



Virginia
Regulatory
Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Virginia Department of Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-531 (2 VAC 5-530)
Regulation Title:	Regulations Governing Milk for Manufacturing Purposes
Action Title:	Proposed/Repeal
Date:	September 10, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The purpose of the proposed regulatory action is to review the regulation for effectiveness and continued need, including the following: Amending the regulation to (1) include the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are intended for human consumption; (2) be consistent with the USDA recommended requirements for milk for manufacturing purposes and processing plant purposes; and (3) develop alternative requirements to foster the developing goats, sheep and water buffalo industries in Virginia.

Due to the extensive amendments to this regulation, it is recommended that 2 VAC 5-530 (Rules and Regulations Governing the Production, Handling and Processing of Milk for Manufacturing Purposes and Establishing Minimum Standards for Certain Dairy Products to be Used for Human

Food)) be repealed and 2 VAC 5-531, Regulations Governing Milk for Manufacturing Purposes adopted concurrently.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Sections 3.1-530.1 and 3.1-530.2 of the Code of Virginia (1950), as amended, (<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+3.1-530.1>) 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.

The Office of the Attorney General has certified that the Department has the statutory authority to promulgate the proposed regulation.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The goals of the proposed 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 proposed regulation will 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 of the regulation is to ensure the safety and wholesomeness of all milk and milk products produced. The existing regulation 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 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 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 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 proposed regulation is consistent with the U.S. Department of Agriculture (USDA) recommended requirements for milk for manufacturing purposes and processing plant requirements. In recent years, USDA recommended minimum quality standards applicable for milk used to make manufactured dairy products have changed. In addition, these recommended requirements include milk from goats and sheep and provide that all milk received at processing plants must be screened for animal-drug residues prior to processing.

The proposed 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.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The proposed regulation requires persons who produce and sell milk from goats, sheep, water buffalo, and other mammals (except humans) for manufacturing purposes or who manufacture and sell cheese, butter, condensed milk, powdered milk, and similar products manufactured from the milk from goats, sheep, water buffalo, and other mammals (except humans) to obtain a permit and comply with the requirements of the regulation for the first time. Persons producing and selling cow's milk for manufacturing purposes or who manufacture and sell cheese, butter, condensed milk, powdered milk, and similar products manufactured from cow's milk are currently required to obtain a permit under the existing regulation.

The proposed regulation contains provisions to foster the developing small-scale cheese processing industry in Virginia. The regulation defines "small-scale cheese plant" to establish which persons qualify for the special considerations and includes exemptions to certain requirements contained in the proposed regulation for small-scale plants processing cheese products.

The proposed regulation uses established standards of identity under the Code of Federal Regulations to define numerous standard and non-standardized cheeses and related products.

The proposed regulation also establishes the following:

Administrative procedures for the Virginia Department of Agriculture and Consumer Services to follow when summarily suspending a permit.

Requirement that manufactured dairy products in final package form for direct human consumption offered for sale in Virginia must have been: (1) pasteurized; (2) made from dairy ingredients that have all been pasteurized; or (3) in the case of cheese, aged above 35° F for a minimum of 60 days.

Specific requirements for permit holders manufacturing dairy products to develop and maintain a product recall plan.

Specific procedures for the Virginia Department of Agriculture and Consumer Services to follow when impounding adulterated or misbranded milk for manufacturing purposes or dairy products.

Specific conditions that allow the Virginia Department of Agriculture and Consumer Services to cancel, suspend, or revoke the permit of any person.

Procedures for private individuals to become certified by the Virginia Department of Agriculture and Consumer Services to inspect and test pasteurization equipment.

An animal drug-residue monitoring program that requires milk to be screened for beta lactam drug-residues prior to processing into dairy products.

A prohibition on the receipt of untreated sewage or septage on a dairy farm and on the feeding of unprocessed poultry litter or unprocessed manure from any animal to lactating dairy animals.

New labeling requirements and definitions for product sell-by dates, frozen and previously frozen cheeses, and the use of the term “fresh” when used to describe a dairy product.

Standards that apply to milk for manufacturing purposes for chemical residues, bacteriological load, somatic cell count, cryoscope, maximum length of time for milk storage on the farm, and temperature.

Standards that apply to dairy products offered for sale for chemical residues, coliform counts, and *Staphylococcus aureus* counts.

Specific requirements that facilities and equipment must meet in order to operate a dairy processing plant.

Specific facility and construction requirements for dairy farms producing milk for manufacturing purposes. Principle areas of change include eliminating installation of a milk storage tank in the milking parlor and adding water supply development and testing criteria.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term “issues” means: 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 include a sentence to that effect.

Public:

The proposed regulation will enhance safety and wholesomeness of manufactured dairy products by including milk for manufacturing purposes and manufactured dairy products produced from the milk of goats, sheep, water buffalo, and other mammals (except humans). The existing regulation covers only those dairy products manufactured from cow’s milk.

The proposed regulation will enhance public confidence in manufactured dairy products by requiring all dairy farms producing milk and all dairy plants manufacturing dairy products to obtain a permit prior to offering any products for sale. Currently, persons using the milk from goats, sheep, water buffalo, or other mammals (except humans) are not required to register with the Virginia Department of Agriculture and Consumer Services prior to offering dairy products for sale. Consumers purchasing dairy products at local farmers’ markets generally expect that the food products being offered for sale are safe, wholesome, and approved for sale to the public. This perception on the part of consumers that food products come from approved sources at farmers’ market’s is partially based on the markets location (usually on public property), with the market being sanctioned and operated by local government.

There are no disadvantages to the public.

Regulated Entities:

The proposed regulation will create a level playing field on which all dairy farmers and dairy processors can compete. Under the existing regulation, only dairy farmers producing milk for manufacturing purposes from cow's milk and dairy processors manufacturing dairy products from cow's milk are required to meet specific facility, equipment, inspection, and quality standards established for the production of manufactured milk and dairy products.

Under the proposed regulation all dairy farmers producing milk for manufacturing purposes must obtain a permit from the Virginia Department of Agriculture and Consumer Services and meet certain facility requirements. Under the existing regulation, dairy farmers currently producing milk from goats, sheep, water buffalo, or other mammals (except humans) are not required to obtain permits from the Virginia Department of Agriculture and Consumer Services or meet certain facility requirements.

Under the existing and proposed regulation dairy plants using cow's milk to produce dairy products must obtain a permit from the Virginia Department of Agriculture and Consumer Services and construct production facilities that provide separate rooms for receiving milk, pasteurization, packaging, dry storage, equipment, laboratory, employee locker rooms, and conduct quality control and laboratory testing programs. Under the existing regulation, persons using milk from goats, sheep, water buffalo or other mammals (except humans) to process dairy products are not required to obtain a permit from the Virginia Department of Agriculture and Consumer Services and may process their dairy products in their home without complying with any specific facility requirements for separation of processing steps in different rooms.

The proposed regulation will foster development of the small-scale dairy industry in Virginia by establishing a definition of a "small-scale cheese plant" and creating exemptions to certain facility and construction requirements for those persons who qualify. The requirements under the proposed regulation for separate rooms: (1) to receive milk; (2) for employees to change their clothes; (3) to operate a laboratory; (4) for paraffining cheese; (5) for rindless block wrapping; (6) for curing cheese; (7) for cleaning and preparing bulk cheese; and (8) for cutting and wrapping cheese are not applicable to a "small-scale cheese plant" if they conduct their cheese processing operations one step at a time in a single room. The provisions for separate rooms are based on prevention of cross-contamination of dairy products caused by conducting multiple operations in the same room at the same time. If operations are conducted one step at a time, sanitation and product safety are maintained. Creating exemptions to facility requirements that do not affect the safety or wholesomeness of dairy products significantly reduces the cost of entering the business of cheese production.

Persons wishing to establish a small-scale cheese plant will find it easier to obtain financing and insurance because their operations would be permitted, inspected, and their products would be tested by the Virginia Department of Agriculture and Consumer Services. Financial institutions and insurance companies consistently want assurances that businesses they lend money to or insure are in compliance with regulatory requirements and under inspection.

The proposed regulation will facilitate sales of manufactured dairy products because many retailers require that any person supplying products to their store must be under inspection, have adequate insurance, and are in compliance with regulatory requirements. The proposed regulation makes it easier for a person to prove that they are in compliance with regulatory requirements because they will have a permit and inspection records to use for this purpose. The proposed regulation is also consistent with federal requirements to ship products in interstate commerce, allowing producers of dairy products access to markets inside and outside Virginia.

The existing traditional cow dairy industry will be better protected from economic harm due to public health incidents associated with dairy products made from the milk of goats, sheep, water buffalo, or other mammals (except humans). When consumers learn of public health outbreaks associated with milk and dairy products, they tend to avoid purchasing and consuming all similar dairy products for a period of time. Public health incidents associated with milk or dairy products made from goats, sheep, water buffalo or other mammals (except humans) tend to negatively impact sales of similar products made from cow's milk.

The primary disadvantage to the regulated entities is that those persons producing milk from goats, sheep, water buffalo, or other mammals (except humans) or producing manufactured grade dairy products from the milk of goats, sheep, water buffalo, or other mammals (except humans) would come under the proposed regulation for the first time. The Virginia Department of Agriculture and Consumer Services is aware of fifteen persons in this category. Five of these operations are considered in compliance with the proposed regulation. Two of these operations have voluntarily ceased sale of all food products to avoid inspection by the Virginia Department of Agriculture and Consumer Services. One of these operations is in litigation with the Virginia Department of Agriculture and Consumer Services. Seven of the remaining operations would have to make facility and equipment improvements to comply with the requirements under the proposed regulation.

Agency:

All dairy farms producing milk and all dairy plants processing manufactured dairy products would be regulated under the same laws and regulations. Currently, the Virginia Department of Agriculture and Consumer Services regulates dairy farms producing cow's milk and dairy plants using cow's milk under the existing regulations governing milk for manufacturing purposes. Those persons producing milk from goats, sheep, water buffalo, or other mammals (except humans) or producing manufactured grade dairy products from the milk of goats, sheep, water buffalo, or other mammals (except humans) are regulated under the Virginia Food Laws.

The Dairy Inspection Program utilizes administrative processes to regulate permitted cow dairies and dairy processing plants using cow's milk. Inspectors conducting inspections under the regulations governing milk for manufacturing purposes also conduct inspections under authority of the grade "A" milk regulations and are trained specifically in the production and processing methods used within the dairy industry.

The Food Safety Program utilizes the criminal justice system to regulate the food industry in Virginia. Violations of the Virginia Food Laws or related regulations must be prosecuted in court. Food Safety Specialists have broad training in food processing and safety; but no specific training related to dairy products or milk production.

Because dairy inspection personnel are not trained in the policies and procedures utilized to conduct inspections, collect samples, and enforce the Virginia Food Laws, a Food Safety Specialist is assigned with a Dairy Inspector to form a joint inspection team. Likewise, a Food Safety Specialist is not trained in the specifics of milk production and dairy product processing. It takes both staff members together to possess the needed knowledge, skills, and abilities to perform adequate sanitary inspections of dairy facilities operated under the Virginia Food Laws.

This situation is causing the Virginia Department of Agriculture and Consumer Services to send two staff members to perform inspections when personnel resources could be utilized more effectively. The proposed regulation will eliminate the need to send more than one staff member to any dairy farm or dairy plant.

The proposed regulation would allow the Virginia Department of Agriculture and Consumer Services to regulate all dairy farms and dairy plants under an administrative process. Administrative processes are much more efficient and economical to enforce than prosecutions in court.

There are no disadvantages to the agency associated with the proposed regulation.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

There are no projected costs to the state to implement and enforce the proposed regulation. The Department currently has a Dairy Inspection Program which operates statewide and is able to assume responsibility for permitting, inspection and enforcement activities at all dairy farms producing milk for manufacturing purposes and dairy plants processing manufactured dairy products. There are currently about thirty-five manufactured grade dairy farms producing milk from cows that are not under routine inspection. All other dairy farms and dairy plants processing manufactured dairy products are already assigned to Dairy Inspectors for purposes of conducting joint inspections with Food Safety Specialists.

There is no projected cost of the proposed regulation on localities.

Individuals affected by the proposed regulation include any person: (1) who produces milk for sale from cows, goats, sheep, water buffalo, or other mammals (except humans); (2) who produces manufactured dairy products for sale from the milk of cows, goats, sheep, water buffalo, or other mammals (except humans); and (3) who markets unpasteurized milk for processing into manufactured dairy products.

An estimated fifty-nine individuals would be affected by the proposed regulation. The Department's best estimate of the cost to affected individuals is as follows:

- Thirty-five dairy farms producing cow's milk for manufacturing purposes. These individuals are basically in compliance with all requirements except two. First, the proposed regulation requires milk storage tanks to be installed in a separate milkroom. Approximately one half of the dairy farms currently have their milk storage tank installed in the milking parlor. The proposed regulation exempts currently operating dairy farms selling milk for manufacturing purposes on July 1, 2001 until July 1, 2006 from having to comply with this requirement. The Department estimates that the cost to construct a milkroom in which to store the milk tank and move the tank and related equipment would be between \$10,000 and \$15,000.

Second, the proposed regulation places new requirements on the location and construction of water supplies used to supply potable water for dairy operations. The proposed regulation exempts currently operating dairy farms selling milk for manufacturing purposes on July 1, 2001 until July 1, 2006 from having to comply with these requirements. The Department estimates that the cost to comply with the new provisions will range between \$500 to correct minor construction violations to as much as \$3,500 to replace an existing well which would be unable to meet the new requirements.
- Six dairy processing plants producing dairy products from cow's milk are in compliance with the provisions of the proposed regulation and would not incur additional cost.
- The Department estimates that thirteen dairy farms producing milk from goats, sheep, water buffalo, or other mammals (except humans) and producing manufactured dairy products would have to make improvements to the building in which they milk their goats, sheep, water buffalo, or other mammals (except humans). The modifications required would include providing concrete floors, doors for the entrance openings, windows, lighting, and screening out insects and rodents. These improvements are estimated to cost between \$3,000 and \$5,000. In addition, eleven of these individuals currently making cheese in their home kitchens would have to provide a separate cheese room for processing milk into cheese. The estimated cost of separate cheese rooms would be between \$10,000 and \$15,000 to construct. The total cost to these individuals would range from a low of \$3,000 to as much as \$20,000 depending on circumstances at each location.
- Two dairy farms planning to produce milk from goats, sheep, water buffalo, or other mammals (except humans) for sale to a dairy plant would be required to provide a separate milking facility and milk room to comply with the proposed regulation. The Department estimates the total cost to these individuals to be between \$10,000 and \$15,000.

- One milk marketing cooperative will be required to provide the Department with test results for bacteria, somatic cells, cryoscope, and animal drug-residues for compliance with the quality standards contained in the proposed regulation. The cost to provide these four tests results on each producer once a month is estimated to be approximately \$17.00 per sample or \$7,140 annually.
- Two dairy farms planning to produce cow's milk and manufacture dairy products would not incur any additional cost to produce cow's milk and manufacture dairy products because these individuals are currently regulated under requirements equivalent to those under the proposed regulation.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The proposed regulation contains many substantive changes and new sections when compared to the existing regulation. In general, substantive changes contained in the proposed regulation include: (1) the addition of the names of numerous cheeses with standards of identity established at the federal level; (2) the inclusion of milk and dairy products made from goats, sheep, water buffalo, and other mammals (except humans) for the first time; (3) a new section regulating cheeses that do not conform to an established standard of identity; (4) a new section establishing the authority and procedures the Department must use to impound milk and dairy products that are misbranded or adulterated; (5) a new section under permits establishing the Department's authority to suspend, cancel, or revoke the permit of a permit holder or to deny a permit to an applicant and the conditions under which the Department may take these actions; (6) new requirements under the permits section require each dairy plant processor to test all of their milk for beta lactam animal drug residues prior to processing; develop a product recall plan; provide certified laboratory testing services for animal drug residues; and freeze, package, label and store milk according to certain requirements; (7) new labeling requirements to include a sell-by date on all dairy products, labeling of frozen or previously frozen cheese, and the use of the term "fresh" when used to describe a dairy product; (8) new quality standards for bacteria counts, somatic cells, cryoscope, temperature, and storage time on the farm for milk for manufacturing purposes; (9) new quality standards for dairy products for bacteria count, coliform, pasteurization, aging, and *Staphylococcus aureus*; (10) numerous new detailed and specific requirements for construction and maintenance of milking facilities, milk storage rooms, and dairy plant processing areas; (11) new exemptions to facility and equipment requirements for small-scale dairy processors of cheese; (12) new animal health requirements for goats, sheep, water buffalo, and other mammals (except humans); (13) new and specific requirements governing employee health and a procedure to follow when infection is suspected; (14) a new section establishing which dairy products may be sold for human consumption; and (15) a new

section establishing administrative procedures and due process provisions for persons whose permit has been summarily suspended. Each of these areas will be more fully discussed in the order they occur in the proposed regulation.

Section 2 VAC 5-531-10 Definitions:

Certain definitions needed for the industry inspection and certification program under the existing regulation were eliminated from the proposed regulation. These terms included “acceptable milk,” “excluded milk,” “farm certification,” “fieldman,” “probational milk,” “quality control supervisor,” and “reject milk.” The proposed regulation does not rely on industry inspection of dairy farms producing milk for manufacturing purposes so these terms were no longer needed. The proposed regulation places the entire responsibility to permit, inspect, sample, and enforce the requirements of the proposed regulation on the Department.

Numerous definitions for cheeses with an established standard of identity at the federal level were added to the proposed regulation. Standards of identity for cheese define the ingredients and the processes that may be used to make a particular cheese and determine minimum moisture, percent fat, percent solids-not-fat, if pasteurization is required, minimum length of time for curing of the cheese, and specific labeling provisions for the cheese when in retail package form. Standards of identity ensure that consumers are able to purchase varieties of cheese with consistent flavor, texture, odor, and cooking properties.

Terms for “adulterated milk,” “adulterated dairy product,” “atmosphere relatively free from mold,” “cancel,” “CFR,” “cheese,” “dairy product,” “deny,” “drug,” “Evaluation of Milk Laboratories,” “fresh,” “Good Manufacturing Practices,” “milk grader,” “milk hauler,” “milkhouse,” “milk producer,” “milk product,” “misbranded milk,” “official laboratory,” “officially designated laboratory,” “official methods,” “other mammals,” “pasteurization,” “person,” “pit,” “process,” “producer,” “producer/processor,” “public,” “raw,” “re-process,” “revoke,” re-work,” “safe and suitable,” “sanitizing treatment,” “small-scale cheese plant,” “suspend,” “Uniform Methods and Rules; Bovine Tuberculosis Eradication-effective January 22, 1999,” and “Uniform Methods and Rules; Brucellosis Eradication-effective February 1, 1998” were added to the proposed regulation to clarify their use in various sections of the proposed regulation.

The terms “dairy farm” and “milk” were changed to include goats, sheep, water buffalo, and other mammals (except humans).

2 VAC 5-531-20 Non-standardized Cheese and Related Products

This new section was added to the proposed regulation to establish the authority to regulate cheeses that do not conform to a standard of identity and other similar products that may be manufactured in permitted dairy plants.

2 VAC 5-531-30 Adulterated or misbranded milk or dairy products.

This new section was added to the proposed regulation to define adulterated or misbranded milk or dairy products, establish the authority to effectively protect the public's health from these products, and establish a procedure to use when impounding adulterated or misbranded milk or dairy products.

2 VAC 5-531-40 Permits.

This new section establishes the requirement to obtain a dairy farm permit to produce milk for manufacturing purposes. The requirement to obtain a permit to manufacture and sell manufactured dairy products is maintained under the proposed regulation. For the first time the milk from goats, sheep, water buffalo, and other mammals (except humans) and the dairy products produced from that milk are included under the proposed regulation. The current regulation covers only the milk from cows and dairy products made from cow's milk. These changes are necessary to ensure that all milk for manufacturing purposes and dairy products are produced under similar conditions and subjected to inspection, sampling, and compliance with quality controls necessary to provide safe and wholesome dairy products for public consumption.

This new section establishes the Department's authority to cancel, suspend, revoke, or deny a permit issued under the proposed regulation. Twenty-six specific conditions are specified under which the Department may exercise the authority to cancel, suspend, revoke, or deny a permit. This section also identifies under which situations the Department may summarily suspend a person's permit. A summary suspension is one that takes effect immediately without the opportunity being provided for the permit holder to contest the suspension prior to its taking effect. Summary suspensions are used in situations where speed is necessary to protect the public from being exposed to a health hazard. These changes clearly define the scope of the Department's authority under its administrative process which is easily understood by citizens and permit holders.

This section also establishes the new ability of the Department to avoid suspending a person's permit if the milk or dairy products in violation are not offered for sale, provides for progressive penalties for repeat offenders of the same requirement, and establishes the authority of the Department to issue extended written notices of intent to suspend a person's permit beyond the period required to correct the violation in cases where a permit holder fails to maintain conditions on his dairy farms or in his dairy plant after repeated written warnings within the previous twelve months.

A new authority under this section allows private citizens to become certified by the Department to conduct inspections and tests of pasteurization equipment.

A new requirement under this section will require a dairy farm permit holder's milk marketing cooperative, broker, or person purchasing his milk to provide the Department with milk sample results if the dairy farm permit holder's milk is shipped out-of-state more than three times in any calendar month.

A new requirement is established for dairy plants to develop a recall plan and submit it to the Department for approval to ensure the permit holder will be able to effectively carry out his

responsibility to protect the public health and well-being from products that present a risk of illness, injury, gross deception, or are otherwise defective.

A new requirement for dairy processing plants to provide certified laboratory facilities and test all of their milk for beta lactam animal drug-residues is established under the proposed regulation. Testing and detection of animal drug-residues is essential to eliminate contaminated milk from being incorporated into dairy products for human consumption.

New requirements for dairy farms include:

A prohibition on accepting untreated sewage and septic tank waste on a dairy farm;

A prohibition on feeding animal manure or other body discharges to lactating dairy mammals;

A prohibition on storing milk in the farm bulk tank from mammals not milked on the dairy farm;

A prohibition on feeding any feed with aflatoxin residues greater than 20 parts per billion or selling any milk with an aflatoxin residue greater than 0.50 parts per billion;

A prohibition on the use of any room used for domestic purposes as part of the inspected dairy farm facility; and

New requirements for the freezing and storing of milk for use in dairy products.

2 VAC 5-531-50 Labeling

New provisions under this section of the proposed regulation require that all dairy products intended for sale to the final consumer must be marked with a sell-by-date to inform consumers about the expected shelf-life of the dairy product. Retailers of dairy products would be prohibited from offering for sale dairy products after the sell-by-date on the package.

New requirements for labeling dairy products with the terms “frozen”, “previously frozen”, and “fresh” have been established under this section.

2 VAC 5-531-60 Standards for milk and dairy products

The following quality standards for milk for manufacturing purposes and dairy products have been added or changed under the proposed regulation:

1. The maximum permitted bacteria count has been lowered from 1,000,000 cells per milliliter to 500,000 cells per milliliter for milk sold from individual dairy farms;
2. The maximum permitted bacteria count for commingled milk has been lowered from 3,000,000 cells per milliliter to 1,000,000 cells per milliliter;

3. The maximum permitted cryoscope test result (a measure of added water) has been established at .530 degrees Hortvet;
4. The maximum permitted somatic cell count (a measure of udder infection) for all species of mammals except goats has been lowered from 1,000,000 cells per milliliter to 750,000 cells per milliliter;
5. The maximum length of time milk for manufacturing purposes can be stored on the dairy farm prior to pickup for delivery to a processing plant has been established;
6. A new requirement for dairy products to be made from pasteurized milk or to be properly aged has been added;
7. New quality standards for the maximum levels of coliform organisms and *Staphylococcus aureus* organisms have been established; and
8. Standards for sediment content in milk for manufacturing purposes have been eliminated.

The proposed regulation more clearly identifies construction, equipment, facility and sanitation requirements for dairy farms and dairy plants than the existing regulation. For dairy farms producing milk for manufacturing purposes and dairy plants manufacturing dairy products a much more comprehensive list of requirements has been included that more closely reflect the federal model ordinance developed by the United State Department of Agriculture. Significant changes compared to the existing regulation under this section include:

1. The allowance under existing regulation for a dairy farm to have a combined milking parlor and milk room has been eliminated;
2. Dairy farms will be required to provide toilet facilities for the first time;
3. Dairy farm water supplies will have to meet new construction criteria for approval;
4. Dairy farmers will be required to clip the hair on the udder and tail of each milking mammal;
5. New requirements for the storage of animal drugs have been added; and
6. Requirements for dairy plants have been organized by general requirements for all dairy plants followed by specific additional requirements for dairy plants producing dry milk products, butter, cheese, process cheese, or condensed milk and similar products.

2 VAC 5-531-70 Requirements for small-scale cheese plants

This new section provides a number of exemptions for small-scale cheese plants to the facility, construction, testing, and equipment requirements for obtaining a permit. The exemptions

allowed do not compromise the ability of the small-scale cheese plant to produce safe and wholesome dairy products.

2 VAC 5-531-80 Animal health

All health requirements for bovines in the existing regulation have been maintained under the proposed regulation. Testing requirements for goats, sheep, water buffalo, and other mammals have been added for brucellosis and tuberculosis. A new section has been added to cover diseases which might affect humans other than brucellosis and tuberculosis.

2 VAC 5-531- 90 Construction plans for dairy farms and dairy plants

The requirement for prior approval of building and facility plans has been maintained under the proposed regulation.

2 VAC 5-531-100 Dairy products which may be sold

A new section specifying which dairy products may be sold for human consumption has been added to the proposed regulation. Dairy products will have to be made from pasteurized milk, pasteurized, or in the case of certain cheeses, aged a minimum of sixty days above 35 degrees Fahrenheit.

2 VAC 5-531-110 Personnel health

The prohibition of persons who have communicable diseases from working with milk and dairy products have been maintained under the proposed regulation.

2 VAC 5-531-120 Procedure when infection is suspected

New procedures have been established under the proposed regulation to deal with situations when there is reason to believe transmission of infection is possible by a person who may have a communicable disease. Procedures for handling dairy products that may have been handled by a person who may be affected by a communicable disease are also established.

2 VAC 5-531-130 Interpretation and enforcement

This new section provides that interpretations of the requirements of the proposed regulation shall be consistent with interpretations accorded with the model federal regulation on which it is based. Because the Administrative Process Act does not apply to summary actions taken by state agencies, an administrative process is established that the Department must follow when summarily suspending a person's permit. This process ensures a person's right to due process under the law.

Alternatives

Please describe the specific 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.

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 is the basis for the existing 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 as follows:

1. Currently there are only about thirty-five dairy farms in Virginia shipping manufactured grade milk. All of these dairy farms ship to a processor in Tennessee. The one manufactured milk plant in Virginia ceased accepting manufactured grade milk in March 2001 and now uses only grade "A" milk. The cost to industry processors of providing field services to producers in Virginia are high because there are so few farms in Virginia. Because of these costs, field services and assistance to manufactured grade dairy farms are often not provided in a timely manner, or industry inspection and enforcement activity are limited and often 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. 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 Department 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 shipping cow's milk. 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, fourteen 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 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.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The Department published a notice in The Virginia Register of Regulations on February 26, 2001 advertising the opportunity to comment on 2 VAC 5-530, Rules and Regulations Governing the Production, Handling and Processing of Milk for Manufacturing Purposes and

Establishing Minimum Standards for Certain Dairy Products to be Used for Human Food. An informal advisory group was formed for the purpose of reviewing the proposed regulation and to make recommendations to the Department relative to its requirements. The advisory group met on April 17 and May 15, 2001.

- **The Department received eighty-five comments from citizens requesting total exemptions from the proposed regulation for persons who: (1) milk their own animals (cows, goats, sheep); (2) make cheese from the milk of their own animals; and (3) offer cheese made from their own animal's milk for sale directly to consumers at their farm or at a farmers' market.**

Many of the commentors are customers of persons milking goats and making cheese and are concerned that the proposed regulation will prevent them from purchasing these same products in the future.

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' markets in Virginia. A number of goat cheese makers currently comply with inspection requirements and sell their cheeses on the farm, in farmers' markets, retail outlets, and through the internet. The proposed regulation does not restrict the sale of cheese in Virginia.

If the regulation were amended to include goats, sheep, and other animals, 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.

There are currently four small-scale cheese operations milking goats or sheep that are in compliance with the proposed regulation. These individuals have demonstrated the ability to provide facilities and equipment that meet the requirements of the proposed regulation and are successfully marketing their cheese to consumers at retail outlets, farmers' markets, over the internet, and at the farm. These operations have shown that the cost of complying with the proposed regulation are not prohibitive and can be considered a cost of entering the business of making and selling cheese. Each of these operations has survived and prospered over the past three years.

The Department considers anyone who sells cheese to be in business. One of the functions of the proposed regulation is to ensure every person who sells cheese is competing on a level playing field. Such is not the case today. Currently, anyone making and selling cheese from cow's milk is required to meet the requirements of the proposed regulation. Persons making and selling cheese made from the milk of goats or sheep are regulated under less specific requirements contained in the Virginia Food Laws. Within the group of people making and selling cheese from goat's milk there is a division between those who are in compliance and those who are not. This situation leads to disparities between the three groups considering their respective cost of production. The current situation provides some individuals with cost advantages over others making the same or similar products.

The proposed regulation is based on the need to ensure the safety and wholesomeness of milk and dairy products offered for sale in Virginia. The Department can not justify exempting any business from complying with the basic public health protections afforded by the proposed regulation for the economic benefit of any person. Every citizen expects and deserves to purchase safe and wholesome milk and dairy products.

Some of 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.

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, goats, and sheep 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'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.

Many of these persons believe it should be a matter of choice for each person to decide what they choose to eat.

For individuals to make a choice implies that they have some basic knowledge on which to base a decision. The Department believes that the average consumer does not possess the basic knowledge to be able to determine if milk and dairy products are safe. Less than three percent of the population lives on a farm or has any understanding of the processes required to produce milk and dairy products safely. Consumers also lack basic understanding of risk factors involved with sanitation, production and processing methods, packaging, handling, labeling, and distribution. The average consumer does not question the safety of food products offered for sale but expects them to be safe. Consumers assume food products are safe because their experience tells them so, not because of their knowledge of food safety.

Consumers also assume that products being offered for sale at farmers' markets or other places established by local government authorities are just as safe as products in grocery stores that come from inspected facilities. The fact that farmers' markets are sanctioned by local government gives people the impression that the food products offered for sale have been sanctioned by local government, when in fact, many of the products for sale may have had no inspection or oversight of any kind from government authorities.

Children are one group of consumers who have no choice. Children will consume what their parents or other adults provide them to eat. Children are unable to determine for themselves what is safe or unsafe to eat. Cheese and dairy products made from unpasteurized milk are associated with a high level of illnesses in disease outbreaks traced to dairy products. Children are often the victims of these diseases.

Some 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 stores.

The Department is unaware of any scientific evidence that supports the allegation that milk and dairy products sold directly from the farm are of superior quality or safer than commercially available products. Some individuals allege that because commercial dairy products are manufactured from the commingled milk from numerous dairy farms that they are more subject to contamination than similar products manufactured by a single farm. The Department believes that all milk and dairy products have the same potential risk of adulteration with pathogens or other organisms. The same steps needed to process milk and dairy products into safe and wholesome foods are necessary for both the individual dairy

farm and the large commercial processor. Where food safety is concerned, smaller does not equate with safer.

- **The Department received thirteen comments in support of allowing the sale of unpasteurized milk and unaged cheese made from unpasteurized milk.**

The issue of unpasteurized milk sales is not open for consideration under the proposed regulation. Another regulation, Regulations Governing Grade “A” Milk, 2 VAC 5-490 regulates the sale of unpasteurized milk in Virginia.

The Department does not believe the sale of unaged cheese made from unpasteurized milk is acceptable for public health reasons. Pasteurization of milk used in unaged cheese is essential to destroying any disease causing organisms that may be present in the milk prior to processing. Pasteurization is the only proven method to ensure the safety of unaged cheese products.

- **The Department received one comment expressing the concern that man-made treatments like pasteurization destroys the medicinal qualities of natural goat’s milk cheese. This commentor also expressed his desire to have all food which is subjected to man-made treatments labeled as “un-natural”.**

The Department is unaware of any scientific evidence supporting the medicinal qualities of unpasteurized goat’s milk cheese or its use in treating human disease. The Department does not believe it is reasonable to label every food product that has been processed in some manner from its original raw form at harvesting as “un-natural”. Labeling of all food products is not an issue under the authority of the proposed regulation.

- **The Department received one comment requesting that goat cheese not be regulated under the proposed regulation or that its sale be allowed.**

The Department agrees that sales of goat cheese should be allowed and the proposed regulation does not prevent the sale of goat cheese. The proposed regulation facilitates the sale of goat cheese and other dairy products by providing a system of permitting, inspection, and testing to ensure the safety and wholesomeness of these products.

- **The Department received one comment from the Virginia State Dairy Goat Association supporting the promulgation of the proposed regulation in compliance with the Administrative Process Act.**

The Department agrees and will comply with all aspects of the Virginia Administrative Process Act while promulgating the proposed regulation.

- **The Department received six comments in support of granting some exemptions to small-scale farmers while maintaining sanitary requirements under the proposed regulation.**

The proposed regulation contains a number of exemptions to equipment and facility requirements for small-scale cheese processors that do not affect the safety of the cheese and dairy products produced.

- **The Department received six comments in support of including the milk of goats, sheep, water buffalo and other mammals (except humans) under the proposed regulation. Commentors included the Virginia State Dairymen’s Association, a veterinarian, two current goat cheese processors, and two consumers.**

All milk possesses the potential to harbor pathogens and act as a vector for the spread of disease. Consumers have the right to expect that all dairy products are equally safe and wholesome to consume. The Department’s first priority is to protect the public health.

- **When determining the name of a cheese product the word “country” or “-like” should be allowed for those products made from goat’s milk that are traditionally defined as cow’s milk products, i.e.: cheddar cheese made from goat’s milk could be called “country cheddar” or “cheddar-like”.**

The standards of identity for cheese specify which cheeses may be produced from cow’s milk, goat’s milk, sheep’s milk, or water buffalo’s milk. Some cheeses can only be legally manufactured from cow’s milk while others can be made from the milk of goats, sheep, or water buffalo, or even with the milk from two or more of those species mixed together. These requirements are important to assure consistent flavor and texture characteristics for consumers. Proper labeling is important for products that move in interstate commerce. Current and proposed labeling requirements do allow alternative and creative names to be used to describe food products, as long as, the name used is not false or misleading and the food does not comply with a standard of identity. Under current requirements, a cheddar cheese made from goat’s milk could be labeled as “cheddar style-cheese made with goat’s milk” or “goat’s milk cheddar-style cheese.”

- **The definition of milk should be modified so that producers have the freedom to come up with new products. (i.e. “...legally provided for in 21 CFR or recognized as non-standard traditional products...”)**

The definition of milk mirrors the definition recommended by the United States Department of Agriculture in its recommended requirements. The purpose of the definition is to limit the nature of the products and processes that may be properly regulated under the proposed regulation. There are numerous products that may be made from milk including beverages, puddings, frozen desserts, and others that are better regulated under different requirements. The definition of milk does not limit the development of new products.

- **The definition of “milk product” is redundant and not needed.**

The definition of “milk product” is needed to define those products that are regulated under the grade “A” regulations as opposed to “dairy products” that are regulated under the proposed regulation.

- **The definition of a “milk hauler” is ambiguous. People who produce milk on their farm and transport it to a kitchen on their farm should be exempt from the milk hauler permit requirements.**

The definition needs to be broad in order to capture the range of possible activities that may occur to move milk from a dairy farm to a processing plant. The Department intends to interpret the definition to be consistent with standard industry practice. Historically, persons who milk their own animals and carry that milk to their processing room to make cheese do not need a permit because their activity does not result in the measuring or sampling of the milk to be used as the basis for payment.

- **Definitions for the words “cancel” and “revoke” should be clarified in the proposed regulation.**

The interpretation of “revoke” has been clarified in Section 2 VAC 5-531-40(H).

- **The pasteurization time/temperature table under the definition of “pasteurization” does not take into account the types of recording thermometers needed. Also, the temperature for vat pasteurization does not account for the air temperature. Therefore, it is misleading to write 145° F for the vat pasteurization temperature because you actually need to get the temperature to 160° F or higher if you take into account the air temperature. The group felt this should be clarified.**

The purpose of having a definition for pasteurization is to place some specific parameters on what constitutes an acceptable process for pasteurization, not to explain how pasteurizers should be operated. The recommendations focus on specific requirements needed for specific pasteurizers, but not all pasteurizers. The proposed regulation addresses these concerns by referencing 3A Sanitary Standards for the design, construction, installation, and operation of pasteurizers. The requirements for pasteurizers are quite extensive and no definition would be adequate to cover all the possibilities.

- **The guidelines used to define a small-scale processor need to be modified. There were suggestions to use, a day’s production, number of gallons produced in a day, total annual production, and define what a large-scale producer would be and anything less would be considered a small-scale producer.**

The definition in the proposed regulation uses the size of the pasteurization equipment or cheese vat to determine if the cheese operation is small scale. This method has the advantage of being clearly observable and easy to determine. Using daily production of cheese or milk or the number of gallons of milk produced over some period of time is harder to determine. Daily production fluctuates for milk and cheese. Many small cheese operations have no way to accurately measure their milk production. Another problem with using production amounts to determine plant status is that the operator determines these figures. The Department is concerned with the possibility of cheese operations qualifying for exemptions as small-scale processors at one time and not another due to fluctuations in production.

Under which set of requirements would the Department regulate a firm whose production qualifies one year and does not the next?

- **Sheep are not covered under the Tuberculosis testing requirements.**

Tuberculosis testing for sheep is required under 2 VAC 5-531-80 Animal Health of the proposed regulation.

- **2 VAC 5-531-20 Non-standardized cheese and related products. This section says that new products are required to be made from pasteurized milk. This should be struck or else add, “unless properly aged.”**

Federal regulations specify that only cheeses that conform to a standard of identity that allows for aging may be made from unpasteurized milk and offered for sale in interstate commerce. In order to be consistent with federal requirements for interstate commerce, non-standardized cheeses must be made from pasteurized milk. These requirements are based on the ability of certain cheeses with a standard of identity to be made safely using the processes described in the standard of identity. The safety of other cheeses that do not conform to a standard of identity is open to question. The Department believes that pasteurization of milk used for non-standardized cheeses is necessary to ensure the food safety of these products.

- **One comment concerning section 2 VAC 5-531-30 Adulterated or Misbranded Milk or Dairy Products suggested the word “possess” should be removed from sections 2 VAC 5-531-30(A) and 2 VAC 5-531-30(B). Section 2 VAC 5-531-30(A) is stating that a producer cannot have misbranded milk in their possession, but some cheeses that are aging and not being offered for sale are not fully labeled. The way this part of the regulation is worded is saying that the producer shouldn’t even have these partially labeled aging products.**

The intent of the requirement is to prevent the sale of adulterated or misbranded products. No person should be entitled to store adulterated products in their establishment where they might inadvertently become intermixed with saleable products. In the case of unlabeled cheese not ready for sale, no violation would have occurred because the products had not been offered for sale to any consumer. The definition of misbranding addresses only products intended or offered for sale.

- **Several negative comments were received concerning the requirement that permit holders must “engage *daily* in the business” for which the permit was issued or the Department could suspend, cancel, or revoke their permit. Questions were raised about how producers who only produce for seasonal farmers’ markets, those who dry off their herds, and those who do not offer their products for sale year round would be affected.**

The Department believes it is important to be able to suspend, cancel, or revoke permits issued under the proposed regulation if the permit holder is no longer engaged in the business for which the permit was issued. Permits may be re-issued after one is cancelled prior to the permit holder going back into business. Current policy allows permits that are seasonal in

nature to be suspended and reinstated as needed. Experience has shown that certain persons don't want their permits cancelled when they cease production because they believe it will be difficult to obtain another permit if they decide to go back into business. The requirement to engage daily in the business provides the Department with a means to cancel permits that are no longer used by their owners.

- **One person suggested striking the words “cancel”, “revoke”, and “deny”, leaving the word “suspend” under the first paragraph of 2 VAC 5-531-40(C). The word “may” is too flexible and should be replaced with another word.**

The first sentence of 2 VAC 5-531-40(C) establishes the Department's authority and regulatory actions concerning permits that may be taken under the proposed regulation. The wording change would have the effect of denying the Department the ability to ever cancel, revoke, or deny a permit. Permits would essentially become permanent and last forever. The Department would be giving up authority and options for dealing with violative permit holders to such a degree that enforcement effectiveness would be compromised. Flexibility is essential to the Department in order to deal effectively with numerous and varying situations that arise over time in order to use the most appropriate enforcement tool available that fits the situation.

- **Concern over using the word “suspend” was expressed when the permit would be voluntarily suspended because the permit holder was not producing enough milk. A less derogatory word should be used instead.**

The Department acknowledges the potential for the term suspend to be considered negative or derogatory. Current policy requires that the term “voluntary suspension” be used when suspending the permit because of seasonal production. Suspension is a term that is easily understood by permit holders, dairy industry personnel, and citizens in general and is therefore a suitable and usable term.

- **The words “re-work” and “re-process” need to be defined.**

Definitions for these terms have been added to the proposed regulation.

- **Concerns over the requirement for a permit holder to provide samples to VDACS at no cost were raised. Providing samples at no cost could become very expensive to the producer should numerous samples or samples of large quantity be collected.**

The Department does not currently pay for milk and milk product samples collected from grade “A” dairy farms or processing plants. Nor does the Department pay for milk samples collected at dairy farms producing milk for manufacturing purposes from cow's milk. The Department does pay for samples collected under authority of the Virginia Food Laws because that is what the Law requires. The Department considers the cost of sampling as a cost of business for dairy farmers producing milk and dairy processors manufacturing dairy products. Department inspections and sampling provide the minimum oversight and quality control program for each of these producers at no cost to them. In most cases, the sample

testing performed by the Department is the only product testing ever performed on products from a particular processor or producer. The cost of testing these products to the Department far exceeds the cost to purchase the products. The Department believes that it is only reasonable for the permit holders to share in the cost of providing these services by providing the milk and dairy product samples at no charge.

- **The word “provide” is unclear and the word “daily” is too vague under section 2 VAC 5-531-40(C)(4).**

The word “provide” means to make available, as in producing milk each day or making dairy products each day. The term “daily” means each day.

- **One person commented that 2 VAC 5-531-40(C)(5) was not necessary and wanted the definition of “public health hazard” included in the regulation.**

Section 2 VAC 5-531-40(C)(5) allows the Department to take permit actions when a permit holder violates certain sections of the Code of Virginia pertaining to the production and processing of milk and dairy products rather than prosecute the violations under criminal law. Not having to make a criminal prosecution is considered an advantage to any permit holder charged with a violation of the Code of Virginia.

The Department believes that the term “public health hazard” is generally understood by the individual citizens, consumers, and the regulated community. A definition of “public health hazard” is not needed in the proposed regulation.

- **One person commented with some suggestions regarding the way somatic cell counts for goats should be handled. The member stated that the lactation process is different in goats than cows and that the 3 out of 5 guideline is not suitable.**

The somatic cell standard established under the proposed regulation is the same as the recommended somatic cell standard under the USDA model requirements for milk for manufacturing purposes. The somatic cell standard was established at the 1,000,000 cell per milliliter for goats because goats are recognized as different than cows and sheep. The somatic cell standard for goats was established at the national level for grade “A” milk at 1,000,000 cells per milliliter. The standard for goats takes into consideration their differences in physiology and increases in somatic cell levels during late lactation. The standard also recognizes the known ability of goat herds in general to meet the standard which has been the experience under the grade “A” program for nearly every goat dairy in Virginia. Permit holders milking goats will need to manage their goat herds to reduce mastitis. Management techniques include dry treating all goats at the end of lactation, coating teats with teat dip after milking to prevent new infections, pre-dipping teats prior to milking to reduce infections, monitoring bulk milk somatic cell counts and taking corrective action, and breeding and freshening goats so that part of the herd is freshening as part of the herd is drying off.

- **One person requested that a specific amount of time to correct deficiencies needs to be defined in the proposed regulation when the Department issues an Official Warning Notice to Suspend a permit.**

The Department must allow sufficient time to correct violations before suspending a permit unless the violation could endanger the public health. To establish a time in the proposed regulation would be like making one solution fit all problems. It would ignore the fact that it will take longer to resurface an eroded concrete floor than to clean dirty milking equipment. The important thing is that the violation needs to be corrected. If an official notice is being issued to get the violation corrected, the permit holder has already had the opportunity to correct the violation because it was marked on the previous inspection. Official notices are only issued when the permit holder has failed to correct a violation on their own after being requested to do so in writing on the inspection sheet.

- **Some comments questioned the need for 2 VAC 5-531-40(C)(22).**

This section allows the Department to deny a permit to any person who has had a similar permit revoked, suspended, or denied in another state if the violation in that state would be a violation in Virginia. The provision may be used to prevent a person with a history of violations in one state from operating in Virginia if the violations are serious enough.

- **One comment did not like the phrase “may suspend from sale” in section 2 VAC 5-531-40(E).**

This section allows the Department the flexibility to suspend a particular product from sale rather than suspend the processing plants permit. This flexibility would allow the other products manufactured by the processor to continue to be sold, is less burdensome on the permit holder, and protects the public health.

- **One comment stated that a recall process/plan should not be the producer’s responsibility, but VDACS’ responsibility.**

It is the responsibility of the permit holder to develop a recall plan for their products. A recall plan is based on the permit holder’s knowledge of the product, its characteristics, shelf life, labeling, and distribution. Only the permit holder can know the essential information concerning their products like the product codes, production quantity, where it was distributed, who the customers were, risk associated with the product, or the way in which the product was handled. All of this information would have to be gotten from the permit holder before the Department could begin to complete a recall plan. The recall plan would need to change every time a new product is added. The purpose of requiring a recall plan is to shorten the time needed to issue a recall notice when it becomes necessary to protect the public from products that present a risk of illness, injury, gross deception, or are otherwise defective. By preparing a recall plan the permit holder will be familiar with their responsibilities and more aware of the conditions that might cause one of their products to be recalled.

- **One comment stated the language under 2 VAC 5-531-40(L)(5) is ambiguous and needs to be clarified. Does this section refer to lots or certain batch numbers of product?**

This section requires that permit holders conducting a recall must notify their known direct accounts that further distribution or use of the products covered under the recall should cease immediately. This would apply only to the products with the codes identified in the recall, if they are coded, or all of the firm's products by that name if they are not coded.

- **One comment recommended the acceptable/unacceptable levels of antibiotics in section 2 VAC 5-531-40(O) be specified.**

Acceptable levels of animal drug residues are referenced under section 2 VAC 5-531-60(A)(3)(f).

- **One comment recommended that compliance with section 2 VAC 5-531-40(O)(e) be added to the exemptions for small-scale processors for clarification. This section requires processing plants to abstain from offering any products for sale until results of animal drug-residue test are known.**

An exemption to the animal drug-residue testing requirements was established under section 2 VAC 5-531-70.

- **One comment stated that the term "human food chain" needs to be modified in section 2 VAC 5-531-40(O)(2) to say, "human and animal food chain" or "any matter covered by the FDA" because antibiotics when given unnecessarily to any animal can cause resistant strains of bacteria.**

The proposed regulation has no authority over animal feeds and therefore can not regulate animal feed. The Food and Drug Administration has procedures in place to evaluate and approve the use of milk adulterated with animal drug-residues in animal feed.

- **One comment recommended that exact time frames be specified in which the permit holder has to supply the requested information under section 2 VAC 5-531-40(Q).**

The requirement for dairy plant permit holders and dairy product distributors to supply the Department with a statement of the true quantities of milk or milk products purchased or sold and a list of all sources from which the dairy plant or distributor received any milk or dairy products is essential information when conducting tracebacks for foodborne illness. This information should be supplied as soon as possible. The Department believes to set any particular timeframe for supplying the records might result in delays in the timely reporting of the records requested.

- **One comment expressed concerns about section 2 VAC 5-531-40(T) and the prohibition on placing milk in a farm bulk tank that has been held without refrigeration.**

This requirement was placed in the proposed regulation to deal with situations that have happened in the past. Some dairy farms do not have milk storage tanks large enough to hold all their milk for proper storage and cooling. In some cases, dairy farmers have stored the milk that would not fit into the milk tank in the wash vats and other vessels until the milk truck arrived to empty the tank. Once the farm tank was emptied, the milk stored in the wash vat and other vessels was poured into the tank, measured, and placed on the milk truck. The proposed regulation prohibits this practice.

- **Referring to section 2 VAC 5-531-40(W), some comments recommended that farm workers who are not family members should be allowed to use the toilet facilities in the producer's home and that toilet facilities in the home should not be subject to inspection.**

Any requirement of the proposed regulation to obtain a permit must be verified by inspection. If a requirement is not going to be monitored, why have the requirement? The purpose of requiring toilet facilities is to encourage persons involved with the processing of milk and dairy products to use the facilities, wash their hands, and return to work as needed. When a toilet facility is located inside someone's home, non-family members, especially hired labor may feel uncomfortable entering the home to use the toilet. The Department believes only family members can enjoy unrestricted access to toilets located in a home.

- **Some comments expressed the belief that because of the labeling requirements pertaining to frozen and previously frozen cheese, it may not be permissible to make cheese from milk that has been frozen. It was suggested that the regulation be amended to allow milk to be frozen prior to making cheese.**

A new section 2 VAC 5-531-40(Y) has been added specifically stating what requirements have to be followed to properly freeze, store, or thaw frozen milk.

- **One comment stated that section 2 VAC 5-531-60(A)(4)(a) is redundant when compared with section 2 VAC 5-531-100 and section 2 VAC 5-531-60(A)(4)(b) is redundant when compared with section 2 VAC 5-531-60(C)(8)(c).**

Section 2 VAC 5-531-60(A)(4)(a) establishes pasteurization of dairy products or the aging of cheese as standards that must be complied with for dairy products manufactured by permitted dairy processing plants in Virginia, as opposed to Section 2 VAC 5-531-100 which places the same requirement on all dairy products being offered for sale to consumers in Virginia no matter where they were manufactured.

Section 2 VAC 5-531-60(A)(4)(b) establishes the standard for phosphatase testing to be used by the Department in testing dairy products. The phosphatase test is a measure of the effectiveness of pasteurization. This section also provides guidelines on how phosphatase results are to be interpreted. Section 2 VAC 5-531-60(C)(8)(c) establishes the methods that a dairy processing plant may use to test for phosphatase.

- **One comment questioned whether the definition of pasteurization was based on the tools or the end result of the process. The comment suggested that a cheaper alternative to the fancy pasteurization equipment be a kettle and thermometer, or as the member called it, “Classic Pasteurization”.**

Current methods of pasteurization are recognized by federal and state governments as proven scientifically to destroy all pathogens in milk and dairy products. The approved methods and equipment have been designed to take into account numerous possibilities and risk factors that are impossible to deal with using a kettle and thermometer. Required features for vat pasteurization equipment include an agitator, air space thermometer, indicating thermometer, recording thermometer, and leak detect valves. These devices ensure that “every particle” of milk or dairy product is heated to the appropriate temperature and held there a minimum of thirty minutes. Approved pasteurization also produces a record of the process for each batch of milk or dairy product that is available for inspection and to verify that the process was performed correctly. A simple kettle on a stove and a thermometer are not equivalent in effectiveness to approved pasteurization for producing safe and wholesome milk and dairy products.

- **One comment recommended changing section 2 VAC 5-531-60(C)(2)(a) of the regulation to allow cats access to dairy processing plant areas.**

All animals, including cats, can be sources of contamination in dairy processing areas. Cats may shed hair, may contaminate food contact surfaces as they move around the plant, and may transfer dirt and pathogens from one area of the plant to another. For basic sanitation reasons, animals should be excluded from dairy processing plants.

- **One comment suggested that the reference in section 2 VAC 5-531-60(B)(1)(a) to “quarters” should be changed because goats don’t have “quarters”.**

The wording has been changed to reference “mammary glands.”

- **One comment expressed the belief that the requirements under section 2 VAC 5-531-70(B)(2) to require the cleaning and sanitizing of a cheese processing room between steps in the processing of cheese is too cumbersome and a waste of time. The requirement for changing one’s clothes is absurd under section 2 VAC 5-531-70(B)(3).**

This section of the regulation deals with exemptions to requirements for separate rooms in cheese processing areas. The requirement for separate rooms is based on the prevention of cross-contamination of milk and dairy products when two or more operations are conducted in the same room at the same time. One example is the requirement for a separate room in which to remove mold and rind from aged cheese products before they are wrapped for sale. During the process of cutting the moldy surfaces from the cheese, the work surfaces in the cheese room become contaminated with mold spores. The mold spores and plant material also settle out of the air onto the walls, tables, floor, and other surfaces in the room. In order to avoid contamination of the cleaned pieces of cheese prior to wrapping, the room needs to be cleaned and all of the work surfaces need to be sanitized. As to the issue of wearing clean

outer clothes to work in a food processing area, the practice is basic sanitation to prevent contamination of the food products being manufactured.

- **One comment stated that the *Staphylococcus aureus* standard under section 2 VAC 5-531-60(A)(5) should limit the number of organisms to less than 3.1/gram and the language in the regulation should specify *Staphylococcus aureus* and not just Staphylococcus.**

The intent of the Department is to set the standard for *Staphylococcus aureus* at a level based on food safety. The limit of detection for many laboratory test methods for *Staphylococcus aureus* is 3.1 organisms per gram. Our food safety concern is with the possibility of toxin production which occurs in detectable amounts above 100,000 organisms per gram. Setting the standard at a maximum of 1,000 organisms per gram allows for a sufficient margin of safety and is well within the ability of industry to comply using standard processing, packaging, and handling procedures. A lower standard can not be justified on the basis of food safety. The regulation references *Staphylococcus aureus* as it is currently written and does not need revision.

- **One comment recommended that the proposed regulation should be amended to require every animal in a goat herd to be tested for Brucellosis annually unless the “milk ring test” under development for goat’s milk is approved by the USDA.**

Section 2 VAC 5-531-80 concerning animal health requirements was amended to allow for the use of a milk ring test when it becomes available.

- **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 for manufacturing purposes, no matter the source, should be regulated under the same 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. Requirements for labeling cheese that has been frozen prior to being offered for sale have been included in the proposed regulation.

- **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, facility and equipment standards.**

The Department strongly supports the adoption of specific requirements tailored to the dairy industry and has modeled 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 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.**

The Department agrees.

- **The Department received one comment recommending that definitions for the terms “Chevre,” “Fromage,” “Goat Cheese,” “Feta Cheese,” “Ricotta Cheese,” “Whole Ricotta,” and “Ricotta made with Whey” be added to the proposed regulation.**

Section 2 VAC 5-531-20 defines non-standardized cheeses and related products. There are too many different terms used to describe various types of cheese to include in the definition section of the proposed regulation. To attempt a comprehensive list may inadvertently miss some names for cheese and would not cover those new cheese products brought to market in the future or those renamed for purposes of avoiding regulatory requirements.

- **The Department received one comment to include the term “Ricotta Cheese” with other milk products under the definition for “Milk Products.”**

Milk products are regulated under the grade “A” regulations for fluid milk products. Ricotta cheese is a manufactured milk product and should not be included under the definition for “milk products.”

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Department, through examination of the regulation, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The Department intends to review this regulation within three years after the amended regulation takes affect.

The specific and measurable goals of this regulation are (1) to protect the public's health, safety, and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth; (2) to ensure the safety of manufactured dairy products through pasteurization and prevention of contamination; and (3) to facilitate the sales of Virginia-manufactured dairy products in intrastate and interstate commerce.

Family Impact Statement

Please provide an 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.

Unless otherwise discussed in this report, the proposed regulation will have no impact upon families.