



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Agriculture and Consumer Services
<b>Virginia Administrative Code (VAC) citation</b>	2VAC5-510
<b>Regulation title</b>	Rules and Regulations Governing the Production, Processing, and Sale of Ice Cream, Frozen Desserts, and Similar Products
<b>Action title</b>	Amending 2VAC5-510 based on recommendations of the Attorney General's Government and Regulatory Reform Task Force
<b>Date this document prepared</b>	December 15, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The proposed amendments to the existing regulation consolidate thirty-one separate sections into fifteen sections and repeal one section to reduce the sheer size of the regulation and make it more user-friendly. Some sections have been amended to use the same words and terms throughout and numerous citations to requirements have been updated to properly identify reference documents and citations to specific sections of the Code of Virginia to make the regulation more easily understood. The changes made are not substantive changes to the requirements of the regulation and do not create any new requirements or modify any existing requirements. The one section that was repealed is currently unenforceable because it was pre-empted by changes to the federal standard of identity for ice cream and the National Labeling and Education Act.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

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On December 6, 2007 the Board of Agriculture and Consumer Services adopted the proposed amendments to 2 VAC 5-510, Rules and Regulations Governing the Production, Processing, and Sale of Ice Cream, Frozen Desserts, and Similar Products

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

Sections 3.1-562.1 and 3.1-562.2 of the Code of Virginia provide the statutory authority for the regulations. These sections do not require the Board of Agriculture and Consumer Services to adopt regulations governing the production, processing and sale of ice cream, frozen desserts and similar products.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

The specific and measurable goals of this regulation:

1. The protection of the public's health, safety, and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth.
2. The ensuring of the safety of ice cream or frozen desserts through pasteurization and prevention of contamination.
3. The facilitation of sales of Virginia ice cream and frozen desserts in intrastate and interstate commerce.

The first specific goal of the regulation is to reduce the risk of death and illness from consuming contaminated ice cream or frozen desserts. From a practical point of view, it is infeasible to determine the exact number of incidents of contamination that have been prevented by the system established through the regulation. Determining the exact number of incidents prevented is not necessary, however, since the regulation requires pasteurization and certain other practices to prevent contamination of these products after they have been pasteurized.

Pasteurization is a heat treatment process which destroys all known disease pathogens and is widely recognized (e.g., by the American Medical Association, the Food and Drug Administration, the United States Department of Agriculture, and state public health departments) as an effective means of destroying pathogens in food products, including ice cream and frozen desserts. Pasteurization is the first principal means by which the regulation seeks to reduce the risk of death and illness. The Department of Agriculture and Consumer Services inspects the pasteurization equipment in each ice cream and other frozen dessert manufacturing facility. The Department also regularly collects samples of ice cream and

other frozen dessert precuts from each manufacturer and tests these samples to make sure that proper pasteurization occurred.

The second principal means by which the regulation seeks to reduce the risk of death and illness is by requiring manufacturers to employ certain practices that prevent contamination after pasteurization has occurred. An example is the requirement that all equipment that comes in contact with any ice cream or other frozen dessert be cleaned and sanitized daily. The department tests each sample for the presence of unacceptable bacteria.

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

This regulation establishes the basic mechanisms to protect public health in each step of the process -- from the initial manufacturing of ice cream and other frozen dessert products to the moment in which the products reach the consumer. The regulation requires that all ice cream and other frozen desserts be manufactured from pasteurized mix. Pasteurization is a heat treatment process which destroys all known disease-producing microorganisms and is widely recognized (e.g., by the American Medical Association, the Food and Drug Administration, the United States Department of Agriculture, and state public health departments) as an effective means of destroying pathogens in food products, including ice cream and other frozen desserts. This step significantly reduces the risk to humans of contracting disease transmitted through consuming contaminated ice cream or frozen desserts. In addition, the regulation sets certain minimum quality standards and inspections which must be met to hold a permit to manufacture ice cream and other frozen desserts. Inspection, sampling, and testing help ensure Virginia citizens safe and properly labeled ice cream and other frozen desserts.

In early October 1994, a nationwide recall of ice cream, sherbet, and frozen yogurt products was instituted by a leading manufacturer because many of these products were contaminated with the bacteria *Salmonella*, which can cause illness and death. By the end of October, as a result of consuming the contaminated frozen dessert products, 61 people across the country had been hospitalized. In 38 states (including Virginia), another 547 cases of food poisoning from consumption of the contaminated products had been confirmed through scientific tests, and another 3,264 cases had been reported in which food poisoning was suspected. The Centers for Disease Control estimates that 500,000 people nationwide were affected as a result of this incident. Without mechanisms to ensure the quality of ice cream and other frozen desserts, incidents similar to this would likely be far more common.

Sales of milk and other dairy products, such as ice cream, are extremely sensitive to reports that reach consumers of contamination or poor quality in those products. Even after the reported problems have been corrected, consumers do not readily return to purchasing these products. Negative perceptions among consumers may be changed over a period of time, but at the cost of lost sales. Maintaining positive consumer attitudes is extremely important to the continued competitiveness and profitability of the ice cream and other frozen desserts industry in Virginia. This regulation provides support for the continued positive perception of ice cream and other frozen desserts as safe, wholesome products. In addition, the standards of identity help assure that ice cream and other frozen desserts sold by any manufacturer meet consumer expectations.

*Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

*Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

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Each of the changes to the regulation were considered and recommended by the Attorney General's Government and Regulatory Reform Task Force, an initiative of Attorney General Robert F. McDonnell and have been reviewed and approved by the administration of Governor Timothy Kaine. All of the changes are needed to reduce the sheer size of the regulation and to make them more understandable and "user-friendly". None of the changes add any new requirements or modify any existing requirements. The regulation is essentially the same as before, except now it is more easily understood by the reader. During the recent periodic review of the regulation, there were no comments received that would conflict with any of the recommendations of the Attorney General's Government and Regulatory Reform Task Force, and agency staff does not anticipate any controversy with any of the amendments.

### Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)*

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There were no changes of substance to the regulation.

### Issues

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If there are no disadvantages to the public or the Commonwealth, please indicate.*

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The primary advantage to the public and businesses of implementing the amended provisions is making the regulation easier to understand and user-friendly.

The primary advantage to the agency and Commonwealth is to foster voluntary compliance with the requirements because they are easier to understand and user-friendly.

There are no disadvantages to implementing the amended regulation.

### Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

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There are no applicable federal requirements.

### Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

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There are no localities that will be particularly affected by the proposed regulation.

### Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

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The agency has considered the following alternatives.

The first alternative considered was to establish less stringent requirements; however this alternative was rejected because there is no known processing methods equivalent to pasteurization in the elimination of all pathogens and the resulting reduction in risk to human health. The requirements for the prevention of contamination before and after processing and packaging would be the same no matter what pathogen reduction process was used.

The second alternative considered was to establish performance standards for frozen desserts that could be tested for to determine safety; however, this alternative was rejected because reliance on sample testing is far less effective in ensuring product safety than the process of pasteurization. When properly performed, pasteurization works all the time for the entire product processed. If an alternative process was allowed based on testing parameters it could not be comparable to the effectiveness of pasteurization because testing is a hit or miss proposition. You could sample the same batch of product five times and recover varying numbers of bacteria in each sample. You are limited by the number of test you can run and the

costs of the testing; whereas, pasteurization kills all pathogens every time. There is simply no comparison between testing and pasteurization.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>	There is no projected additional cost to the state to implement the regulation since there are no substantive changes.
<b>Projected cost of the regulation on localities</b>	There is no cost to localities since ice cream and frozen desserts are exempt from local supervision and inspection.
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	The regulation affects any person or business who manufactures, packages and sells ice cream and frozen desserts at wholesale.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	The agency estimates there are seventeen small businesses affected by the regulation.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	There are no additional projected cost of the regulation for affected individuals and businesses because all entities are in compliance with the current requirements.

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

The first alternative considered was to not regulate the ice cream and other frozen desserts industry at all. This alternative was rejected because it could undermine public confidence in the safety and quality of Virginia ice cream and other frozen dessert products. In addition, many other states require all ice cream and other frozen dessert products to have been inspected in the state in which they were manufactured. Without a government-sanctioned inspection program (as established through the statute and the regulation), Virginia-made ice cream and

other frozen desserts probably could not be sold in many other states, which would put Virginia manufacturers at a competitive disadvantage.

The second alternative considered was a program run by industry with some limited regulatory oversight to monitor and certify the program. Because of the market's extreme sensitivity to quality and contamination issues in relation to dairy products, this was rejected also as less likely than a state-controlled program to enhance the public confidence in the safety and quality of ice cream and other frozen desserts.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.*

The regulation does not have an impact upon families.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
2 VAC 5-510-10		Definition of "3-A Sanitary Standards"	Correct the name of International Association of Milk, Food and Environmental Sanitarians to its current name of International Association of Food Protection and state the standards can be obtained from 3-A Sanitary Standards, Incorporated.
2 VAC 5-510-50 & 2 VAC 5-510-60		Identity statement for Frozen Custard and Frozen Custard Mix	Combine two sections in 2 VAC 5-510-50 and repeal 2 VAC 510-60 to shorten the regulation.
2 VAC 5-510-70 &		Identity statement for Ice Milk and Ice Milk Mix	Repeal both sections because they have been pre-empted by federal regulation and

2 VAC 5-510-80			law.
2 VAC 5-510-90 & 2 VAC 5-510-100		Identity statement for Fruit Sherbets and Fruit Sherbet Mix	Combine both sections into 2 VAC 5-510-90 and repeal 2 VAC 5-510-100 to shorten the regulation.
2 VAC 5-510-110 2 VAC 5-510-120		Identity statement for Water Ices and Water Ice Mix	Combine both sections into 2 VAC 5-510-110 and repeal 2 VAC 5-510-120 to shorten the regulation.
2 VAC 5-510-130 2 VAC 5-510-140		Identity statement for Non fruit Sherbets and Nonfruit Sherbet Mix.	Combine both sections into 2 VAC 5-510-130 and repeal 2 VAC 5-510-140 to shorten the regulation.
2 VAC 5-510-150 2 VAC 5-510-160		Identity statement for Nonfruit Water Ices and Nonfruit Water Ice Mix	Combine both sections into 2 VAC 5-510-150 and repeal 2 VAC 5-510-160 to shorten the regulation.
2 VAC 5-510-170 2 VAC 5-510-180		Identity statement for Artificially Sweetened Ice Cream and Artificially Sweetened Ice Cream Mix	Combine both sections into 2 VAC 5-510-170 and repeal 2 VAC 5-510-180 to shorten the regulation.
2 VAC 5-510-190 2 VAC 5-510-200		Identity statement for Artificially Sweetened Ice Milk and Artificially Sweetened Ice Milk Mix	Combine both sections into 2 VAC 5-510-190 and repeal 2 VAC 5-510-200 to shorten the regulation.
2 VAC 5-510-210 2 VAC 5-510-220 2 VAC 5-510-230		Identity statement for Frozen Yogurt, Frozen Yogurt Mix and shipping Frozen Yogurt Mix.	Combine three sections into 2 VAC 5-510-210 and repeal 2 VAC 5-510-220 and 2 VAC 5-510-230 to shorten the regulation.
2 VAC 5-510-240 2 VAC 5-510-250		Identity Statement for Quiescently Frozen Confection and Quiescently Frozen Confection Mix	Combine both sections into 2 VAC 5-510-240 and repeal 2 VAC 5-510-250 to shorten the regulation.
2 VAC 5-510-260 2 VAC 5-510-270		Identity Statement for Quiescently frozen dairy confection and Quiescently Frozen Dairy Confection Mix	Combine both sections into 2 VAC 5-510-260 and repeal 2 VAC 5-510-270 to shorten the regulation.
2 VAC 5-510-290 2 VAC 5-510-300		Identity Statement for Mellorine and Mellorine Mix	Combine both sections into 2 VAC 5-510-290 and repeal 2 VAC 5-510-300 to shorten the regulation.
2 VAC 5-510-310 2 VAC 5-510-320		Identity Statement for Pavevine and Pavevine Mix	Combine both sections into 2 VAC 5-510-310 and repeal 2 VAC 5-510-320 to shorten the regulation.
2 VAC 5-510-330 2 VAC 5-510-340		Identity Statement for Lowfat Pavevine and Lowfat Pavevine Mix	Combine both sections into 2 VAC 5-510-330 and repeal 2 VAC 5-510-340 to shorten the regulation.
2 VAC 5-510-350		Identity Statement for Freezer Made Milk Shake	Combine both sections into 2 VAC 5-510-350 and repeal 2 VAC 5-510-360 to shorten the



2 VAC 5-510-360		and Freezer Made Milk Shake Mix	regulation.
2 VAC 5-510-390 2 VAC 5-510-400		Identity Statement for Imitation Frozen Desserts and Imitation Frozen Desserts Mix	Combine both sections into 2 VAC 5-510-390 and repeal 2 VAC 5-510-400 to shorten the regulation.
2 VAC 5-510-410		Prohibition on adulterated or misbranded frozen desserts or frozen desserts mix.	Correct typographical error by changing the word “of” to “or” in this section in the phrase “frozen dessert <u>of</u> frozen dessert mix”
2 VAC 5-510-420		Issuing, suspension and revocation of permits.	Correct citation to formal hearing pursuant to §2.2-4020 of the Code of Virginia.
2 VAC 5-510-500		Facilities Requirements	Properly cite the current names for 3-A Sanitary Standards documents referenced under the regulation.
2 VAC 5-510-510		Equipment and Utensils Requirements	Properly cite the current names for 3-A Sanitary Standards documents referenced under the regulation.