

ASSOCIATED INDUSTRIES OF VERMONT

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AIV appreciates the opportunity to follow up on our testimony from April 22 on H.536. As we noted at that time, we support the underlying provisions of H.536 as introduced to address testing and labeling for baby food products. These provisions are consistent with those in a number of other states that collectively include more than 60 million people, representing a critical mass in the market and supporting a consistent labeling requirement without creating potential supply issues for Vermont.

However, we do have concerns about the provisions added to the bill to include infant formula in the definition of baby food products under certain conditions. Infant formula is regulated much differently, and more strictly, than baby food generally. Infant formula already meets very strict EU requirements regarding heavy metals addressed in H.536.

There are several primary concerns with the infant formula provisions: ensuring that any information regarding heavy metals in infant formula is provided in the proper context of safety and regulatory requirements, consistency with FDA requirements, and a critical market mass of states with consistent testing and labeling laws.

The FDA is currently undertaking a major initiative, Operation Stork Speed, which will develop much of the context and regulatory requirements for heavy metals in infant formula. The results of this initiative are still pending. In addition, no other state has yet included infant formula in the definition of baby food products requiring labeling. It is not known whether or how future actions in other states might align with the approach in H.536 or emerging FDA requirements.

Although H.536 as passed by the House includes a trigger of California or any two other states enacting similar legislation before infant formula would be covered in Vermont, it is not clear that infant formula would be treated the same such that there would be the consistency across states as there is currently for baby food products, that there would be a critical mass in the market like there is currently for baby food products (in particular, any two other states could be a very small share of the market, and even California alone might pose challenges), and the timelines implicit in the provisions do not account for selling existing inventories or – even more critically – the fact that the FDA must approve infant formula labels and that approval process can be lengthy.

Ultimately, it would be more prudent to leave infant formula out of H.536 and revisit this issue next legislative session to see what has developed with the FDA and Operation Stork Speed as well as any actions in other states.

However, short of that approach we would recommend amending the trigger provisions in H.536 to address key concerns:

- increasing the threshold to a critical market mass (ideally similar to the current conditions for baby food products),
- requiring a report and legislative recommendations rather than automatic enactment to allow for greater consistency and avoid unintentional interstate or federal conflicts or other complications, and
- adequate flexibility to accommodate the sale of existing inventories and the time required for FDA approval of labels and related issues.

A model amendment addressing these concerns is attached for the Committee's consideration.

Thank you for your consideration of these concerns and recommendations, and we look forward to continuing to work with the Committee and other stakeholders on this issue.

Recommended Amendments to H.536

1. Strike Section 2 and Section 3(b).
2. Insert a new Section 2:

Section 2. Infant Formula

(a) The Attorney General shall provide written notification to the House Committee on Agriculture, Food Resiliency, and Forestry and to the Senate Committee on Health and Welfare upon the Attorney General's determination that any combination of states with an aggregate population of at least 60,000,000 people have enacted legislation with requirements substantially comparable to the requirements of this act regarding baby food products and all of the following:

(1) the inclusion of infant formula in the definition of baby food product;

(2) the prohibition on the sale and distribution of infant formula that contains a toxic heavy metal exceeding U.S. Food and Drug Administration limits;

(3) the required testing of infant formula sold or distributed in the State for toxic heavy metals; and

(4) the labeling of infant formula and the provision of information about toxic heavy metals in infant formula.

(b) No later than 6 months following the notification in (a), the Attorney General, in consultation with the Department of Health, shall submit to House Committee on Agriculture, Food Resiliency, and Forestry and to the Senate Committee on Health and Welfare a report including:

(1) an update and overview of federal and state actions addressing toxic heavy metals in infant formula; and

(2) any recommendations for legislation to address toxic heavy metals in infant formula, including provisions to suspend requirements in cases of supply shortages, accommodate the continued sale of inventory in stock, and accommodate the need to comply with labeling and related requirements of the U.S. Food and Drug Administration.