

FSMA – FOOD DEFENSE, Mitigation Strategies for Intentional Adulteration

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Important Terms

- **Actionable process step [APS]** means:
 - a point, step, or procedure in a food process where a significant vulnerability exists,
 - where mitigation strategies can be applied, and
 - the mitigation strategies applied here significantly minimize or prevent the significant vulnerability.

Important Terms

- **Key Activity Types (KATs): activities consistently ranked as the most vulnerable, regardless of food commodity. Four KATS.**
 - **Bulk liquid receiving and loading,**
 - **Liquid storage and handling,**
 - **Secondary ingredient handling, and**
 - **Mixing and similar activities.**





Important Terms

- **Vulnerability Assessment**

- *Significant vulnerability* means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following:
 - (1) Potential public health impact (e.g., severity and scale) if a contaminant were added,
 - (2) degree of physical access to the product, and
 - (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.

Food Defense Plan Outline

- Prepare and implement a written Food Defense Plan.
- Identify significant vulnerabilities and actionable process steps (APS).
- Identify and implement mitigation strategies at each APS.
- Establish and implement mitigation strategies management components.

Food Defense Plan Outline

- Establish and implement food defense monitoring procedures.
- Establish and implement food defense corrective action.
- Establish and implement specified food defense verification activities.
- Conduct a reanalysis of the food defense plan.

Food Defense Plan Outline

- All individuals who perform required food defense activities are documented as qualified to perform their assigned duties.
- Establish and maintain written records

Food Defense Plan

Important details:

- Food defense is agent agnostic.
- Food defense plans are facility-specific.

Food Defense ≠ HACCP or PC

PC-HF Hazard analysis:

- (1) Known or reasonably foreseeable hazards
- (2) **Severity of the illness or injury if the hazard were to occur**
and
- (3) Probability that the hazard will occur in the absence of preventive controls.

IA Vulnerability assessment:

- (1) **The potential public health impact (e.g., severity and scale)**
if a contaminant were added;
- (2) Degree of physical access to the product; and
- (3) Ability of an attacker to successfully contaminate the product.

Food Defense is not HACCP or PC

- The same skills, industry knowledge, and analytical thinking are required for both HACCP/PC and Food Defense.
- But the goal is different.

Compliance dates:

- Large business, more than 500 FTE
July 26, 2019
- Small business, less than 500 FTE
July 27, 2020
- Very small business, under \$10 million inflation adjusted
July 26, 2021 (documentation of 3 year dollar volume only)

Exemptions

- A very small business. Under \$10 million (inflation adjusted rolling three year average, now \$11 million and change)
- Warehouses, except the food in liquid storage tanks or when sampling takes place
- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact
- Activities that fall within the definition of “farm”

Exemptions

- Animal food
- Alcoholic beverages
- On-farm manufacturing, processing, packing, or holding by a small or very small business of certain low-risk foods having low-risk production practices.

What are mitigation strategies?

Anything that:

- Limits access

- Provides more visibility

- Records activity in facility or on grounds

- Enhanced employee screening

- Seals and tamper evident closures

<https://www.fda.gov/food/food-defense-tools-educational-materials/mitigation-strategies-database>

You are probably already using Food Defense strategies

- Restricted access to your property.
- Perimeter fence and locked doors.
- Restricted access for visitors, contractors, and employees.
- Security cameras.
- Secured storage of chemical supplies used by sanitation and maintenance.

Phase 1 FDA Inspections begin March 2020 – Quick Check

- To be conducted during routine food safety inspections
- High level review of Food Defense Plan (FDP)
- For Industry education and
- Provide FDA with evidence of credible oversight

Phase 1 FDA Inspections begin March 2020 – Quick Check

- Gather baseline industry, facility, and compliance data
- Data to prioritize future comprehensive inspections
- Quick-Check will inform FDA where more focused industry assistance is needed

Phase 1 FDA Inspections begin March 2020 – Quick Check

- The Quick Check will be a short inspectional program of approximately 10 questions related to the requirements of a food defense plan.
 - “Show me xxx in your food defense plan”
- No records will be collected during Quick Check

Phase 2 FDA Inspections begin after “several years” of Quick Check

- Data from Quick Check to guide FDA in deciding where to conduct in-depth IA inspection.
- Comprehensive food defense inspections will be made at only a limited number of prioritized facilities
- Conducted by specially trained investigators
- Will include a critical evaluation of FDP, conclusions, rationale

Closing observations

- The IA rule is short (about 15 pages), direct, and IMO the simplest of the seven foundational FSMA rules.
- The challenge is not understanding, but just doing it.
- FDA web site has many Food Defense resources.

Questions?