U.S. Food and Drug Administration (FDA) Virtual Listening Sessions
Food Allergen Thresholds and Their Potential Applications

February 19-20, 2026
10-11:30 a.m. ET and 2-3:30 p.m. ET

Listening Session Topic Purpose and Discussion Questions

Listening Session A

Food allergen threshold concepts

The purpose of this session is for individuals and organizations to share thoughts and perspectives on available data and concepts for establishing risk-based thresholds for application in various food allergen management and risk assessment situations.

Discussion questions:

1. What does the term "allergen threshold" mean to you? Please provide examples of situations where risk-based thresholds can or should be applied.

2. What are your thoughts on the Food and Agriculture Organization (FAO) proposed risk-based reference doses for major food allergens? What are the benefits and other possible applications of this approach, including considerations for risk management? Are there other approaches or additional data that you think should be considered? If so, please provide details.

3. We understand that establishing food allergen thresholds could allow greater standardization, transparency and flexibility for stakeholders. We also acknowledge that thresholds will not eliminate all risks of an adverse reaction. With this in mind, are there other potential opportunities or barriers to consider? If so, please explain.

4. How can the public and private sectors work together to assist stakeholders in understanding and applying allergen thresholds? What are the opportunities and barriers to achieving the actions you are recommending?

Listening Session B

Applications of food allergen thresholds – Labeling perspectives

The purpose of this session is for individuals and organizations to share ideas and perspectives on how risk-based thresholds can provide options for effective communication and labeling strategies to ensure consumers can make informed decisions.

Discussion questions:

1. What are your thoughts about the FAO proposed reference doses and framework for risk-based allergen advisory statements (e.g. "may contain [allergen]")? What are the opportunities and barriers for such an approach? Should FDA consider different levels of threshold for different advisory statements to communicate higher or lower allergen risk?

2. Advisory statements (e.g. "may contain [allergen]") are currently voluntary. If the threshold-based advisory statement approach is established but is not adopted by the entire industry, what specific types of efforts by government agencies, industry, consumer advocacy groups, and health care professionals are necessary to ensure that the advisory statement provides benefit to consumers?

3. What are your thoughts about the FAO proposed framework (i.e. reference dose with an additional margin of exposure/safety) to evaluate potential exemptions from mandatory allergen labeling? What are the benefits of this approach? What are other possible applications of this approach? Are there other approaches that you think should be considered? If so, please provide details.

4. In a product labeled "gluten-free," some situations (e.g., presence of gluten due to cross-contact) may allow a defined concentration of gluten at less than 20 parts per million (ppm). For products with an "allergen-free" claim or similar claims, FDA would expect there to be no allergen in a product, including unintended allergen presence due to cross-contact. Should FDA continue with this approach or are there risk-based approaches that you think could be considered for "allergen-free" claims?

Listening Session C

Applications of food allergen thresholds – Manufacturing perspectives

The purpose of this session is for individuals and organizations to provide thoughts and ideas for how risk-based thresholds can be used in manufacturing, procurement, and assessment of product safety.

Discussion questions:

1. Generally speaking, allergen cross-contact controls include procedures and practices that significantly minimize or prevent the unintentional incorporation of a food allergen into a food during storage, handling, and use. How should thresholds be applied in the context of allergen cross-contact controls? Can thresholds be used as part of the information to determine whether or not the controls are adequate? What are the opportunities and barriers to achieving the actions you are recommending?

2. We realize that even after implementation of appropriate allergen cross-contact controls, there may be situations which lead to a possible unintended allergen presence in the food and a potential risk to public health. How should thresholds be applied/considered to assess safety of the product (e.g. when to remove product from the market and/or submit a report to the reportable food registry (RFR))? What are the opportunities and barriers to incorporating the factors you are recommending?

3. Are there specific considerations in the application of food allergen thresholds for finished products versus raw materials and ingredients? What are the opportunities and barriers regarding the considerations you have identified?

4. We understand there may be unique considerations for certain product categories and allergen combinations with respect to allergen cross-contact controls (e.g. milk in dark chocolate, sesame in the baking industry). Acknowledging these issues, are there other specific food categories that require considerations based on factors such as product characteristics and processing methods? If so, please provide details.

Listening Session D

Practical considerations for adopting food allergen thresholds

The purpose of this session is for individuals and organizations to share perspectives and practical considerations for adopting and implementing food allergen thresholds.

Discussion questions:

1. Will the potential applications of allergen thresholds lead to an increase in consumer trust in product labels? If so, what specific actions could be taken to achieve the goal of giving consumers with food allergies the ability to make more informed food choices and improve quality of life? What are the opportunities and barriers to achieving the actions you are recommending?

2. If food allergen thresholds are considered to be beneficial, how can the public and private sectors work together to implement thresholds with the goal of helping consumers with food allergies find foods that are safe for them to consume? How would you measure success in a risk-based system? What endpoints could be examined and through what methods?

3. We understand there may be barriers to analytical and sampling methodologies for food allergens. Acknowledging these issues, please share any innovative, successful policies and strategies that different stakeholders are using to address these concerns and ensure adequate allergen controls. If those activities are on a small scale, do they have the potential to be scaled up? If so, how?

4. Thinking about everything discussed during the public meeting, are there any important, specific issues that we have not yet discussed (e.g. risk assessment assumptions, data gaps, individuals managing multiple food allergies, unintended consequences, and emerging allergens - including gluten-containing grains and ingredients containing alpha-gal)? Please elaborate.