

April 13, 2023

Dear Manufacturers and Developers of New Plant Varieties:

The Food and Drug Administration (FDA or we) is aware that some companies are exploring the transfer of genes for proteins that are food allergens (including major food allergens) into new plant varieties used for food. For example, a developer could add the gene for an allergenic animal protein to a new plant variety to provide a non-animal source of the protein for use as an ingredient in another food. This could result in the presence of an unexpected allergen in that food. Because adverse reactions to food allergens can be severe or even life-threatening, including when the allergen is present at low levels, we think it is important to reach out to manufacturers and developers now, while such plant varieties are still in early research and development stages. We are not aware of any foods currently in the U.S. market from these types of new plant varieties. Like all food producers, developers of new plant varieties containing an unexpected allergen have a responsibility to ensure that the products they market are safe and lawful. In addition to the food safety risks, if unexpected and unlabeled allergens enter the food supply, this could have other consequences for food producers, such as needing to recall the affected products.

We write today to strongly encourage developers of such new plant varieties to talk to us after having carefully considered in the earliest stages of product development the steps that would be necessary to comply with relevant legal requirements and keep materials from their plants segregated from other plants and foods to ensure that allergens are not unintentionally transferred into food. Failure to keep such materials strictly segregated would thwart the most effective way that people with food allergies have to prevent allergic reactions, which is by avoiding foods that contain allergens.

We note that since FDA published its 1992 policy on food from new plant varieties,<sup>1</sup> we are aware of only one case in which a company transferred a gene from a major food allergen into a crop plant, a gene for a Brazil nut protein into a soy variety to improve its nutritional profile for animal feed. Upon discovery that the transferred Brazil nut protein was an allergen, the developers voluntarily discontinued development of the new variety because of the food safety risk to individuals allergic to Brazil nuts. The developers were concerned that they could not ensure that the modified soybean would not inadvertently get into human food, even though they intended it only for use in animal feed.

If you are developing a plant variety with a transferred gene that encodes a food allergen (which we also refer to as a “transferred allergen” for brevity), stewardship practices are likely to be more challenging and complicated than with other crops. When considering your proactive risk management plan, you will likely have to significantly bolster standard mitigation strategies and practices (e.g., segregation of crops) to provide the level of food safety assurance necessary to prevent inadvertent mixing of foods containing a transferred allergen with other foods. For example, planting, harvesting, transporting, and storage of seeds and grains from many plant varieties used for food occurs in bulk quantities and requires specialized machinery (e.g., planters, combine harvesters, grain augers, silos). Growers, transporters, processors, food manufacturers, and others in the food production chain responsible for ensuring crop segregation may need to follow special precautions related to seed development and planting, storage of harvested material, and thorough cleaning of machinery at each step sufficient to prevent inadvertent commingling of these new plant varieties and their products with other varieties and products that do not contain the allergen.

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<sup>1</sup> Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992)

While requiring label declaration for the presence of an allergen is generally FDA's approach to inform people with food allergies of the presence of an allergen,<sup>2</sup> labeling may be insufficient or inappropriate to address all food allergen safety risks—particularly if, before entering the food supply, these new plant varieties are inadvertently commingled with similar varieties that do not contain the allergen.

Consequently, developers would need to ensure that allergenicity information about an allotment of a particular crop containing a transferred allergen remains associated with the allotment through the supply chain (e.g., seed development, planting, harvesting, storage, transport, and processing) in a manner that enables responsible parties to ensure that the allotment is not mistaken for or used as its counterpart food that does not contain the allergen.

We urge developers of products involving transfer of a gene for an allergen to a new plant variety used for food to fully consider the potential allergenicity issues related to these products. We believe it is critically important to consider whether you and your partners throughout the supply chain can reliably establish and maintain conditions, from farm to processing to consumption, under which such new plant varieties, and protein-containing materials from such varieties, do not inadvertently enter the food supply, and are properly labeled when they are intentionally part of the food supply. You have a responsibility to market safe and properly labeled food and to meet the requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). If it is not feasible to implement all measures that are needed to comply with these requirements and protect people who have a food allergy from an unexpected allergen, we think it would be prudent to reconsider your product development plan.

FDA supports innovations in food production and formulation. However, manufacturers, developers, and FDA share a collective responsibility for food safety. Since 1994, FDA has operated a voluntary premarket consultation program for foods from new plant varieties. This program is intended to protect consumers by helping the food industry ensure that foods from their new varieties meet relevant requirements under the FD&C Act prior to market entry. We are available for consultation as you consider development and marketing of such products and strongly encourage you to engage with us very early in your product development process.

Sincerely,

Kristi Muldoon-Jacobs, Ph.D.  
Director, Acting  
Office of Food Additive Safety

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<sup>2</sup> For example, the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines major food allergens as milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and sesame (section 201(qq) of the FD&C Act). A food is misbranded if it contains a major food allergen and fails to declare that allergen on its label using the allergen's common or usual name (section 403(w) of the FD&C Act).