC 5-501 Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk

Department of Agriculture and Consumer Services

Town Hall Action/Stage: 5409 / 8793

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Summary of the Proposed Amendments to Regulation

The Board of Agriculture and Consumer Services (Board) proposes amendments to the *Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk* to conform the regulation to the 2017 revision of the U.S. Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), which is the most recent revision, and to better satisfy FDA audit requirements.

Background

The Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk establish 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 current and proposed regulations state that it is unlawful for any person who does not possess a permit from VDACS to: (i) operate a bulk milk pickup tanker; (ii) sample, measure, and collect milk from farm bulk milk cooling or holding tanks; (iii) sample, measure, or receive milk in cans or containers into any milk plant, receiving station, or transfer station; (iv) possess or transport official milk samples; (v) collect official milk samples from bulk milk pickup tankers or milk transport tanks; or (vi) collect official milk samples of pasteurized milk or pasteurized milk products from a milk plant.

The FDA's PMO is the basic standard used in the voluntary Cooperative State-United States Public Health Service/FDA Program for the Certification of Interstate Milk Shippers; a program participated in by all fifty states, the District of Columbia and U.S. Trust Territories. In practice, dairy farms and milk haulers must follow the rules within the PMO in order for Virginia milk to be accepted in other states and jurisdictions.

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 revision 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 negatively affect the Virginia dairy industry's ability to ship and sell milk out of state.

In certain instances, the regulation 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.

Estimated Benefits and Costs

The current regulation requires that each bulk milk sampler be evaluated by VDACS at least once during the first year after his permit is issued and a minimum of once every two years thereafter as a condition of permit renewal. Bulk milk sampler is defined as any person who holds a permit issued by VDACS to collect, store, or transport official milk samples. According to VDACS, with the current 24 month interval for inspecting samplers, the agency has found it difficult to satisfy FDA audits. Consequently, the Board proposes to decrease the interval between evaluations from the current two years to 18 months. Additionally, the Board proposes to require that the permittee contact VDACS if he has not been evaluated within the 18 months following the last evaluation.

VDACS believes that the 18 month requirement would help the agency better meet FDA requirements concerning the effectiveness of their enforcement and established policies and procedures. According to the agency, the evaluator only observes the permittee working, and does not stop them, ask any questions, or ask them to go anywhere that they were not already going to. Thus the proposed more frequent evaluations does not appear to produce cost for the permittees. The proposed requirement that the permittee contact the agency if he has not been evaluated within the last 18 months is a small additional burden. Overall, these proposed changes are slightly more stringent than is specified in the 2017 PMO, 1 but VDACS believes it is necessary to practically satisfy the FDA and not put approval of the Commonwealth's milk program at risk.

Proposed Amendments to Conform to 2017 PMO

As stated above, 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. Thus, any small increases in costs due to proposed changes to conform the regulation to the PMO very likely are outweighed by the benefit of the continued ability to ship milk out of state by abiding by the most recent version of the PMO.

Other than the changes to the bulk milk sampler evaluations, all other proposed amendments strictly conform the regulation to the 2017 PMO. According to VDACS, all regulated entities (milk haulers and dairy farmers) are already complying with the 2017 PMO. Although some proposed amendments are technical changes such as lighting and thermometer placement that are not likely to have substantive impact in practice, the following changes to the PMO and regulation may have had or could have some impact.

The current regulation states that each person who holds a permit to produce milk shall store a minimum of the past 30 days bulk milk pickup tickets in his milk room for use by VDACS if he ships his milk by bulk shipment. The Board proposes to repeal this requirement. This could reduce recordkeeping costs for dairy farmers, but VDACS believes most would likely keep the tickets as a business practice.

¹ More stringent does not violate the requirements of the PMO.

The current regulation requires that dairy farmers store in their 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. The proposed regulation allows an option to use electronic records, and specifies how VDACS would have access to the electronic records. Providing an electronic option could reduce costs for interested farmers, and allow easier access to the information for VDACS staff.

Each person who operates a dairy farm and installs a recording thermometer on the farm bulk cooling or holding tank must under the current regulation maintain a minimum of a 30-day supply of unused recorder charts designed for the specific recording thermometer installed and must maintain a minimum of the past 60 days of used charts for purposes of inspection. The Board proposes to increase the timeframe for which a dairy farm operator with a recording thermometer must maintain used recorder charts from 60 days to six months. This increases recordkeeping costs.

The existing regulation requires that milk be delivered to a milk plant, transfer station, or receiving station within 24 hours of last pickup. The Board proposes to eliminate this requirement. According to VDACS, this is no longer necessary with modern insulating technology. Additionally, it has not been practical to enforce. To the extent that haulers have followed this requirement, this proposed change would increase their flexibility and reduce costs.

The Board also proposes to adopt the 2017 PMO by reference. Beyond the changes addressed above, this extends 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; establishes 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; and provides clarifications.

Businesses and Other Entities Affected

The proposed amendments affect the 10 permitted contract milk haulers and 469 dairy farms in the Commonwealth.² In practice, the proposed amendments do not appear to

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² Data source: VDACS

substantively increase costs for these entities because VDACS reports that all regulated entities are already complying with the 2017 PMO.

Localities³ Affected⁴

The proposed amendments would affect localities that have dairy farms. The proposed amendments do not introduce costs for local governments.

Projected Impact on Employment

The proposed amendments do not appear to affect total employment.

Effects on the Use and Value of Private Property

By maintaining compliance with the latest version of the PMO and helping attain approval in FDA audits, the proposed amendments help ensure that milk produced in Virginia can be transported and sold beyond the Commonwealth's borders. This helps maintain the value of Virginia's dairy farms.

Small Businesses⁵ Affected:

VDACS estimates that all of the 10 permitted contract milk haulers and all 469 dairy farms are small businesses. However, the proposed amendments do not appear in net to adversely affect small businesses because VDACS reports that all regulated entities are already complying with the 2017 PMO.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and

³ "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

⁴ § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

⁵ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.