



Virginia  
Regulatory  
Town Hall

## Periodic Review and Notice of Intended Regulatory Action Agency Background Document

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| <b>Agency Name:</b>        | Agriculture and Consumer Services   |
| <b>VAC Chapter Number:</b> | 2 VAC 5-530   |
| <b>Regulation Title:</b>   | Production, Handling, and Processing of Milk for Manufacturing Purposes and Establishing Minimum Standards for Certain Dairy Products to be Used for Human Food |
| <b>Action Title:</b>       | Amend   |
| <b>Date:</b>               | July 7, 2000  |

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

### Summary

*Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.*

A regulation that establishes: (1) the requirements to produce and sell cow's milk for manufacturing purposes; (2) the requirements to obtain a permit to process and sell cheese, butter, condensed milk, powdered milk, and similar products; (3) and minimum standards that dairy farms and dairy plants must meet in producing and processing milk for manufacturing

purposes, including pasteurization, cooling, storage, quality-control tests, packaging, and labeling requirements.

### Basis

*Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.*

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Sections 3.1-530.1 and 3.1-530.2 of the Code of Virginia (1950), as amended provide the statutory authority for the regulation. These sections do not require the Board of Agriculture and Consumer Services to adopt regulations governing milk for manufacturing purposes.

### Public Comment

*Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.*

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The Department published its notice in The Virginia Register of Regulations on April 10, 2000, advertising the opportunity to comment on this regulation pursuant to Executive Order Number Twenty-five (98). An informal advisory group was not formed for the purpose of assisting with this periodic review.

The Department received twelve comments from citizens who were opposed to making any change in the regulation. The current regulation applies only to milk and milk products made from cow's milk. These citizens are opposed to the regulation being amended to include goats or goat's milk. Issues of concern to these citizens include:

1. Many of these individuals have been milking goats and making cheese for sale to the public. Typically, sales occur from their farms, at farmers markets, directly to restaurants, retail outlets, and through the Internet. These individuals, and in some cases their customers, do not want the regulation changed to include goats or goats milk.
2. If the regulation were amended to include goats, some of these individuals contend they would be put out of business because they can not afford to comply with the public health and safety requirements that persons making cheese from cow's milk currently comply with.
3. These individuals contend that their cheese and dairy products do not constitute any risk to the consuming public. They cite the absence of reported public health outbreaks in Virginia as proof that they are correct in their assertions.

4. Many of these persons believe it should be a matter of choice for each person to decide what they choose to eat.
5. Two of these individuals allege that dairy products sold directly from the farm are superior in quality and safer than other commercially available products at retail.

In response to the concerns expressed by these citizens, the Department would like to emphasize that the most important reason for the manufactured milk regulations to exist is to ensure the safety and wholesomeness of milk and dairy products. Secondary functions of the regulation provide for the labeling of dairy products to prevent deception, establish standards of identity, and provide a level playing field on which all persons may compete.

The Department's position is that all milk and milk products have the same potential to carry pathogenic organisms. The fact that the milk came from a cow, sheep, goat, water buffalo or other mammal makes no difference. 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 monogytogenes, 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 regulation is essential to ensure the safety of these products.

The Department can find no justification for exempting certain individuals from complying with basic public health protections. The regulation of the production of safe and wholesome milk and dairy products sold to the public cannot become secondary to economic issues. Products that meet the requirements could continue to be sold at farms or farmers' markets.

The Department's position is that milk and dairy products which are not regulated or inspected do constitute a significant public health risk. The current system of disease reporting in the United States requires many persons to become sick at about the same time to be detected and reported. In some cases major outbreaks of illness associated with the consumption of soft cheeses have gone on for months before they were recognized by the public health system. There are however, numerous reports from around the United States documenting disease outbreaks caused by milk and dairy products made from cow's milk as well as goat's milk. There have been outbreaks of Brucella melitensis caused by the consumption of Mexican-style soft cheese in Colorado in 1973 and in Texas during 1983, 1985, and 1998. The outbreaks in 1983 and 1985 infected 43 people, hospitalized 21 people and resulted in one death. The Texas

Department of Health reported 16 cases of brucellosis in 1998 and fourteen of those individuals had consumed goat dairy products. *Brucella melitensis* is carried by goats and causes brucellosis in humans. In December 1999, Texas officials determined a herd of goats in Starr County was infected with *Brucella melitensis*. Texas officials destroyed the entire herd of 120 goats to prevent the spread of the disease to other animals and humans.

The Department's position is that the most compelling reason to include goats and goat's milk, as well as the milk from other mammals, under the regulation is food safety. Providing services to ensure the safety of milk and dairy products for consumption by the citizens of Virginia is a basic function of state government.

The Department can find no merit to the argument that including goat's milk products in the regulation would prevent cheese from being sold at the farm or farmers' market. Some goat cheese makers currently comply with the regulation and sell at farmers' markets.

The Department received ten comments from citizens who stated that if goats or goat's milk were to be included in the regulation, they would demand a total exemption from the requirements of the regulations for sales on the farm and at farmer's markets. The Department can find no justification for exempting certain individuals from complying with basic public health protections afforded by the regulation based on the location where their product is marketed.

The Department received comments from one milk marketing cooperative representing 216 Virginia producers, one statewide dairy producer association representing 706 producers, and two citizens supporting the regulation of all milk under the same requirements. The Department strongly supports the position that all milk, no matter the source, should be regulated under one regulation.

The Department received comments from two citizens supporting certain labeling requirements for cheese. They requested that all cheese be properly labeled and a requirement be established for labeling cheese which has been frozen. The Department believes that all food products should be properly labeled.

The Department received one comment from a citizen supporting the adoption of many specific requirements for persons making cheese from goat's milk including requirements for permitting, inspection, sampling, testing, facilities and equipment standards. The Department strongly supports the adoption of specific requirements tailored to the dairy industry and intends to model the regulation after the United States Department of Agriculture Recommended Requirements for Milk for Manufacturing Purposes and its Production and Processing. This federal model regulation forms the basis for regulating non-grade "A" milk and milk products in the United States.

The Department received one comment from a citizen supporting certain exemptions to some of the requirements for separate rooms and facilities in the regulation based on the size of the operation. This citizen recommended that the Department consider using gross receipts or number of units produced as methods of determining who would qualify for the exemptions. The

Department agrees that certain concessions need to be made for small-scale dairy producers and processors. The Department intends to propose exemptions from certain requirements which will not adversely affect food safety based on size considerations.

The Department received one comment from a citizen recommending that the Governor include one member on the Board of Agriculture and Consumer Services representing the dairy industry that is not associated with the cattle industry. The appointment of members of the Board of Agriculture and Consumer Services is not under the purview of the Department.

The Department received one comment requesting that common sense be used during the review of the regulation.

### Effectiveness

*Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.*

The regulation is effective in achieving its specific and measurable goals in regards to the regulation of cows' milk; however, the regulation does not apply to milk and milk products produced from goats, sheep, water buffalo, or from other mammals. The effectiveness of the regulation would be enhanced if the public health and safety requirements of the regulation extended beyond cow's milk to all milk and milk products no matter what the source of the milk.

The first specific goal of the regulation is to reduce the risk of death and illness from consuming contaminated manufactured dairy products. This is accomplished through the requirement of pasteurization or aging at specific temperatures in the case of certain cheeses as effective means of destroying pathogens in food products, including manufactured dairy products. The regulation also requires the plant to employ certain practices that prevent contamination after pasteurization or aging. The Department inspects the pasteurization equipment in each plant that processes manufactured dairy products. The Department also regularly collects samples of manufactured dairy products from each plant and tests these samples to make sure that proper pasteurization occurs. Records and procedures are evaluated to ensure proper aging.

The second specific goal of the regulation is to facilitate sales of Virginia-manufactured dairy products, both in-state and within interstate commerce. Measuring success in attaining this specific goal is difficult because it involves measuring intangibles, such as public perception, as factors in buying decisions. Using certain advertising and marketing techniques, such as focus groups and telephone surveys, may give indications of the importance of the intangibles, but the public sector is currently not structured to employ these techniques. Thus, it is probably infeasible to identify a measure that would accurately reflect the role of the regulation in facilitating sales. We would conclude that the second goal is specific, but progress in attaining it is not easily measured.

The regulation is clearly written and easily understood by the individuals and entities affected.

## Alternatives

*Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.*

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The agency has considered, during the course of this review, 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 agency to monitor and certify the program. This alternative is the basis for the present regulation. 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 arrangement 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 discussed as follows:

1. Currently there are only about forty dairy farms in Virginia shipping manufactured grade milk. Of these, eleven farms ship to one plant in Virginia and the rest ship to a processor in Tennessee. The costs to industry processors of providing field services to producers in Virginia is high because there are so few farms in Virginia and the farms that are here are split between intrastate and out-of-state plants. Because of these costs, field services and assistance to manufactured grade dairy farms is often not provided in a timely manner, or industry inspection and enforcement activity is limited and often focused more on quality issues than regulatory requirements. Higher quality services could be provided to these dairy farmers by Agency staff

currently providing inspection and enforcement activities for the Grade “A” dairy industry. In addition to customer services which could be provided, the Agency believes compliance with regulatory requirements would also be enhanced.

2. The current system was established for the traditional dairy farm producing cow’s milk for sale to dairy processors. This traditional type of dairy is fast disappearing 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 Agency believes that the number of manufactured grade dairy farms has fallen below the critical number necessary to maintain a viable manufactured milk industry in Virginia. The current system of regulating manufactured grade dairy farms does not take into account this trend in Virginia. 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;

3. The growth area in manufactured grade dairy farms and processing is with small scale producers milking goats, sheep, or water buffalo and producing specialty cheeses on the farm. Currently, twelve cheese processors are under inspection, with an additional two or three 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 Agency provides inspection services for the dairy farm operations and their associated dairy processing. Agency inspectors spend significant time and resources providing advice and assistance to these small scale operations. The Agency 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.

4. Small scale producers will have difficulty meeting all of the requirements included under the USDA recommended requirements for dairy farms and plants. USDA recommended requirements for dairy plants include provisions for separate rooms for pasteurization, raw milk receiving, packaging and handling, curing, and dry storage. Dairy plants are also required to provide employee lockers and dressing rooms along with bathroom facilities. Many of these requirements may be unduly burdensome for a small scale processor. The Agency believes that special requirements need to be developed for small scale processors which will ensure the safety of all foods produced but not require the extensive facilities under the USDA recommended requirements for dairy plants.

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 Agency personnel. Under this type of program the agency 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 Agency. The Agency 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.

### Recommendation

*Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.*

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The Agency recommends that the regulation be amended for the following reasons:

The regulation should include the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are intended for human consumption. The primary purpose for the regulation's existence is to ensure the safety and wholesomeness of all milk and milk products produced. The regulation currently covers only cow's milk, but there is significant production of dairy products offered for sale for human consumption made from the milk of goats, sheep, and water buffalo. All of the risks to human health associated with cow's milk are applicable to milk and milk products made from goat's milk, sheep's milk, or water buffalo milk. The same public health and safety measures need to be applied to all milk and milk products no matter what species of mammal the milk is from.

The regulation should be amended to be consistent with the USDA recommended requirements for milk for manufacturing purposes and plant requirements. In recent years the USDA recommended minimum quality standards applicable for milk used to make manufactured dairy products have changed. In addition, these recommended requirements include goat's and sheep's milk and provide that all milk received at processing plants must be screened for animal-drug residues prior to processing.

The regulation should be amended to include milk from goats and sheep to foster those developing industries in Virginia. The current regulation was written without consideration for goats and sheep, which have different needs and problems than cows. Not only are goats and sheep much smaller animals, they produce much smaller quantities of milk per animal. This volume problem makes it very expensive to transport the small quantities of goat's or sheep's milk produced on these dairy farms to processing plants. The lack of an economical alternative for transporting small volumes of milk makes it imperative that requirements be developed for such producers who want to process their own cheese and other manufactured dairy products for sale to consumers.

The regulation needs to be re-written in the active voice.

### Substance of Proposed Action

*Please detail any changes that would be implemented.*

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Raw milk quality standards at the farm level would be changed to conform to the USDA recommended requirements. The standard plate count requirement for unpasteurized milk would decrease from the current 1,000,000 cells/ml to 500,000 cells/ml. The somatic cell count standard for unpasteurized milk would decrease from 1,000,000 cells/ml to 750,000 cells/ml. A requirement that all milk be tested for the presence of animal drug-residues prior to processing would be established.

Persons milking goats, sheep, water buffalo, or other mammals (the milk from which is intended for human consumption) would fall under the manufactured milk regulations for the first time. These individuals would be required to obtain permits from the Agency and comply with inspection, facilities, and quality requirements contained in the regulations.

### Family Impact Statement

*Please provide a preliminary analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.*

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Unless otherwise discussed in this report, this regulation has no impact upon families.