Asthma and Allergy Foundation of America

June 12, 2025

Re: Comments on the World Allergy Organization ACT-UP! Consensus Recommendations on Precautionary Allergen Labelling

Dear Dr. Fiocchi, Dr. Turner, and Members of the ACT-UP! Steering Committee and Expert Panel,

I am writing to you on behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world. We are dedicated to improving the quality of life for people with allergic diseases and asthma through education, support, advocacy and research.

In the United States, about 20 million people have food allergies.[1,2] A recent study found that across all age groups, the rate of emergency room visits for food-related anaphylaxis increased by 124% from 2005 through 2014.[3] The 2004 Food Allergen Labeling And Consumer Protection Act, or FALCPA, established important standards for allergen labeling for major food allergens, but does not address precautionary allergen labeling.

AAFA strongly supports both the process and the draft recommendations of the WAO, ACT-UP process on precautionary allergy labeling. Overall, this is a well-written, clear, and well-organized effort to demonstrate consensus among a group of international stakeholders regarding an approach to improving declaration, disclosure, and policy regarding precautionary labeling practices for unintended allergen presence (UAP). While a sample of 25 members and 70% threshold trend towards minimum requirements, they are within accepted limits of acceptability for a modified Delphi process.

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[1] Ng, A.E. & Boersma, P. (2023). NCHS Data Brief, no 460: Diagnosed allergic conditions in adults: United States, 2021. National Center for Health Statistics. https://dx.doi.org/10.15620/cdc:122809

[2] Zablotsky, B., Black, L.I., & Akinbami, L.J.(2023). NCHS Data Brief, no 459: Diagnosed allergic conditions in children aged 0-17 years: United States, 2021. National Center for Health Statistics. https://dx.doi.org/10.15620/cdc:123250

[3] Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." J Allergy Clin Immunol Pract. 2017 Jan - Feb;5(1):171-175.

We do wish to highlight the paucity of US members, in particular practicing pediatric allergists with expertise in food allergy or US advocacy group stakeholders, as a potential limitation that should be denoted in the manuscript limitations (among other representatives who were not included in the stakeholder group). However, overall the high level of near-unanimous consensus with most statements is very encouraging.

AAFA offers the following feedback:

1) To the greatest extent possible, PAL language and reference threshold should be as similar as possible across different jurisdictions to promote harmony in a global manufacturing economy and support the needs of the food allergic traveler.

2) We support developing a clear system to designate the presence of unintended allergen presence that differentiates this content from intended major allergen content and a product that lacks any major allergen.

3) We discourage defensive PAL practices for UAP which does not directly share equipment/handling and pose a plausible direct risk being in a product.

4) We support using a discrete protein level rather than a concentration-based threshold (ppm). Specifically, we support the ED_{05} as the appropriate reference level representing an evidence-based threshold optimizing patient protection and reliable, consistent protein detection.

5) We discourage deriving a reference dose based on cross-reactivity if unknown, and encourage levels be empirically derived rather than estimated.

6) Gluten labeling for celiac disease has distinct risks and consequences of ingestion from food allergen labeling for IgE-mediated allergy, and should not be lumped together under the same policy.

7) All stakeholders should agree to the reasonableness and feasibility of implementing a specific PAL policy, and such policy should be thoroughly vetted for pitfalls and vulnerabilities

8) An implementation strategy should be planned in advance to support policy roll-out, though the policy and implementation are beyond the scope of this document.

9) The decision to consume products with PAL is a shared decision between patient and supervising clinician, who has the duty to provide evidence-based PAL education to support patients.

As we continue to collaborate on precautionary labeling policy here in the United States, we look forward to observing the ongoing work of the WAO, ACT-UP group. If you would like any additional information about AAFA, please contact our Vice President of Advocacy and Policy, Jenna Riemenschneider at jennar@aafa.org.

Sincerely,

Kenneth Mendez

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America