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## Periodic Review and Small Business Impact Review Report of Findings

<b>Agency name</b>	Board of Agriculture and Consumer Services
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	2 VAC 5-560
<b>VAC Chapter title(s)</b>	Rules and Regulations Pertaining to Labeling and Sale of Infant Formula
<b>Date this document prepared</b>	September 8, 2020

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the **Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code**.

### Acronyms and Definitions

*Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.*

### Legal Basis

*Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.*

Section 3.2-109 of the Code of Virginia (Code) establishes the Board of Agriculture and Consumer Services (Board) as a policy board with the authority to adopt regulations in accordance with the provisions of Title 3.2 of the Code.

Section 3.2-5101 of the Code authorizes the Board of Agriculture to adopt regulations that will promote honesty and fair dealing in the interest of consumers that purchase food products, including regulations that establish standards of identity and tolerances or limits of variability.

Section 3.2-5121 grants the Board authority to adopt regulations for the efficient enforcement of Article 3 of the Food and Drink Law (Va. Code § 3.2-5100 *et seq.*), which pertains to adulteration, misbranding, and false advertising of food.

**Alternatives to Regulation**

*Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.*

The existing regulation requires the calendar month and year to appear on all containers of powdered or liquid infant formula. Furthermore, it requires that the expiration date be established by the manufacturer utilizing valid scientific data. Lastly, it declares any infant formula sold either beyond the expiration date or with no expiration date to be adulterated. This makes it possible to have substandard and/or out of date infant formula removed from sale. The agency could attempt to enforce the standards relating to infant formula via the general statutes in the Food and Drink Law. However, those statutes lack the specific language necessary to enforce existing standards. Thus, it would not be possible to ensure that infants consume formula with the appropriate nutritive value without this regulation. It is possible to adopt existing federal regulations relating to infant formula. However, those regulations are likely to be significantly more burdensome to the industry without full application in a retail environment. Therefore, this regulation is the most efficient and least burdensome method of achieving the purpose of the regulation. This regulation provides for a significant level of public health protection for infants.

**Public Comment**

*Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

No comments were received during the public comment period.

The agency did not form an informal advisory group to assist in this periodic review.

**Effectiveness**

*Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.*

This regulation is necessary for the protection of the health, safety, and welfare of infants within the Commonwealth as it ensures that they consume infant formula that clearly meets the nutrition requirements for an infant. The regulation is clearly written and easily understandable.

## Decision

*Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).*

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While the substance of this regulation provides for a significant level of public health protection relative to infants and does not need to be amended, the regulation does require an amendment to update a reference to the Code of Virginia. A reference in the regulation to a section in Title 3.1 of the Code, which was recodified as Title 3.2, needs to be amended to reflect the recodification.

## Small Business Impact

*As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.*

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This regulation continues to be necessary because it ensures infant formula produced and sold at retail meets minimum acceptable standards regarding infant formula nutrition. Nutrients contained in infant formula can degrade over time, thus producing an inferior product incapable of meeting the nutritional needs of infants. The regulation also ensures that consumers are informed regarding expiration dates and the quality of the infant formula that they are buying. The agency has not received any complaints or comments regarding this regulation. The regulation is written in a form that is not overly complex and is easily understandable by regulators as well as the regulated industry. Federal regulations also establish mandates for infant formula. However, these mandates are complex and burdensome to the industry and are configured to apply primarily to large infant formula manufacturers participating in significant interstate commerce that are regularly inspected by the U.S. Food and Drug Administration. The subject regulations are typically enforced at both large and small manufacturers participating in both intrastate and interstate commerce as well as at retail food store locations. An attempt to strictly enforce overly complex federal standards at both manufacturers and retail locations within the Commonwealth would likely be overly burdensome to the industry. Since the last time this regulation was evaluated, there have not been significant changes in technology, economic conditions, or other factors that would render the regulation non-relevant. This regulation was promulgated with due concerns for industry and has minimal impact on small businesses.

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