European Federation of Allergy and Airways Diseases Patients' Associations

EFA STATEMENT ON PRECAUTIONARY ALLERGEN LABELLING (PAL)

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March 2025

Towards a Precautionary Allergen Labelling that empowers consumers and protects patients

(Through this statement, EFA wishes to express its full support to the recently adopted Dutch policy on the application of the Precautionary Allergen Labelling [PAL]. Initially addressed to the Chair of the Codex Committee on Food Labelling [CCFL] in the context of the last committee meeting in Canada, the statement remains timely and indicative of the perspective of the European food allergy patient community on key aspects of this highly important topic for their health and safety).

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the Europe-wide umbrella organisation representing more than 200 million people in Europe living with allergy, asthma, atopic eczema and chronic obstructive pulmonary disease (COPD). EFA has 45 member organisations in 26 European countries.

EFA follows closely and with great interest the ongoing discussions around Precautionary Allergen Labelling (PAL), at both the EU and the international level. We have warmly welcomed the CCFL work on developing Guidelines for the Use of Precautionary Allergen Labelling (PAL), contributing the perspective of the European food allergy patient community.

In addition, EFA greatly values the consultations that brought together experts from FAO and WHO to discuss key issues on allergen risk assessment. Reports 2 and 3 from that consultation refer to crucial technical aspects for allergen risk assessment, and recommend avenues to harmonise the use of PAL. [1,2] We firmly believe that the implementation of these recommendations can further decrease the risk of anaphylaxis due to exposure to food allergens, while limiting the unnecessary restriction of food choices that occur with the overuse of PAL.

The ongoing question and analysis about the most effective approach to set standards for allergen reference doses (RfDs) is of outmost importance to the EFA community. After consultations with our Food Allergy Working Group, with other patient organisations outside Europe, and with experts from the medical community and allergen risk assessors**, EFA unequivocally backs the use of RfDs derived from a 5% eliciting dose (ED05).**

There are three main reasons that underpin our patient preference for ED05 as the method to derive allergen RfDs and therefore accurate PAL:

1. **Choose a truly protective and nuanced approach.** Despite ED01 (1% eliciting dose) theoretically being the more protective approach, ED01-based RfDs would not necessarily lead to significant

[1] FAO and WHO 2022, *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. https://doi.org/10.4060/cc2946en

[2] FAO & WHO 2023, *Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens*, Meeting report. Food Safety and Quality Series No. 16. Rome. https://doi.org/10.4060/cc6081en

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health benefits at population level, as shown by recent research[3]. These data are aligned with the recommendation of the FAO/WHO expert consultation report 2 (pp 93)[4]. In parallel, consumers who might still react at levels below ED05 should continue to be protected and catered for. To this end, EFA calls for intensified efforts to **identify patients at risk of reaction to lower reference doses through medical testing and evaluation**, together with an **appropriate education strategy** towards all stakeholders involved in the food chain and processes.

2. **Align with existing technology and methods.** There are already available analytical methods for the detection of allergen presence at the level of ED05[5].
3. **Prevent confusion and ensure meaningful PAL statements.** Set by definition at a very low level, the use of ED01-derived RfDs for PAL would likely lead to a proliferation of unnecessary PAL statements, as food manufacturers will be incentivised to use PAL for all unintended allergen presence above the 1% level to avoid risks. From a food allergy patient perspective, this would worsen the problem of PAL overuse in the market, but also further undermine consumer trust in PAL statements and lead to unnecessary restrictions or risky consumption behaviours.

Based on the above considerations, EFA thinks that ED05 constitutes the optimal approach for RfDs as it **balances the need for patient's safety, while safeguarding the ability to make accurate food choices for people with food allergy.** We hope that the three principles outlined above will guide the work of the CCFL in the upcoming steps of this process, and we look forward to continuing contributing to it.

Finally, EFA would like to stress that, in terms of making informed food choices, clear information on unintended allergen presence is as important to consumers with food allergies as mandatory ingredient information. Although PAL is not part of the GSLPF itself and a guideline leaves more room for flexibility, we would like to ask CCFL and Codex to propose the most precise and binding framework possible.

The EFA food allergy patient community would immensely value clarity on PAL, both when PAL needs to be used, in which case it should preferably be included as part of a comprehensive 'Allergen Statement'; and when PAL is not needed, so that these food products are clearly identifiable by consumers with food allergy as suitable food choices. In both cases, the use of PAL or not must be determined by a proper risk assessment.

We thank you in advance for your consideration.

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The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is an independent non-profit organization based in Brussels, connecting 45 patient associations from 26 countries. As a patient-led organisation, we advocate for the rights and well-being of people living with allergies, asthma, and chronic obstructive pulmonary disease (COPD) across Europe. We bring the voices of patients to European-level policies, research priorities, and initiatives, ensuring their needs are represented in decisions that impact their health.

EFA is grateful to its food allergy community of members and especially to its Food Allergy Working Group for their valuable expert perspective leading to the development of this statement.

[3] P.J. Turner et al., 'Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis', Journal of Allergy and Clinical Immunology, August 2021 https://www.jaci-inpractice.org/action/showPdf?pii=S2213-2198%2821%2900907-7

[4] Idem

[5] T. Holzhauser et al., 'Are current analytical methods suitable to verify VITAL® 2.0/3.0 allergen reference doses for EU allergens in foods?', November 2020 https://www.sciencedirect.com/science/article/pii/S0278691520305998?via%3Dihub

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