



**GIANT
LEAPS**

POLICY BRIEF 5

Food allergy

OBJECTIVE

This policy paper aims to raise awareness on potential food allergy issues related to the dietary shift from animal-based to alternative proteins. It serves as a call for risk assessors and risk managers from both governments and companies as well as scientists and food allergic consumers to accelerate and promote this transition, while ensuring those with food allergies can make safe food choices.

KEY POLICY RECOMMENDATIONS

A dietary shift from animal-based foods to foods based on alternative proteins is expected to reduce the environmental impact of food production and consumption. However, this transition also may come with potential food safety concerns in the area of food allergy that must be addressed proactively. To ensure a safe and effective dietary shift, the following recommendations are provided, along with a Call for Action for three main stakeholder groups.

Recommendations

1. Establish a comprehensive surveillance system for emerging food allergies
2. Enhance food allergy prevalence data collection across Europe
3. Further develop, validate and standardise allergenicity risk assessment tools
4. Promote cross-sector collaboration on allergenicity risk assessment
5. Provide targeted training for risk assessors and applicants in allergenicity risk assessment and food labelling regarding allergenic risks
6. Strengthen consumer protection through evidence-based labelling of allergenic risks
7. Support consumer-/ patient education on understanding food labels with regards to allergenic risks of novel proteins
8. Support research on genetic and environmental factors in food allergies

Call for Action

1. Governments and regulators: Establish EU-wide surveillance and early-warning systems for emerging food allergies and ensure regulatory frameworks (including labelling relating to allergenic risks and risk assessment guidance) remain adaptive and science-based. Ensure adequate stakeholder education and compliance with market authorisations.
2. Scientists and research institutions: Generate robust, regulatory-relevant evidence on emerging food allergens and validate new approach methodologies (NAMs) for allergenicity assessment to support reliable and timely safety evaluations together with effective training in allergenicity risk assessment.
3. Food business operators: Integrate allergenicity risk assessment early in product development through safety-by-design approaches and provide transparent, high-quality data to support regulatory assessments and consumer protection, and inform risk communication strategies.



What is a food allergy?

A food allergy can be defined as an adverse reaction to foods which occurs reproducibly on oral exposure to a given food and is mediated by the immune systems. In contrast, a food intolerance may also be a reproducible adverse reaction to food but does not have an established or likely immunological mechanism. There are several types of immune-mediated adverse reactions:

- (1) IgE-mediated food allergies may result in rapid onset of severe reactions (usually <2 hours) and may manifest with a variety of signs and symptoms that can involve the digestive, respiratory, cardiovascular and/or cutaneous organ systems. The severity of reactions varies from mild (e.g., hives) to severe (e.g., anaphylaxis, respiratory or cardiovascular problems including respiratory or cardiac arrest).
- (2) Non-IgE (cell)-mediated food allergies more commonly affect only the gastrointestinal tract in a subacute or chronic way and are typically delayed in onset (>2 hours). They include eosinophilic gastroenteritis, eosinophilic oesophagitis (EoE), food protein-induced enterocolitis (FPIES), food protein-induced proctitis/proctocolitis and enteropathy.
- (3) Coeliac disease is an immune-mediated disorder that is largely characterised by chronic inflammation of the small intestinal mucosa, involving activation of specific types of T-cells upon consumption of gluten. This can result in atrophy of intestinal villi causing malabsorption syndromes and which manifests itself in a variety of ways either during childhood or later in adulthood. Symptoms can include diarrhoea, abdominal cramping, pain, and distension. Atypical coeliac disease characterised by the absence of gastrointestinal symptoms is increasingly being diagnosed because of improved *in vitro* and other diagnostic tests. Related conditions are dermatitis herpetiformis and gluten ataxia.

Existing frameworks for safety assessment of alternative proteins

Many alternative proteins have a history of use within the European Union and UK – including foods such as pea protein and Quorn. These foods are regulated through existing food law and must meet the requirements that they are not injurious to health. The EU maintains an (informal) searchable Novel Food Catalogue of foods which indicates whether an ingredient or food has a history of consumption in the EU prior to May 1997 (<https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search>).

Foods and food ingredients considered to be Novel Foods (i.e. a food that was not consumed “significantly” by humans within the EU prior to the 15th of May 1997) need to undergo a safety assessment prior to being given a marketing authorisation. These include e.g.,

- Traditional foods from third countries that have a proven history of safe consumption for at least 25 years in countries outside the EU and UK.
- Foods created using cutting-edge technologies or new production processes (e.g., cell-cultured meat, milk proteins produced by precision fermentation or nanotechnology).
- Ingredients derived from plants, microorganisms, fungi, algae, or animal sources not typically eaten in the EU before 1997.
- Ingredients where the molecular makeup has been intentionally modified.

The European Food Safety Authority provides guidelines for assessment of novel foods (EFSA Panel on Nutrition et al., 2024), although new protein sources produced by genetically modified organisms (GMO) can be subject to risk assessment through the GMO framework (EFSA Panel on Genetically Modified Organisms et al., 2025). Currently the EFSA guidance mainly addresses the potential for a novel protein to cause a reaction in individuals with pre-existing food allergies (so-called cross-reactive allergies). This is because there are no validated predictive methods currently available for assessing the potential for a novel protein to cause new food allergies (so-called *de novo* sensitisation) and adds uncertainty to this element of the risk assessment process. GIANT LEAPS [Policy Brief #3](#) identifies several issues, challenges and opportunities around Novel Foods in EU and UK.

POLICY RECOMMENDATIONS

Several policy recommendations that can address emerging food allergy concerns, risk assessment tools, and the safety of novel foods can be provided. These policy recommendations aim to address the increasing complexity of food allergy risk management in Europe, especially in light of the rise of alternative proteins and other novel foods:

Recommendation 1: Establish a comprehensive surveillance system for emerging food allergies

Build a collaborative platform between outpatient clinics, patient organisations, and researchers to monitor new food allergies as they emerge. Emerging “new” food allergies are likely to be of very low prevalence and will not be identified in a population prevalence study. Instead, approaches such as sentinel surveillance (Stone & Horney, 2018) and registries (“AHRQ Methods for Effective Health Care,” 2014) need to be utilised for systematic, ongoing collection of data from selected providers (e.g., expert food allergy clinics, patient advocacy organisation) to detect emerging food allergies. This could be built on the GIANT LEAPS alternative protein study (AltProt; described in Deliverable 3.4), to help identify emerging food allergens at an early stage, including allergic consumer feedback on allergic reactions associated with novel foods and alternative proteins.

Rationale: Early detection and reporting of emerging allergies could help mitigate potential public health risks. Having a system in place to track new allergens can lead to quicker response and adaptation in allergen labelling and safety standards. This would provide evidence to identify a watch list of emerging food allergens as recommended by the FAO-WHO expert consultation on risk assessment of food allergens (FAO-WHO, 2022).

Recommendation 2: Enhance food allergy prevalence data collection across Europe

Revise and update the EuroPrevall project tools to conduct a new, large-scale, pan-European study on the prevalence and severity of food allergies in both children and adults and building on the EuroPrevall and PAFA studies (Lyons et al., 2019; Lyons et al., 2020). This should include environmental and dietary factors, such as the shift to plant-based proteins and climate change’s impact on pollen allergies. It should facilitate an ongoing Europe-wide, longitudinal study to monitor and track food allergies, which could be modelled on Japan’s ongoing IgE-mediated allergy surveys, with a focus on inclusivity across various demographic factors (age, gender, ethnicity, and socioeconomic status) (Ito et al., 2023; Sugizaki et al., 2023).

Rationale: The patterns of food allergies may have shifted significantly over the past two decades. Regular data collection will help policymakers understand emerging risks and guide public health interventions effectively. Data from such studies could inform the development of allergen labelling regulations and public health policies (see above FAO-WHO, 2022).

Recommendation 3: Further develop, validate and standardise allergenicity risk assessment tools

Invest in the further development, validation and standardisation of allergenicity risk assessment tools developed by the GIANT LEAPS project, such as *in vitro* digestion models and immune-toxicology assays. These tools should undergo further development and interlaboratory trials to ensure their robustness and reliability for safety assessments.

Rationale: Accurate risk assessments are crucial for evaluating the safety of novel foods, especially as the industry adopts alternative protein sources. Ensuring that these tools are validated and standardised will enhance their credibility and effectiveness in predicting food allergy risks.

Recommendation 4: Promote cross-sector collaboration on allergenicity risk assessment

Facilitate stronger collaboration between researchers, food industry stakeholders, consumer-/ patient-representatives and regulatory bodies to establish consistent guidelines for the safety assessment of novel foods. This could include sharing data on food allergens, exposure assessments, and clinical relevance to create a unified approach to risk assessment [see also GIANT LEAPS [Policy Brief #3](#)].

Rationale: Given the rapid pace of technological advancements in food production and risk assessment, a collaborative, transparent approach ensures all stakeholders are aligned in maintaining food safety while embracing innovation.

Recommendation 5: Provide targeted training for risk assessors and applicants in allergenicity risk assessment and food labelling regarding allergenic risks

Create specialised training programmes for applicants and risk assessors involved in the safety assessment of novel foods including food labelling regarding allergenic risks. This training should focus on new approach methodologies (NAMs) and their integration with advancements in artificial intelligence and computational biology. It could build on the approach taken through NP/EFSA/NIF/2025/01 – Training course in allergenicity risk assessment of innovative proteins in food and feed (<https://www.efsa.europa.eu/en/call/npefsanif202501-training-course-allergenicity-risk-assessment-innovative-proteins-food-and>).

Rationale: As novel foods and alternative proteins become more prevalent, ensuring that risk assessors are well-versed in the latest tools and methodologies will strengthen the integrity of food safety evaluations and support the adoption of a “safety-by-design” approach.

Recommendation 6: Strengthen consumer protection through evidence-based labelling of allergenic risks

Update and standardise precautionary labelling guidelines regulations to include risks posed alternative proteins and novel food ingredients. This should be evidence-based on the findings from food allergy prevalence studies and risk assessments (Fiocchi et al., 2016).

Rationale: Clear, accurate allergen labelling is essential for protecting consumers, especially those with food allergies. Adapting guidelines and regulations in a timely manner will help prevent accidental allergic reactions and ensure consumer safety.

Recommendation 7: Support consumer-/ patient education on understanding food labels with regards to allergenic risks of novel proteins

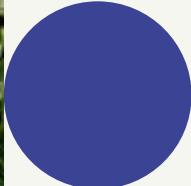
Provide a strategy and programme on international level with regards to education of consumers and patients with allergies and the general public on understanding food labels and the risks of allergic reactions related to novel food and alternative protein sources.

Rationale: Consumer research from GIANT LEAPS shows that consumers with allergies do not feel confident about identifying novel foods and alternative proteins and would welcome education of the public with regards to allergenic risks and novel food and alternative proteins.

Recommendation 8: Support research on genetic and environmental factors in food allergies

Fund and prioritise research into genetic risk factors (e.g., HLA type) and environmental influences (e.g., climate change) that contribute to the development of food allergies, particularly those related to specific foods like peanuts, hazelnuts, fruit and shellfish (Arnau-Soler et al., 2025; Skypala, 2025).

Rationale: A deeper understanding of the genetic and environmental factors influencing food allergies can improve predictive models, particularly those used for allergenicity risk assessment of novel foods, as well as enabling more targeted prevention strategies and treatments.



CALL FOR ACTION

To enable a safe and timely transition towards healthy and sustainable diets that fully harness the potential of alternative proteins, coordinated action on food allergy risk management is required.

For governments and regulators:

- ✓ Establish EU-wide surveillance and early-warning systems for emerging food allergies and ensure regulatory frameworks, including allergen labelling and risk assessment guidance, remain adaptive and science-based to accommodate novel foods and ensure adequate consumer education.

For scientists and research institutions:

- ✓ Generate robust, regulatory-relevant evidence on emerging food allergens and validate new approach methodologies (NAMs) for allergenicity assessment to support reliable and timely safety evaluations.

For food business operators:

- ✓ Integrate allergenicity risk assessment early in product development through safety-by-design approaches and provide transparent, high-quality data to support regulatory assessments and consumer protection and ensure correct allergen information.

BACKGROUND INFORMATION

New foods, new food allergies?

Whereas new treatments are being developed for food allergies (see info box), the mainstay remains avoidance of the causative food. Consequently, supporting consumers in making safe food choices through labelling and appropriate dietary advice is critical. Indeed, food avoidance places a significant burden on food allergic individuals and their caregivers adversely impacting on quality of life with food label reading becoming a way of life, increasing time shopping and often restricting social activities through fear of accidental reactions when eating out of the home (Howe et al., 2014; Santos et al., 2023; Strinnholm et al., 2017). This extends to increased economic cost incurred through, for example, purchase of more expensive foods, increased healthcare costs and time taken out of work for attending doctors' appointments (Bilaver et al., 2019).

Although novel foods must undergo a rigorous safety assessment prior to being placed on the market, there are uncertainties, especially in the allergenicity risk assessment process, which arise from a lack of mechanistic understanding as to why some foods, such as peanut, are so much more allergenic than soybean and why some people, and not others, develop food allergy. The introduction of alternative protein ingredients into the marketplace, derived from either novel or conventional food sources, is already causing the development of new IgE-mediated allergies. For example, reactions have been reported to pea isolate (Abi-Melhem & Hassoun, 2023; Lavine & Ben-Shoshan, 2019). Therefore, improving the evidence base and improving the tools used for safety assessments and subsequent management decisions is critical to assuring the safety of consumers in the drive for alternative, more sustainable dietary protein.

The GIANT LEAPS project has developed new tools to help improve the assessment of immune-toxicological and allergenic risks posed by such alternative protein ingredients. Comprising an integrated

set of *in silico* and *in vitro* test methods they are designed to predict the likelihood of whether a novel protein poses a risk to the existing food allergic population (so-called cross-reactive allergies) and the likelihood of causing new food allergies (*de novo* sensitisation). In addition, instruments have been developed to provide a means of post-market surveillance to understand how the paradigm shift in dietary proteins may impact on adverse reactions and (particularly) food allergies in future, which can also provide an indicator as to the effectiveness of the current risk assessment approaches.

During the course of this research, data gaps have been identified together with the next steps required to apply these tools and instruments in the wider community and to realise their potential.

Identification of emerging food allergies

It is unclear how the dietary shift to alternative proteins will be realised in practice and hence what impact it will have on the patterns and prevalence of food allergies in the European population. For example, if the uptake of alternative proteins derived from legumes is high this may result in an increase in the prevalence of allergies to peas, chickpeas and lentils. Conversely, insects have the potential to cause new food allergies and trigger reactions in individuals with crustacean food allergies, but if they remain a niche food product, they may have little impact on the prevalence patterns of food allergy. In the face of such uncertainties and concerns, the recent FAO-WHO expert consultation on food allergens identified the need for a watch list of established three main criteria for establishing foods of public health importance that trigger food allergies, namely prevalence (i.e. the size, age, gender and ethnicity of the population at risk) (FAO-WHO, 2022). In Japan there is a regular survey of IgE-mediated food allergy undertaken in a network of outpatient clinics in an ongoing manner (Ito et al., 2023; Sato et al., 2024) which provides evidence to inform public health policy, including the updating of food allergen labelling regulations.

However, there are inherent biases in the way in which patients get referred into healthcare systems and consequently it is crucial that the prevalence of a disease is determined in an unselected study population using a sample frame designed to capture a representative proportion of the population under study with regards gender, age, ethnicity and socioeconomic status (Celentano, 2019). It is now more than 20 years since the EuroPrevall project set out to define the patterns and prevalence of food allergies across Europe (Lyons et al., 2019; Lyons et al., 2020; Mills et al., 2007; Schoemaker et al., 2015). The recent PAFA study in UK adults has shown that the patterns of food allergy in adults has changed over the last 30 years with a significant increase in prevalence with around 7% of UK adults now experiencing some type of food allergy (Mills et al., 2007).

It is therefore timely to revisit the prevalence of food allergy across Europe building on the updated EuroPrevall tools used in the PAFA study which could:

- Assess whether the patterns, prevalence and severity of food allergies in adults and children have changed in the past 20 years;
- Identify environmental factors that may influence patterns and prevalence of a disease such as the dietary shift and the impact of climate change on inhalant allergies to pollen, such as birch, which are recognised drivers of food allergy;
- Complement the development of a survey of emerging food allergies in outpatient clinics and patient organisations, building on the GIANT LEAPS alternative protein study (AltProt; described in Deliverable 3.4), which can provide data indicating the emergence of new food allergies at an early stage, including allergic consumer feedback on allergic reactions associated with novel foods and alternative proteins.

In addition to providing important public health data, such a study could support filling of data gaps identified in GIANT LEAPS which currently limit the utility of *in silico* predictive models (see below) including:

- Genetic factors, such as HLA type, which have been recognised as risk factors for allergies to certain

foods such as peanut but for which data are lacking for important European food allergens such as hazelnut, walnut, apple and kiwi;

- Mapping of B- and T-cell epitopes involved in driving major food allergies.

Validation of the in GIANT LEAPS allergenicity/immunotoxicology risk assessment toolbox

The GIANT LEAPS project partners, together with the ITN ALLPret (<https://www.allpret.eu/>), have developed a variety of tools for allergenicity risk assessment of novel foods. Several are sufficiently developed – such as exposure assessment, phylogenetic analysis and numerical scores for assessments of clinical relevance (Mills et al., 2024) – to allow their implementation in the risk assessment process. However, others require further validation and interlaboratory trials to assess their utility and establish whether they have the robustness and repeatability required for use in safety assessments. These include:

- i. An *in vitro* digestion for allergenicity risk assessment which is harmonised with those used for nutritional assessment which provides an indicator of the exposure of the gut mucosal immune system to immunologically relevant proteins/peptides;
- ii. Serum IgE testing using immunoassays and effector cells to improve outcomes for predicting the likelihood of cross-reactive allergies indicated by bioinformatic tools;
- iii. Gut epithelial models for immune-toxicology, modelling the “atopic gut” and *in vitro* cellular studies for assessing likelihood of new allergies building towards an *in vitro* model of the gut follicular epithelium which plays a pivotal role in determining the balance between tolerance (the “normal” state) and sensitisation (the “allergic” state).

Training for applicants and risk assessors for novel foods safety assessments

The development of New Approach methodologies (NAMs) and the pace of technological developments in the food industry together with advances in computational biology and informatics driven by artificial intelligence means there is an urgent need to skill all the stakeholders in the novel foods safety assessment to ensure its integrity and assure the safety of novel foods whilst being proportionate about the risks involved. Training in new approaches is critical to ensure a safety-by-design approach is adopted – thereby identifying and mitigating risks at early stages in development and ensuring preparation of high-quality evidence-based risk assessment dossiers.

Consumer-/ Patient information and education

Consumers with food allergies depend on accurate and reliable information regarding the presence of ingredients and unintended allergen presence in food that can pose a risk to their health to make safe food choices. This requires risk-based harmonised allergen information on food labels and allergen information for non-prepacked food regarding novel foods and alternative proteins. Programmes are needed for consumer education on food labelling – specifically related to allergen information and identifying risks associated with novel foods and alternative proteins.

ABOUT GIANT LEAPS

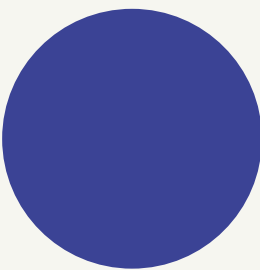
The EU-funded project GIANT LEAPS aims to accelerate the dietary shift towards a more sustainable and healthier food system, aligning with the EU Green Deal objectives and the Farm to Fork Strategy. The ambition of GIANT LEAPS is to transform European diets by reducing the consumption of traditional animal-based proteins, targeting a goal where 50% of total protein dietary intake is derived from alternative protein sources – such as plants, microalgae, insects, and single-cell proteins – by 2030. To achieve this goal, GIANT LEAPS employs a multi-actor approach, actively engaging with policymakers, production sectors, and European citizens. This collaboration fosters key innovations, methodologies, datasets and information that empower all stakeholders in the food system to make informed decisions, strategic investments, and sustainable choices. Ultimately, the project seeks to facilitate a large-scale dietary shift towards alternative protein-rich foods, maximising both nutritional and environmental impacts.

DISCLAIMER

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