



Virginia
Regulatory
Town Hall

**Proposed Regulation
Agency Background Document**

Agency Name:	Virginia Department of Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-501 (2 VAC 5-500)
Regulation Title:	Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk
Action Title:	Proposed/Repeal
Date:	December 21, 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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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) require permits for milk pickup trucks, milk transport tanks, laboratories, and persons testing milk samples for pay purposes, persons collecting official milk samples in dairy plants, and milk tank truck cleaning facilities; and (3) establish administrative enforcement procedures for the Agency to follow when summarily suspending a permit.

Due to the extensive amendments to this regulation, it is recommended that 2 VAC 5-500 (Rules and Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk or Milk Samples from the Farm to the Processing Plant or Laboratory) be repealed and 2 VAC 5-501, Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk adopted concurrently.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, 3.1-530.2, 3.1-535, and 3.1-535.1 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 (Board) "...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 the Board 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. Section 3.1-535 authorizes the Board to make and enforce rules governing applications for certificates to manipulate the Babcock or other centrifugal machine for the purpose of determining the composition of milk or cream for purposes of inspection, to determine the composition or value of milk or cream, or to sample or weigh milk or cream as a basis for payment in buying or selling. Section 3.1-535.1 authorizes the Board "...to promulgate and enforce rules and regulations governing the equipment, standards, and procedures used in the receiving, weighing, measuring, sampling, and testing of milk or other fluid dairy products when the results are to be used for the purpose of inspection, check testing, or as a basis for payment in buying or selling."

The Office of the Attorney General has certified that the Board 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) to protect the public's health and welfare with the least possible costs and intrusiveness to the citizens of the Commonwealth; (2) ensure the safety and quality of milk produced in Virginia by establishing temperatures at which milk must be kept on the farm and in the dairy plant, and by establishing equipment-design, construction,

installation, and use requirements which protect milk from contamination during storage, transfer, and delivery; and (3) establish standards to be used in measuring, collecting, and evaluating milk samples for purposes of determining its components (such as fats, solids, and protein which are the basis for determining how much the farmer is to be paid for his milk) and its suitability (determined by the amount of bacteria it contains, among other things) for consumption by humans.

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 proposed regulation is to ensure the safety and quality 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 monocytogenes*, which causes fever, vomiting, and can lead to still-births in pregnant women; and *Coxiella burnetii*, which causes Q fever. Some of these diseases can be fatal.

Milk is an excellent growth medium for most organisms including many pathogens. The fact that spoilage organisms and pathogens can grow in milk if they are present or introduced later by poor handling practices makes milk and milk products potentially hazardous if they are not properly processed, handled, packaged, and stored. The regulation ensures the safety and quality of milk by: (1) requiring all milk to be cooled and stored at temperatures that prevent or slow the growth of pathogens and spoilage organisms; (2) requiring milk to be cooled to storage temperatures quickly and maintained thereat to reduce the time pathogens and spoilage organisms have to grow while the temperature of the milk is being reduced to storage temperature; and (3) requiring minimum equipment-design, construction, installation, and use requirements that protect milk from contamination during storage, transfer, and delivery.

The proposed regulation establishes standards to be used in measuring, collecting, and evaluating milk samples for purposes of determining its components (such as fats, solids, and protein which are the basis for determining how much the farmer is to be paid for his milk) and its suitability (determined by the amount of bacteria it contains, among other things) for consumption by humans. Milk samples used for inspection and pay purposes must be truly representative of the entire shipment of milk marketed to protect the buyer and the seller. The proposed regulation establishes: (1) the procedures that must be followed to accurately measure the amount of milk being shipped; (2) the types of equipment that may be used to collect and store official milk samples; and (3) the minimum information that must be recorded on the seller's weigh ticket and the sample container.

The proposed regulation also establishes chain of custody requirements for official milk samples by: (1) requiring persons to obtain a permit to weigh and sample milk prior to weighing or sampling any milk; (2) establishing sample collection, storage, and transportation procedures; (3) establishing equipment and records requirements; and (4) provisions for sample security. Establishing chain of custody for milk samples is essential to enforce the safety and quality requirements on permit holders. The inability of the Agency to establish chain of custody on any individual milk sample renders the results of laboratory tests on the sample unenforceable.

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 includes the milk of goats, sheep, water buffalo, and other species of mammals if the milk or dairy products are intended for human consumption. The existing regulation covers the milk from cows only. The primary purpose of the proposed regulation is to ensure the safety and quality of milk produced on Virginia dairy farms. Safety and quality of milk is ensured by requiring all milk for human consumption to be refrigerated and handled in ways which protect the milk from contamination.

The proposed regulation is consistent with the requirements of the Pasteurized Milk Ordinance (PMO) for grade "A" milk which includes the milk from cows, goats, and sheep. The PMO is a model federal regulation for states to adopt which governs the regulation of grade "A" milk and milk products nationwide. The PMO was amended by the May 1999 Interstate Milk Shippers Conference to require permits for milk haulers, persons who weigh and sample milk, milk pickup tanks, and milk transport tanks. Compliance with the provisions of the PMO is essential to maintain Interstate Milk Shipper (IMS) ratings. An IMS rating of ninety or better is required to ship grade "A" milk and milk products out of state. Once every two years each grade "A" milk supply and dairy processor is rated for compliance with the requirements of the PMO. Failure to achieve a satisfactory score of ninety or better prevents receiving states from accepting any milk from the affected milk supply. The only options available to dairy farmers whose supply of milk fails an IMS rating is to market their milk production for manufacturing purposes at substantially reduced pricing or dump it on the farm.

The proposed regulation includes recording thermometer specifications which are consistent with the PMO. The May 1999 Interstate Milk Shipper's Conference modified the PMO to include requirements for recording thermometers to be installed on grade "A" farm bulk milk tanks with specific design and installation requirements.

The PMO was amended in May 2001 to require permits for a milk tank truck cleaning facility and the evaluation of anyone who collects milk samples at a dairy plant once every two years. The proposed regulation includes provisions for permits for persons to operate a tank truck cleaning facility or to sample milk in a dairy plant.

The proposed regulation also establishes certain procedures for permitting laboratories and persons who sample and test milk for pay purposes.

The proposed regulation includes provisions for the cooling, storing, measuring, and sampling of milk without the use of a bulk tank. The existing regulation was developed without considering the needs of small-scale milk producers or milk produced from species other than cows. The small-scale production of goat's milk, sheep's milk, water buffalo's milk, or the milk from other mammals intended for human consumption is not suitable for refrigerated bulk milk tanks. Bulk milk tanks typically require fifty or more gallons of milk to operate properly. Small-scale producers of goat's milk, sheep's milk, or water buffalo's milk seldom produce more than a few gallons of milk per milking, making the use of bulk tanks unfeasible. To foster the developing small-scale dairy industry in Virginia, alternatives to bulk tanks were included in the proposed regulation.

The proposed regulation eliminates all references to fees. Fees used to be charged for milk hauling permits but the authority for them was eliminated by the General Assembly in 1996.

The proposed regulation requires dedicated milk transport tanks to be used to haul any pasteurized milk, milk products, or frozen desserts mix when the products will not be re-pasteurized at the plant where they are packaged. The primary focus for the regulation is to ensure milk safety. Contaminated milk transport tanks are believed to have caused a large public health outbreak associated with the consumption of ice cream in 1994. The company received pasteurized ice cream mix in milk transport tanks which were also used to haul raw eggs from an egg cracking plant. The transport tanks were not properly washed and sanitized after hauling the raw eggs and salmonella was introduced into the ice cream mix that was being transported. Re-pasteurization of the mix in the plant prior to packaging or use of dedicated tankers would have avoided this serious public health outbreak. This outbreak caused illness in more than two thousand people nationwide.

The proposed regulation requires the collection of two identical milk samples at each pickup. Currently, a great deal of Virginia's milk is marketed out of state, making the collection of milk samples for compliance with PMO requirements difficult. If milk haulers were required to collect two identical samples from each dairy farm on their milk pickup route, Agency personnel could collect one set of milk samples before the load leaves Virginia and the other set of milk samples could accompany the load to its final destination. This will save time and travel costs for inspectors that currently travel to individual dairy farms to procure milk samples needed for compliance with the PMO.

The proposed regulation was re-written in the active voice.

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 the safety and quality of milk and milk products produced from the milk of goats, sheep, water buffalo, and other mammals by requiring the same protections for all milk as are currently required for cow's milk.

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. The proposed regulation has been crafted to comply with the requirements of the PMO, the United States Department of Agriculture's (USDA) Recommended Requirements for Milk for Manufacturing Purposes, and the needs of a developing small-scale dairy industry in Virginia. The proposed regulation governs the cooling, storage, sampling, transporting, and testing of all milk for human consumption produced in Virginia. Currently, only producers and processors of grade "A" milk, manufactured grade milk producers, and processors of cow's milk are included under the existing regulation. Persons producing or processing milk from goats, sheep, water buffalo, or other species of mammals are currently regulated under the Virginia Food Laws and related regulations. The Virginia Food Laws and related regulations do not require a permit and are not specific to the dairy industry but are applicable to all food production and processing. Requirements under the Virginia Food Laws and related regulations for milk producers and processors are significantly less stringent than those imposed on Virginia's grade "A" and manufactured grade milk producers and processors. There are currently 950 grade "A" and manufactured grade dairy farms, 14 grade "A" milk processors, and four cheese processors who are regulated under the current regulation. There are seven small-scale cheese processors currently being inspected under the Virginia Food Laws and related regulations. The Agency is aware of another six persons who may be producing cheese for sale from goat's milk, who have ceased production of cheese to avoid inspection, or who are appealing convictions for violations of the Virginia Food Laws related to their cheese production and sales. Each of the thirteen persons who engage in the small-scale production of cheese from goat's or sheep's milk will be regulated for the first time under the proposed regulation.

The proposed regulation will require each person formerly regulated under the Virginia Food Laws to: (1) provide a milkhouse or milkroom of sufficient size in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils can be conducted; (2) cool their milk to 40 degrees F or less (but not frozen) within two hours after milking; (3) provide containers for storing or transporting any milk that are made from food grade materials that are easily cleanable; and (4) determine the amount of milk offered for sale or purchased in gallons or pounds. Five of the thirteen persons regulated under the Virginia Food Laws are in substantial compliance with the proposed regulation. The other eight persons and any person who wishes to enter the dairy business producing milk in the future would need to provide a milkhouse or milkroom on his dairy farm to be in substantial compliance.

Persons employed by a milk plant who are responsible for collecting milk samples from milk tank trucks for laboratory testing prior to receipt of the milk into the plant will be required to obtain a permit from the Agency and to be evaluated at least once during the first year after their permit is issued and every two years thereafter as a condition for permit renewal. This requirement is essential to conform with the PMO and IMS requirements and strengthens the Agency's ability to establish chain of custody for milk samples used as a basis for regulatory actions.

Persons employed by the Agency and the Virginia Department of Health who sample milk or milk products in a milk plant will be required to obtain a permit from the Agency and be evaluated at least once during the first year after their permit is issued and every two years thereafter as a condition for permit renewal. This requirement is essential to conform with the PMO and IMS requirements and strengthens the Agency's ability to establish chain of custody for milk samples used as a basis for regulatory actions.

New permitting requirements have been established for persons who wish to operate a milk tank truck cleaning facility. This requirement is essential to conform with the PMO and IMS requirements and establishes the facilities necessary to wash and sanitize milk tank trucks. Currently, there is one facility in Virginia that washes milk tank trucks that formally was permitted as a milk transfer station. Because the facility no longer handles any milk at their transfer station, they no longer qualify to hold a transfer station permit. Obtaining a permit to operate a milk tank truck cleaning facility will help ensure that milk tank trucks washed and sanitized by the firm will be accepted by milk plants receiving milk and milk products transported in them.

Persons transporting pasteurized milk, pasteurized milk products, and pasteurized frozen dessert mix to or from milk plants will be required to use only dedicated tankers for hauling these products if the products will not be pasteurized again prior to packaging in the milk plant receiving them. This requirement is intended to prevent the cross-contamination of pasteurized milk or milk products with unpasteurized milk or milk products that may be transported in the same tank immediately before the pasteurized milk or milk product is loaded.

Agency:

The cooling, storing, sampling, and transporting of milk would be regulated under the same laws and regulations for all dairy farms producing milk in Virginia. The cooling, storing, sampling, and transporting of milk on grade "A" dairy farms producing milk from cows, goats, or sheep and manufactured grade dairy farms producing milk from cows are regulated under the existing regulation. Dairy farms producing manufactured grade milk from goats, sheep, water buffalo, or other mammals (except humans) are currently regulated under the Virginia Food Laws and related regulations.

The Dairy Inspection Program utilizes administrative processes to regulate grade "A" dairy farms and manufactured grade dairy farms. 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 causes the Agency 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 will allow the Agency 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 Agency 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 and dairy plants processing dairy products. Agency staff will have to modify existing educational and testing materials used for milk haulers who weigh and sample milk for use in instructing and testing dairy plant samplers and regulatory personnel who collect official milk samples in dairy plants. The agency may provide onsite training programs for employees of milk plants or local health departments to facilitate the rapid and efficient permitting of all individuals who will be required to hold permits after the proposed regulation becomes effective. Because

agency staff currently provide study materials and administer tests to milk haulers around the state there is no projected additional costs to the state as a result of new permits for dairy plant samplers. The elimination of joint inspections of dairy farms and dairy plants under the Virginia Food Laws and related regulations will free Agency inspection personnel for other inspection duties.

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

Individuals affected by the proposed regulation include any person who:

- (1) operates a grade "A" dairy farm producing milk from cows, goats, or sheep;
- (2) operates a manufactured grade dairy farm producing milk from cows;
- (3) operates a manufactured grade dairy farm producing milk from goats, sheep, water buffalo, or other mammals (except humans) currently regulated under the Virginia Food Laws and related regulations;
- (4) contracts or subcontracts for the hauling of milk;
- (5) measures, samples, or transports any milk;
- (6) operates a pay purpose laboratory; and
- (7) samples and tests milk for pay purposes.

The proposed regulation establishes several new permits that will be required. The agency does not currently charge a fee for any permits issued pursuant to the existing regulation and does not intend to charge a fee for any permits issued pursuant to the proposed regulation.

There are approximately 925 grade "A" dairy farms and 25 manufactured grade dairy farms in Virginia. There is no projected cost of the proposed regulation to these individuals because they are currently regulated and in compliance under the existing regulation.

There are approximately thirteen individuals who operate a dairy farm producing manufactured grade milk from goats, sheep, water buffalo, or other mammals (except humans) currently regulated under the Virginia Food Laws and related regulations. These individuals will be required to provide a milkhouse or milkroom in which to cool, handle, and store milk and to wash, sanitize, and store milk containers and utensils. The cost to each individual will depend on whether they have an existing building that can be modified for use as a milkhouse or milkroom. The modifications required would include providing concrete floors, doors, windows, lighting, plumbing, floor drains, wash vats, and handwashing facilities within an existing structure. The estimated costs for these improvements is approximately \$3,000. If the person was constructing a milkhouse from the ground up the costs are estimated to be approximately \$10,000. The total cost to these individuals would range from a low of \$3,000 to a high of \$10,000.

There are currently thirty-nine contract haulers and subcontract haulers operating in Virginia. These individuals will be required to provide seals or locks on the openings into each milk tank truck they operate in order to maintain tank truck security. Many openings into tank trucks will need to be fitted with a means to attach a seal or lock. Currently, most wash vents installed in tank trucks are not equipped with a means to seal or lock them. Most tank trucks have three vents of this kind. The one time cost to provide a means to seal or lock each opening into a tank truck is estimated at \$200 for each tanker. The cost to provide reusable locks for each tank truck

is estimated to be \$50. The cost to provide disposable seals for each opening into a tank truck is estimated to be fifty cents per day or \$182.50 each year per tanker. There are approximately 300 milk tank trucks in service in Virginia at this time. The average costs of the proposed regulation to each contract hauler would be approximately \$250 per tank truck. Due to the cost of seals their use will be very limited.

Contract haulers and subcontract haulers will be required to obtain a permit for each milk tank truck they operate and to identify each milk tank truck with numbers and letters assigned by the Agency. The Agency estimates the cost for milk haulers to comply with this requirement will not exceed \$100 each year to cover the processing of applications for each tank's permit and renewals. Contract haulers and subcontract haulers are considered to be in general compliance with the proposed regulation regarding other requirements.

There are 491 persons currently permitted to measure, weigh, and sample milk. Each of these persons will be required to be evaluated at least once during the first year after permitting and every other year thereafter as a condition of permit renewal. The Agency attempts to evaluate each milk hauler operating in Virginia at least once every two years; however, the Agency has been able to evaluate only about 200 of the 491 milk haulers. Many milk haulers who hold permits never actually pickup or transport any milk during the year. Other milk haulers work as relief drivers filling in on weekends, holidays, and sick days for full time personnel. The Agency estimates that the cost of the proposed regulation to the approximately 300 milk haulers holding permits who have not been evaluated will be the time taken to contact the Agency to make arrangements to be evaluated to avoid the loss of their ability to have their permit renewed.

There are approximately forty employees of milk plants who receive milk and collect official milk samples that will be required to obtain a permit and be evaluated on how well they follow sampling procedures. The only cost to these individuals or their employer is the time it will take them to read an instructional handout or attend a training session and complete a test to obtain the permit. The Agency estimates the cost of the proposed regulation at \$30 per employee to cover two hours of each employee's time being used for training and testing.

There are ten employees of state and local health departments who collect official milk samples at milk plants who will be required to become permitted. The only cost to these individuals is the time it will take them to read an instructional handout or attend a training session and complete a test to obtain the permit. Each of these individuals is currently sampling milk in milk plants and no cost of the proposed regulation is estimated other than their time spent performing official duties.

There are currently no laboratories or persons testing milk for pay purposes in Virginia.

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. Changes will be discussed in the order in which they occur in the proposed regulation.

Section 2 VAC 5-501-10 Definitions:

Definitions for “bulk milk hauler”, “bulk milk pickup tanker”, “bulk milk pickup tanker commingled milk”, “bulk milk sampler”, “cancel”, “dairy plant sampler”, “dairy product”, “deny”, “milk product”, “milk tank truck”, “milk tank truck cleaning facility”, “milk transport tank”, “official milk sample”, “other mammals”, “pay purpose laboratory”, “permit”, “raw”, “receiving station”, “revoke”, “summarily suspend”, “suspend”, and “3-A Sanitary Standards” were added to the proposed regulation.

The definition for “dairy farm” was amended to include milk obtained from sheep, water buffalo, and other mammals (except humans) and offered for sale for human consumption.

The definition for “milk” was amended to include the milk of goats, sheep, water buffalo, and other mammals (except humans) intended for human consumption.

The definition for “milk plant” was amended to include any place dairy products are collected, handled, processed, stored, pasteurized, aseptically processed, bottled, packaged, or prepared for distribution.

The definition for “milk producer” was amended to include any person who operates a dairy farm and sells or offers any milk for human consumption.

The definition for “person” was amended to include institutions.

The definition for “transfer station” was amended to include the transfer of dairy products.

The definition for “transport commingled milk” was amended to include raw milk product or dairy product if they are loaded onto a transport tank.

The definition for “transport milk tank” was eliminated.

2 VAC 5-501-20 Intent, scope, and interpretation:

2 VAC 5-501-20(A) was amended to include the hauling, transferring, handling, and delivery of milk, milk products, and dairy products between one milk plant and another and to include the handling and testing of milk, milk product, and dairy product samples in laboratories if the test results will be used as a basis for payment.

2 VAC 5-501-20(C) was amended to include in its scope references to: (i) the establishment of minimum cooling and storage requirements for milk on the farm and in transport; and (ii) pay purpose laboratories. The existing regulation covered only milk marketed under the bulk system

while the scope of the proposed regulation covers all milk in Virginia no matter how it is stored, cooled, or transported.

2 VAC 5-501-30 Permits:

2 VAC 5-501-30(A) was amended to require persons to obtain a permit who: (1) sample, measure, or receive milk in cans or containers into any milk plant, receiving station, or transfer station; (2) possess or transport official milk samples; (3) collect official milk samples from bulk milk pickup tankers or milk transport tanks; and (4) collect official milk samples of pasteurized milk or pasteurized milk products from a milk plant.

Additional changes to 2 VAC 5-501-30(A) require permit holders to: (1) pass a test if they fail to renew their permit within one year after it expires before a new permit may be issued; and (2) be evaluated at least once during the first year they hold a permit by Agency personnel and every two years thereafter as a condition of permit renewal.

2 VAC 5-501-30(B) was included to require persons who operate a milk tank truck cleaning facility to obtain a permit.

2 VAC 5-501-30(C) maintains permitting requirements for contract haulers and subcontract haulers under existing regulation and establishes: (i) new permit requirements for bulk milk pickup tankers and milk transport tanks; (ii) a numbering system to identify each milk tank truck; and (iii) required information to be reported on the application for a milk tank truck permit.

2 VAC 5-501-30(D) establishes the requirement for a person to obtain a permit to operate a pay purpose laboratory or sample and test milk for pay purposes. Each permit expires on December 31 next following the date of issuance and is renewed annually.

2 VAC 5-501-30(F) establishes under what circumstances the Agency may cancel, suspend, revoke, or deny a permit. The section defines the Agency's regulatory authority and powers of enforcement under the proposed regulation.

2 VAC 5-501-30(G) establishes under what circumstances the Agency may summarily suspend the permit of any person.

2 VAC 5-501-30(H) establishes a new requirement for the individual producer milk samples representing each load of farm pickup milk to accompany the load to its destination and forbids any person from removing the last complete set of samples from the load prior to delivery.

2 VAC 5-501-30(I) establishes a new requirement for persons operating a dairy farm to store their milk pickup tickets for the past sixty days in the milkroom for inspection purposes.

2 VAC 5-501-30(J) establishes a new requirement for each dairy farmer to abstain from selling any milk after his milk tests positive for excessive drug residues until a followup milk test is negative for excessive drug residues.

2 VAC 5-501-30(K) establishes the authority for the Agency to issue a permit to milk haulers and samplers operating in Virginia if they hold permits issued by other states without requiring the person to pass a test.

2 VAC 5-501-30(L) establishes a new requirement for milk tanks used for direct loading on dairy farms in Virginia to ensure the ability to collect official milk samples.

2 VAC 5-501-30(M) establishes a new requirement for milk haulers to use dedicated tanks to transport pasteurized milk products in bulk if the products will not be pasteurized again in the plant of receipt prior to packaging.

2 VAC 5-501-40 Milkhouse or milkroom; construction and facilities:

This section maintains requirements under the existing regulation for milk rooms and more clearly defines requirements for lighting, ventilation, hand washing facilities, potable water, storage of milk tickets, and requires all milk sales from the farm to be to a permitted milk plant.

2 VAC 5-501-50 Cooling temperature and storage standards for milk stored on a dairy farm:

This section maintains limits on the maximum length of time grade “A” milk and manufactured grade milk may be stored and used for human consumption under the existing regulation. This section establishes uniform cooling temperature requirements for all milk stored on dairy farms.

2 VAC 5-501-60 Construction and operation of farm bulk milk cooling or holding tanks recording thermometers, interval timing devices, and other required milkhouse or milkroom facilities:

This section maintains requirements under the existing regulation for hose ports, hose port aprons, bulk milk cooling or storing tanks, recording thermometers, and interval timing devices. New requirements under this section specify minimum clearance distances around, above, below, and under bulk milk tanks, prior approval before equipment installation, and more detailed design and installation criteria for acceptable recording thermometers and interval timers.

2 VAC 5-501-70 Measuring, sampling, and testing:

This section maintains requirements under the existing regulation for determining the quantity of milk in bulk milk tanks, converting volumetric measurements of milk to weight measurements of milk, collection of milk samples, and testing of milk samples for butterfat.

New provisions of the proposed regulation establish requirements: (i) for persons who wish to measure and sample milk not stored in a bulk milk tank, (ii) for containers used to store milk on the farm; (iii) for a pay purpose laboratory; (iv) for samplers of bulk milk tanks to collect two samples for each tank; (v) for milk samples to be held in the possession of a person permitted to collect or transport milk samples; and (vi) for persons who wish to test milk for pay purposes.

2 VAC 5-501-80 Farm bulk milk pickup tanker and milk transport tank requirements:

This section maintains requirements under the existing regulation for milk pickup and transport tanks. The proposed regulation was amended to: (i) require farm bulk milk pickup tanks and milk transport tanks to comply with 3-A Sanitary Standards; (ii) specify the sample supplies, collection, and storage equipment required to be provided by the milk hauler or milk sampler; (iii) require a tank truck to be cleaned and sanitized once every 72 hours; (iv) limit multiple milk pickups from dairy farms during a 24 hour period without washing and sanitizing the tank truck between deliveries to a milk plant; (v) provide an enclosure in which to store inspection records so they remain with the milk tank truck; (vi) provide a means to lock or seal each opening into a milk tank truck; (vii) establish milk pickup, measuring, and sampling procedures that must be followed to collect official milk samples from bulk milk tanks; (viii) establish milk sampling procedures that must be followed when collecting milk samples from milk pickup or transport tanks; (ix) require a person's signature rather than their initials on tank truck wash tags; (x) require each milk tank truck to be sealed or locked when unattended; (xi) require the reporting of incidents of tampering with the locks or seals on milk tank trucks; and (xii) establish chain of custody procedures that must be followed by persons collecting and transporting milk samples.

2 VAC 5-501-90 Sanitation requirements for a milk tank truck cleaning facility:

This new section of the proposed regulation establishes requirements for permitting a milk tank truck cleaning facility separate from a receiving station or transfer station.

2 VAC 5-501-100 Interpretation and enforcement:

This new section of the proposed regulation establishes that the administrative process used to make case decisions under the regulation will comply with the Virginia Administrative Process Act and creates an administrative process for the Agency to use when summarily suspending permits.

2 VAC 5-501-110 Regulation superseded:

This new section of the proposed regulation alerts the reader to the fact that the proposed regulation is intended to supersede the current regulation when the proposed regulation becomes effective.

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.

The Agency has considered the following alternatives.

The first alternative considered was not to have this regulation, but the Agency rejects this alternative because the regulation ensures the efficacy of pasteurization. Also, this alternative would not comply with recommended standards of the United States Department of Health,

Education and Welfare, or the United States Department of Agriculture. Failure to comply with these recommended standards would effectively bar the sale of milk outside of Virginia.

A second alternative considered was to institute a third-party certification program which would perform the necessary testing, inspection, and evaluation functions currently provided by Agency personnel. Third-party certification refers to a system in which a person, organization, or party, separate from either the dairy industry or the Agency, would perform necessary testing, inspection, and evaluation services.

Holders of permits, dairy farmers, milk-marketing cooperatives, and dairy plant processors would be charged a fee for services rendered through third-party certification. The Agency would have to continue to issue and renew all permits in order to take regulatory actions against permit holders. This alternative would transfer the majority of the cost of inspection, testing, and certification to industry while freeing Agency resources for use in other program areas. This alternative was rejected for the following reasons: (i) the transfer of costs to industry from a program entirely funded through general funds would be an additional tax on the dairy industry; (ii) the dairy industry would likely pay much more in user fees than the Agency currently spends to operate the program; (iii) the Agency would have to create and operate a program to supervise and certify the third-party group, reducing the anticipated savings to the Agency; and (iv) legal concerns involving the chain of custody for milk samples and the ability to defend regulatory actions in administrative or court proceedings would be more complicated and cumbersome, further reducing any savings to the Agency.

The third alternative considered was to keep the regulation in its current form and continue to provide the required services through the Agency. This alternative was selected for the following reasons:

1. The Agency can operate the program more efficiently than other alternatives considered;
2. Confidence in the quality of milk samples used to determine the value of milk is enhanced by vesting the responsibility for the program with the Commonwealth; and
3. This alternative provides for a more uniform administration of the program statewide, since it is administered through just one office, which has control of all aspects of the program.

Public Comment

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

The Agency published a notice in The Virginia Register of Regulations on June 7, 2001 advertising the opportunity to comment on 2 VAC 5-500, Rules and Regulations Governing the Cooling, Storing, Sampling, and Transporting of Milk or Milk Samples from the Farm to the Processing Plant or Laboratory. An informal advisory group was not formed for the purpose of

reviewing the proposed regulation and to make recommendations to the Agency relative to its requirements. The Agency received no comments relative to the regulation.

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 Agency, through examination of the regulation, has determined that the regulation is clearly written and easily understood 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 Agency 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 and quality of milk produced in Virginia; and (3) to establish standards to be used in collecting and evaluating milk samples.

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.