



ALERTS

FDA Issues More Guidance On Intentional Adulteration Of Food Rule

February 26, 2020

As part of its implementation of the Food Safety Modernization Act, the U.S. Food & Drug Administration (FDA) published a final rule four years ago titled, "[Mitigation Strategies to Protect Against Intentional Adulteration.](#)" The [final installment](#) of the lengthy guidance documents on the rule, which seeks to help regulated food companies develop and implement a food defense plan (FDP), was issued recently.

[Comments](#) on the final installment are due by June 15, 2020.

The term intentional adulteration broadly refers to several types of acts, including:

- Those intended to cause wide-scale public health harm, such as acts of terrorism focused on the food supply
- Acts of disgruntled employees, consumers, or competitors
- Economically motivated adulteration

Acts intended to cause wide-scale public health harm are associated with the intent to cause significant human morbidity and mortality. The guidance states that the other forms of adulteration are typically intended to attack the reputation of a company or obtain economic gain; thus, attacks intended to cause wide-scale public health harm to humans are ranked as the highest risk and the rule is focused on addressing those acts and not acts of disgruntled employees, consumers or competitors, or economically motivated acts.

The intentional adulteration rule applies to the owner, operator or agent in

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charge of a domestic or foreign food facility that manufactures/processes, packs or holds food for consumption in the United States and is required to register under Section 415 of the Food, Drug & Cosmetic Act, unless one of several exemptions provided in the regulations applies.

The guidance seeks to help regulated food companies develop and implement a food defense plan (FDP). In accordance with the new rule's requirements, the guidance provides information on the following topics:

- The components of an FDP and the importance of each component
- How to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps
- How to identify and implement mitigation strategies for the actionable process steps associated with a facility's processes
- How to identify and apply the mitigation strategies management components (i.e., food defense monitoring, food defense corrective actions, and food defense verification)
- The reanalysis requirements associated with the FDP
- The education, training, and/or experience required for individuals who perform certain activities
- The recordkeeping requirements associated with the FDP and its implementation

This final installment includes chapters on corrective action, verification, reanalysis, and record-keeping.

As always, the FDA's guidance documents do not establish legally enforceable responsibilities, but rather describe the FDA's current thinking on a topic.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, the chair of the firm's Food, Drug and Device Practice Group, at 317-231-7392 or lynn.tyler@btlaw.com.

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