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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 5-531
Regulation title(s)	Regulations Governing Milk for Manufacturing Purposes
Action title	Fast-track action to amend 2 VAC 5-531 to ensure consistency and uniformity with 2 VAC 5-490, Grade "A" Milk Regulations, as well as applicable portions of the Food and Drug Administration's "Pasteurized Milk Ordinance" and the United States Department of Agriculture's guidance document entitled "Milk for Manufacturing Purposes and its Production and Processing."
Date this document prepared	February 9, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The *Regulations Governing Milk for Manufacturing Purposes* establishes minimum sanitary standards for manufactured grade raw dairy farms and dairy manufacturing plants. The standards address the safe and sanitary construction and operation of manufacturing facilities at the farm and processing plant, construction requirements, pasteurization requirements, standards for cheese and related dairy products, manufacture of raw milk aged cheese, handling of adulterated products, permits, labeling, sample testing requirements, good manufacturing practices, and requirements for small scale cheese manufacturing

plants. The current regulation is based on the United States Food and Drug Administration’s (FDA) Pasteurized Milk Ordinance, and the United States Department of Agriculture’s (USDA) guidance document, “Milk for Manufacturing Purposes and its Production and Processing”, which establishes recommended requirements for states. The proposed changes are consistent with the current relevant federal standards, the FDA’s 2013 revision of the Pasteurized Milk Ordinance and the 2011 revision of USDA’s guidance document, and Virginia’s *Regulations Governing Grade “A” Milk* (2 VAC 5-490 *et seq.*).

Substantive changes include:

- (1) 2VAC 5-531-10 Definitions. Updated dates and address information for reference documents.
- (2) 2VAC 5-531-50 Permits: Removed requirement for cryoscope (added water) tests conducted on permit holder’s milk for manufacturing purposes. Cryoscope testing is a milk quality issue and not a milk safety issue. Removal of requirement for this test brings the manufacturing regulation in line with the newly revised Grade “A” Milk regulation, 2VAC-5-490. Removed word "cryoscope" in other sections that refer to testing of milk for added water.
- (3) 2 VAC 5-531-70 Standards for Milk and Dairy Products: Removed details on well placement and requirements and referenced instead Appendix D of the Grade “A” Pasteurized Milk Ordinance, 2013 revision, for details on well placement and requirements. This change is to bring manufacturing regulation in line with newly revised Grade “A” Milk regulation, 2VAC 5-490.
- (4) Removed expired exemptions.
- (5) Updated information on Documents Incorporated by Reference.

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.

"CFR" means the Code of Federal Regulations.

Pasteurized Milk Ordinance (PMO), 2013 Revision: Federal ordinance defining milk and milk products and pasteurization and regulating the inspection of dairy farms and milk plants and the examination, labeling, pasteurization, distribution, and sale of milk and milk products. The PMO provides requirements for dairy farms and milk plants.

Milk for Manufacturing Purposes and its Production and Processing: Guidance document issued by the United States Department of Agriculture providing regulatory requirements for the production and processing of manufactured milk products on dairy farms and milk plants. This document serves as a companion document to the FDA’s Pasteurized Milk Ordinance.

Cryoscope: An instrument used for determining the temperature at which a liquid freezes. In milk samples the cryoscope test determines if any water has been added to raw milk as a way to increase the volume of milk sold.

Grade “A”: Any milk or milk product that complies with the standard of identity provided for in 21 CFR Part 131 to include fluid milk and milk products, yogurt, and cottage cheese.

Manufactured Grade Milk products: Any milk or milk product that is not defined in 21 CFR Part 131 to include standardized hard and soft cheeses (with the exception of cottage cheese), butter, and dairy based puddings.

3-A Sanitary Standards: the standards for dairy equipment and accepted practices formulated by the 3-A Sanitary Standards Committees representing the Dairy Industry.

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 11, 2014, the Board of Agriculture and Consumer Services adopted amendments to 2 VAC 5-531, *Regulations Governing Milk for Manufacturing Purposes*.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 3.2-109 of the Code of Virginia establishes the Board of Agriculture and Consumer Services (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 Pasteurized Milk Ordinance and the U.S. Department of Agriculture's Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The proposed amendments will bring the regulation in line with current federal standards as established by the 2013 revision of the Pasteurized Milk Ordinance and the 2011 revision of the U.S. Department of

Agriculture's (USDA) recommended requirements for milk for manufacturing purposes and processing plant requirements and with the Virginia *Regulations Governing Grade "A" Milk* (2 VAC 5-490 et seq.). The goal of these amendments is to make necessary updates to the Virginia Administrative Code to allow the agency to continue protecting the public's health, safety, and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth by ensuring the safety and wholesomeness of all milk and milk products sold or offered for sale for human consumption.

Milk is an excellent growth medium for most organisms including many pathogens. The fact that spoilage organisms and pathogens can grow in milk if they are present or introduced later by poor handling practices makes milk and milk products potentially hazardous if they are not properly processed, handled, packaged, and stored. The requirement for pasteurization or aging at specific temperatures in the case of certain cheeses as effective means of destroying pathogens in manufactured dairy products will reduce the risk of death and illness from consuming contaminated manufactured dairy products. The regulation also requires the plant to employ certain practices that prevent contamination after pasteurization or aging. The regulation is essential to ensure the safety of these products. The regulation also facilitates sales of Virginia-manufactured products by providing for the labeling of dairy products to prevent deception, establishing standards of identity, and providing a level playing field on which all persons may compete.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The proposed amendments are noncontroversial changes and will bring the regulation in line with current federal standards and the testing requirements of the current Virginia *Regulations Governing Grade "A" Milk*. None of the revisions add any new requirements. The removal of the requirement for cryoscope testing will not affect the safety of the milk supply or the finished products.

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 elimination of the requirement for cryoscope testing. Cryoscope testing is used to determine whether water was added to milk and addresses a milk quality issue not a milk safety issue. The elimination of the requirement for this test brings this regulation in line with the recently revised *Regulations Governing Grade "A" Milk*, 2 VAC 5-490, which no longer requires this test.
2. The removal of specific details on well placement and requirements. References to Appendix D of the Grade "A" Pasteurized Milk Ordinance, 2013 revision have been incorporated to provide requirements regarding well placement and related issues. This change will harmonize this regulation with the recently revised *Regulations Governing Grade "A" Milk*, 2 VAC 5-490.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

1. The primary advantage of the regulation is to aid in safely manufacturing dairy products through proven controls, testing methods, and sampling protocols. This ensures that the public is afforded the opportunity to consume a safe product.
2. The primary advantage to the agency and Commonwealth is that the regulation ensures that the Commonwealth can adequately protect the public. The requirements will also ensure the continued intrastate and interstate sales of manufactured products, which will ultimately benefit Virginia’s economy. Elimination of the cryoscope test will also allow the agency to focus on sampling and testing in areas that are food safety related.
3. The pertinent matter of interest to the regulated community, the public, and government officials is the allowance of permitted facilities to sell their safe, inspected, and properly labeled dairy products in intrastate and interstate commerce.

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 proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no requirements in the regulation that are more restrictive than applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

The proposed regulation will not impact any one locality more than another.

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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or

reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

The agency has considered the following alternatives.

Alternative regulatory methods have been analyzed, and the agency feels that abolishing or establishing less stringent regulations will result in unsafe dairy products. This will lead to foodborne illness outbreaks and expose the public to unnecessary danger.

In addition to compromising the safety of dairy products, the establishment of less stringent requirements would be inconsistent with existing federal requirements as well as the requirements of other states. This would jeopardize the ability of manufactured milk producers to ship their products interstate. If this scenario occurs, it would have a significant negative impact on Virginia’s dairy industry and the Commonwealth’s economy. Less stringent requirements would also result in manufactured dairy products that are not produced in environments that would ensure their optimal safety.

Reporting requirements within the regulations are minimal but essential to ensure that each facility produces a safe milk product. The elimination or reduction of records requirements and the frequency of reporting relative to the records such as those involving pasteurization, animal drug testing, or water quality testing for either large or small businesses would create an unacceptable health risk for the public and would likely lead to an increase in dairy related foodborne illnesses. Reporting requirements are already consolidated and simplified. Requirements in these regulations already reflect reasonable straightforward performance standards that are easily complied with. Performance standards apart from the subject regulatory requirement would likely result in unsafe dairy products.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>There is no projected additional cost to the state to implement the proposed regulation since there are no significant changes.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no projected costs to localities as all manufactured dairy farms and processing facilities are inspected and permitted by the state agency.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>The regulation affects any person or business that manufactures; packages; and sells cheese, butter, and other manufactured grade dairy products at wholesale and retail.</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>The agency estimates there are 40 businesses affected by the regulation. All of these businesses are small businesses.</p>

<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>There are no additional projected costs of the regulation for affected individuals and businesses because all entities are in compliance with the current requirements and the proposed amendments prescribe no additional requirements.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Benefits include the manufacture, packaging, and sale of safe and wholesome dairy products for intrastate and interstate sale.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

The following alternatives were considered:

One alternative considered was not to regulate milk for manufacturing purposes at all. This alternative was rejected because it could undermine public confidence in the healthfulness and quality of manufactured dairy products. With no regulatory oversight, the opportunity for the industry to produce and public to consume unsafe dairy products would be significant. This in turn would result in an increase in dairy related foodborne illness. Although an advantage is that the Commonwealth no longer has the expense of regulating this industry, the disadvantage is that there is an unacceptable level of risk to the consumer. Additionally, milk product producers would not be allowed to ship their products interstate. If this scenario were to occur, it would negatively impact Virginia’s dairy industry and the Commonwealth’s economy. This alternative, and the disadvantages that it would precipitate, would apply to both large and small businesses.

The second alternative considered was to provide less stringent requirements for small businesses than those that currently exist. However, the establishment of less stringent requirements would be inconsistent with existing federal requirements as well as the requirements of other states. Although there would be some level of regulatory oversight in place, less stringent requirements would still create an unacceptable level of risk to the consumer. Additionally, as noted above, milk product producers would not be allowed to ship their products interstate which would negatively impact the Virginia dairy industry and, by extension, the Commonwealth’s economy.

Public participation notice

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please 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.

The agency received no comments during the periodic review public comment period that began on August 11, 2014, and ended on September 1, 2014. The regulation is necessary for the protection of public health, safety, and welfare and is clearly written and easily understandable by both regulators and the industry. The agency has determined that there is a continued need for this regulation with some revisions. Without the regulation, the safety of manufactured milk products would be compromised. Although portions of the regulation are necessarily detailed to ensure dairy product safety, in general, the regulation is not complex and is easily understandable. There is minimal overlap with existing related state regulations and statutes. The minimal overlap occurs because the regulations and statutes all address various types of dairy products (i.e. both manufactured milk products and Grade "A" milk, which is addressed in 2 VAC 5-490, are required to be pasteurized). There is no significant duplication or overlap relative to existing federal statutes and regulations. This regulation is continually evaluated at a programmatic level to ensure that it is adequate to address issues and concerns within the manufactured milk industry. There have been no significant changes in technology, economic conditions, and other dairy related areas affected by the regulation since 2007 when the regulation was last amended.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulations and proposed amendments provide guidance and manageable, enforceable provisions for mitigating dairy related risk factors known to cause foodborne illness. It is a goal of all government food safety agencies within the United States to reduce the occurrence of foodborne illness and ensure that foods available to consumers are safe. Ensuring the safety of dairy products and reducing the level of foodborne illness directly impact the family and family stability by positively affecting a family's disposable income; improving family health; reducing medical care costs; reducing absences from the work place; and reducing mental, physical, and emotional pain and suffering.

The regulation may help increase economic self-sufficiency and disposable family income within the dairy community because it encourages small scale artisanal cheese and butter manufacturing in that the

regulation results in the protection of the safety and wholesomeness of these products without requiring that the manufacturers incur large start-up and equipment costs.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10		Definition of "Evaluation of Milk Laboratories" 1995 revision	Updated revision date for "Evaluation of Milk Laboratories", a document incorporated by reference. This will ensure uniformity with applicable portions of latest version of USDA Federal Model Document, "Milk for Manufacturing Purposes and its Production and Processing". This modification will clarify the proposed requirements.
10		Definition of "Official Methods" 2002 revision	Updated to 2012 revision of Official Methods of Analysis of AOAC International. This modification will clarify the proposed requirements.
10		"Uniform Methods and Rules: Bovine Tuberculosis Eradication" 1999 revision	Updated to 2005 version of USDA document titled "Uniform Methods and Rules: Bovine Tuberculosis Eradication". Contact information also updated. This modification will clarify the proposed requirements.
10		"Uniform Methods and Rules: Brucellosis Eradication" 1998 revision	Updated to 2003 version of USDA document entitled, "Uniform Methods and Rules: Brucellosis Eradication." This modification will clarify the proposed requirements.
10		3-A Sanitary Standards 2001 revision	Updated to 2013 revision of 3-A Sanitary Standards' document. "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
50 C 12		Requirement for cryoscope	Removed requirement for cryoscope

and 20		tests to be conducted on milk for manufacturing purposes	testing. This will not impact the safety of the milk supply or the quality of the milk for manufacturing purposes. Removal of requirement will decrease the cost to the agency's laboratory services for testing equipment, supplies and labor. It will also ensure that the regulation is consistent with the requirements of 2 VAC 5-490.
50 K		Development of recall plan by May 27, 2005	Removed date as all permitted facilities have active recall plans presently in effect and recall plans are a requirement to receive a permit for new facilities.
50 O 3		Animal drug testing requirements allow for plants to have until July 26, 2005, to comply with requirement of this section	Removal of date. All permitted manufacturing plants receiving Grade "A" milk presently comply with animal drug residue requirements. All future permitted facilities will be required to comply with requirement before receiving a permit to operate.
70 A 1		Standards for milk	Removed reference to "cryoscope". This will not impact the safety of the milk supply or the quality of the milk for manufacturing purposes.
70 B 1 e 1		Existing farms shall be exempt from requirement of subsection to provide separate milk house until July 1, 2006	Removal of date. All permitted manufacturing dairy farms presently comply with this requirement. All future permitted facilities will be required to comply with requirement before receiving a permit to operate.
70 B 1 h 1 and 2		Construction requirements of wells for dairy farms.	Removed requirements and added reference to construction standards of Appendix D of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision. The removal of specific requirements will allow for consistency across all regulations in the Commonwealth governing milk for Grade "A" and manufacturing purposes at the dairy farm.
70 C 2 o 7 and 8		Construction requirements of wells for manufacturing plants	Removed requirements and inserted reference to construction standards of Appendix D of the Grade "A" Pasteurized Milk Ordinance, 2013 Revision. The removal of specific requirements will allow for consistency across all regulations governing plant receiving and manufacturing Grade "A" and manufacturing milk.
90 2 and 4		Animal Health	Updated dates to newest revisions of the Uniform Methods and Rules for Tuberculosis and Brucellosis
110		Date of January 26, 2005, as date for compliance with regulation as per dairy products that may be sold	Removed date as all new businesses comply with regulation in order to obtain permit to do business in Virginia.
140		Interpretation and	Updated dates to newest revision of USDA

		Enforcement	document.
DIBR		Documents incorporated by reference	Updated dates to provide uniformity with current federal ordinances and state regulations. This modification will clarify the proposed requirements.