



Photo: New Food Magazine

## COVID-19 Impacts FSMA Rule: Mitigation Strategies for Protecting Food Against Intentional Adulteration

Intentional adulteration...*when a food product is intentionally contaminated by a person or group of people, either internal or external to a food business, has become even a greater concern as food processors battle through the challenges and ramifications of COVID-19.* The most common cause of intentional adulteration within the food supply chain has been disgruntled employees seeking revenge on their employer or co-workers. On July 26, 2019, the FSMA final rule for intentional adulteration came into force: **Mitigation Strategies to Protect Food Against Intentional Adulteration**. This final rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, and economic disruption of the food supply.

Examples of intentional adulteration have included:

**2018:** Australian-grown strawberries were implicated in [deliberate sabotage involving sewing needles](#).

**2016:** At least 33 people, including five children, died in District Layyah, Punjab Pakistan [after eating a purposely poisoned laddu](#), a baked confection. One of the owners confessed to mixing the pesticide into the sweets after an argument with his brother and co-owner.

**2015:** Beer served at a funeral in Mozambique was [contaminated with bongkrelic acid](#), resulting in 75 deaths and more than 230 people falling ill.

**2002:** A jealous business rival poisoned food products of a competitor with a strong rat poison. As a result, 38 people were killed, mostly schoolchildren, and approximately 200 people were hospitalized.

Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

As the coronavirus SARS-CoV-2 (COVID-19) began to emerge and circulate throughout numerous food processing facilities this year, and plants were pushed to maintain, and in some cases dramatically increase production, an adequate labor force was mandatory. This elevated the need to implement additional strategies to mitigate the possibility of intentional adulteration. As virus outbreaks occurred and food manufacturers competed to attract, and train new hires, companies began to and continue to run a greater risk of becoming more vulnerable to intentional adulteration threats. Supervisors, faced with an abundance of additional new accountabilities and challenges, as they implement and regulate new preventative policies and procedures and onboard new, unfamiliar personnel, face an increased risk for intentional adulteration. Although the final rule remains definitive, food processors must integrate ramifications of COVID-19 into the design and content of their food safety plan strategy.

To learn more about how to create and implement an effective Food Defense Plan that includes mitigation strategies against the threat of Intentional Adulteration, food processors are encouraged to have their Food Defense Team members take the VIRTUAL class being offered next week by the Food Innovation Center (mornings of October 14 & 15, 2020.)

<https://foodinnovation.rutgers.edu/2020-intentional-adulteration-vulnerability-assessments-food-defense-qualified-individual-training/>

The **Mitigation Strategies to Protect Food Against Intentional Adulteration** rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.

This rule is designed to primarily cover large companies whose products reach great numbers of people, originally exempting smaller companies. However, as of July 27, 2020, smaller companies (averaging more than \$10 million in sales in the previous three years and that employ fewer than 500 full-time equivalent employees) must comply.

According to a recent announcement, FDA will begin conducting routine inspections of small businesses for compliance with this rule in March 2021. Following a lengthy pause since March 2020, FDA recently re-initiated surveillance inspections for food businesses.

For further information

<https://www.fda.gov/media/98085/download>

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