Intentional Adulteration *Final*

Final Rule: Protecting Food Against Intentional Adulteration

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

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Background

Mitigation Strategies to Protect Food Against Intentional Adulteration

- Proposed on December 24, 2013
- Public comments: More than 200 for the original proposal
- Final rule publication date: May 27, 2016

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What Does the IA Rule Do?

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

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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 domestic and imported food
- Some exemptions and modified requirements apply

Exemptions

- Very small businesses*
- 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
- 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 FD&C Act

Exemption: Very Small Businesses

- The rule does not apply to very small businesses (VSBs)
  - Averaging less than $10,000,000 per year, in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee
- VSBs are required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption

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

Food Defense Plan – Vulnerability Assessment

- Must consider the possibility of an inside attacker
- Outcome of assessment must be written
- Key Activity Types are considered an appropriate method to conduct a vulnerability assessment

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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
- Removed distinction between “broad” and “focused”

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

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

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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

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Training

- Food defense awareness
- Proper implementation of mitigation strategies at actionable process steps*
- Certain components of the food defense plan*

*Individuals may also 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** (see slide 6): 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)

Planned 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

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For More Information

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- To contact FDA about FSMA and find the online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

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Intentional Adulteration Final Rule: Implementation Framework

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IA Inspection Framework Concept

- Food defense looks at public health with a unique perspective
  - Food defense presents a very different risk to public health than food safety poses
- IA rule creates a regulatory environment where facilities have a great deal of flexibility
  - IA rule does not prescribe a particular VA method or specific mitigation strategies
- Regulators will require specialized training to determine facility compliance
  - Judgment calls will be required to determine compliance

Inspection Framework Approach

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- Two-Tiered Inspectional Approach*
  - Food Defense Plan Quick-Check
    - Conducted on all covered facilities
    - Very low burden on agency and industry
    - Very little required training for investigators
  - Food Defense Inspection
    - Conducted only on a limited number of prioritized facilities
    - Focus inspectional resources on were IA risk is highest
    - Specialized training for investigators
  - Rolled out in a staged implementation timeline
    - Build food defense expertise of regulators and industry

*beginning when relevant compliance dates pass

Staged Implementation

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- Stage 1: Outreach and Data-Collection
  - Initiate Food Defense Plan Quick-Check
  - Communicate IA rule requirements to industry
  - Gather baseline industry, facility, and compliance data
  - Enhance cooperative working environment with industry
- Stage 2: Build Food Defense Inspection Program
  - Identify and train food defense investigators
  - Develop facility identification method and process
    - Identify “Tier-1” facilities and prioritize for food defense inspections
  - Initial Phase of food defense inspections begin
    - Build regulator expertise and refine inspection approach for consistent IA rule implementation

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Staged Implementation

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- Stage 3: Established IA Rule Compliance Program
  - Conduct food defense plan quick-check on covered facilities during routine food safety inspections
  - Food defense inspections on identified Tier-1 facilities
  - Continue to refine implementation approach, as appropriate
  - Food Defense Assignments developed as needed
    - Event base assignments
      - Such as political conventions, presidential inaugurations, other national special security events
    - Need based assignments
      - Such as in response to a credible threat to the food supply

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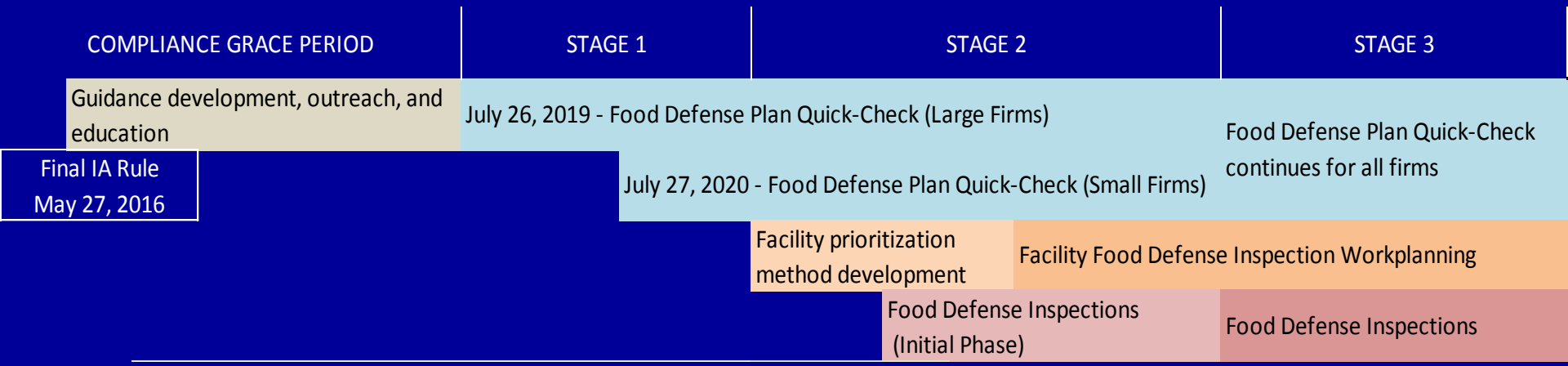
Notional Implementation Timeline



Intentional Adulteration Final Rule: Training

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Training Requirements

- Food defense awareness and proper implementation of mitigation strategies at actionable process steps
- Certain components of the food defense plan*
  - Preparation of the food defense plan
  - Conduct of vulnerability assessments
  - Identification of mitigation strategies at actionable process steps and the explanation for how these strategies significantly minimize or prevent the significant vulnerabilities
  - Reanalysis

*Individuals may also be qualified by education or experience

Who Will Be Trained?

- Industry
  - Personnel from covered firms
  - Lead instructors (domestic/international)
- Regulators
  - Investigators involved in compliance inspections of covered firms

Intentional Adulteration Subcommittee Formation

- IA Subcommittee has been formed within Food Safety Preventive Controls Alliance (FSPCA)
- Multi-year effort to secure funding necessary to establish IA Subcommittee
- Funding source: FDA/Center for Food Safety and Applied Nutrition/Office of Analytics and Outreach

Notional Training Development Activities

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