

# 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 where 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

COMPLIANCE GRACE PERIOD

STAGE 1

STAGE 2

STAGE 3

Guidance development, outreach, and education

July 26, 2019 - Food Defense Plan Quick-Check (Large Firms)

July 27, 2020 - Food Defense Plan Quick-Check (Small Firms)

Food Defense Plan Quick-Check continues for all firms

Final IA Rule  
May 27, 2016

Facility prioritization  
method development

Facility Food Defense Inspection Workplanning

Food Defense Inspections  
(Initial Phase)

Food Defense Inspections

# 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

Role of Individual	Method of Training – <i>Current thinking and subject to change</i>
Individuals assigned to an actionable process step (including temporary and seasonal personnel)	Online module – Food Defense Awareness
Supervisors of those individuals assigned to an actionable process step (including temporary and seasonal personnel)	Online module – Food Defense Awareness
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>the preparation of the food defense plan</li> </ul>	Online module – Food Defense Plan Preparation
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>the vulnerability assessment</li> </ul>	In-person one day training – Conducting Vulnerability Assessments
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>the vulnerability assessment using only Key Activity Types</li> </ul>	Online module – Key Activity Types
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>the identification and explanation of mitigation strategies</li> </ul>	Online module – Mitigation Strategies
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>Reanalysis</li> </ul>	Online module – Reanalysis



# Themes from Questions

# Themes

- Terminology
- Applicability of HACCP-type framework to IA
- Mitigation strategies



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