

Statement to the consultation on the revision of EU legislation on Food Information to Consumers (Directorate General for Health and Food Safety)

March 2022

According to the overarching objectives of the EU Farm-to-Fork strategy, improving consumer information through labelling is a key aspect of healthy food consumption and to ensure a sustainable food system 'from farm to fork'.

EFA calls on the European Commission to use this opportunity to demonstrate the **implications of nutrition in preventing chronic diseases**. This important aspect has not been referred to in the materials related to this consultation. However, EU action on the impact of food labelling on preventing cancer is clearly included in Europe's Beating Cancer Plan¹ and the subsequent implementation roadmap².

Beyond cancer, there is robust science demonstrating that access to information on food and diets has notably impact on the occurrence of other chronic diseases too, such as allergy and airways diseases, especially during pregnancy, infancy and childhood^{3,4}. For EFA, the current revision of the Regulation 1169/2011 on Food Information to Consumers (FIC) must also consider the needs of allergy and asthma patients to be coherent with its goals and policy framework.

While often downplayed, **food allergy is a common and potentially life-threatening chronic disease**. It represents a significant burden for patients' health, as exposure to a food allergen has consequences ranging from risks of a mild allergic reaction to an extremely dangerous anaphylaxis event. In addition, **food allergy also leads to social, emotional and economic costs**, which affects patients' Quality of Life as a whole. When it comes to food choices, our community of food allergy patients across Europe face risks related to food labelling on a daily basis.

It is therefore striking and regrettable that the current legislative gaps on allergen labelling are not being considered within the current revision of the FIC Regulation. **EFA calls strongly on the European Commission DG SANTE to include allergen labelling, and especially Precautionary Allergen Labelling (PAL), within the scope of this revision**, with objectives that are comparable to those set for nutritional labelling: harmonisation, predictability and better health protection.

Precautionary Allergen Labelling

¹ European Commission, 'Europe's Beating Cancer Plan: Communication from the Commission to the European Parliament and the Council', 2021, https://ec.europa.eu/health/system/files/2022-02/eu_cancer-plan_en_0.pdf

² European Commission, Europe's Beating Cancer Plan implementation roadmap, 2021 https://ec.europa.eu/health/system/files/2022-01/2021-2025_cancer-roadmap1_en_0.pdf

³ J. Alwarith, J. Kahleova et al. 'The role of nutrition in asthma prevention and treatment', *Nutr Rev*, 2020, <https://pubmed.ncbi.nlm.nih.gov/32167552/>

⁴ A. Mazzocchi, C. Venter et al, 'The Role of Nutritional Aspects in Food Allergy: Prevention and Management', *Nutrients*, 2017, <https://pubmed.ncbi.nlm.nih.gov/28792480/>

Article 21 of the FIC Regulation requires the mandatory declaration of the 14 recognised allergens in prepack food. Specifically, these allergens must be (a) indicated in the list of ingredients, and (b) emphasised through a typeset that distinguishes them from the rest of the ingredients, for example using a different font, style or background colour.

Aside from mandatory labelling of ingredients, the FIC Regulation also refers to other types of allergen information. These include the Precautionary Allergen Labelling (PAL), a voluntary labelling system used by manufacturers to indicate potential unintended allergen presence in food due to cross-contact in the production cycle e.g., manufacturing, processing, storage, or transportation. PAL statements are given in various forms such as 'may contain...', 'may contain traces of...', 'manufactured in a facility that also processes...'.

EFA views allergen labelling (and therefore PAL) as very much a safety issue. Already, Regulation (EC) 178/2002 ('General Food Law') makes certain information mandatory for the consumer's benefit (Article 14). According to the Regulation, food must be safe to eat, and therefore if it is harmful to health, it is considered unsafe. Moreover, the law defines food safety conditions that consider the health needs (for example, possible allergic sensitivity) of certain vulnerable consumers. **Any label that does not report, or provides incorrect or incomplete, information on allergens represents a severe risk to the health of allergic consumers,** as an anaphylactic reaction can lead to death.

The current Article 36 of the FIC Regulation fleshes out general requirements on voluntary information. Importantly, it also indicates the European Commission's commitment to adopt specific implementation acts of such requirements. However, this development has not yet occurred which leaves open a daily uncertainty for allergic patients.

As EFA has demonstrated in its 2019 report 'FoodDetectives - Quality of Life for People with Food Allergies in Europe: A Menu for Improvement'⁵, that **the lack of specific legal provisions and requirements on the use of PAL, and the resulting absence of a harmonised approach across Europe, has led to an inconsistent but also excessive use of PAL**^{6,7}. The lack of stricter regulatory terms on the use of PAL has led to a situation where food operators often use PAL simply to protect themselves against product liability claims due to allergens in food^{8,9}. **In its current use, PAL protects food operators rather than consumers.**

Consequently, consumers with food allergy often find themselves making their own interpretations of PAL statements. On the one hand, some consumers decide to avoid products with such statements altogether, unnecessarily restricting their food options;

⁵ European Federation of Allergy and Airways Diseases Patients' Associations (EFA), 'FoodDetectives – Quality of Life for People with Food Allergies in Europe: A Menu for Improvement', 2019, https://www.efanet.org/images/EFA_FoodDetectives_Report.pdf

⁶ G. A. Zurzolo et al., Hidden Allergens in Foods and Implications for Labelling and Clinical Care of Food Allergic Patients, *Curr Allergy Asthma Rep*, 2012, <https://link.springer.com/article/10.1007%2Fs11882-012-0263-6>

⁷ C. B. Madsen et al., Can we define a level of protection for allergic consumers that everyone can accept?, *Regulatory Toxicology and Pharmacology*, 2020 <https://www.sciencedirect.com/science/article/pii/S027323002030177X>

⁸ J. M. Soon, L. Manning, "May Contain" Allergen Statements: Facilitating or Frustrating Consumers?, *Journal of Consumer Policy*, 2017, <https://link.springer.com/article/10.1007/s10603-017-9358-8>

⁹ A. DunnGalvin et al., Precautionary allergen labelling: perspectives from key stakeholder groups, *Allergy*, 2015 <https://onlinelibrary.wiley.com/doi/full/10.1111/all.12614>



whereas other patients are prone to adopt risk-taking behaviours, accepting the possibility of a potential allergic reaction¹⁰. Overall, **consumers tend to lose trust in the current food labelling system** and see their fear and anxiety increase when deciding which foods to consume.

A lack of PAL harmonisation and the resulting confusion is also perceived as a reputational risk for the food sector. FoodDrinkEurope, the European-level association of food manufacturers, has published a Guideline on necessary EU actions for a defined framework for the application of PAL. This guideline is based on single wording; a quantitative risk assessment abasis; and transparent quantitative limits derived using the most up to date, relevant and robust scientific data¹¹.

EFA considers that neglecting allergen labelling, and in particular PAL, in the ongoing revision of the FIC Regulation is a missed opportunity to address legislative issues around food information holistically and decisively. EFA firmly believes that it is time for the European Commission to take the necessary steps to protect the health of consumers with food allergies by:

- ❖ **Harmonising EU-wide rules on Precautionary Allergen Labelling**, based on common wording and conditions for use, in line with Article 36 of the FIC Regulation.
- ❖ Encouraging and financing scientific research **to establish reference doses for the 14 recognised allergens** listed in the Annex II of the FIC Regulation, on the basis of a common approach to quantitative risk assessment.

As ever, EFA stands ready to convey allergy patients' needs to the EU institutions and agencies and work closely together to provide the highest food quality information and standards.

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 43 national associations from 25 countries and channel their knowledge and demands to the European institutions. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care and a safe environment.

Sincere thanks to the members of the EFA Food Allergy Working Group for their valuable contribution to EFA's response in this consultation.

¹⁰ A. DunnGalvin et al., Precautionary allergen labelling: perspectives from key stakeholder groups, *Allergy*, 2015 <https://onlinelibrary.wiley.com/doi/full/10.1111/all.12614>

¹¹ FoodDrinkEurope, Precautionary Allergen Labelling (PAL): A Science-based Approach Based on Quantitative Risk Assessment, 2021, <https://www.fooddrinkeurope.eu/resource/guidelines-on-precautionary-allergen-labelling/>

