Updates
October 04, 2023

On September 26, 2023, the U.S. Food & Drug Administration (FDA) added two new chapters to the agency's draft guidance (the Draft Guidance): Chapter 11: Food Allergen Program and Chapter 16: Acidified Foods.

These additions aim to facilitate compliance with FDA's current good manufacturing practices (CGMPs) and preventive controls for human food.

Background

Pursuant to the Food Safety Modernization Act (FSMA), since 2011, FDA has placed an increased focus on preventing food safety problems rather than relying primarily on reacting to problems after they occur. *See* 88 Fed. Reg. 66,457, 66,458 (Sept. 27, 2023). FSMA recognized the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. *Id.*

In September 2015, FDA published its final rule titled *Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food*, now codified at 21 C.F.R. Part 117 (Part 117). Subsequently in August 2016, FDA released Draft Guidance to facilitate compliance with the final rule, and the agency has made iterative additions to the Draft Guidance over time. With this most recent update, the agency provides recommendations on (1) how to establish and implement a food allergen program and (2) how manufacturers of acidified foods may leverage their established procedures and processes to meet the requirements of the acidified foods regulations and FDA's requirements under the preventive controls for human foods rule.

What's New?

Chapter 11: Food Allergy Program. Here, FDA explains how to establish and implement a food allergen program, providing multiple, detailed recommendations to help food facilities comply with CGMPs and preventive controls for human food. More specifically, Chapter 11 outlines steps to protect against food allergen cross-contact and to ensure that the finished food is properly labeled with respect to the major food allergens: milk, egg, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and, most recently, sesame.

First, Chapter 11 covers voluntary allergen advisory statements. These apply in situations where cross-contact cannot be avoided despite adherence to CGMPs and preventive controls. FDA makes clear, however, that allergen advisory statements cannot replace conformance with applicable CGMP requirements and allergen cross-contact controls.

Second, FDA draws the connection between CGMPs and preventive controls in the context of a food allergen program and recommends that food facilities design and implement CGMPs with an eye towards adapting CGMP measures to also serve as an effective allergen cross-contact preventive control. Indeed, FDA explains that "the measures that you take to comply with the CGMP requirements should be in place before you conduct your hazard analysis and identify risk-based preventive controls to address specific hazards, such as the food allergen hazards." Thus, in FDA's view, preventive controls for allergen cross-contact should "complement and enhance" the CGMP control measures in a food facility's food allergen program.

Based on the foregoing, FDA recommends that food facilities consider adapting one or more CGMP compliance measures to also serve as a preventive control by combining a CGMP measure with one or more preventive control management components. As one example, FDA highlights that a manufacturer's CGMP food equipment cleaning measure could be combined with a preventive control management component, such as observing whether the equipment is visibly clean. Such a combination could complement and enhance compliance with CGMP regulations for preventing allergen cross-contact through sanitary operations.

Chapter 11 contains numerous other examples and recommendations, including with regard to supplier approval, and merits a careful review. More broadly, this chapter builds upon FDA's Draft Compliance Policy Guide on Major Food Allergen Labeling and Cross-Contact, released in May 2023, which sets out the agency's enforcement policy regarding major food allergen labeling and cross-contact.

Chapter 11 also contains key information for food facilities that handle sesame. In rolling out the addition of Chapter 11 to the Draft Guidance, FDA called out sesame given its recent addition as the ninth major food allergen with the passage of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, effective January 1, 2023. Sesame must now be disclosed on food labels when it is present in a food, and businesses should therefore implement controls to significantly minimize or prevent sesame allergen cross-contact. But, FDA believes some manufacturers are intentionally adding sesame to products that previously did not contain sesame and are labeling the products to indicate its presence, rather than taking appropriate measures to minimize or prevent cross-contact. In light of this development, FDA encourages industry to follow the Draft Guidance to significantly minimize or prevent allergen cross-contact and undeclared allergens. In FDA's announcement of updated Draft Guidance, FDA Commissioner Robert Califf specifically encouraged manufacturers "to follow the guidelines in the draft guidance updates released today to prevent allergen cross-contact and ensure proper labeling" and stated FDA's openness to engaging with stakeholders "interested in finding solutions, within [the agency's] authorities, that meet the needs of consumers with food allergies."

Chapter 16: Acidified Foods. Manufacturers of acidified foods must comply with specific requirements, such as production and process controls (21 CFR 114) and emergency permit control regulations (21 CFR 108.25). FDA's addition of Chapter 16 explains how acidified food manufacturers can meet both the agency's specific acidified foods requirements *as well as* requirements under the preventive controls for human food rule. Notably, the chapter highlights specific requirements under the preventive controls rule that directly correspond to requirements under FDA's acidified food regulations. But, it also points out key differences and, thus, the need to confirm whether established procedures and processes facilitate compliance with all applicable requirements.

What's Next?

FDA welcomes comments regarding the Draft Guidance and the new chapters by March 25, 2024. While comments can be submitted at any time, FDA has designated this March deadline so that comments may be incorporated prior to the agency beginning work to finalize the Draft Guidance.

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