Intentional Adulteration Rule Update

Food and Drug Administration
Food Defense and Emergency Coordination Staff
Outline

• IA Rule Overview
• Guidance
• Inspection/Compliance
• Training
• Themes from Outreach
• Q & A
Background

*Mitigation Strategies to Protect Food Against Intentional Adulteration*

- Required under Food Safety Modernization Act
- Proposed on December 24, 2013
- Public comments: More than 200 for the original proposal
- Final rule publication date: May 27, 2016
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
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
What Is Required?

• Food defense plan
  – Vulnerability assessment
  – Mitigation strategies
  – Procedures for food defense monitoring
  – Food defense corrective action procedures
  – Food defense verification procedures

• Training
• Reanalysis
• Records
Compliance Dates

• **Very small businesses**: 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
Inspection/Compliance Update
Inspection Framework Approach

• Two-Level 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
Notional Implementation Timeline

<table>
<thead>
<tr>
<th>COMPLIANCE GRACE PERIOD</th>
<th>STAGE 1</th>
<th>STAGE 2</th>
<th>STAGE 3</th>
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</thead>
<tbody>
<tr>
<td>Guidance development, outreach, and education</td>
<td>July 26, 2019 - Food Defense Plan Quick-Check (Large Firms)</td>
<td>July 27, 2020 - Food Defense Plan Quick-Check (Small Firms)</td>
<td>Food Defense Plan Quick-Check continues for all firms</td>
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<tr>
<td>Final IA Rule May 27, 2016</td>
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<td>Facility prioritization method development</td>
<td>Facility Food Defense Inspection Workplanning</td>
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<td>Food Defense Inspections (Initial Phase)</td>
<td>Food Defense Inspections</td>
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Training Update
Training and Technical Assistance - 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
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
<table>
<thead>
<tr>
<th>Role of Individual</th>
<th>Method of Training – <em>Current thinking and subject to change</em></th>
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<tbody>
<tr>
<td>Individuals assigned to an actionable process step (including temporary and seasonal personnel)</td>
<td>Online module – Food Defense Awareness</td>
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<tr>
<td>Supervisors of those individuals assigned to an actionable process step (including temporary and seasonal personnel)</td>
<td>Online module – Food Defense Awareness</td>
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<td>Individual(s) conducting or overseeing:</td>
<td>Online module – Food Defense Plan Preparation</td>
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<td>• the preparation of the food defense plan</td>
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<td>Individual(s) conducting or overseeing:</td>
<td>In-person one day training – Conducting Vulnerability Assessments</td>
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<td>• the vulnerability assessment</td>
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<td>Individual(s) conducting or overseeing:</td>
<td>Online module – Key Activity Types</td>
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<td>• the vulnerability assessment using only Key Activity Types</td>
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<td>Individual(s) conducting or overseeing:</td>
<td>Online module – Mitigation Strategies</td>
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<td>• the identification and explanation of mitigation strategies</td>
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<td>Individual(s) conducting or overseeing:</td>
<td>Online module – Reanalysis</td>
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<td>• Reanalysis</td>
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Themes from Questions
Themes

• Terminology

• Applicability of HACCP-type framework to IA

• Mitigation strategies
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