



Virginia
Regulatory
Town Hall

**Final Regulation
Agency Background Document**

Agency Name:	Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-531 (2 VAC 5-530)
Regulation Title:	Regulations Governing Milk for Manufacturing Purposes
Action Title:	Final/Repeal
Date:	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Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed.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matters or changes contained in the final new regulation, amendments to an existing regulation, or the regulation being repealed.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 5-530) 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 and intended for human consumption; (2) be consistent with the USDA recommended requirements for milk for manufacturing purposes and processing plant purposes; and (3) include alternative requirements to foster the developing goats, sheep and water buffalo industries in Virginia.

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

being repealed and 2 VAC 5-531 (Regulations Governing Milk for Manufacturing Purposes) adopted concurrently.

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 5-531, Regulations Governing Milk for Manufacturing Purposes and simultaneously repealed 2 VAC 5-530, Rules and Regulations Governing the Production, Handling and Processing of Milk for Manufacturing Purposes and Establishing Minimum Standards for Certain Dairy Products to be Used for Human Food.

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 and 3.1-530.2 of the Code of Virginia (1950), as amended, (<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+3.1-530.1>) provide the discretionary authority for the regulation. Section 3.1-530.1 of the Code of Virginia authorizes the Board of Agriculture and Consumer Services "...to establish definitions, standards of quality and identity, and to adopt and enforce regulations dealing with the issuance of permits, production, importation, processing, grading, labeling, and sanitary standards for milk, milk products, and those products manufactured or sold in semblance to or as substitutes therefor." Section 3.1-530.2 directs State Board of Agriculture and Consumer Services to be guided "...by those regulations recommended from time to time by the United States Department of Health, Education and Welfare and the United States Department of Agriculture" when adopting regulations for the purpose of sanitation and to prevent deception.

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

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

The final regulation includes the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are intended for human consumption. The primary purpose of the regulation is to ensure the safety and wholesomeness of all milk and milk products sold or offered for sale for human consumption. The existing regulation covers only cow's milk, but there is significant production of dairy products offered for sale for human consumption made from the milk of goats, sheep, and water buffalo.

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

Milk is an excellent growth medium for most organisms including many pathogens. The fact that spoilage organisms and pathogens can grow in milk if they are present or introduced later by poor handling practices makes milk and milk products potentially hazardous if they are not properly processed, handled, packaged, and stored.

The requirement of pasteurization or aging at specific temperatures in the case of certain cheeses as effective means of destroying pathogens in manufactured dairy products will reduce the risk of death and illness from consuming contaminated manufactured dairy products. The regulation also requires the plant to employ certain practices that prevent contamination after pasteurization or aging. The regulation is essential to ensure the safety of these products.

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

requirements. In recent years, USDA recommended minimum quality standards applicable for milk used to make manufactured dairy products have changed. In addition, these recommended requirements include milk from goats and sheep and provide that all milk received at processing plants must be screened for animal-drug residues prior to processing.

The final regulation facilitates sales of Virginia-manufactured products by providing for the labeling of dairy products to prevent deception, establishing standards of identity, and providing a level playing field on which all persons may compete.

Substance

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

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

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

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

The final regulation also establishes the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

Issues

Please provide a statement identifying the issues associated with the 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.

Public:

The final regulation enhances the safety and wholesomeness of manufactured dairy products by including milk for manufacturing purposes and manufactured dairy products produced from the milk of goats, sheep, water buffalo, and other mammals (except humans). The existing regulation covered only those dairy products manufactured from cow's milk.

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

There are no disadvantages to the public.

Regulated Entities:

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

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

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

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

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

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

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

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

to make facility and equipment improvements to comply with the requirements under the final regulation.

Agency:

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

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

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

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

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

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

There are no disadvantages to the agency associated with the 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.

Section 2 VAC 5-531-10 Definitions, was modified to include the following standardized cheeses and related products: asiago fresh cheese; asiago medium cheese; asiago old cheese; asiago soft cheese; blue cheese; brick cheese; brick cheese for manufacturing; caciocavallo siciliano cheese; cheddar cheese; cheddar cheese for manufacturing; club cheese; colby cheese; colby cheese for manufacturing; cold-pack cheese; cold-pack cheese food; cold-pack cheese food with fruits, vegetables, or meats; cook cheese; cream cheese; cream cheese with other foods; edam cheese; gammelost cheese; gorgonzola cheese; gouda cheese; granular and stirred curd cheese; granular cheese for manufacturing; grated cheese; grated American cheese food; gruyere cheese; hard cheeses; hard grating cheeses; high-moisture jack cheese; koch kaese; limburg cheese; low-moisture part-skim mozzarella and scamorza cheese; low-moisture mozzarella and scamorza cheese; low sodium cheddar cheese; low sodium colby cheese; monterey cheese and monterey jack cheese; mozzarella cheese and scamorza cheese; muenster and munster cheese; muenster and munster cheese for manufacturing; neufchatel cheese; nuworld cheese; parmesan and reggiano cheese; part-skim mozzarella and scamorza cheese; part-skim spiced cheeses; pasteurized blended cheese; pasteurized blended cheese with fruits, vegetables, or meats; pasteurized cheese spread; pasteurized cheese spread with fruits, vegetables, or meats; pasteurized neufchatel cheese spread with other foods; pasteurized process cheese; pasteurized process cheese food; pasteurized process cheese food with fruits, vegetables, or meats; pasteurized process cheese spread; pasteurized process cheese spread with fruits, vegetables, or meats; pasteurized process cheese with fruits, vegetables, or meats; pasteurized process pimento cheese; provolone cheese; romano cheese; roquefort cheese; samsoe cheese; sap sago cheese; semisoft cheeses; semisoft part-skim cheeses; skim milk cheese for manufacturing; soaked curd cheese; soft ripened cheeses; spiced cheeses; spiced, flavored standardized cheeses; swiss and emmentaler cheese; swiss cheese for manufacturing; washed curd cheese; and washed curd cheese for manufacturing.

A new section 2 VAC 5-531-20 *Standardized cheeses and related products* was added to establish requirements for certain standardized cheeses and related products that have a standard of identity under 21 CFR Part 133.

Section 2 VAC 5-531-50(K) was modified to require each permit holder operating a dairy plant to submit his recall plan for approval to the Virginia Department of Agriculture and Consumer Services by May 1, 2004 rather than “within one hundred twenty days after the effective date of this regulation”.

Section 2 VAC 5-531-50(O)(3) was modified to require existing dairy plants holding permits on January 1, 2004 (the effective date of the regulation) to provide an officially designated laboratory for supplying load confirmation and producer traceback animal drug-residue results by July 1, 2004 rather than “a maximum of six months from the effective date of this regulation”.

Section 2 VAC 5-531-70(B)(1)(e)(1) was modified to establish January 1, 2004 as the effective date of the regulation rather than stating the effective date as “the effective date of the regulation”.

Section 2 VAC 5-531-70(B)(1)(h)(2)(g) was modified to establish January 1, 2004 as the effective date of the regulation rather than stating the effective date as “the effective date of the regulation”.

Section 2 VAC 5-531-110(A) was modified to establish January 1, 2004 as the effective date of the regulation rather than stating the effective date as “the effective date of the regulation”.

A new section 2 VAC 5-531-160, *Effective date of regulation* was added to establish January 1, 2004 as the effective date of the regulation.

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.

The Department published a notice in The Virginia Register of Regulations on September 9, 2002 advertising the opportunity to comment on 2 VAC 5-531, Regulations Governing Milk for Manufacturing Purposes. An informal advisory group was not formed for the purpose of reviewing the final regulations and to make recommendations to the Agency relative to its requirements. The Agency received a total 168 comments from citizens, the affected industry, and the Virginia State Dairy Goat Association. The following comments relative to the final regulation were received:

- **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 final regulation which the Agency will respond to after each.

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

The Department can find no merit to the argument that including goat's milk products in the final regulation would prevent cheese from being sold at the farm or farmers' markets in Virginia. A number of goat cheese makers currently comply with inspection requirements and sell their cheeses on the farm, in farmers' markets, retail outlets, and through the internet. The final regulation does not restrict the sale of cheese in Virginia.

- **If the existing regulation were amended to include goats, sheep, and other animals, some of these individuals contend they would be put out of business because they can not afford to comply with the public health and safety requirements that persons making cheese from cow's milk currently comply with.**

There are currently 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 final 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 final 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.

The Department 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 final 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.

- **Some of these individuals contend that their cheese and dairy products do not constitute any risk to the consuming public. They cite the absence of reported public health outbreaks in Virginia as proof that they are correct in their assertions.**

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

The Department's position is that all milk and milk products have the same potential to carry pathogenic organisms. The fact that the milk came from a cow, sheep, goat, water buffalo, or other mammal makes no difference. Numerous diseases of humans have been documented to be present in the milk of lactating mammals. Brucellosis and tuberculosis are two well-known and documented diseases which are capable of being spread from cows, goats, and sheep to humans through their milk. Other common pathogens associated with milk and dairy products are: *Staphylococcus*, noted for its toxin production; *Streptococcus*, which causes strep-throat; *Campylobacter jejuni*, which infects the lining of the intestine and causes bloody diarrhea; *Escherichia coli*, which is responsible for causing bloody diarrhea and Hemolytic Uremic Syndrome; *Salmonella*, which also causes diarrhea; *Yersinia enterocolitica*, which causes severe abdominal pain; *Listeria monogytogenes*, which causes fever, vomiting, and can lead to still-births in pregnant women; and *Coxiella burnetii*, which causes Q fever. Some of these diseases can be fatal.

Milk is an excellent growth medium for most organisms including many pathogens. The fact that spoilage organisms and pathogens can grow in milk if they are present or introduced later by poor handling practices makes milk and milk products potentially hazardous if they are not properly processed, handled, packaged, and stored. The regulation is essential to ensure the safety of these products.

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

people, hospitalized 21 people, and resulted in one death. The Texas Department of Health reported 16 cases of brucellosis in 1998 and fourteen of those individuals had consumed goat dairy products. *Brucella melitensis* is carried by goats and causes brucellosis in humans. In December 1999, Texas officials determined a herd of goats in Starr County was infected with *Brucella melitensis*. Texas officials destroyed the entire herd of 120 goats to prevent the spread of the disease to other animals and humans.

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

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

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

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

- **Some of these individuals allege that dairy products sold directly from the farm are superior in quality and safer than other commercially available products at retail stores.**

The Department is unaware of any scientific evidence that supports the allegation that milk and dairy products sold directly from the farm are of superior quality or safer than commercially available products. Some individuals allege that because

commercial dairy products are manufactured from the commingled milk from numerous dairy farms that they are more subject to contamination than similar products manufactured by a single farm. The Department believes that all milk and dairy products have the same potential risk of adulteration with pathogens or other organisms. The same steps needed to process milk and dairy products into safe and wholesome foods are necessary for both the individual dairy farm and the large commercial processor. Where food safety is concerned, smaller does not equate with safer.

- **The final regulations should include provisions to establish a certified raw milk program in Virginia.**

Certified raw milk dairies typically operate under stricter inspection and sampling requirements and offer unpasteurized milk for sale to the public. The issue of unpasteurized milk sales is not open for consideration under the final regulation. Another regulation, Regulations Governing Grade “A” Milk, 2 VAC 5-490 regulates the sale of unpasteurized milk in Virginia.

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

- **I object to the need for “daily operations” to maintain a permit. I am concerned about requiring people to make cheese five days a week and forcing dairy animals into unnatural production cycles.**

The issue for the Department occurs when a permit holder ceases to produce milk for manufacturing purposes or ceases the production of cheese but does not want to cancel his permit. The regulations require the Department to conduct inspections and collect samples for compliance with the requirements of the regulation; however, the dairy farm or processor is not operating. In this situation, the regulations establish the criteria by which the permit holder’s permit may be suspended, cancelled or revoked. Seasonal operations may be suspended during the dry months for the milking animals and reinstated when the animals freshen again. The Department currently operates with similar requirements under the grade “A” milk regulations. The Department considers the requirement for daily operations reasonable.

- **The final regulation is geared to large commercial manufacturing operations that wholesale or retail their products in commerce and are unsuitable for small scale operations.**

The Department disagrees. The regulation is written to ensure the safety and quality of milk and dairy products. The principles of safe food production and processing are not related to the size of the operation, but to the nature of the products being produced. The regulation

contains many exemptions for small-scale operations which do not affect product safety, but will significantly reduce the cost of complying with the requirements.

- **The final regulation is designed to protect big business from competition.**

The Department disagrees. The total volume of cheese produced in Virginia can be measured in tons per year. Large scale processors will produce tons of cheese each day of operation for distribution nationwide. Cheese processors in Virginia are not considered a threat to large national processors because our total volume is so small and the types of cheese being offered are very different and do not compete for the same customer.

- **I am concerned about the broad definition of non-standardized cheese. How do you know whether a cheese actually conforms to a standard type without expensive testing?**

The final regulation is intended to cover all cheese production. In order to regulate all cheese production, the regulation must cover the standardized cheeses described by 21 CFR Part 133 and any other type of cheese that someone may want to make and sell. The broad definition of non-standardized cheese ensures that all cheeses are regulated under the regulation.

The only way to know if a cheese conforms with its standard of identity is to: (i) compare the process by which it was made to the process described in its standard of identity; (ii) compare its ingredients to those allowed under the standard of identity; and (iii) test the cheese for total solids and percent moisture to determine if it meets the minimum percent fat and solids required by the standard of identity. The Department will perform the testing necessary to determine if a cheese product conforms with its standard of identity if it is necessary for labeling or enforcement actions.

- **All non-standardized cheeses should not be required to be made from pasteurized milk.**

The Department disagrees. In order to be consistent with federal requirements, a cheese may be made from unpasteurized milk only if an alternative procedure to pasteurization is provided for by federal regulations, such as in 21 CFR Part 133 for curing of certain cheese varieties.

- **The regulation should contain an exemption to pasteurization for the manufacture of Ricotta cheese. The cheese is held at 190-200 degrees F for some time, so why pasteurize?**

The Department disagrees. Ricotta cheese does not have a standard of identity under 21 CFR Part 133 and therefore must be made from pasteurized milk. The milk from which the whey was obtained must have been pasteurized. Pasteurization is required to eliminate any pathogens from the milk prior to processing the cheese. Holding milk or whey at 190-200 degrees F is not considered legal pasteurization. Pasteurization must occur in properly designed and operated equipment approved by the Department.

- **I am concerned about private inspectors for pasteurization equipment and the added cost to cheese makers.**

The provisions to allow private individuals to become certified by the Department to test and seal pasteurization equipment allows cheese makers another option in addition to Department inspectors for checking and approving their pasteurization equipment. There are cheese makers who have hired outside consultants to check their pasteurization equipment prior to Department inspectors conducting their initial inspection of the equipment. This option is strictly at the option of the cheese maker. The Department will continue to provide pasteurization equipment testing and sealing for regulatory purposes. One advantage to using a private inspector approved by the Department for checking pasteurization equipment is that the Department will accept their work rather than interrupting the facilities production schedule again to conduct the testing and sealing ourselves.

- **The final regulation will ban non-cow milk dairy products currently being imported in Virginia.**

The Department disagrees. The importation of cheese and dairy products into Virginia from outside the Commonwealth is governed by the federal government. The final regulation is consistent with federal laws and regulations allowing any dairy products that may legally enter the United States to enter Virginia.

- **The final regulation should be amended to allow untreated wood shelving for use in cheese aging.**

The Department disagrees. The final regulation requires all dairy equipment that comes in contact with any milk or milk product to be constructed of materials that are smooth, easily cleanable, and non-absorbent. Wood is not suitable for a food contact surface because it absorbs moisture, is not smooth or easy to clean. Because wood is porous and absorbs moisture, it is not possible to achieve an effective sanitizing treatment.

- **I support the final regulation because I enjoy cheese and like purchasing it at farmers markets.**

The Department agrees.

- **I support the exemptions for small-scale processors under the final regulation. The exemptions are reasonable and acceptable.**

The Department agrees.

- **I can not support a total exemption to the regulation for anyone making cheese because I have been in plenty of dirty little dairies. Many home cheese makers in the U.S. do not have much training and may be unfamiliar with the signs of contamination or animal diseases. Most consumers do not have much knowledge about dairy products. Home cheese makers selling at farmer's markets could cause severe fluctuations in the**

market, as they have with eggs and vegetables, making it very difficult for those who have invested in a processing business to gauge supply and demand in a niche market. I see a major bureaucratic nightmare in attempting to determine if all these little herds, especially goat herds, are closed or not. An exemption would allow sales at farmer's markets which bypasses inspection of the farm by the consumer.

The Department agrees.

- **I support an exemption to the final regulation if: (i) all sales are required to be at the farm; (ii) no advertising is allowed; and (iii) total sales are limited.**

The Department disagrees. The principal reason for the inclusion of goats, sheep, water buffalo, and other mammals to be included in the final regulation is to ensure the safety and quality of all milk and dairy products sold or offered for sale for human consumption.

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

dairy plant processing areas; (11) new exemptions to facility and equipment requirements for small-scale dairy processors of cheese; (12) new animal health requirements for goats, sheep, water buffalo, and other mammals (except humans); (13) new and specific requirements governing employee health and a procedure to follow when infection is suspected; (14) a new section establishing which dairy products may be sold for human consumption; and (15) a new section establishing administrative procedures and due process provisions for persons whose permit has been summarily suspended. Each of these areas will be more fully discussed in the order they occur in the final regulation.

Section 2 VAC 5-531-10 Definitions:

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

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

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

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

2 VAC 5-531-20 Standardized cheeses and related products

This new section establishes requirements for certain standardized cheeses and related products that have a standard of identity under 21 CFR Part 133.

2 VAC 5-531-30 Non-standardized Cheese and Related Products

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

2 VAC 5-531-40 Adulterated or misbranded milk or dairy products.

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

2 VAC 5-531-50 Permits.

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

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

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

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

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

A new requirement is established for dairy plants to develop a recall plan and submit it to the Department for approval to ensure the permit holder will be able to effectively carry out his responsibility to protect the public health and well-being from products that present a risk of illness, injury, gross deception, or are otherwise defective.

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

New requirements for dairy farms include:

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

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

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

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

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

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

2 VAC 5-531-60 Labeling

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

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

2 VAC 5-531-70 Standards for milk and dairy products

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

1. The maximum permitted bacteria count has been lowered from 1,000,000 cells per milliliter to 500,000 cells per milliliter for milk sold from individual dairy farms;
2. The maximum permitted bacteria count for commingled milk has been lowered from 3,000,000 cells per milliliter to 1,000,000 cells per milliliter;
3. The maximum permitted cryoscope test result (a measure of added water) has been established at .530 degrees Hortvet;
4. The maximum permitted somatic cell count (a measure of udder infection) for all species of mammals except goats has been lowered from 1,000,000 cells per milliliter to 750,000 cells per milliliter;
5. The maximum length of time milk for manufacturing purposes can be stored on the dairy farm prior to pickup for delivery to a processing plant has been established;
6. A new requirement for dairy products to be made from pasteurized milk or to be properly aged has been added;
7. New quality standards for the maximum levels of coliform organisms and *Staphylococcus aureus* organisms have been established; and
8. Standards for sediment content in milk for manufacturing purposes have been eliminated.

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

1. The allowance under existing regulation for a dairy farm to have a combined milking parlor and milk room has been eliminated;
2. Dairy farms will be required to provide toilet facilities for the first time;
3. Dairy farm water supplies will have to meet new construction criteria for approval;
4. Dairy farmers will be required to clip the hair on the udder and tail of each milking mammal;
5. New requirements for the storage of animal drugs have been added; and

6. Requirements for dairy plants have been organized by general requirements for all dairy plants followed by specific additional requirements for dairy plants producing dry milk products, butter, cheese, process cheese, or condensed milk and similar products.

2 VAC 5-531-80 Requirements for small-scale cheese plants

This new section provides a number of exemptions for small-scale cheese plants to the facility, construction, testing, and equipment requirements for obtaining a permit. The exemptions allowed do not compromise the ability of the small-scale cheese plant to produce safe and wholesome dairy products.

2 VAC 5-531-90 Animal health

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

2 VAC 5-531- 100 Construction plans for dairy farms and dairy plants

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

2 VAC 5-531-110 Dairy products which may be sold

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

2 VAC 5-531-120 Personnel health

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

2 VAC 5-531-130 Procedure when infection is suspected

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

2 VAC 5-531-140 Interpretation and enforcement

This new section provides that interpretations of the requirements of the final regulation shall be consistent with interpretations accorded with the model federal regulation on which it is based.

Because the Administrative Process Act does not apply to summary actions taken by state agencies, an administrative process is established that the Department must follow when summarily suspending a person's permit. This process ensures a person's right to due process under the law.

2 VAC 5-531-150 Regulation superseded

This new section alerts the reader to the fact that 2 VAC 5-531, Regulations Governing Milk for Manufacturing Purposes supersedes the existing regulation 2 VAC 5-530, Rules and Regulations Governing the Production, Handling and Processing of Milk for Manufacturing Purposes and Establishing Minimum Standards for Certain Dairy Products to be Used for Human Food.

2 VAC 5-531-160 Effective date of regulation

This new section establishes January 1, 2004 as the day on which 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.

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