



Virginia Department of Planning and Budget **Economic Impact Analysis**

2 VAC 5-560 Rules and Regulations Pertaining to Labeling and Sale of Infant Formula
Department of Agriculture and Consumer Services
Town Hall Action/Stage: 5713 / 9251
October 15, 2021

Summary of the Proposed Amendments to Regulation

As the result of a 2021 periodic review,¹ the Board of Agriculture and Consumer Services (Board) is proposing to update two references to the Code of Virginia.

Background

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. 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 and retailers must ensure that expired infant formula is not sold to consumers.

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.

¹ <https://townhall.virginia.gov/L/ViewPReview.cfm?PRid=1984>

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 in 2008.² The correct reference to the statute is now § 3.2-5123(a)(1). The proposed amendment updates the reference so that it refers to the correct section of the Code of Virginia.

Similarly, 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. This section of the Code that is referenced, Va. Code §3.1-395(a)(3), also no longer exists due the recodification of Title 3.1 in 2008. The regulation should reference Va. Code § 3.2-5122(3). The proposed change updates the reference so that it refers to the correct section of the Code.

Estimated Benefits and Costs

The proposed changes simply update references to the Code of Virginia regarding misbranding and unfit food without any change in regulatory requirements. Therefore, no significant economic effect is expected other than improving the accuracy of the regulatory text.

Businesses and Other Entities Affected

This regulation applies to one manufacturer of infant formula in the Commonwealth and approximately 9,000 retail establishments that may be offering infant formula for sale. No adverse economic impact³ on any entity is indicated.

Small Businesses⁴ Affected:

The proposed amendments do not adversely affect small businesses.

Localities⁵ Affected⁶

The proposed amendments do not introduce costs for local governments and do not affect any particular locality.

² <https://lis.virginia.gov/cgi-bin/legp604.exe?ses=081&typ=bil&val=ch860>

³ Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

⁴ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “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.”

⁵ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

⁶ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.

Projected Impact on Employment

The proposed amendments do not affect total employment.

Effects on the Use and Value of Private Property

No impact on the use and value of private property or on the real estate development costs is expected.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.