CENTER FOR Science IN THE Public Interest
Your Food and Health Watchdog

May 18, 2026

Office of Food Safety Food and Drug Administration (FDA)
Dockets Management Staff (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via regulations.gov

Re: Virtual Public Meeting and Listening Session on Food Allergen Thresholds and Their Potential Applications (FDA-2026-N-1304)

To Whom it May Concern,

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the topic of food allergen thresholds and their potential applications. This comment will focus on the use of thresholds in better aligning precautionary allergen labeling (PAL) statements (e.g. "may contain peanuts") with product risk to ensure meaningful communication to consumers. Specifically, we call on the FDA to issue regulations defining specific PAL statements and requiring that any such claims are informed by adequate risk assessment incorporating such thresholds.

CSPI is an independent consumer advocacy organization with an over 50-year track record of working for food safety, nutrition, and health. CSPI is funded by individual donations; subscriptions to our magazine, Nutrition Action; and foundation grants. We accept no funding from corporations. We support evidence-based and community-informed policies that are grounded in what is best for people's health, including increasing equitable access to nutritious food, enhancing the transparency of food labels, and ensuring that our food is safe. CSPI has worked to improve safety and transparency for consumers with food allergies and was the first national group to call for sesame to be labeled as an allergen, a policy adopted under the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021.

I. FDA Legal Authority to Regulate PAL

Under current FDA guidance, PAL statements are allowed, but not required, on food packages, and are regulated only to the extent of ensuring they are truthful and not misleading.[1] This status quo means food companies determine PAL labeling on an individual basis, resulting in a wide array of statements that has left consumers confused.

[1] U.S. Food and Drug Administration. Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry. OMB Control No. 0910-0792. January 2025.

However, FDA does have potential authority to define with more particularity when a food is misbranded for labeling that "is false or misleading in any particular."[2] The agency also has the "authority to promulgate regulations for the efficient enforcement"[3] of provisions of the federal Food Drug and Cosmetics Act. FDA could rely on these authorities to promulgate rules defining mandatory requirements for the use of precautionary allergen statements to ensure they are not misleading. This could include streamlining the number of statements in use as well as requiring that any such claims are informed by adequate risk assessment.

If FDA determines that it lacks specific authorities needed to adequately regulate PAL, it should request additional authority from Congress. Such new authority could help ensure that FDA completes rulemaking, avoids judicial challenge, and has robust standards and enforcement mechanisms to facilitate compliance. In particular, Congress can ensure that FDA has authority to require risk assessment and application of PAL in cases where manufacturers are not already using such statements, a valuable enforcement tool.

II. Thresholds in the Use of Standardized PAL

To ensure that PAL is aligned with risk, FDA should establish clear quantitative thresholds that would trigger recommended application of a PAL statement. This will ensure that manufacturers apply such labeling consistently in cases where unintended allergen presence (UAP) could occur at levels exceeding the threshold (measured, for example, in milligrams per serving).

This quantitative approach could improve on process-based approaches such as applying PAL to any product manufactured on shared equipment with a major allergen, because it can account for varying preventive control options in different processing environments, tailored to each product and allergen. For example, if shared equipment is thoroughly cleaned and such cleaning is verified to have removed all traces of allergen protein, requiring all products processed on such equipment to bear a "processed on shared equipment" statement would be unnecessary. In addition, a rule that only relies on shared equipment would ignore other potential hazards, such as airborne particulate contamination.

III. Benefits of Better Regulation of PAL

PAL statements can be used by food manufacturers to indicate the potential for unintended presence of food allergens. A survey by Gupta *et al* of 3008 food-allergic individuals in 2019 found that respondents rely on such statements in making purchasing decisions and even utilize the specific wording of PAL to inform those decisions.[4] For example, the majority of respondents (85.5 percent) never purchase products with a "May contain traces of allergen" label, while a minority (35.0 percent) would never purchase a product with a label stating "Good manufacturing practices used to segregate ingredients in a facility that also processes allergen."[5] Yet, because these statements are not regulated, such phrases are not required to align with the

[2] 21 U.S.C. § 343(a)(1).
[3] 21 U.S.C. § 371(a).
[4] Gupta R, Kanaley M, Negris O, Roach A, Bilaver L, Understanding precautionary allergen labeling (PAL) preferences among food allergy stakeholders. *J Allergy Clin Immunol Pract.* 2021;9:254-64.
[5] *Ibid.*

underlying risk of UAP, and manufacturers may vary in determining which risks warrant the application of PAL as well as the type of statement used.

If PAL were meaningfully aligned with UAP risk, foods bearing PAL labeling would be substantially more likely to contain UAP than those without. Yet product testing research indicates that this is not the case. Only a small number of studies have tested for UAP in foods both with and without PAL.[6] While it at least one study has found a higher likelihood of peanut, but not milk or egg, in products bearing PAL,[7]other studies have found that UAP was no more likely to be present when PAL was present.[8] And one study by Bedford et al. of 100 U.S. dark chocolate bars sampled in 2013-14 found that while 8 percent of products with PAL statements contained peanut, the allergen was present in 17 percent of those without PAL, meaning prevalence was actually higher in unlabeled products.[9] This evidence, while limited, is adequate to demonstrate that PAL is not a reliable indicator of risk under the current system.

Additional research could facilitate better understanding of this issue across allergens and product classes. In particular, additional studies testing for UAP in products with and without PAL could help assess whether the preventive control requirements of the Food Safety Modernization Act of 2011, which went into full effect only in 2016-2018,[10] have had an impact on PAL accuracy.

In addition, both qualitative and quantitative studies could help to assess whether the accuracy of PAL statements can be further improved through better risk assessment practices. Such research could assess whether the accuracy of PAL labeling improved after adoption of a standardized approach in another jurisdiction, such as the VITAL program in New Zealand. Studies could also qualitatively describe how thresholds were applied in specific individual manufacturing environments, with quantitative results demonstrating greater alignment between PAL and UAP after such measures were put into place.

While such additional studies could be helpful, it is clear that the status quo, where PAL is unregulated, has not produced consistent, reliable PAL statements across product and allergen categories, which is the outcome consumers need. Standardizing PAL could better ensure that consumers understand the underlying risk being communicated by providing a set of clearly defined label statements that align with the underlying risk of UAP. Such a system, if

---

[6] Schaible A, Kabourek J, Elverson W, Venter C, Cox A, Groetch M, Precautionary allergen labeling: Avoidance for all? *Curr Allergy Asthma Rep*. 2024;24:81–94.

[7] Ford LS, Taylor SL, Pacenza R, Niemann LM, Lambrecht DM, Sicherer SH. Food allergen advisory labeling and product contamination with egg, milk, and peanut. *J Allergy Clin Immunol*. 2010;126:384–5. ("Peanut, but not milk or egg, was significantly (P< .05) more likely to be found in products with an advisory statement than in products without.")

[8] Remington BC, Baumert JL, Marx DB, Taylor SL. Quantitative risk assessment of foods containing peanut advisory labeling.
Food Chem Toxicol. 2013;62:179–87. ("No significant difference was found in the frequency of detectable peanut in products with advisory labeling for peanut (12/159) and products that had no mention of peanut on the label (2/49) (P = 0.20).")

[9] Bedford B, Yu Y, Wang X, Garber EAE, Jackson LS. A limited survey of dark chocolate bars obtained in the United States for undeclared milk and peanut allergens. *J Food Prot.* 2017;80(4):692–702.

[10] U.S. Food and Drug Administration. FSMA final rule for preventive controls for human food. Content current as of January 6, 2025. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food (Accessed May 18, 2026).

implemented effectively, would result in stronger alignment between the presence/absence of PAL and the presence/absence of UAP, promoting consumer confidence.

A secondary benefit of such labeling could be a reduction in unnecessary food recalls. Allergens were responsible for 43.5 percent of all FDA food recalls between 2020 and 2022.[11] While the majority of these are the result of labeling errors or use of the wrong ingredient, 16.7 percent of food allergen recalls are rooted in problems with cross-contact controls, such as a positive product allergen test.[12] Concern over such recalls may drive manufacturers toward the perverse outcome of addressing cross-contact hazards by adding allergens to the product recipe because this allows them to declare the allergen as an ingredient. Once declared as an ingredient, a food will not be recalled due to presence of that allergen.

CSPI previously documented this phenomenon after sesame labeling was introduced in the United States, when some manufacturers moved to comply with the law by adding sesame to product recipes.[13] Standardized PAL could be an alternative way for manufacturers to declare the risk of unintended sesame presence and thereby effectively warn consumers of possible UAP, reducing incentives to add sesame or other major allergens as an ingredient.

However, the benefit of standardizing PAL in deterring this practice would be limited by the fact that, as we discuss further below, the presence of a PAL statement generally should not absolve a manufacturer from its obligation to recall a product likely to contain UAP. Instead, such statements can be considered in an assessment of public health risk that should also include any information about the quantitative amount of allergen present. This lack of bright line certainty against recall means that manufacturers that have engaged in adding sesame as an ingredient to ensure products will not be recalled for UAP will be unlikely to discontinue this practice even after PAL labeling is required for such products.

IV. Selecting a Threshold for use in PAL

FDA should identify a threshold that will avoid serious adverse reactions, taking into account the needs of highly sensitive consumers.

The Food and Agriculture Organization and World Health Organization (FAO/WHO) of the United Nations recently issued international recommendations on using food allergen threshold levels to inform PAL statements on packaged food products.[14] That expert committee considered options to set a reference dose based on the "eliciting dose" or dose at which any objective

---

[11] Beach, C. (2023, March 15). *Report finds an enormous increase in the number of food items recalled in 2022*. Food Safety News. https://www.foodsafetynews.com/2023/03/report-finds-enormous-increase-in-number-of-food-items-recalled-in-2022/ (Accessed May 18, 2026)

[12] Sharma GM, Ma Y, Luccioli S, Recalls associated with food allergens and gluten in FDA-regulated foods from fiscal years 2013 to 2019. J Food Prot. 2023;86(4):100069.

[13] Center for Science in the Public Interest. Petition to FDA to notify manufacturers that they cannot mitigate allergen cross-contact risks by adding sesame and other major allergens to foods. Citizen Petition. January 30, 2023. https://www.cspi.org/sites/default/files/2023-01/Petition%20to%20Prohibit%20Allergen%20Addition.pdf (Accessed May 18, 2026).

[14] Food and Agriculture Organization and World Health Organization. Risk assessment of food allergens – Part 2: Review and establish threshold levels in foods for the priority allergens, Meeting Report. Food Safety and Quality Series No. 15. Rome. 2022. https://doi.org/10.4060/cc2946en (Accessed May 18, 2026).

symptoms are elicited during food challenge studies, affecting both 5 percent (ED05) and 1 percent (ED01) of food-allergic individuals.[15]

In considering the ED05 and ED01 thresholds, the expert committee reviewed data from oral challenges in controlled clinical settings using an escalating dose to calculate a population distribution at each individual's minimum eliciting dose, a dose at which adverse reactions are typically mild to moderate. The ED05 reference dose was also validated with peanut, milk, and hazelnut allergy using single-dose challenges.[16]

The expert committee found that exposure to the ED01 dose would result in 0.4 per 1000 peanut-allergic individuals estimated to react with anaphylaxis versus 2.3 per 1000 at the ED05, and predicted that most cases would resolve without treatment, with the risk of fatal reaction to the ED05 exposure estimated to be <1 per million. Ultimately, the committee determined that refining from the ED05 to the ED01 would not meaningfully reduce public health impact because fatal anaphylaxis is generally rare (less than 1 per 100,000 person-years) and no fatal reactions have been reported in the literature following exposure at or below the ED05. The decision was also informed by concerns that manufacturers would be unable to consistently verify the ED01 threshold using current best commercially-available tests, making the standard less practicable. The final reference dose recommendations in the report were therefore derived from the ED05 value, expressed in milligrams of total protein from the allergenic source, with any decimals rounded down to the nearest milligram to simplify application.[17]

FDA has a choice in adopting its own national standard independent of the WHO/FAO recommendations. Adopting the WHO/FAO reference dose values derived from the ED05 would put the US in harmony with international standards, be easier for manufacturers to verify with testing in some settings, and would likely reduce the overall amount of products bearing PAL statements. However, a more protective standard based on the ED01 would offer greater assistance to sensitive individuals seeking to utilize PAL in purchasing decisions.

Given that an estimated 33 million people in the United States have at least one food allergy,[18] 1.6 million U.S. consumers could be conservatively estimated to react to at least one allergen at a reference dose based on the ED05. Any system of standardized PAL should be designed to adequately meet the needs of this group. Moreover, while fatal anaphylaxis is the most extreme harm that can occur and appears to have been a key consideration in the FAO/WHO decision, evidence describing fatal exposure is highly limited. The FAO/WHO expert panel acknowledged this gap, and even stated that "[t]he rarity of fatal reactions and their limited relevance in the context of managing unintended allergen presence makes fatal reactions an inappropriate basis for characterizing the hazard posed by such a presence."[19] Moreover, non-fatal anaphylaxis is an

---

[15] *Ibid.*
[16] *Ibid.*
[17] *Ibid.*
[18] Food Allergy Research and Education. Food allergy facts and statistics for the U.S. Last updated April 18, 2024. https://www.foodallergy.org/sites/default/files/2024-07/FARE%20Food%20Allergy%20Facts%20and%20Statistics_April2024.pdf (Accessed May 18, 2026)
[19] Food and Agriculture Organization and World Health Organization. Risk assessment of food allergens – Part 2: Review and establish threshold levels in foods for the priority allergens, Meeting Report. Food Safety and Quality Series No. 15. Rome. 2022. https://doi.org/10.4060/cc2946en (Accessed May 18, 2026).

important clinical outcome, and adopting the ED01 in lieu of the ED05 would reduce the risk of overall anaphylaxis from 2.4 to 0.4 per 1000 exposures by allergic individuals, a meaningful reduction.

We therefore recommend that the FDA adopt the ED01 threshold, either requiring PAL for risks above a reference dose based on the ED01, or creating a two-tier PAL system where one message is provided for risk above the standard international ED05-based reference dose (e.g. "may contain…"), and an alternative message offered to communicate risk between the ED05 and the ED01, and any risk under the ED01 threshold is unlabeled.

Irrespective of the threshold used, messaging used to convey risk to consumers (e.g. "may contain," "not suitable for," etc.) should be tested to ensure clarity of understanding prior to adoption.

V. Risk Assessment

Another set of challenges in adopting a more standardized PAL system relates to applying risk assessment across multiple production environments. Ideally, the effectiveness of allergen controls could be verified by statistically robust product sampling to ensure that preventive controls within a system reliably produce product with protein amounts falling below the threshold reference dose. For example, a product lacking PAL (and thereby communicating that risk is below the ED01) should have a calculated 95 percent confidence interval for the estimate of potential contamination below the ED01.

However, current regulations allow manufacturers to use methods other than product testing to verify risk assessment, and developing robust end-product testing programs to verify the accuracy of PAL statements across diverse production environments may be impracticable. In light of this, manufacturers should be encouraged to err on the side of caution, resolving any uncertainty by applying a PAL statement if a risk assessment reveals that the amount of allergen potentially present approaches the threshold dose.

VI. Limitations of Standardized PAL

Even with improvements, standardized PAL will have some limitations.

First, regulation of PAL cannot be expected to ensure that all products with UAP are labeled with a precautionary statement. This is because a statement printed on a label can only address predictable risks, and mistakes involving the wrong ingredient or the wrong label are a common source of UAP resulting in recalls. These mistakes are generally not foreseeable and therefore cannot be addressed in advance through application of PAL.

Second, regulation of PAL cannot be expected to ensure that all products with PAL statements contain UAP. This is because the risk of UAP tends to be episodic, and printed labels must account for all circumstances that might be anticipated to occur during production. It may be appropriate that a substantial proportion, even a majority, of products bearing PAL will not contain UAP, if such labeling is needed to ensure that any products that do contain UAP are consistently labeled for such risk.

In light of these factors, research may be needed to more fully understand the extent to which PAL labeling accuracy can be improved through the application of a standardized PAL approach employing thresholds.

Educational messaging will also be needed to ensure that consumers understand both the benefits and limitations of standardized, risk-based PAL.

An additional challenge is that PAL labeling likely will have limited utility in guiding decisions related to product recalls. While it is theoretically reasonable to forgo recommending a recall if a manufacturer is certain the risk remains below the reference dose, verifying this may be impracticable given the limited information typically available at the time a recall must be initiated. This is because a root cause assessment needed to inform the amount and extent of the contamination may not have been completed at that point a recall is being considered. Such uncertainty poses challenges even for products labeled with PAL, as the possibility of presence of UAP well above the allergen threshold dose has the potential to pose significant clinical risks, even if a PAL statement is provided. For this reason, a product with known UAP generally should be deemed adulterated and removed from commerce even if it bears PAL advising of potential risks, as such labeling does not clearly convey the known presence of UAP.

Finally, FDA should consider how requiring PAL can create perverse incentives to apply such labels even in cases where the label is not warranted. FDA can and should prohibit such practices by requiring documentation of risk assessment, but enforcing such a requirement will be challenging. This is because FDA inspection generally occurs infrequently and prioritizes risks likely to result in injury, not the over-application of precautionary statements, which limits access but does not increase risk of consumer injury.

There is also a possibility that some manufacturers will view mandatory PAL as an opportunity reduce investment in effective good manufacturing practices or preventive controls, even though FDA rules clarify that PAL is not a substitute for such safety measures.[20] Incentives to invest in such controls would be particularly reduced if FDA were to consider a product with UAP to be not adulterated if labeled with PAL (i.e. if by applying such statements, manufacturers could avoid a product recall and the associated financial risk of such an event). This is another reason not to rely too heavily on PAL in making recall recommendations.

VII. Recommendations

FDA should provide more meaningful and useful mandatory PAL labeling through the following actions:

1. Issue regulations defining specific PAL statements and require that any such claims are informed by adequate risk assessment.

[20] U.S. Food and Drug Administration. Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry. OMB Control No. 0910-0792. January 2025.

2. Adopt a reference dose that takes into account the needs of highly sensitive US consumers, adopting either the ED01 or a two-tiered system that discloses risks below the ED05.
3. Clarify that recalls will still generally be recommended for UAP even in foods bearing PAL statements.
4. Funding or carrying out additional research, including:
    a. Sampling of U.S. products with and without PAL, covering multiple product categories and allergens to better understand the baseline for current accuracy of PAL in the United States.
    b. Additional single-dose food challenge studies to validate any reference dose adopted in the United States.
    c. Consumer testing of any proposed label recommendations to ensure adequate consumer comprehension.
    d. Assessment of the potential benefits of PAL standardization, including studies demonstrating that the accuracy of PAL can be improved through the application of thresholds in risk-assessment.

We appreciate FDA engaging in dialogue on methods to improve allergen regulation, and look forward to seeing action from the agency to benefit U.S. consumers,

Sincerely,

Sarah Sorscher, JD/MPH
Director of Regulatory Affairs, Center for Science in the Public Interest

Peter Lurie, MD
President, Center for Science in the Public Interest