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Fast-Track Regulation
Agency Background Document

Agency name	Board of Agriculture and Consumer Services
Virginia Administrative Code (VAC) Chapter citation(s)	2 VAC 5-560
VAC Chapter title(s)	Rules and Regulations Pertaining to Labeling and Sale of Infant Formula
Action title	Amendments to update references to Title 3.1 of the Code of Virginia
Date this document prepared	March 25, 2021 Detail of Changes section of this document revised on September 9, 2021, to include an explanation for the proposed revision to the regulation's forms section. Detail of Changes section of this document revised on October 15, 2021, to include additional explanation for the proposed revision to Section 70.

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.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This regulation requires that any container of infant formula manufactured or sold in the Commonwealth of Virginia conspicuously show the calendar month and year after which the product is not to be sold or used for human consumption.

Manufacturers of infant formula sold or offered for sale in the Commonwealth must keep on hand and provide when requested by the Commissioner of Agriculture and Consumer Services (Commissioner) or his agent scientific data establishing the expiration date. Since, for many children, infant formula is the sole source of nutrition during the initial stages of life, manufacturers must ensure scientifically that infant

formula consumed contains the appropriate spectrum and quality of nutrients required for growth and development as long as the formula is consumed by the expiration date.

The regulation provides that any infant formula manufacturer knowingly filing incorrect or unverifiable data with the Commissioner or placing an expiration date upon a shipping carton, container, or any consumer package that is inconsistent with the data filed with the Commissioner shall be considered to have misbranded the formula.

The regulation also states that any manufacturer, distributor, dealer, or other person who offers for sale or sells infant formula without an expiration date, or who offers for sale or sells infant formula after the expiration date shown, shall be deemed to be offering for sale a product that is unfit for food.

The misbranding provision in this regulation references a section of the Code of Virginia (Code) that addresses misbranding. The section of the Code that is referenced, Va. Code § 3.1-396(a), no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5123(a)(1). The proposed amendment updates the reference so that it refers to the correct section of the Code of Virginia.

The section of this regulation pertaining to the sale of a product unfit for food references a section of the Code that addresses adulterated food products. The section of the Code that is referenced, Va. Code § 3.1-395(a)(3), no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5122(3). The proposed amendment updates the reference so that it refers to the correct section of the Code of Virginia.

Acronyms and Definitions

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

"Board" means the Board of Agriculture and Consumer Services.

Statement of Final Agency Action

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.

On March 25, 2021, the Board adopted amendments to 2 VAC 5-560, *Rules and Regulations Pertaining to Labeling and Sale of Infant Formula*, to reflect current Code citations.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

A periodic regulatory review of this regulation identified references to the Code of Virginia that are outdated and inaccurate. These sections needed to be amended to reflect an accurate Code reference.

This rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process because the proposed amendments simply ensure the regulation and the Code references contained therein are updated and accurate.

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 and 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 establishes the Board as a policy board with the authority to adopt regulations in accordance with the provisions of Title 3.2 of the Code.

Section 3.2-5121 grants the Board authority to adopt regulations for the efficient enforcement of Article 3 of the Food and Drink Law (Va. Code § 3.2-5120 *et seq.*), which pertains to the adulteration, misbranding, and false advertising of food.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of the proposed amendments is to ensure that the regulation and its references are accurate.

The proposed amendments protect the health, safety, and welfare of Virginia's citizens in that they ensure that the regulation and the Code references contained therein are current and enforceable. A current and enforceable infant formula regulation will ensure that infants receive and consume infant formula that is nutritious and capable of supporting their growth, health, and wellbeing.

The goal of the proposed amendments is to ensure a regulation with references to the Code of Virginia that are accurate, updated, and enforceable.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The misbranding provision in this regulation references a section of the Code that addresses misbranding. The section of the Code that is referenced, Va. Code § 3.1-396(a), no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5123(a)(1). The proposed amendment updates the reference so that it refers to the correct section of the Code.

The section of this regulation pertaining to the sale of a product unfit for food references a section of the Code that addresses adulterated food products, Va. Code § 3.1-395(a)(3), which no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5122(3). The proposed amendment updates the reference so that it refers to the correct section of the Code.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The proposed amendments will ensure an accurate, updated, and enforceable regulation. The amended regulation will further ensure that infant formula is not sold beyond the scientifically determined expiration date and will further ensure that infants will consume nutritionally sound formula in order to ensure their health, growth, and development.

The primary advantage to the agency and Commonwealth is that the agency can ensure an enhanced degree of public health protection by ensuring that infant formula consumed in the Commonwealth is nutritionally sound.

There do not appear to be any disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no requirements in this proposal that are more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected:
There are no other specific state agencies particularly affected by the proposed amendments.

Localities Particularly Affected:
There are no specific localities particularly affected by the proposed amendments.

Other Entities Particularly Affected:
There are no specific entities particularly affected by the proposed amendments.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees, or revenues resulting from the proposed amendments.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues resulting from the proposed amendments.
For all agencies: Benefits the regulatory change is designed to produce.	The proposed amendments will ensure the accuracy of the regulations and will assist in ensuring the safety and nutritional value of infant formula, which will, in turn, engender a greater level of confidence by the public that both the agency and the Commonwealth are taking the necessary steps to provide an appropriate level of public health protection.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs, savings, fees, or revenues resulting from the proposed amendments.
Benefits the regulatory change is designed to produce.	The proposed amendments will ensure the accuracy of the regulations and will assist in ensuring the safety and nutritional value of infant formula, which will, in turn, engender a greater level of confidence by the public that both the agency and the Commonwealth are taking the necessary steps to provide an appropriate level of public health protection.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be	As the proposed amendments are technical in nature and do not alter the regulatory requirements, individuals, businesses, or other entities will not be affected.

affected, include a specific statement to that effect.	
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	As the proposed amendments are technical in nature and do not alter the regulatory requirements, individuals, businesses, small businesses, or other entities will not be affected.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs for affected individuals, businesses, or other entities resulting from the proposed amendments.
Benefits the regulatory change is designed to produce.	The proposed amendments will ensure the accuracy of the regulations and will assist in ensuring the safety and nutritional value of infant formula, which will, in turn, engender a greater level of confidence by the public that both the agency and the Commonwealth are taking the necessary steps to provide an appropriate level of public health protection.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The alternative to the proposed amendments would be to leave the regulation in place without the proposed amendments. This would result in a regulation that is inaccurate and potentially unenforceable.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

Establishment of less stringent compliance requirements will likely result in the sale of outdated infant formula, which will ultimately decrease the safety of formula consumed by infants. This is likely to affect the health, growth, and development of infants consuming the formula.

There are no schedules or deadlines for compliance currently established. There are no reporting requirements associated with this regulation.

There are no design or operational standards contained in this regulation. Therefore, there is no need to establish alternate performance standards.

The exemption of small businesses from the requirements of this regulation will result in an increased possibility of the sale and consumption of infant formula that is substandard and potentially harmful to infants.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-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: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board of Agriculture and Consumer Services is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulatory changes, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall website at: https://townhall.virginia.gov.

Comments may also be submitted by mail or email to:
Ryan Davis, Program Manager
VDACS Office of Dairy and Foods
P.O. Box 1163
Richmond, VA 23218
Ryan.Davis@vdacs.virginia.gov

In order to be considered, comments must be received by 11:59 p.m. on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

2VAC5-560-50. Misbranding.
The misbranding provision in this regulation references a section of the Code that addresses misbranding. The section of the Code that is referenced, Va. Code § 3.1-396(a), no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5123(a)(1). The proposed amendment updates the reference so that it refers to the correct section of the Code.

2VAC5-560-70. Sale of a product unfit for food.
The section of this regulation pertaining to the sale of a product unfit for food references a section of the Code that addresses adulterated food products, Va. Code § 3.1-395(a)(3), which no longer exists, as Title 3.1 of the Code was recodified subsequent to the establishment of this regulation. The regulation should reference Va. Code § 3.2-5122(3). The proposed amendment updates the reference so that it refers to the correct section of the Code.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
50	N/A	Knowingly filing incorrect or unverifiable data with the commissioner, or placing an expiration date upon a shipping carton, container or any consumer package which is inconsistent with the data filed with the commissioner, shall be considered to be misbranding under § 3.1-396(a) of the Code of Virginia.	The proposed amendment updates the reference to the Code that is included in this section. Title 3.1 of the Code was recodified as Title 3.2, and the proposed amendment updates the regulation accordingly to ensure regulation accuracy.
70	N/A	Any manufacturer, distributor, dealer, or other person who offers for sale or sells infant formula without an expiration date, or who offers for sale or sells infant formula after the expiration date shown, shall be deemed to be offering for sale a product unfit for food within the meaning of § 3.1-395(a)(3) of the Code of Virginia.	The proposed amendment updates the reference to the Code that is included in this section. Title 3.1 of the Code was recodified as Title 3.2, and the proposed amendment updates the regulation accordingly to ensure regulation accuracy. Additionally, the agency proposes to amend this section to more accurately describe the referenced subdivision of the section of the Food and Drink Law pertaining to adulterated food.

FORMS	N/A	The Inspection Report is currently listed in the Forms Section.	The agency has determined the Inspection Report is not a reporting form used to administer the regulation and, as such, should not be listed in this section.