



Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Agriculture and Consumer Services
Virginia Administrative Code (VAC) citation	2VAC5-531
Regulation title	Regulations Governing Milk For Manufacturing Purposes
Action title	Amending 2VAC5-531 based on recommendations of the Attorney General's Government and Regulatory Reform Task Force
Date this document prepared	December 15, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The proposed amendments to the existing regulation will correct confusing language under one section concerning official notices issued to permit holders who violate the same requirement twice within a twelve-month period and will amend another section by using the same words and terms throughout and correcting citations to specific sections of the Code of Virginia to make the regulation more easily understood. The changes made are not substantive changes to the requirements of the existing regulation and do not create any new requirements or modify any existing requirements.

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 6, 2007 the Board of Agriculture and Consumer Services adopted the proposed 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 law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Sections 3.1-530.1 and 3.1-530.2 of the Code of Virginia provide the discretionary authority for the regulation. Section 3.1-530.1 of the Code of Virginia authorizes the Board of Agriculture and Consumer Services "...to establish definitions, 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, and those products manufactured or sold in semblance to or as substitutes therefor." Section 3.1-530.2 directs State Board of Agriculture and Consumer Services to be guided "...by those regulations recommended from time to time by the United States Department of Health, Education and Welfare and the United States Department of Agriculture" when adopting regulations for the purpose of sanitation and to prevent deception.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 goals of the regulation are to (1) protect the public's health and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth; (2) ensure the safety of manufactured dairy products through pasteurization and prevention of contamination, and (3) facilitate the sales of Virginia manufactured dairy products in intrastate and interstate commerce.

The regulation includes the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are intended for human consumption. The primary purpose of the regulation is to ensure the safety and wholesomeness of all milk and milk products sold or offered for sale for human consumption.

All milk and milk products have the same potential to carry pathogenic organisms. Numerous diseases of humans have been documented to be present in the milk of lactating mammals. Brucellosis and tuberculosis are two well-known and documented diseases which are capable of being spread from cows and goats to humans through their milk. Other common pathogens associated with milk and dairy products are: *Staphylococcus*, noted for its toxin production; *Streptococcus*, which causes strep-throat; *Campylobacter jejuni*, which infects the lining of the intestine and causes bloody diarrhea; *Escherichia coli*, which is responsible for causing bloody diarrhea and Hemolytic Uremic Syndrome; *Salmonella*, which also causes diarrhea; *Yersinia enterocolitica*, which causes severe abdominal pain; *Listeria monocytogenes*, which causes fever, vomiting, and can lead to still-births in pregnant women; and *Coxiella burnetii*, which causes Q fever. Some of these diseases can be fatal.

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 of 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 is consistent with the U.S. Department of Agriculture (USDA) recommended requirements for milk for manufacturing purposes and processing plant requirements.

The regulation 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?

Please note: If an objection to the use of the fast-track process is received within the 60-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 (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Each of the changes to the regulation were considered and recommended by the Attorney General's Government and Regulatory Reform Task Force, an initiative of Attorney General Robert F. McDonnell, and have been reviewed and approved by Governor Timothy Kaine's administration. All of the changes are needed to make the regulation easier to understand and "user-friendly". None of the changes add any new requirements or modify any existing requirements. The regulation is essentially the same as before, except now it is easier for the reader to understand. During the public comment period there were no comments received that would conflict with any of the recommendations of the Attorney General's Government and Regulatory Reform Task Force, and agency staff does not anticipate any controversy with any of the amendments.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

There are no substantive changes to the regulation.

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.

The primary advantage to the public and businesses of implementing the amended provisions is making the regulation easier to understand and user-friendly.

The primary advantage to the agency and Commonwealth is to foster voluntary compliance with the requirements because they are easier to understand and user-friendly.

There are no disadvantages to implementing the amended regulation.

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.

Because there are no substantive changes to the regulation there are no requirements being considered that are more restrictive than 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.

There are no localities that will be particularly affected by the proposed regulation.

Regulatory flexibility analysis

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.

The first alternative considered was to establish less stringent requirements; however this alternative was rejected because there is no known processing methods equivalent to pasteurization in the elimination of

all pathogens and the resulting reduction in risk to human health. The requirements for the prevention of contamination before and after processing and packaging would be the same no matter what pathogen reduction process was used.

The second alternative considered was to establish performance standards for manufactured dairy products that could be tested to determine safety; however, this alternative was rejected because reliance on sample testing is far less effective in ensuring product safety than the process of pasteurization. When properly performed, pasteurization works all the time for the entire product processed. If an alternative process was allowed based on testing parameters it could not be comparable to the effectiveness of pasteurization because testing is a hit or miss proposition. You could sample the same batch of product five times and recover varying numbers of bacteria in each sample. You are limited by the number of tests you can run, which organisms are tested for and the costs of the testing; whereas, pasteurization kills all pathogens every time. There is simply no comparison between sample testing and pasteurization.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	There is no projected additional cost to the state to implement the regulation since there are no substantive changes.
Projected cost of the regulation on localities	There is no cost to localities since entities processing milk for manufacturing purposes are not regulated by local government authority.
Description of the individuals, businesses or other entities likely to be affected by the regulation	The regulation affects any person or business who operates a dairy farm producing raw milk for manufacturing purposes or who manufactures, processes, packages and sells any manufactured dairy product (butter, cheese, powdered milk, condensed milk).
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 (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.	The agency estimates there are sixteen small businesses affected by the regulation.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There are no additional projected costs of the regulation for affected individuals and businesses because all entities are in compliance with the current requirements.

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.

During the periodic review, the Department considered the following alternatives.

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. In addition, many other states require all manufactured dairy products to have been inspected in the state in which they were manufactured. Without a government-sanctioned inspection program (as established through the statute and the regulation), Virginia-made butter, cheese, powdered milk, and other manufactured dairy products probably could not be sold in many other states, which would put Virginia manufacturers at a competitive disadvantage.

The second alternative considered was a program run by industry with some limited oversight by the Department to monitor and certify the program. This alternative places state oversight and resources in the plants where dairy products are processed. Under this system, each dairy processor is responsible for inspection, milk quality testing, field services, and record keeping for every dairy farm supplying them with milk.

The advantages of this alternative are that:

1. This option conforms to United States Department of Agriculture recommended requirements;
2. Fewer public resources are required to operate the program; and
3. Supervision of the supply of milk for manufacturing purposes can be maintained through a system of farm surveys and review of plant records.

The disadvantages to this alternative are as follows:

1. Currently there are no dairy farms in Virginia shipping manufactured grade milk or milk plants processing manufactured grade milk. If there were any dairy farms shipping manufactured grade milk the cost to industry processors of providing field services to producers in Virginia would be high because of the small number of farms. Because of these costs, field services and assistance to manufactured grade dairy farms would not likely be provided in a timely manner and industry inspection and enforcement activity would be focused more on quality issues than regulatory requirements. Higher quality services could be provided to these dairy farmers by Department staff currently providing inspection and enforcement activities for the Grade "A" dairy industry. In addition to customer services which could be provided, the Department believes compliance with regulatory requirements would be enhanced.
2. This option was established for the traditional dairy farm producing cow's milk for sale to dairy processors. This traditional type of dairy has disappeared in Virginia. Manufactured grade dairy farms have very limited options for selling their milk and are subject to high milk hauling rates compared to their counterparts in the grade "A" industry. The number of manufactured grade dairy farms has fallen below the critical number necessary to maintain a viable manufactured milk industry in Virginia shipping cow's milk. There is an adequate supply of grade "A" milk to meet all the needs of dairy processors making butter, powder, condensed milk, cheese, and other manufactured grade dairy products; and
3. The growth area in manufactured grade dairy farms and processing is with small-scale producers milking cows, goats, or sheep and producing specialty cheeses on the farm. Currently, sixteen

cheese processors are under inspection, with an additional one or two new facilities opening each year. These individuals typically do not purchase any milk from other sources and produce limited quantities of cheese for sale locally. Because these producer/processors are utilizing their own milk, the Department provides inspection services for the dairy farm operations and their associated dairy processing. Department inspectors spend significant time and resources providing advice and assistance to these small scale operations. The Department considers the small-scale production of cheeses to have significant growth potential in Virginia and wants to continue to provide support services to this developing industry.

A third alternative considered was a program that does not rely on the plants for implementing much of the regulation’s inspection and testing, and instead would have all inspection services and regulatory functions performed by Department personnel. Under this type of program, the Department would be responsible for performing all inspection, sampling, testing, enforcement, and regulatory activities for all dairy farms producing milk for use in manufactured dairy products and for all dairy processing facilities. This is the alternative endorsed by the Department. The Department strongly believes that existing personnel can provide the services needed by traditional dairy farms producing milk for manufacturing purposes as well as assisting the developing small-scale dairy processors. The regulations governing manufactured grade milk should apply to all persons making cheese and dairy products, not just to those made from cow’s milk. One important purpose of any regulation is to provide a level playing field on which all in the industry can compete equally.

Family impact

Please assess the impact of the proposed 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 regulation does not have an impact upon families.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
2 VAC 5-531-50		Authority to issue official notice to permit holder when violations exist more than twice in twelve months.	Section wording is modified to correct existing confusing language to make the intent of the section easier to understand.

2 VAC 5-531-140		Interpretation and Enforcement	Amended the section to use the same words and terms throughout and correct citations to specific sections of the Code of Virginia to make the regulation easier to understand.
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