FSMA
Mitigation Strategies to Protect Food Against Intentional Adulteration
Implementation Update
21 Code of Federal Regulations Part 121

Donald Kautter
September 2019
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

<table>
<thead>
<tr>
<th>FSPCA Training Course</th>
<th>Delivery Method</th>
<th>Intended Audience – Food Professionals who do the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food Defense Awareness</strong></td>
<td>ONLINE TRAINING</td>
<td>• Workers at Actionable Process Steps (e.g., front line food workers)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Supervisors of Workers at Actionable Process Steps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Satisfies requirement in § 121.4(b)(2)</td>
</tr>
<tr>
<td><strong>AVAILABLE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Overview of IA Rule</strong></td>
<td>ONLINE TRAINING</td>
<td>• Any stakeholder interested in learning more about the IA rule requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• This course is not associated with any IA rule training requirement</td>
</tr>
<tr>
<td><strong>AVAILABLE</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### FSPCA IA Rule Standardized Curriculum Recognized by FDA

<table>
<thead>
<tr>
<th>FSPCA Training Course</th>
<th>Delivery Method</th>
<th>Intended Audience – Food Professionals who do the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducting Vulnerability Assessments (VAs) using Key Activity Types (KAT)</td>
<td>ONLINE TRAINING</td>
<td>• Conduct VAs using the KAT Method only</td>
</tr>
<tr>
<td>Conducting Vulnerability Assessments AVAILABLE</td>
<td></td>
<td>• Conduct VAs using the 3 Fundamental Elements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• This 1-day course must be taught by approved and trained FSPCA VA Lead Instructors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prerequisite: FSPCA KAT Online Training Course</td>
</tr>
<tr>
<td>Identification and Explanation of Mitigation Strategies</td>
<td>ONLINE TRAINING</td>
<td>• Identify Mitigation Strategies to implement at Actionable Process Steps</td>
</tr>
<tr>
<td>AVAILABLE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Defense Plan Preparation and Reanalysis</td>
<td>ONLINE TRAINING</td>
<td>• Prepare the Food Defense Plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Conduct Reanalysis activities</td>
</tr>
</tbody>
</table>
Guidance

• Draft Guidance – 3 parts:
  – 1\textsuperscript{st} – 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
  – 2\textsuperscript{nd} – additional, detailed, and flexible method to identify a facility’s most vulnerable points, as well as information regarding training and qualifications
    • Available now
  – 3\textsuperscript{rd} – 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