



May 19, 2026

*Submitted electronically via regulations.gov*

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Food Allergen Thresholds and Their Potential Applications  
Docket No. FDA-2026-N-1304**

The Food Industry Association (FMI) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) docket on "Food Allergen Thresholds and Their Potential Applications". FMI applauds FDA for identifying allergens as a priority and taking on this important issue through meetings with stakeholders in 2024–2025 and hosting the public meeting and listening sessions in February 2026. We encourage FDA to move forward with risk-based allergen thresholds as a risk management tool to allow for stronger allergen management programs, as well as clarity and transparency for consumers.

As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at [www.FMI.org](http://www.FMI.org).

FMI and its members prioritize food safety and programs to support the health and safety of consumers. Allergen awareness and management are of great importance to the food industry, and we work to ensure that all consumers have access to safe, wholesome and healthy foods. Our comments below focus on the four topics addressed at the public meeting held on February 18, 2026, and the subsequent listening sessions on February 19 and 20, 2026.

**Available data and concepts for establishing risk-based thresholds for application in various food allergen management and risk assessment situations**

FMI supports the establishment of science-based, risk-informed food allergen thresholds grounded in quantitative risk assessment and population-based eliciting dose (ED) data. Substantial work by international expert bodies, including FAO/WHO expert consultations, demonstrates that reference doses derived from ED<sub>05</sub> values are sufficiently protective of public health while avoiding unnecessary restrictions that do not meaningfully reduce risk. Substantial



evidence has been published documenting that reactions occurring at or below ED<sub>05</sub> are uniformly mild to moderate, with no increase in the relative probability of severe outcomes when compared with lower EDs.<sup>1,2</sup>

Globally recognized publications such as FAO/WHO risk assessments, Codex Alimentarius deliberations, and the Voluntary Incidental Trace Allergen Labeling (VITAL) program provide a strong scientific foundation for FDA's consideration.<sup>3</sup> Even with significant research on allergen exposure and labeling, there is insufficient data to establish science-based thresholds for some allergens. The FAO/WHO committee acknowledged that their threshold for certain allergens—like almond, pecan, pistachio, etc.--is provisional and not based on data specific to those allergens.<sup>1</sup> FDA should avoid adopting thresholds that are not based on data specific to that allergen.

VITAL is the most established program with significant research supporting the framework. The transition of VITAL from ED<sub>01</sub> based reference doses (VITAL 3.0) to ED<sub>05</sub> -based reference doses (VITAL 4.0) reflects the growing scientific consensus that ED<sub>05</sub> values appropriately balance consumer protection and food availability, without meaningful increases in public health risk.<sup>1</sup> FMI encourages FDA to formally recognize ED<sub>05</sub>-derived reference doses as the basis for allergen thresholds applied across regulatory decision-making contexts.

Importantly, FMI emphasizes that thresholds should be applied in a risk-based manner that considers allergen-specific characteristics, food matrices, serving sizes, and consumption data as ED<sub>05</sub> values are expressed as total milligrams of allergenic protein consumed. This approach is consistent with FDA's longstanding conclusion that quantitative, population-based risk assessment provides the most transparent and scientifically robust foundation for establishing allergen thresholds.<sup>4</sup>

### **Options using risk-based thresholds for effective communication and labeling strategies to ensure consumers can make informed decisions**

Risk-based thresholds can serve as a critical tool for improving the clarity, consistency, and credibility of allergen-related communications to consumers. As FDA has previously recognized, the absence of defined thresholds can lead to inconsistent enforcement, increased reliance on precautionary allergen labeling (PAL), and reduced usefulness of allergen information for consumers.<sup>4</sup>

Incorporating thresholds into an allergen advisory labeling framework would help determine when advisory statements are warranted due to unavoidable cross-contact, while reinforcing that such labeling cannot substitute for robust Good Manufacturing Practices (GMP) and allergen preventive controls. Threshold-informed risk assessments would support more consistent labeling decisions and reduce unnecessary over-labeling, thereby improving consumer trust and decision-making.<sup>1,4</sup>

Threshold-based approaches also have potential applications beyond advisory labeling, including informing decisions related to allergen declarations and exemption evaluations under FALCPA.<sup>6</sup> FDA previously highlighted that regulatory thresholds could provide clarity in determining whether an ingredient “does not contain allergenic protein” or “does not cause an allergic response that poses a risk to human health.”<sup>4</sup> Any such applications should be accompanied by clear FDA guidance and consumer education to ensure appropriate interpretation and use.

The establishment of food allergen thresholds has important implications for food labeling, providing a science-based foundation for clearer, more consistent communication with consumers. In the absence of defined thresholds, manufacturers often rely on PAL, which can result in over-labeling and reduced usefulness of allergen information for individuals managing food allergies. Risk-based thresholds could help determine when advisory statements are truly warranted due to unavoidable cross-contact, while reinforcing that such labeling cannot replace robust allergen controls and GMPs. When applied within a transparent regulatory framework and supported by appropriate consumer education, thresholds have the potential to improve label credibility, reduce unnecessary precautionary statements, and better enable consumers to make informed, food choices.

### **Practical considerations for the use of risk-based thresholds in manufacturing, procurement, and assessment of product safety**

The application of allergen thresholds provides a structured, quantitative framework for managing allergen risks. By establishing scientifically derived thresholds, stakeholders can enhance risk-based decision-making within manufacturing facilities and throughout supply chains when used as part of a comprehensive allergen management system. FDA has previously acknowledged that allergen thresholds could play a valuable role in informing allergen hazard analyses, evaluating preventive controls, and assessing product safety—particularly in manufacturing and processing environments where cross-contact risks may be present.<sup>4</sup> Thresholds can serve as a useful tool to inform risk assessments for determining the need for allergen advisory labeling on finished products; however, they should not be used by suppliers or food manufacturers as a ‘target’ for risk management.<sup>4</sup> An approach based on ED<sub>05</sub> reference doses is generally appropriate, but there are circumstances in which a risk assessment would be inconsistent. For example, in bulk commodities, allergenic proteins might not be distributed homogeneously. While risk assessments should be utilized where feasible, it is important to recognize that supply chain variability may necessitate the use of additional or alternative risk management tools.

Thresholds may also improve consistency and predictability in recall decision-making. FDA has previously encouraged exploration of how thresholds could reduce unnecessary Class I recalls

and Reportable Food Registry (RFR) incidents without increasing public health risk which is an outcome that would reduce food waste while focusing regulatory and industry resources on situations posing the greatest risk to consumers.<sup>4</sup>

However, meaningful implementation depends on the availability and reliability of analytical testing methods. As recognized in both FDA's earlier risk assessments and by international expert bodies, current limitations in allergen detection, including matrix effects, variability across methods, and limits of detection, must be considered when applying quantitative thresholds.<sup>1,4</sup> FDA should account for these practical constraints when developing any threshold-based framework to ensure it is both scientifically sound and feasible to implement. It is also important to ensure that the introduction of risk-based thresholds does not shift the focus from a risk assessment-based approach to routine analytical testing.

Overall, the applications of thresholds could improve allergen controls in manufacturing, in processing and at points throughout the food supply chain. Thresholds provide a quantitative risk assessment metric and could significantly reduce the overuse of PAL.

### **Potential opportunities and barriers for adopting and implementing food allergen thresholds**

The adoption of food allergen thresholds presents important opportunities to modernize allergen risk management, improve regulatory consistency, and better align U.S. policy with international practice. International experience and FDA's own prior analyses both support the conclusion that thresholds can improve regulatory transparency, inform enforcement discretion, and provide a clearer scientific basis for allergen-related decisions across the food system.<sup>1, 4</sup>

At the same time, FMI recognizes several barriers that must be addressed, including variability in analytical capabilities, lack of harmonized exposure assessment assumptions, and the risk of consumer misunderstanding without appropriate education. FMI has previously emphasized the need for clear guidance on how thresholds would be applied in enforcement and regulatory decision-making.<sup>5</sup> FMI encourages the Agency to prioritize timely guidance to offer adequate clarity to impacted stakeholders, and ensure that any rulemaking does not precede industry capability or consumer understanding, which can lead to unintended consequences.

As international bodies such as the FAO/WHO continue to advance the application of reference doses for specific food allergens, the use of thresholds presents an important opportunity to enhance regulatory clarity and promote global harmonization. Alignment with this approach can support greater consistency across jurisdictions, reduce regulatory complexity for companies, and help mitigate potential trade barriers.

## Summary

We encourage FDA and partner agencies to proceed with evaluating allergen thresholds and the regulatory applications to modernize allergen management, as well as to support consumers with food allergies with the information needed to make informed decisions. Working with the scientific community internationally, FDA has access to the most up-to-date information available to inform future policies.

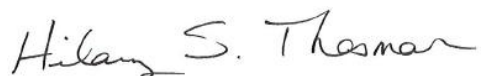
To realize the full benefits of allergen thresholds, FDA should prioritize clear industry guidance, alignment with international scientific consensus, and targeted consumer education. Thresholds should be implemented as a flexible, risk-based tool that complement existing allergen management programs and preventive controls.

In summary, to improve the clarity and utility of the PAL statement:

- (1) FDA should adopt a threshold-based framework for PAL to minimize unnecessary dietary limitations for individuals with food allergies;
- (2) FDA should establish clear criteria specifying when PAL is warranted, such as when estimated allergen exposure exceeds the applicable reference dose; and
- (3) FDA should recommend that PAL not be used when estimated exposure remains below the established threshold.

We appreciate the opportunity to comment on the public meeting and information presented, and we look forward to working with the agency as you develop policies on this important topic.

Sincerely,



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Chief Science Officer and SVP Food and Product Safety

## References

- <sup>1</sup> FAO/WHO. (2022). *Risk Assessment of Food Allergens – Part 2: Review and Establish Threshold Levels in Foods for the Priority Allergens*. Food Safety and Quality Series No. 15.
- <sup>2</sup> FAO/WHO. (2024). *In Brief: Food Allergen Reference Doses*. Food and Agriculture Organization of the United Nations.
- <sup>3</sup> Allergen Bureau. (2024). *Food industry guide to the voluntary incidental trace allergen labelling (VITAL) program* (Version 4.0). <https://vital.allergenbureau.net>.
- <sup>4</sup> Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket. (May 13, 2013). 77 *Federal Register* 74485 – 74486.
- <sup>5</sup> FMI Comment Letter (May 13, 2013) Docket Number FDA-2012-N-0711 [https://www.fmi.org/docs/default-source/comments-filed/fda-risk-assessment-for-establishing-food-allergen-thresholds-\(may-13-2013\).pdf?sfvrsn=7f11d96f\\_0](https://www.fmi.org/docs/default-source/comments-filed/fda-risk-assessment-for-establishing-food-allergen-thresholds-(may-13-2013).pdf?sfvrsn=7f11d96f_0)
- <sup>6</sup> 21 U.S. Code § 343