



Periodic Review / Retain Regulation Agency Background Document

Agency name	Virginia Department of Agriculture and Consumer Services
Virginia Administrative Code (VAC) citation	2 VAC 5-560
Regulation title	Rules and Regulations Pertaining to Labeling and Sale of Infant Formula
Document preparation date	March 23, 2011

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.

Sections 3.2-5101 and 3.2-5121 of the Code of Virginia provide the legal basis for the promulgation of these regulations and authorizes the Board of Agriculture and Consumer Services to adopt regulations, as needed, for the efficient enforcement of the Virginia Food Laws.

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

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 and that the manufacturer submit said data to the agency upon request. 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 This makes it possible to have substandard and/or out of date infant formula removed from sale. It would not be possible to ensure that infants consume formula with the appropriate nutritive value without these regulations. This regulation is more stringent than existing federal regulations (which have not been adopted by the Commonwealth). Existing federal regulations provide similar requirements

but do not require that the manufacturer submit the established safety data to the agency and do not provide for the removal of infant formula that is being sold either beyond the expiration date or with no expiration date. This regulation should be retained because it provides a significantly greater level of public health protection for infants. Therefore, this regulation is the most efficient and least burdensome method of achieving the purpose of the regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The agency received no comments during the public comment period.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

This regulation meets the criteria set out in Executive Order 14 (2010) because it is necessary for the protection of public health, safety, and welfare of infants within the Commonwealth. It is clearly written and easily understandable.

Result

Please state that the agency is recommending that the regulation should stay in effect without change.

The agency is recommending that the regulation should remain in effect without change.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) 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, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

This regulation is necessary for the protection of public health and the safety and welfare of infants in the Commonwealth. It enables the Commonwealth to require that infant formula not be sold beyond the required expiration date thus ensuring that infants consuming these products ingest formula that will provide a full range of both macro and micronutrients to ensure their continued health and growth. The regulation is not complex in that it provides information relating to expiration dates, the scientific data

required to establish expiration dates and labeling and enforcement in a straightforward, easily understandable manner. The regulation is concise and is not lengthy. There is a minor amount of overlap with federal infant formula regulations. Federal regulations require that manufacturers provide expiration dates on infant formula containers and they also require that manufacturers test infant formula to ensure that products sold within the expiration date contain the appropriate level of nutrients. However, federal regulations do not require that manufacturers provide testing data to the agency regarding infant formula quality and do not state that infant formula is “unfit for food” if sold past the expiration date. Additionally, the federal regulations have not been adopted by the Commonwealth. 2 VAC 5-560 does contain these requirements thus ensuring that infants do not consume substandard formula. Technology and economic conditions have not changed significantly relative to infant formula. The manufacturing process is essentially unchanged since the adoption of these regulations and it is still vitally important for infants to consume infant formula with an adequate complement of both macro and micro nutrients. Consequently, the regulation is still relevant and is important to ensure the health of infants. This regulation has minimal impact on small businesses and should be retained.

Family impact

Please provide an analysis of the regulation’s impact on the institution of the family and family stability.

This regulation is expected to positively impact the institution of the family and family stability. This regulation helps to provide a safe and nutritious product to infants that consume infant formula. Requiring that manufacturers utilize verifiable scientific data to ensure that infant formula sold within the expiration date contains the macro and micro nutrients necessary for infants and providing for the removal of infant formula that is being offered for sale beyond the expiration date will ensure the health and well being of infants. Furthermore, ensuring the health of these infants will reduce medical care costs, reduce absences from the workplace by parents who may need to attend to infants affected by substandard infant formula and will reduce mental, physical and emotional pain and suffering by affected infants and/or their parents.