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US FDA considering change in nutrition labeling that communicates food allergy risks

To provide better protection for consumers who have food allergies, the United States Food and Drug Administration (FDA) is considering a major change in the way nutrition labels on packaged foods communicate about potential food allergy risks due to cross-contact.

Drawbacks of the current system

Under the existing US Food Allergen Labeling and Consumer Protection Act (FALCPA), the nine major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans and sesame) must be declared in ingredient lists on packaged foods. However, this requirement does not extend to cross-contact allergens that unintentionally may be included in a food, for instance, during manufacturing or packaging on shared equipment or within the same facility.

Instead, manufacturers have the option to voluntarily disclose the presence of a cross-contact allergen by using an allergen advisory statement (AAS), also known as precautionary allergens labeling (PAL), that could say “may contain a specific food allergen” or “manufactured in a facility that produces a specific food allergen.” Companies are expected to be truthful and not use precautionary labels as a substitute for allergen controls.

Still, the FDA has set no upper limit for the amount of cross-contaminant in food products. Furthermore, there is no US fed-



eral regulation or guidance as to when and how to use AAS or PAL. Consequently, AAS usage is inconsistent. Food packages that lack warnings may contain sufficient allergens to trigger reactions in patients. Conversely, products with precautionary labels may have little or no detectable allergen if risk-averse manufacturers use warning statements to give themselves legal protection.

“[Companies] want clarity. They don’t know where they stand with the FDA in regard to trace amounts and the correct way to label,” said Steven Gendel, PhD, a food safety consultant and former FDA food allergen coordinator, in an article published by *Allergic Living*. He noted that cross-contact labels do not necessarily protect manufacturers from liability or recalls and indicated undeclared allergens are the cause of up to 40 percent of food recalls.

Consumers who rely on labels to determine food safety are also

confused, according to a survey by Ruchi Gupta MD, MPH, a pediatrician and allergist and her team at Northwestern University. They found only approximately half of those managing allergies knew use of allergen advisory statements is voluntary. In addition, many respondents believed that “may contain” and “manufactured in a facility” reflected different levels of risk, which they do not.

Thresholds: A scientific, risk-based approach

In place of allergen advisory statements, the FDA is considering use of a standardized warning statement to indicate whether, due to cross-contact, an allergen is likely to be present above a predetermined level. That level—called a threshold or reference dose—is the amount of allergenic protein a person can consume before allergic symptoms occur.

Thresholds can be determined by newer food challenge and

oral immunotherapy studies that allow researchers to estimate a dose or level at which 95 percent of people with a given allergy are unlikely to react or develop symptoms. Up to 5 percent of highly sensitive individuals could react to exposures below those levels but study data suggest if reactions occur, they would be low risk and of low consequence.

Importantly, using threshold labeling, a food would not need to be completely allergen-free to avoid use of a precautionary label; rather the amount of cross-contaminant in the food would only need to be below the established level.

However, allergen thresholds created from population data cannot predict with certainty whether an individual will react [to an allergen]. “Patients most likely will not know if they are one of the 5 percent who might still react. So while an informative label is helpful, not all individuals will be reassured by that,” Brian Vickery, MD, chief of the Division of Allergy and Immunology, Emory University, explained to *Allergic Living*.

Threshold labeling has been endorsed by both the Food and Agriculture Organization (FAO), a specialized agency of the United Nations, and the World Health Organization (WHO). In addition, the FDA has published several guidance documents that address various areas of allergen risk assessment and management in which allergen thresholds may be applied.

The *Allergic Living* article explained proposed thresholds have been developed by the FAO and are between 1 and 5 milligrams for most top allergens. Specifically, thresholds are 1 mg for walnut, pecan, cashew, pistachio and almond; 2 mg for peanut, egg, milk and sesame; 3 mg for hazelnut; 5 mg for wheat and fish; and 200 mg for crustacean shellfish. Experts stressed the levels are conservative and lower than the tolerance level for the majority of allergic individuals.

An FDA public meeting

In February 2026, the FDA held a one-day virtual public meeting titled, “Food Allergen Thresholds and Their Potential Applications,” followed by two days of virtual public listening sessions. Nearly 1,800 people registered for the events, including FDA scientists, academic researchers, food manufacturers, food industry representatives, retailers, healthcare professionals, patient advocates, consumer groups and families of food allergic patients.

The FDA noted that before the public event, they met with several targeted stakeholders from industry, consumer and health professional groups to gather input on the published allergen threshold data and identify data gaps and scientific needs for establishing or applying thresholds. They stated the sessions “yielded valuable insights regarding the use of risk assessments and allergen thresholds.”

Listening sessions and key themes

The event included eight listening sessions on the following four topics, during which views of about 130 people were heard:

- Food allergen threshold concepts
- Applications of food allergen thresholds—labeling perspectives
- Applications of food allergen thresholds—manufacturing perspectives
- Practical considerations for adopting food allergen thresholds

An FDA summary of the event provided detailed information on the following key themes from the listening sessions:

- Broad support for a risk-based allergen threshold framework
- Labeling considerations for implementing allergen thresholds
- Operational and technical challenges in implementing allergen thresholds

- Strategic path forward for potential allergen threshold implementation

Broad support for thresholds

Overall, there was “broad support” for transition to a harmonized, risk-based framework for food allergen thresholds. The current lack of federal regulations or guidance for AAS was identified as a primary driver of their overuse and inconsistent application, leading to consumer confusion, decreased trust in food labels and unnecessarily restricted choices for food-allergic consumers. Science-based thresholds such as those proposed by the FAO and WHO were considered important to help provide clarity for consumers, create consistency for industry (globally) and implement a better framework for risk management. Participants identified the need to clearly define an allergen threshold, not as an absolute guarantee of individual safety, but as a population-based risk management tool. The scientific term “reference dose” was preferred to signify a level of an allergen not expected to cause a reaction in a large majority of the allergic population. Most stakeholders described the reference dose as a workable public health tool designed to make the food supply safer for the greatest number of people. Setting a threshold to assure zero risk for every individual was generally seen as unrealistic. In addition, a few stakeholders expressed concerns about using thresholds in general. For example, some consumers noted concern for the most sensitive food-allergic individuals.

Labeling considerations for implementation

Participants discussed the practical application of thresholds and expectations for use of AAS versus absolute “allergen-free” claims. Opinions were mixed about whether the FDA should mandate a single, consistent pro-

protective standard or grant manufacturers the flexibility to choose a protective level within a given range. Most comments supported a simple, single-statement system that would prioritize consumer clarity. However, there were proposals for a tiered system that could communicate varying levels of risk. Some stakeholders commented that “allergen-free” claims demand a zero-tolerance standard, not a risk-based standard, because the prevailing consumer perception is that “free” means there would be no allergen in a product, and deviating from this expectation would be misleading. A dual approach was discussed for use of a mandatory, risk-based framework for AAS alongside a stricter, enforceable standard for any “allergen-free” claim. Potential exemptions from mandatory labeling were also discussed.

Operational and technical challenges

Participants detailed challenges to allergen management within a food facility and the supply chain. Comments identified limitations in existing analytical testing methods and the need for standardized, validated analytical methods and reference materials that are reliable across diverse foods. There was widespread agreement that thresholds are most effectively applied to the validation of preventive controls, particularly sanitation and cleaning procedures for shared equipment, rather than routine finished product testing. Comments also cited potential agricultural co-mingling and cross-contact in shared transportation, discussed a current lack of data transparency in the supply chain with a need for quantitative information about cross-contact, and noted guidance should translate clinical reference doses (milligrams of protein) into actionable limits (concentrations). Overall, participants wanted clear and comprehensive FDA guidance

to clarify the relationship among thresholds, AAS and enforcement actions. Some mentioned that sesame labeling was a cautionary example of unintended consequences when there is regulatory uncertainty.

A path for potential implementation

Thresholds were recognized as an opportunity to increase consumer trust and improve quality of life by empowering consumers with reliable information. Two areas were identified as necessary for moving forward: 1) Reforming the current AAS system and 2) Establishing a comprehensive, collaborative public-private educational campaign. Overall, discussions included the need for harmonization and highlighted policy considerations and technical barriers that must be addressed for any new approach to be successful.

The FDA article also noted the overarching goal shared by all parties is to develop a food allergen strategy that empowers consumers, expands safe food choices and improves the quality of life for the food-allergic community through clear, consistent and reliable information.

Mandatory usage versus voluntary compliance

According to *Allergic Living*, some listening session participants spoke about the need for a mandatory labeling system. Those supporters included Food Allergy Research and Education (FARE), a nonprofit patient advocacy organization. Another comment came from Steven Gendel who said, “For consumers to trust new, risk-based allergen labels, [they have] to be applied the same way by every food company, with standard criteria and wording. The only way to decrease confusion about these [PAL] labels is if everyone is playing on the same field.” Jill Mindlin, a patient advocate, remarked that, “If [the system] remains voluntary, things will be exactly the same as

where we are today, which is a mass of confusion.”

A new way of thinking about allergy management

Allergic Living also reported on another key concern, described by Caroline Moassessi, vice president of community relations, Food Allergy and Anaphylaxis Connection Team (FAACT). She explained the use of thresholds would be “a mindset change” for food-allergy families. “For patients and families long told to totally avoid foods containing their allergen, thresholds would represent a new way of thinking about allergy management. Some may welcome expanded food choices, but others may be wary of labels that imply a low—but not zero—risk,” she said. “Patients, healthcare providers, restaurants and other food-services providers will all need to be educated about thresholds and how to read labels.” The article also quoted Jennifer Holley, a parent from an allergic family who said, “I don’t know that I would trust somebody to put my child’s life at risk with a threshold. And as a consumer I don’t know that I would choose a product with a threshold.”

Next steps

After the public meeting, the FDA invited additional comments until May 14. They plan to publish themes from the meeting later in 2026. To date, they have not established or endorsed any allergen thresholds.

For general questions about the public meeting or listening sessions, contact the FDA’s Public Engagement Staff at PublicEngagement@fda.hhs.gov.

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