

Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Department of Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-510
Regulation Title:	Rules and Regulations Governing the Production, Processing and Sale of Ice Cream, Frozen Desserts and Similar Products
Action Title:	Amend
Date:	May 8, 2001

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

This regulation requires a permit to manufacture, process, or sell ice cream and

similar frozen desserts in Virginia. The regulation establishes standards of identity,

labeling requirements, quality standards, and requires pasteurization for ice cream, frozen

desserts, and similar products.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

Sections 3.1-562.1 and 3.1-562.2 of the Code of Virginia (1950), as amended, 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.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

The Department published its notice in The Virginia Register of Regulations on February 12, 2001 advertising the opportunity to comment on this regulation pursuant to Executive Order Number Twenty-five (98). The agency did not receive any public comments regarding this regulation. An informal advisory group was not formed for the purpose of assisting with this periodic review.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The specific and measurable goals of this regulation are:

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.

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.

Through its review of this regulation, the agency has determined that the regulation is not clearly written or easily understood by the individuals and entities affected.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The agency has considered, during the course of this review, the following alternatives:

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.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

It is the agency's recommendation that this regulation be amended. However, since the amendments would be extensive, it is recommended that the existing regulation be repealed and a new regulation be adopted concurrently. The new regulation will clarify current requirements, include specific requirements not addressed in the present regulation, and conform with the most recent recommendations of the United States Department of Agriculture and the Food and Drug Administration for plants processing ice cream and frozen desserts.

Substance of Proposed Action

Please detail any changes that would be implemented.

Proposed changes/additions to the regulation are as follows:

Reference the federal Food, Drug and Cosmetic Act (and certain federal regulations thereunder) to support certain elements of the regulation.

Amend the standards of identity for ice cream and frozen desserts to conform to the standards of identity for ice cream and frozen desserts at the federal level.

Include frozen desserts for which standards of identity have not been established. (There are a number of new frozen dessert products which incorporate ingredients not currently included under the regulations. These frozen dessert products are not currently subject to the safety and quality standards that all other frozen desserts have to meet.)

Clarify the difference between requirements for: (1) retail shops making ice cream and selling directly to the final consumer; (2) restaurants that wish to make and serve ice cream and frozen desserts for sale to their customers; (3) push carts, mobile units, and commissaries: and (4) manufacturers of ice cream and frozen desserts who wholesale their products.

Amend the regulation to allow retailers to make frozen dessert mix from pasteurized ingredients. (The current regulation requires that all ice cream and frozen desserts mix be pasteurized after being made up even though pasteurized ingredients are used.)

Amend the regulation to conform with the most recent recommendations of the United States Department of Agriculture and the Food and Drug Administration for plants processing ice cream and frozen desserts.

Require permits for retail frozen dessert shops, push carts, mobile units, and commissaries or depots. (These entities are under inspection currently; however, they are not required to have a permit or contact the agency prior to starting up their business.)

Prohibit the manufacture of ice cream and frozen desserts in a person's home or any area used for domestic purposes. (Fourth Amendment protections of the U.S. Constitution make it difficult to enter and enforce inspection and sanitation requirements when the production facilities are also part of the person's home. Existing permitted facilities would be grandfathered for as long as they were in continuous operation.)

Require wholesalers of ice cream and frozen desserts to pasteurize all of their ice cream and frozen desserts mix in the plant where it is packaged. (Existing plants would be exempted from this requirement as long as they were in continuous operation.)

Family Impact Statement

Please provide a preliminary analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income. Unless otherwise discussed in this report, this regulation has no impact upon families.