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Regulatory Alert: FDA Publishes Final Food Defense Rule

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On May 27, 2016, the U.S. Food and Drug Administration (FDA) released the final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration. The Final Rule requires certain food facilities to take security measures to prevent acts intended to cause wide-scale harm. This document summarizes the key points of the regulation:

What facilities are covered under the regulation?

U.S. and foreign facilities required to register under the Bioterrorism Act that process and pack human food.

What facilities are exempt under the regulation?

- Facilities owned by businesses that have less than $10,000,000 in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g. held for a fee)
- Facilities engaging solely in the holding of food (e.g. a grocery distribution center or warehouse), except the holding of food in liquid storage tanks
- Farms (generally)
- Alcoholic beverage facilities
- Animal food facilities

What activities are exempt under the regulation?

- Packing, re-packing, labeling or relabeling of food where the container that directly contacts the food remains intact
- Activities of a farm subject to the Produce Safety Rule
- On-farm manufacturing, processing, packing, or holding of shell eggs and game meats by a business with fewer than 500 full time employees or a business with less than $10,000,000 in sales of human food if such activities are the only activities conducted by businesses subject to the Preventive Controls for Human Food Rule.

What are facilities generally required to do under the Final Rule?

- Facilities must prepare and implement a written food defense plan
- The food defense plan must include:
    - A written vulnerability assessment

  - Written mitigation strategies
  - Written procedures for monitoring of the implementation of mitigation strategies
  - Written procedures for corrective actions
  - Written procedures for verification

What must the vulnerability assessment contain?

- A vulnerability assessment must be conducted for each type of food manufactured, processed, packed, or held at the facility using appropriate methods to evaluate each point, step or procedure in operations to identify significant vulnerabilities and actionable process steps.
- Methods must include at a minimum, an evaluation of:
  - The potential public health impact if a contaminant were added
  - The degree of physical access to the product
  - The ability of an attacker to successfully contaminate the product
- The assessment must consider the possibility of an inside attacker
- Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step or procedure either was or was not identified as an actionable process step.

What are mitigation strategies?

Mitigation strategies are risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps (a point, step or procedure where a significant vulnerability exists), and that are consistent with the current scientific understanding of food defense at the time of the analysis.

What are the required components of the mitigation strategies?

- Food defense monitoring
- Food defense corrective actions
- Food defense verification

When must I reanalyze my food defense plan?

- Whenever a significant change made in the activities conducted at the facility creates a potential for a new vulnerability or a significant increase in a previously identified one;
- Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;
- Whenever you find that a mitigation strategy, combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and
- Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding;

- Reanalysis of the food defense plan as a whole must be conducted at least once every 3 years

How long must records be retained?

At least 2 years after the date they were prepared.

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