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Protecting Against Intentional Adulteration – U.S. FDA Requirements

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What Is the U.S. FDA's Intentional Adulteration (IA) Regulation?

- Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm
- Uses a HACCP-type approach, but with important differences from the Preventive Controls for Human Food rule
- Is risk-based and flexible

Who Is Covered by the IA Rule?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
 - Not farms or retail food establishments
- Applies to U.S. domestic and imported food
- Some exemptions and modified requirements apply

Exemptions

- Very small businesses averaging less than US\$10M per year
- Holding of food, except holding of food in liquid storage tanks
- Packing, repacking, 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

Exemptions

- Manufacturing, processing, packing, or holding food for animals
- Alcoholic beverages at certain facilities (under specified conditions)
- On-farm manufacturing/processing, packing, or holding by a small or very small business, of eggs (in-shell, other than RACs) or certain types of game meats, if such activities are the only activities conducted by the business subject to section 418 of the Act

What Is Required?

- Food defense plan
 - Vulnerability assessment
 - Mitigation strategies
 - Procedures for food defense monitoring
 - Food defense corrective action procedures
 - Food defense verification procedures
 - Records
- Training

Key Terms

- Actionable process steps
- Mitigation strategies

Food Defense Plan – Vulnerability Assessment

- Identification of those points at highest risk, i.e., actionable process steps
- For each point, step, or procedure, a facility must consider, at a minimum:
 - Potential public health impact
 - Degree of physical access to product
 - Ability of an attacker to successfully contaminate the product
- Outcome of assessment must be written

Food Defense Plan – Mitigation Strategies

- Measures to ensure significant vulnerabilities at actionable process steps are significantly minimized or prevented
- Must be implemented for each actionable process step
- Must include written explanation for how strategy minimizes vulnerability

Food Defense Plan – Mitigation Strategy Management Components

- Food defense monitoring
- Food defense corrective actions
- Food defense verification
 - As appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of the mitigation strategy and its role in the facility's food defense system

Food Defense Plan – Food Defense Monitoring

- Facility must have written procedures, including the frequency they are to be performed, for monitoring the mitigation strategies (as appropriate to the nature of the mitigation strategies)
- Monitoring must be documented in records subject to verification

Food Defense Plan – Food Defense Corrective Actions

- Facility must have written procedures for steps to be taken when mitigation strategies are not properly implemented (as appropriate to the nature of the actionable process step and the nature of the mitigation strategy)
 - Identify and correct a problem
 - Reduce likelihood of recurrence
- Corrective actions must be documented in records subject to verification

Food Defense Plan – Food Defense Verification

- Includes (as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system):
 - Verification of monitoring and corrective actions
 - Verification that mitigation strategies are properly implemented through records review or other activities
- Verification must be documented in records

Reanalysis of Food Defense Plan

- At least every three years
- Whenever there is a significant change that creates the potential for a new vulnerability or a significant increase in one previously identified
- When there is new information about potential vulnerabilities associated with a food operation or facility

Reanalysis of Food Defense Plan

- When a mitigation strategy is not properly implemented
- Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats, or developments in scientific understanding

Training

- Food defense awareness
- Proper implementation of mitigation strategies at actionable process steps
- Certain components of the food defense plan
- Individual may be qualified by education or experience

Records

- Establish and maintain certain records, including
 - Food defense plan
 - Food defense monitoring, corrective action, and verification records
 - Documentation related to training of personnel
- Use of existing records

Compliance Dates

- **Very small businesses** (under US\$10M): Five years (July 26, 2021)
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Four years (July 27, 2020)
- **All other businesses:** Three years (July 26, 2019)

FDA Guidance

- Vulnerability assessment
- Mitigation strategies
- Food defense monitoring, corrective actions, and verification
- Recordkeeping
- A Small Entity Compliance Guide to assist small and very small businesses to comply with the rule

Training and Technical Assistance - International

- Plans include
 - Collaborating with the Food Safety Preventive Controls Alliance on capacity building through its International Subcommittee
 - Working with regulatory counterparts and multinational organizations
 - Developing and disseminating outreach, education, and technical materials
 - Establishing training and technical assistance networks

Technical Assistance

- **Food Defense Mitigation Strategies Database**
- <http://www.accessdata.fda.gov/scripts/fooddefensemitigationstrategies/>
- Browse by Category
- Or Search by Keyword
- Choose a Point, Step, or Procedure
- Review Strategy List

Training and Technical Assistance – U.S. Domestic

- Established the Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance to create training and technical assistance programs
- The FDA FSMA Technical Assistance Network has been established

Questions ?

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