

## Instructions on How to Submit Comments to the Food and Drug Administration Regarding Food Allergen Thresholds and Their Potential Applications

***Comment Period Ends May 19, 2026***  
***Docket Number: FDA-2026-N-1304***

Food allergies affect millions of Americans and their families, and proper identification, understanding and avoidance of hazardous allergen exposures in food products is key to maintaining good health. The major food allergens in the U.S. are milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame. Major food allergens can cause immediate, life-threatening reactions (anaphylaxis) if present at sufficient amounts in products.

Advances in allergen risk assessment have demonstrated that certain low-level exposures, or thresholds are not likely to elicit reactions in the vast majority of individuals allergic to those foods. This has led to consideration of risk-based approaches in allergen hazard management.

Possible applications of thresholds include risk assessments to support the following: petitions for labeling exemptions; compliance and enforcement actions; development of policies for allergen advisory statements (AAS); and development of guidance for industry on allergen cross-contact controls. The U.S. Food and Drug Administration (FDA), in collaboration with various stakeholders including industry, consumer groups, healthcare professionals, individual firms, retailers, and academic researchers, is hosting a virtual public meeting followed by listening sessions on food allergen thresholds and their potential applications. The FDA will review input received at the public meeting and listening sessions and comments received through the docket to determine next steps, prioritize potential actions, and advance our food allergen threshold approaches to benefit public health.

We invite all interested persons to provide information on topics related to food allergen thresholds and their potential applications, including topics discussed during the public meeting presentations, panel discussions, and listening sessions, such as:

- available data and concepts for establishing risk-based thresholds for application in various food allergen management and risk assessment situations
- options using risk-based thresholds for effective communication and labeling strategies to ensure consumers can make informed decisions
- practical considerations for the use of risk-based thresholds in manufacturing, procurement, and assessment of product safety
- potential opportunities and barriers for adopting and implementing food allergen thresholds

### How to Submit Comments:

#### Option 1: Electronic Submission (Recommended)

- **Website:** <https://www.regulations.gov>
- **Search for:** Docket No. FDA-2026-N-1304
- **Deadline:** May 19, 2026, by 11:59 PM Eastern Time

Please note that late, untimely comments submitted after May 19, 2026, will not be considered. The [Regulations.gov](https://www.regulations.gov) electronic filing system will accept comments until 11:59 p.m. at the end of May 19, 2026.

Option 2: Written Submission

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

Deadline: Must be postmarked or have a delivery service acceptance receipt on or before May 19, 2026

Note: The comment due date indicated on Regulations.gov is based on Eastern Standard Time. In this instance, the comment due date is listed as **May 19, 2026**, so comments are due on that date by 11:59 PM ET.

Please also note that comments are not retrievable once submitted. To make changes, you must submit another comment that refers to your previous comment, corrects any errors, and/or re-states your position or opinion.