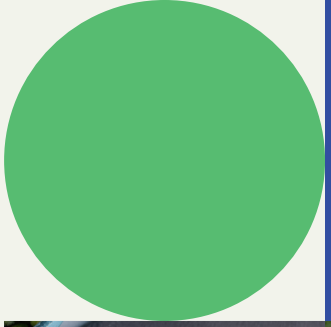
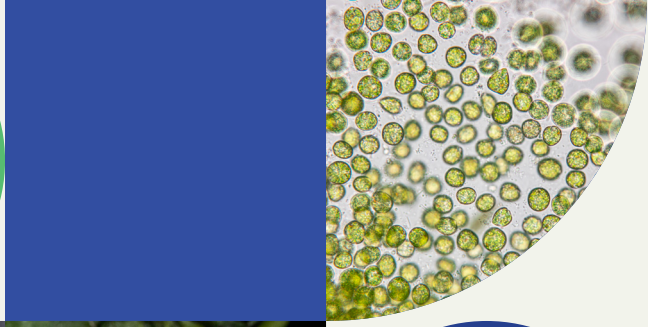


GIANT LEAPS

POLICY BRIEF 2

Ensuring Food Safety In The Protein Transition

2026

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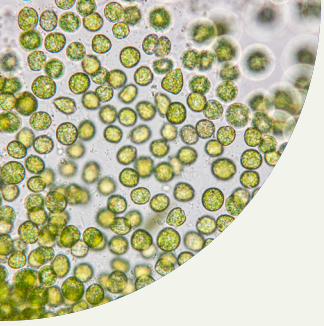


OBJECTIVE

This policy paper aims to raise awareness of the safe-by-design approach to prevent and control potential food safety 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 government and companies as well as scientists to accelerate and promote this dietary transition, while maintaining the safety of the diet, taking a safe-by-design approach.

KEY POLICY RECOMMENDATIONS

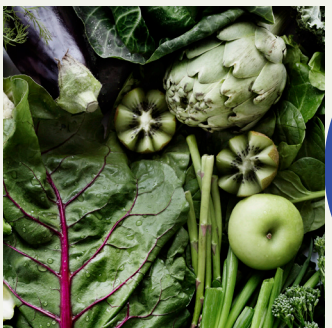
A dietary shift from animal-based foods to foods based on alternative proteins is expected to reduce the environmental impact of food production and consumption. However, this transition also may come with potential food safety concerns that must be addressed proactively. To ensure a safe and efficient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

Recommendations

1. Implement a safe-by-design approach
2. Update the regulatory framework for chemical and microbiological hazards
3. Use New Approach Methodologies in novel food (NF) risk assessment
4. Enhance risk assessment for food allergens
5. Ensure the availability of up-to-date population intake data for exposure assessment
6. Promote Post-Launch Monitoring to ensure food safety in the digital age
7. Adopt risk-benefit assessment

Call for Action

1. Governments and regulators: regularly update assessments, provide targeted research funding and establish a data-sharing framework
2. Scientists and research institutions: develop improved protocols, conduct longitudinal studies and work closely with policymakers
3. Food business operators: implement a safe-by-design approach, enhance post-launch safety surveillance and engage in public-private partnerships to generate robust safety data



POLICY RECOMMENDATIONS

Recommendation 1: Implement a safe-by-design approach

Alternative proteins may introduce new hazards or lead to the emergence of known hazards an unexpected context. It is recommended that food business operators (FBO) apply a safe-by-design approach, which helps identify hazards that may arise when shifting towards alternative proteins. This approach begins with mapping potential food safety hazards in the raw materials used in new food formulations, followed by an inventory of the effects of processing these raw materials into the final product. This can help FBOs make informed choices regarding the selection of raw materials and process settings to minimise food safety risks. The evaluation can then be integrated into the FBO Hazard Analysis and Critical Control Points (HACCP) system.

Recommendation 2: Update the risk assessments for chemical and microbiological hazards

The current regulatory framework (Commission Regulation (EU) 2073/2005) sets microbiological criteria for foodstuffs in high-risk categories, such as ready-to-eat foods, meat, dairy and fish products. However, no such criteria or limits exist for alternative protein-derived food products. Similarly, while legal limits for chemical hazards for plant-based materials used for producing plant-based alternatives have been established (Commission Regulation (EU) 2023/915), there are none for emerging alternatives, such as novel foods derived from algae or insects. Risk assessments including food products made from alternative proteins are needed to investigate whether legal limits are required for both chemical and microbiological hazards in alternative protein-derived foods. As a starting point, risk profiles were defined for insects and more recently also for microalgae and cultivated meat[a].

Recommendation 3: Use New Approach Methodologies (NAMs) in novel food risk assessment

The use of animals in laboratory testing is currently a barrier to innovation. The use of NAMs in food safety risk assessment offers a promising alternative[11,12]. However, NAMs are not yet well integrated into current regulatory risk assessment frameworks. Guidance for food ingredients and novel foods, including the revised NF guidance[6], mentions them only briefly under general principles. The potential use of NAMs opens up opportunities for innovation in safety testing by focusing more on human-relevant data and using the most scientifically up-to-date methods.
To advance their use:

✓ Scientists should further develop and validate NAMs

✓ Regulatory bodies should update guidance documents to reflect the latest science and provide more flexibility for the use of NAMs.

Recommendation 4: Enhance risk assessment for food allergens

The risk assessment of potential food allergens and protein toxins in alternative protein sources presents ongoing challenges:

✓ A lack of consensus on what is considered a tolerable risk for allergenicity, sensitisation and elicitation[13], and

✓ Protein toxins are not specifically covered in existing or revised NF guidance[6].

Recent EFSA-funded research concluded that tools for allergenicity risk assessment are at different stages of development[14]. Risk assessment tools for cross-reactive allergies are more advanced and only require refinement to enhance the risk assessment process. However, prediction of de novo sensitisation remains uncertain, as the mechanisms underlying development of food allergy are not yet fully understood. Therefore, updating allergen databases is a priority, and efforts should focus on further developing protein databases and expanding associated tools for assessing potential allergenicity and toxicity. These uncertainties also highlight the need for complementary post-launch monitoring (see Recommendation 6).

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Cultivated meat
a. FAO-WHO. Food safety aspects of cell-based food. (FAO-WHO, 2023).

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Recommendation 5: Ensure the availability of up-to-date population intake data for exposure assessment

Exposure is a critical component of risk assessment, and with rapidly shifting diets, it is vital to have actual intake data available. It is increasingly challenging to ensure that population intake data surveys are up-to-date and cover relevant populations and population groups. It is recommended that authorities explore the potential of applying recent and advanced digital approaches for intake surveys to expand and more rapidly update regional population food intake data. Data gathered should be stored as soon as possible after collection in databases that are openly accessible and user-friendly to allow a broad range of applications, such as in the EFSA Comprehensive European Food Consumption Database[15].

Recommendation 6: Promote Post-Launch Monitoring to ensure food safety in the digital age

With the rapid development of artificial intelligence (AI) in this digital age, the potential value of post-launch monitoring (PLM) should be re-visited[16,17]. PLM approaches allow verification of whether the intake assessment that was predicted for a novel food is as expected and as utilised in the original risk assessment. PLM can also be used to monitor emerging issues in a country following the introduction of a new food ingredient, enabling the rapid implementation of risk management labelling, as is done for food allergens. PLM is therefore gaining attention, particularly in relation to novel proteins and associated issues such as de novo sensitisation[18]. It is recommended to take up PLM in regulation or guidance documents.

Recommendation 7: Adopt risk-benefit assessment

A safe-by-design approach and risk assessments are essential for the safe introduction of novel foods based on alternative proteins. However, focussing solely on the potential adverse effects of alternative proteins may provide a limited view on their overall impact on human health. Therefore, it is recommended that scientists apply a risk-benefit assessment, which evaluates both the negative and positive health effects of food intake, using different intake scenarios, by integrating nutritional aspects with chemical and microbiological risk assessments[19].

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CALL FOR ACTION

To ensure a safe and efficient dietary shift towards healthy and sustainable diets, in which the potential of alternative proteins is fully exploited without unnecessary delays, we recommend the following actions for key stakeholders:

For governments and regulators:

✓ Regularly update risk assessment guidance to fully leverage scientific developments

✓ Consider the implementation of post-launch monitoring (PLM) as a complementary approach to a priori food safety evaluations

✓ Provide targeted funding for research on New Approach Methodologies (NAMs) and on identifying emerging food safety risks, such as de novo sensitisation.

✓ Establish an EU-wide data-sharing framework to facilitate easy access to alternative protein safety data and to up-to-date population alternative protein intake data

For scientists and research institutions:

✓ Develop improved and harmonised safety assessment protocols for alternative proteins, ensuring consistency across Europe.

✓ Conduct longitudinal studies on the positive and negative health impacts of novel protein sources, addressing knowledge gaps in allergenicity and food safety risks, and including risk-benefit assessment.

✓ Work closely with policymakers to ensure scientific evidence informs regulatory guidance and decisions in a timely manner.

For food business operators:

✓ Implement a safe-by-design approach in product development, ensuring early identification and mitigation of potential hazards.

✓ Leverage AI and digital monitoring tools to enhance post-launch food safety surveillance.

✓ Engage in public-private partnerships with research institutions to generate robust safety data and validate the safety of novel food products.

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Impact of the dietary shift on food safety

Nutritious and safe food for all is essential for promoting health and preventing disease. As the world population grows, the pressure on climate, land use and water quality increases, and the need for healthy diets and nutritious foods from a sustainable food system becomes more urgent. Achieving this requires a balance between meeting nutritional adequacy (nutritional security), the availability of safe and sufficient foods for all (food safety and security) and production within planetary boundaries (sustainability).

Within the GIANT LEAPS project, the aim is to optimise the diet by shifting towards alternative protein sources. These alternative proteins may belong to a variety of protein categories such as plant-based proteins, micro- and macroalgae proteins, bacterial and fungal proteins, insect proteins, precision fermented proteins and cultured meat[1,2]. While this transition has the potential to reduce the environmental impact of food production, it may also raise food safety considerations. The safety of the (new) ingredients and food products has to be assured, a priori, which is a shared responsibility of governments and food business operators (FBOs).

Alternative proteins may present several important food safety hazards. For example, the production environments for lab-grown proteins and insects could harbour novel pathogens, posing unique challenges[3]. Recent literature reviews performed within the GIANT LEAPS project[4,5] showed that both chemical and microbiological hazards can be present in plant-based protein sources and eventually in food analogues, such as meat and dairy substitutes, derived from these sources. Currently, food analogues prepared from protein sources that are allowed on the EU market do not require a risk assessment and no legal limits exist for the "contaminant-food" pairs included in the review[4].

Beyond food safety hazards, emerging alternative plant-based proteins, such as fava beans or lentils, may also contain plant secondary metabolites, including antinutritional factors, phytoestrogens and oligosaccharides. Furthermore, alternative proteins can have allergenic properties, causing new allergic responses (de novo sensitisation) or cross-reactions with existing allergens in sensitive individuals. Processing alternative protein sources to extract proteins or formulate food analogues may reduce food safety issues but – depending on processing conditions - may also lead to the formation of processing contaminants. Currently, there is a lack of data to assess the safety after processing[3].

Regulation and the dietary shift

The protein transition currently faces challenges related to the regulatory framework and risk assessment required to evaluate the safety. Prior to market introduction, the European Food Safety Authority (EFSA) must assess the safety of alternative protein ingredients and derived foods that do not have a history of safe use in Europe, i.e. that are identified as novel foods. Upon request by the European Commission, EFSA performs risk assessments on the safety of a novel food considering factors such as production methods, nutritional quality of products, the potential presence of microbiological and chemical food safety hazards, toxins and allergens. Recently, updated guidance on the scientific requirements for an application for authorisation of a novel food (NF) under Regulation (EU) 2015/2283 has been published[6].

The possible animal testing slows the introduction of novel foods into the EU market, particularly for products that will be marketed as vegan. To address this, the risk assessment procedure could prioritise alternatives over the use of experimental animals, aligning with Directive 2010/63/EU, which legally mandates the replacement, refinement and reduction of the use of animals for scientific purposes. The integration of the so-called New Approach Methodologies (NAM) could facilitate replacement of animal testing. Second, the lack of data on the safety and allergenicity of various alternative proteins and their processing complicates decision-making for risk assessors and risk managers in both government and FBOs.

[1]New Approach Methodologies are scientific methodologies to assess the safety and potential adverse health effects of substances, including foods or ingredients, without the use of traditional animal testing. Human-relevant data is generated using in silico, in vitro and/or in chemico methods.

Risk assessment

Risk assessment evaluates the adverse effects on human health due to exposure to food safety hazard(s) via food consumption in four sequential steps:

1. Hazard identification - identifying potential safety hazards in food.
2. Hazard characterisation - assessing the impact of the hazard on human health using dose-response curves.
3. Exposure assessment - estimating the degree of human intake of the hazard via food consumption.
4. Risk characterisation - integrating the previous three steps to estimate the likely adverse human health effects related to the food product assessed[7].

Microbiological food safety

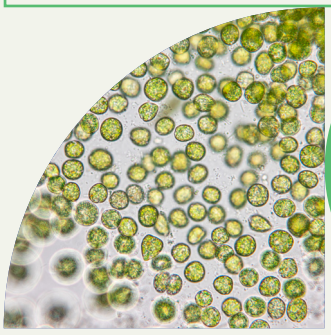
Microbiological food safety focuses on preventing the proliferation of harmful micro-organisms, such as bacteria, viruses and parasites, in the food supply chain. Contamination can occur at any stage, from farm to table, and may arise from various factors, such as insufficient control over incoming raw materials, poor hygiene practices, inadequate sanitation or improper food handling. During storage, pathogens may grow or produce toxins, which can result in human health implications[8].

Chemical food safety

Chemical food safety relates to contaminants that may be present in foods, including human-introduced substances such as pesticides, veterinary drugs, PFAS, micro-plastics, food additives as well as naturally occurring compounds. While man-made chemicals serve various purposes, including enhancing productivity and preserving food quality, their presence in food products above acceptable levels can pose health risks to consumers. Naturally occurring compounds may include natural toxins produced by plants, fungi and algae, which may also end up in the final food product. Additionally, some foods may contain anti-nutritional factors that can reduce nutrient uptake and lead to gastrointestinal problems or reduced metabolic performance[8].

Allergens

Allergens are typically proteins that trigger a response in the immune system resulting in an allergic reaction in sensitive individuals[9]. New foods also have the potential to become “new” allergens. They require risk assessment to inform their proper management.



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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 protein, 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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