

FSMA

**Mitigation Strategies to Protect Food Against
Intentional Adulteration
Implementation Update**

21 Code of Federal Regulations Part 121

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ICBC

Agenda

- Quick Refresher on the Regulation
- Regulation Implementation – Inspection Strategies
- Regulation Implementation - Training
- Regulation Implementation – Guidance

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

What Is Required?

- Food defense plan
 - Vulnerability assessment
 - Mitigation strategies
 - Food defense monitoring procedures
 - 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

- 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
 - Comprehensive food defense inspections
 - Critical evaluation of the plan and the implementation of the plan

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 facilities and prioritize for the comprehensive 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 concerns

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

Inspection Strategies

Food defense plan Quick-Check inspection

- Credible oversight of the IA regulation
- New regulatory territory – no previous compliance data
- Anticipate numerous years of the Quick-Check in order to ascertain a baseline level of information
- Baseline will allow compliance oversight and education during the Quick-Check and data for prioritizing the comprehensive inspections
- Quick-Check will also allow regulators to prioritize guidance and/or additional training needs that may be identified and to provide current guidance to the industry if they are unaware or need additional assistance

Quick-Check IA Inspections



- The Quick-Check is anticipated to be approximately 12 questions in a guided conversation that will be backed up by visual observation and confirmation of those items discussed in the Quick-Check
 - “Show me that in your food defense plan”
- No records will be collected
- No plans will be collected
- Specific implementation activities will not be assessed
- Anticipation is that this Quick-Check will not be a deep-dive into the plan – confirmation of required sections of the food defense plan and requirements of the plan itself
- Training to conduct this Quick-Check is anticipated to be a 60-90 minute webinar to be held in 2020 prior to the rollout of the Quick-Check inspections



Quick-Check IA Inspections

- Awareness of coverage
- Food Defense Plan (21 CFR 121.126)
 - Written and implemented
 - Written vulnerability assessment
 - Identify significant vulnerabilities
 - Identify actionable process steps
 - Written explanations, as required
 - Written mitigation strategies
 - Required explanations
 - Written procedures for monitoring of the implementation of the mitigation strategies
 - Written procedures for food defense corrective actions
 - Written procedures for food defense verification

Quick-Check IA Inspections



- Method utilized for the vulnerability assessment (21 CFR 121.130)
- Qualified individuals (21 CFR 121.4(c)(3)(i-iii))
 - Preparation of the food defense plan
 - Conduct of the vulnerability assessment
 - Identification and explanation of the mitigation strategies
 - Reanalysis
- Food defense plan signed and dated appropriately (21 CFR 310)

Inspection Strategies

Comprehensive food defense inspections

- Conducted only at a limited number of prioritized facilities
- Conducted by specially trained investigators
- Critical evaluation of FDP, vulnerability assessment, mitigation strategies, management components, etc.
- Generates significantly more detailed compliance information
- Pilot with federal investigators – then reassess program for federal and state investigators

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



Training/Assistance



- Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance (FSPCA) for IA rule training development and delivery
- Courses for industry are very far along and publication is anticipated shortly
- Specific “Regulator Courses” for IA rule are also being developed (e.g., for the IA Quick-Check and the Comprehensive Inspections)
- Technical assistance – the FDA FSMA Technical Assistance Network (TAN) is fully operational for receiving questions from the industry and other stakeholders





FSPCA IA Rule Standardized Curriculum Recognized by FDA



FSPCA Training Course	Delivery Method	Intended Audience – Food Professionals who do the following:
Food Defense Awareness AVAILABLE		<ul style="list-style-type: none"> • Workers at Actionable Process Steps (e.g., front line food workers) • Supervisors of Workers at Actionable Process Steps • Satisfies requirement in § 121.4(b)(2)
Overview of IA Rule AVAILABLE		<ul style="list-style-type: none"> • Any stakeholder interested in learning more about the IA rule requirements • This course is not associated with any IA rule training requirement

FSPCA IA Rule Standardized Curriculum Recognized by FDA



FSPCA Training Course	Delivery Method	Intended Audience – Food Professionals who do the following:
Conducting Vulnerability Assessments (VAs) using Key Activity Types (KAT) AVAILABLE		<ul style="list-style-type: none"> Conduct VAs using the KAT Method <u>only</u>
Conducting Vulnerability Assessments AVAILABLE		<ul style="list-style-type: none"> Conduct VAs using the 3 Fundamental Elements This 1-day course must be taught by approved and trained FSPCA VA Lead Instructors Prerequisite: FSPCA KAT Online Training Course
Identification and Explanation of Mitigation Strategies AVAILABLE		<ul style="list-style-type: none"> Identify Mitigation Strategies to implement at Actionable Process Steps
Food Defense Plan Preparation and Reanalysis		<ul style="list-style-type: none"> Prepare the Food Defense Plan Conduct Reanalysis activities

Guidance

- Draft Guidance – 3 parts:
 - 1st – simple, cost-effective way to identify the most vulnerable parts of the production process, outlines numerous ways to guard against IA, as well as ways to monitor the operation
 - Available now
 - 2nd – additional, detailed, and flexible method to identify a facility's most vulnerable points, as well as information regarding training and qualifications
 - Available now
 - 3rd – corrective actions, verification, reanalysis, and recordkeeping

Guidance Chapters



- **Introduction**
- **Ch 1 Food Defense Plan**
- **Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps**
 - Sections 2A-E, including background and Key Activity Types (KATs) as a Method for Conducting a VAs
 - Section 2F: Evaluating the Three Fundamental Elements to Identify Significant Vulnerabilities and Actionable Process Steps
- **Ch 3 Mitigation Strategies for Actionable Process Steps**
- **Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring**
- Ch 5 Mitigation Strategies Management Components: Food Defense Corrective Actions
- Ch 6 Mitigation Strategies Management Components: Food Defense Verification
- Ch 7 Reanalysis
- Ch 8 Education, Training, or Experience
- Ch 9 Records
- **Appendix 1. Food Defense Plan Worksheets**
- Appendix 2. Mitigation Strategies in the Food Defense Mitigation Strategies Database
- Appendix 3. Calculating Small Business and Very Small Businesses Sizes

Next Steps



- In the future, we anticipate:
 - Publication of part 3 of IA rule guidance
 - Release of updated Food Defense Plan Builder
 - Remaining training courses will be rolled out and available via FSPCA
 - Continued engagement with stakeholders at meetings, technical exchanges, conferences
 - Begin the Quick Check inspections