



Virginia  
Regulatory  
Town Hall

## Final Regulation Agency Background Document

<b>Agency Name:</b>	Agriculture and Consumer Services
<b>VAC Chapter Number:</b>	2 VAC 5-501 (2 VAC 5-500)
<b>Regulation Title:</b>	Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk
<b>Action Title:</b>	Final/Repeal
<b>Date:</b>	May 28, 2003

Please refer to the Administrative Process Act (§ 2.2-4006 *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* for more information and other materials required to be submitted in the final regulatory action package.

### Summary

*Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the final new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the final action was published.*

The final regulation amends the existing regulation (2 VAC 5-500) to: (1) include the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are sold or offered for sale 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 the existing regulation, 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Sampling and Transporting of Milk or Milk Samples from the Farm to the Processing Plant or Laboratory) is being repealed and 2 VAC 5-

501, Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk adopted concurrently.

Substantive changes made since the final regulation was published include: (i) modifying the definition of a “dairy farm” to encompass only those farms selling or offering for sale any milk, dairy product, or milk product for human consumption; (ii) allowing sample dippers, sample dipper containers, and sanitizer to be provided by the operator of each dairy farm rather than requiring the contract hauler or subcontract hauler to provide the sample dipper, sample dipper container, and sanitizer on his bulk milk pickup tanker; and (iii) adding the requirement for persons with a bulk tank installed in their milkhouse to provide a switch and 220-volt grounded weatherproof electrical outlet as part of their milkroom facilities for use by the contract hauler.

### Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.*

On May 15, 2003 the Board of Agriculture and Consumer Services adopted 2 VAC 5-501, Regulations Governing the Cooling , Storing, Sampling and Transporting of Milk and simultaneously repealed 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.

### 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 final changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the final, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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 final 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 final 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.*

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The goals of the final 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 final regulation includes the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are sold or offered for sale for human consumption. The primary purpose of the final regulation is to ensure the safety and quality of all milk and milk products produced. The existing regulation covered 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 final 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 final 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 final 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 final 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 of the regulatory action's detail.*

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The final regulation includes the milk of goats, sheep, water buffalo, and other species of mammals if the milk or dairy products are sold or offered for sale for human consumption. The existing regulation included the milk from cows only. The primary purpose of the final 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 offered for sale or sold for human consumption to be refrigerated and handled in ways which protect the milk from contamination.

The final 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 final 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 final regulation includes provisions for permits for persons to operate a tank truck cleaning facility or to sample milk in a dairy plant.

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

The final 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 are included in the final regulation.

The final 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 final 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 final 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 final regulation is written in the active voice.

## Issues

*Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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.*

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### Public:

The final regulation enhances 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. Some individuals assert that the final regulation prevents the public access to unpasteurized and unaged cheeses that may be offered for sale at some farmer's markets by requiring pasteurization of unaged cheeses; however, unaged cheese products are currently required to be pasteurized by 21 CFR Part 133 adopted for enforcement in Virginia under the authority of the Virginia Food Laws. Because unaged and unpasteurized cheese products are already illegal to sell or offer for sale for human consumption by regulations adopted under the authority of the Virginia Food Laws, the Agency does not believe the final regulation has any impact on the availability of unaged and unpasteurized cheese products to the public. The final regulation enhances the Agency's ability to enforce the prohibition on the sale of unaged and unpasteurized cheese products which may be the reason some individuals assert that the final regulation prevents the public access to unpasteurized and unaged cheese products.

#### Regulated Entities:

The final regulation will create a level playing field on which all dairy farmers and dairy processors can compete. The final 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 final regulation governs the cooling, storage, sampling, transporting, and testing of all milk offered for sale or sold 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 940 grade "A" and manufactured grade dairy farms, 14 grade "A" milk processors, and seven cheese processors who are regulated under the current regulation. There are six 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 twelve 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 final regulation.

The final regulation will require each person formerly regulated under the Virginia Food Laws to: (1) provide a milkhous 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. Four of the twelve persons regulated under the Virginia Food Laws are in substantial compliance with the final 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 a 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 for sale for human consumption 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 final regulation eliminates the need to send more than one staff member to any dairy farm or dairy plant.

The final regulation will allow the Agency to regulate all dairy farms and dairy plants under the same 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 final regulation.

### Statement of Changes Made Since the Final Stage

*Please highlight any changes, other than strictly editorial changes, made to the text of the final regulation since its publication.*

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In response to comments received by the Agency the following changes were made to the final regulation:

The definition of “Dairy farm” was modified in the final regulation to include only those farms selling or offering for sale any milk, dairy product, or milk product for human consumption. The definition of “Dairy farm” under the proposed regulation could be interpreted to include dairy farms which were not offering their milk, dairy products, or milk products for sale for human consumption, but were consuming the products themselves or giving them away. The Agency does not intend to regulate what milk, dairy products, or milk products a person may prepare for themselves and consume or give away.

The requirement for each person who operates a dairy farm and installs one or more farm bulk cooling or holding tanks in his milkhouse to install a 220-volt grounded weatherproof electrical outlet on the outside of the milkhouse and switch to control electrical power to the electrical outlet inside the milkhouse was added to the final regulation as §§ 2 VAC 5-501-60(A)(7) and 2 VAC 5-501-60(A)(8).

A new § 2 VAC 5-501-80(H) was added to allow sample dippers, sample dipper containers, and sanitizer to be supplied by the dairy farmer rather than by the contract hauler or subcontract hauler picking milk up at the dairy farm.

### Public Comment

*Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.*

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**The Agency published a notice in The Virginia Register of Regulations on September 9, 2002 advertising the opportunity to comment on proposed regulation 2 VAC 5-501, Regulations Governing the Cooling, Storing, Sampling, and Transporting of Milk. 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 comments from the Virginia Dairy Goat Association, one milk contract hauler and six citizens which included the following comments relative to the proposed regulation:**

- The final regulation should include an exemption for any farmer who processes milk from his own animals exclusively and sells the resulting dairy products directly to the final consumer either on the farm or at farmers' markets. Farmers subject to the exemption and offering dairy products for sale would be required to: (i) post a sign that the farm is neither permitted nor inspected; (ii) label each individually packaged dairy product sold with a statement that the dairy product has been produced at a farm that is neither permitted nor inspected; and (iii) maintain a brucellosis certified-free herd and a tuberculosis-free accredited herd.

The Agency disagrees. There were a number of different issues raised to support the inclusion of an exemption to the regulation which the Agency will respond to after each.

- The opportunity to comment on the proposed regulation was lost to many persons that will be affected by the proposed regulation because the Notice of Intended Regulatory Action (NOIRA) published in the *Virginia Register* was not written clearly enough for the reader to understand who may be affected.

The Agency disagrees for the following reasons: (1) The NOIRA published May 7, 2001 in Volume 17, Issue 17 of the *Virginia Register of Regulations* clearly states “The purpose of the proposed action is to review the regulation for effectiveness and continued need, including the following: the need to include certain other species of mammals if the milk or dairy products are intended for human consumption;...”; (2) The notice of proposed regulations published on September 9, 2002 in Volume 18, Issue 26 of the *Virginia Register of Regulations* states, “The purpose of the proposed action is to (i) make the regulations applicable to the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are intended for human consumption;...”; (3) The Agency believes both of the notices published in the *Virginia Register of Regulations* are sufficiently broad in scope to alert the reader as to who may be affected by the proposed regulation; and (4) the Agency did receive comment from the Virginia State Dairy Goat Association in response to the notice of propose regulations published on September 9, 2002.

- No dairy goat associations in the State were informed of the change in scope of the regulation, nor was their input sought as was done with the *Regulations Governing Milk for Manufacturing Purposes*.

The Agency is not required to form an advisory group as was done with the regulations governing manufactured grade milk or to inform every individual or association who might be affected by the proposed regulation that it may impact them. The Agency is required to publish notice of intended regulatory actions, proposed regulations, and final regulations for persons and organizations to review to determine if they believe the proposed action will affect them. The Agency has fully complied with all requirements to inform the public concerning the proposed regulation changes. The fact that the Agency did receive a comment from the Virginia State Dairy Goat Association indicates that they were able to determine the proposed regulation did affect them.

- The proposed regulations are unnecessary and would impose unneeded and costly requirements on the small and mid-sized producers.

The final regulation includes the milk of goats, sheep, water buffalo, and other species of mammals if the milk or dairy products are sold or offered for sale for human consumption. The existing regulation included the milk from cows only. The primary purpose of the final 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 offered for sale or sold for human consumption to be refrigerated and handled in ways which protect the milk from contamination.

The final 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 final 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 are included in the final regulation.

The final 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 final 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 regulation will impose costly requirements on small and mid-sized dairies putting small producers out of business and discouraging new entrepreneurship.

There are currently six small-scale cheese operations milking goats or sheep that are in compliance with the final 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 Agency considers anyone who sells cheese to be in business. One of the functions of the final 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 final 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 final regulation for the economic benefit of any person. Every citizen expects and deserves to purchase safe and wholesome milk and dairy products.

- I believe there should be some mention in the section dealing with milk house construction that requires electrical outlets and switches used for the 220 amp circuits for milk truck pumps be properly installed and repaired. We have experienced problems with electrocution hazards due to improper or no maintenance of these switches.

The Agency agrees and has included a requirement for each person who operates a dairy farm and installs one or more farm bulk cooling or holding tanks in his milkhous to install a 220-volt grounded weatherproof electrical outlet on the outside of his milkhous and a switch to control the electrical power to the 220-volt electrical outlet located on the inside of his milkhous. Inclusion of these items in the final regulation will allow the Agency to monitor the equipment to ensure it is maintained in good repair.

- I am concerned with the frequency that my drivers slip and fall from ladders, which are needed to access the milk tank lids for sampling. Often the ladders are not attached to the tank but are leaned against the tank creating the potential for accidents.

The Agency is concerned about the risk of personnel falling from ladders while accessing milk tank lids for sampling purposes also; however, the Agency does not believe this particular problem can be appropriately addressed under the final regulation. The principal responsibility for ensuring the safety of someone collecting milk samples from milk tanks must rest with the individual themselves. Each person climbing a ladder to access a milk tank lid should make sure the equipment he is using is in good repair and securely positioned against the tank prior to climbing up to access the lid.

- The regulation appears to require milk trucks to carry the sampling dippers and sanitizing solution. We do not currently have these kits attached to our trucks and would have to purchase them. We have been using dippers and sanitizer supplied by the farmers.

The Agency agrees that farmers should be allowed to supply sample dippers and sanitizer as is the current practice for many dairy farms in Virginia. The final regulation has been changed to allow dairy farmers to supply the sample dipper and sanitizer.

- The new regulations also call for each receiving plant to agitate the trailer loads of milk before they are sampled. It is my experience that most of the dairy plants in Virginia do not have this capability and that a significant expense would be required to add this equipment. I also believe it would have a financial impact on milk haulers who will be required to spend that much more time at the plant.

This is not a new requirement. The final regulation maintains the requirement for providing agitation under the existing regulation § 2 VAC 5-500-80(A) which states, "When milk is received from farm bulk milk pickup tanks or transport milk tanks that are not equipped with an approved adequate method for agitation, the milk plant or receiving station or transfer station shall provide an approved means for thoroughly mixing milk in the tank so that representative samples of the milk may be collected." The requirement for agitation is necessary to be consistent with the provisions of the PMO.

- The definition of "dairy farm" should not include people who make cheese from their own milk and consume it themselves or give it away.

The Agency agrees. The definition of "dairy farm" has been modified to apply only to those persons selling or offering for sale any milk, dairy product, or milk product for human consumption.

- I am opposed to the proposed regulations.

The Agency is unable to evaluate this comment because it was not accompanied by any reason why the person held this view.

## Detail of Changes

*Please detail any changes, other than strictly editorial changes, that are being final. 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 crosswalk - of changes implemented by the final regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.*

The final 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 final 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 final 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 final 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 final 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: (1) minimum clearance distances around, above, below, and under bulk milk tanks; (2) installation of a 220-volt weatherproof, grounded electrical outlet to be installed on the outside of the milkhouse for use by the contract hauler to operate the milk pump on his bulk milk pickup tank; (3) installation of a switch to control the electrical power to the 220-volt on the inside of the milkhouse; (4) prior approval must be obtained before

equipment installation takes place, 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 final 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 final 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; (xii) establish chain of custody procedures that must be followed by persons collecting and transporting milk samples; and (xiii) allow sample dippers, sample containers, and sanitizer to be provided by the dairy farmer rather than requiring the contract hauler or subcontract hauler to supply them.

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

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

### Family Impact Statement

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

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