

Alternative Proteins and Allergy Risk

Is the promise of alternative proteins complicated by their allergenic potential?

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The world's population seems to have a carnivorous appetite, [consuming 467 million metric tons of fish, poultry, pork, and beef in 2020](#). But our worldwide love affair with animal-based protein comes at a cost. [In 2021 livestock production contributed to 14.5% of anthropogenic greenhouse gas \(GHG\) emissions](#). This, along with considerable water and land requirements, makes livestock production a central contributing factor to climate change. To protect our planet and ensure food availability for future generations, the search is on to cultivate more sustainable food sources, reducing the negative impact on land, air, water, soil, and the climate while preserving ecosystem habitats.

As environmentally sustainable substitutes for animal-based protein, alternative proteins—including cultured meat and plant-based, insect, and single-cell proteins—are gaining worldwide favor. This shift in diet is expected to be huge, with the [World Economic Forum predicting](#) the “alternative-protein market will increase to more than seven times its current size over the next decade and a half, from a current 13 million metric tons a year to 97 million metric tons by 2035, when it will make up 11% of the overall protein market.”

But are we creating a potential public health challenge by introducing such a major change into our diets? Not all protein sources are created equally in their nutritional quality, and protein is the single major cause of food allergies. [An estimated 3 to 10% of adults and 8% of children worldwide suffer from an Immunoglobulin E \(IgE\)-mediated allergy to food proteins of varying sources](#). Identifying, measuring, and quantifying the allergen risks of new alternative proteins is uncharted territory because few toxicology models exist to support risk assessment and the regulations are still evolving.

Alternative Proteins, Alternative Risks

At first glance, new protein sources may seem like a quick fix for reducing the impact of food production on climate change, but they can introduce new safety issues that require new or additional risk management measures to address them. Take

cultured meat grown in fetal bovine serum-based media, for instance, which can contain viruses or infectious prions. Plant-based meat, like soy or texturized vegetable proteins, may contain anti-nutrients such as lectins, while insect proteins may introduce microbiological risks. Single-cell protein sources, such as microalgae, fungi, and bacteria, can also present specific food safety risks including mycotoxins and phycotoxins.

Alternative proteins also carry the additional risk of allergies, the [fourth most common chronic disease in the world](#). It's possible that increased exposure to new sources of proteins in the world diet might create *de novo* sensitization in populations who have not previously consumed these proteins, resulting in increased prevalence of allergic immune responses. Cross-reactivity in consumers already sensitized to proteins with structures similar to these new alternative proteins might also magnify the risk of adverse allergic reactions.

An additional, often-missed aspect is the impact of processing on the potency of food allergens in provoking adverse reactions. Manufacturing and processing applications, including cooking, heating, enzyme treatments, and sterilization processes, can increase allergenicity. For example, roasted peanuts are much more potent than boiled peanuts, so smaller doses of roasted peanuts are needed to trigger allergic reactions. Heightened awareness of the potential allergenicity risk of alternative proteins

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and targeted risk management measures will be needed to effectively manage this dietary shift to prevent adverse impacts on public health.

Ensuring Food Safety for Mass Production

The necessary regulatory framework to ensure the safety of alternative proteins for future mass production is still being developed. [Alternative protein sources are likely to be regulated as novel foods](#). Codex Alimentarius standards will help provide international guidance on alternative proteins to ensure harmonization across countries as they become more widely used across the globe. Administered jointly by the UN's Food and Agriculture Organization and the World Health Organization, the Codex provides a "[key set of global practices, guidelines, and standards that influence international food trade, safety, and regulation, often serving as the basis for national legislation](#)."

While the Codex Committees on Food Hygiene and Labeling already have standards for allergen labeling and control to avoid cross contamination, other guidelines are less clear, such as criteria to determine when an alternative protein is considered enough of a public health risk to be classified as a controlled allergen and what's the quantitative safety threshold for how much undeclared allergenic protein in a product is too much.

Ensuring alternative protein compliance with new and evolving regulations will require a thorough understanding of allergenicity risk potential and the critical risk management measures needed. This includes using risk assessment tools to identify, characterize, and quantify the risk for potential cross-reactivity and developing new customized tests and risk assessment tools to identify and manage risk for *de novo* sensitization in the absence of validated *in vivo* toxicology models. By managing the allergenicity

risks of new proteins, stakeholders—including food manufacturers, retailers, and suppliers—will be able to meet regulatory thresholds and get alternative protein products to market while protecting the consumer.

How Exponent Can Help

Exponent's Chemical Regulation & Food Safety practice has extensive experience designing risk management models for manufacturers and retailers to incorporate regulatory requirements and expected best practices into practical approaches to effectively support both consumer risk protection and business operations. We examine the processing impacts, toxicity, nutritional value, and intended use of novel proteins to provide advice on risk and status from a regulatory perspective and targeted risk management measures. Leveraging a robust weight-of-evidence approach, we examine *de novo* sensitization as well as cross-reactivity through data-intensive literature reviews to unearth any history of adverse reactions. We also help clients navigate complex U.S., EU, and UK food ingredient and labeling regulations, as well as global food standards produced by Codex Alimentarius. Our expertise extends to all areas of maintaining food safety in the food system, including innovative production and processing; mass production, storage, and distribution; and retail addressing allergens, pathogens, chemical contaminants, food contact materials, and physical hazards.



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