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Food, Drug & Device Law Alert - FDA Publishes Proposed Rule On Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

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As part of the process of implementing the Food Safety Modernization Act (FSMA), the FDA recently published a proposed rule titled “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.” The accompanying materials explain that the rule seeks to protect the food supply against acts of terrorism designed to cause widespread and significant harm to public health. The rule is expressly not designed to cover acts of disgruntled employees, consumers or competitors designed to harm a company’s reputation – even though harm to public health may occur – or economically motivated adulteration (although it discusses an approach to this latter problem also).

The proposed rule would establish various food defense measures that a food facility required to register with FDA would be further required to implement to protect against the intentional adulteration of food. According to the summary, the defense measures require covered facilities to complete the following:

- Prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification.
- Identify any actionable process steps, using one of two procedures. FDA has determined that the presence of one or more of (1) bulk liquid receiving and loading, (2) liquid storage and handling, (3) secondary ingredient handling, and (4) mixing and similar activities during a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability and that food is at high risk of intentional adulteration caused by acts of terrorism at these times. Facilities may identify actionable process steps using the FDA-identified key activity types or conduct their own facility-specific vulnerability assessments.
- Identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated.
- Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.
- Establish and implement corrective action procedures that must be taken if focused mitigation strategies are not properly implemented.

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- Verify that monitoring is being conducted and appropriate decisions about corrective actions are being made; verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities; and conduct a reanalysis of the food defense plan.

- Ensure that personnel and supervisors assigned to perform actionable process steps receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies.

- Establish and maintain certain records, including the written food defense plan; written identification of actionable process steps and the assessment leading to that identification; written focused mitigation strategies; written procedures for monitoring, corrective actions, and verification; and documentation related to training of personnel.

The proposed effective date is 60 days after a final rule is published. The FDA is providing a longer timeline, however, for facilities to comply with the final rule. Facilities, other than small and very small businesses, would have one year after the effective date to comply with the rule. Small businesses (i.e., those employing fewer than 500 persons) would have two years after the effective date to comply with the proposed rule. Very small businesses (i.e., businesses that have less than $10 million in total annual sales of food, adjusted for inflation) would be considered a qualified facility (i.e., exempt from most of the rule) and would have three years after the effective date to comply with a requirement that they maintain records related to their exempt status.

A copy of the proposed rule can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys:

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