

FSMA Chat

Mitigation Strategies to Protect Food

Against Intentional Adulteration

Implementation Update

IA regulation “Refresher”

Background

- Last of 7 foundational FSMA rules
- Final rule: May 27, 2016
- 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



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 Food, Drug, and Cosmetic Act (FD&C) Act
 - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply – see the IA Fact Sheet
 - <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf>

What Is Required?

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

Compliance Dates

- Businesses that are not small or very small: July 26, 2019
- Small businesses (a business with fewer than 500 full-time equivalent employees): July 27, 2020
- Very small businesses (modified requirements): July 26, 2021



Inspection Strategies



Inspection Framework

- Two-level inspectional approach
 - Food defense plan Quick-Check inspection
 - Conducted on covered facilities during food safety inspections
 - High level review of Food Defense Plan (FDP)
 - Comprehensive food defense inspections
 - Conducted only at a limited number of prioritized facilities
 - Conducted by specially trained investigators
 - Critical evaluation of FDP, conclusions, rationale⁸

Staged Implementation



- Stage 1: Outreach and Baseline-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
 - Build food defense expertise of regulators and industry
 - Provide a level of credible oversight of the regulation

Staged Implementation



- Stage 2: Build comprehensive food defense inspection program
 - Identify and train food defense investigators
 - Develop facility identification method and process
 - Identify “Level 1” facilities and prioritize for food defense inspections
 - Initial Phase of comprehensive food defense inspections begin
 - Continue to expand regulator expertise and refine inspection approach for consistent IA rule implementation
 - Acknowledgement of information protection concerns¹⁰

Staged Implementation

- Stage 3: Established IA rule compliance program
 - Conduct food defense Quick-Check on covered facilities during routine food safety inspections, as appropriate
 - Comprehensive food defense inspections on identified prioritized facilities
 - Continue to refine implementation approach, as appropriate
 - Anticipate that, like now, food defense assignments may be developed as needed
 - Event-based 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

Quick-Check IA Inspections

- Credible oversight of the IA regulation
- Baseline will allow compliance oversight and education during the Quick-Check and data for prioritizing the comprehensive inspections
- Quick-Check will also enable more focused assistance for industry if they are unaware or need additional assistance

Quick Check IA Inspections

- The Quick Check will be conducted through a short inspectional protocol of approximately 10 questions that are relevant to the requirements of a food defense plan.
 - “Show me that in your food defense plan”
- No records will be collected
- 60-90 minute regulator training prior to the rollout of the Quick-Check inspections
- Quick Checks will be included in contract inspection conducted by our state partners.

Food Defense Facility Inspection

- Conducted on prioritized facilities identified through food defense specific analysis
 - Limited number of inspections focused on facilities with increased food defense risk – “Level 1 Facilities”
- Detailed review of food defense plan and inspection to determine status of plan implementation in the facility (1-2 days)
- Conducted by investigators with specialized food defense training
 - CFSAN Food Defense SMEs available for real-time consultation & technical support

Timing of Inspections



- **First Compliance Date: July 26, 2019**
 - Businesses with > 500 employees and > \$10 million in annual food sales
- **Begin Quick Checks: March 2020**
 - Enable industry time to refine food defense plans with the benefit of recently released or pending guidance, training, and tools.
 - Educate while we regulate
- **Begin Comprehensive Food Defense Inspections: Mid-2020s**
 - Build baseline data, develop prioritization, training

Thank you

- FDA's website has additional information that is available for review at your convenience
 - Factsheets
 - Q/A documents
 - Full text of the IA rule
 - Guidance