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US FDA takes new steps for evaluating additional food allergens

The US Food and Drug Administration (FDA) has issued a draft guidance that, when finalised, will outline the agency’s approach to evaluating the public health importance of food allergens that are not one of the major nine food allergens identified by law

By **Manbeena Chawla** | April 19, 2022



us-fda-takes-new-steps-for-evaluating-additional-food-allergens

WordPress post #22267

For allergens that are not one of the major nine food allergens identified in US

The US Food and Drug Administration (FDA) has issued a draft guidance that, when finalised, will outline the agency’s approach to evaluating the public health importance of food allergens that are not one of the major nine food allergens identified by law in the US (non-listed food allergens).

Currently, the major food allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans, though more than 160 foods are known to cause food allergic reactions. Sesame becomes the ninth major food allergen, effective Jan. 1, 2023.

"The nine major food allergens don’t currently represent all foods nationwide that people are allergic to or that cause food hypersensitivities," said Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition. "This draft guidance is part of the FDA’s efforts to evaluate emerging evidence about other non-listed food allergens that can cause serious reactions in a consistent and transparent manner, which can inform potential future actions to better help protect the health of consumers."

The draft guidance focuses on immunoglobulin E antibody (IgE)-mediated food allergies, which are capable of triggering anaphylaxis and are considered the most severe and immediately life-threatening food allergies. Food allergic reactions caused by the nine major food allergens are all IgE-mediated. The draft guidance describes the approach the FDA generally intends to take when evaluating the public health importance of a non-listed food allergen.

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