

# **Food Safety Modernization Act: Intentional Adulteration Rule Requirements**

**Food and Drug Administration**  
Food Defense and Emergency Coordination Staff

# Outline

- IA Rule Overview
- Vulnerability Assessment Overview
- Key Activity Types as a VA Method
- Mitigation Strategies
- Guidance
- Inspection/Compliance
- Training

# Background

## *Mitigation Strategies to Protect Food Against Intentional Adulteration*

- Last of 7 foundational rules under Food Safety Modernization Act
- 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

# 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 FD&C Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

# 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)



# Vulnerability Assessment Requirement

# Key Terms

- **Vulnerability** – means the susceptibility of a point, step, or procedure in a facility’s food process to IA
- **Significant Vulnerability** – means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A SV is identified by a vulnerability assessment.
- **Actionable Process Step** – a point, step, or procedure in a food process where a significant vulnerability exists

# Food Defense Plan – Vulnerability Assessment

- Identification of those points at highest risk, i.e., actionable process steps
- For each point, step, or procedure, a facility must consider, at a minimum:
  - Potential public health impact
  - Degree of physical access to product
  - Ability of an attacker to successfully contaminate the product

# Food Defense Plan – Vulnerability Assessment

- Must consider the possibility of an inside attacker
- Outcome of assessment must be written
- Key Activity Types are considered an appropriate method to conduct a vulnerability assessment

# Key Activity Types

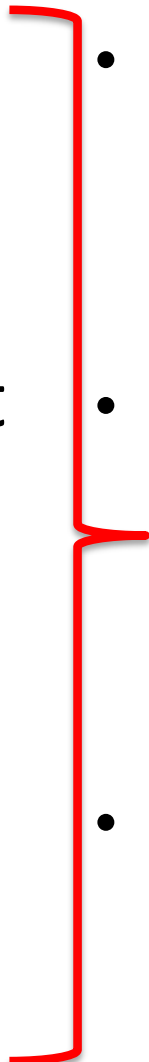
# FDA Vulnerability Assessments

- HSPD-9 requires FDA to conduct vulnerability assessments of the food system and identify mitigation strategies (issued Jan 2004)
- FDA has conducted assessments on a wide variety of products/processes including:
  - Manufactured food products & processes
  - Retail (Grocery Store & Retail Food Service)
  - Transportation & Distribution
  - Concessions & Catering
- Form the foundation of FDA's food defense program
  - Tools, training, resources, guidance and IA rule are informed by vulnerability assessments

# Identification of Key Activity Types

- FDA food defense VA data analysis shows
  - Certain processing steps repeatedly ranked high across VAs, regardless of food
    - “It is not the food that is vulnerable, it is what we do to the food that makes it vulnerable” – R. Newkirk
  - Focus on the activity being conducted at high ranking processing steps
  - Common vulnerabilities can be organized into generalized activity groups
    - = FDA Identified Key Activity Types

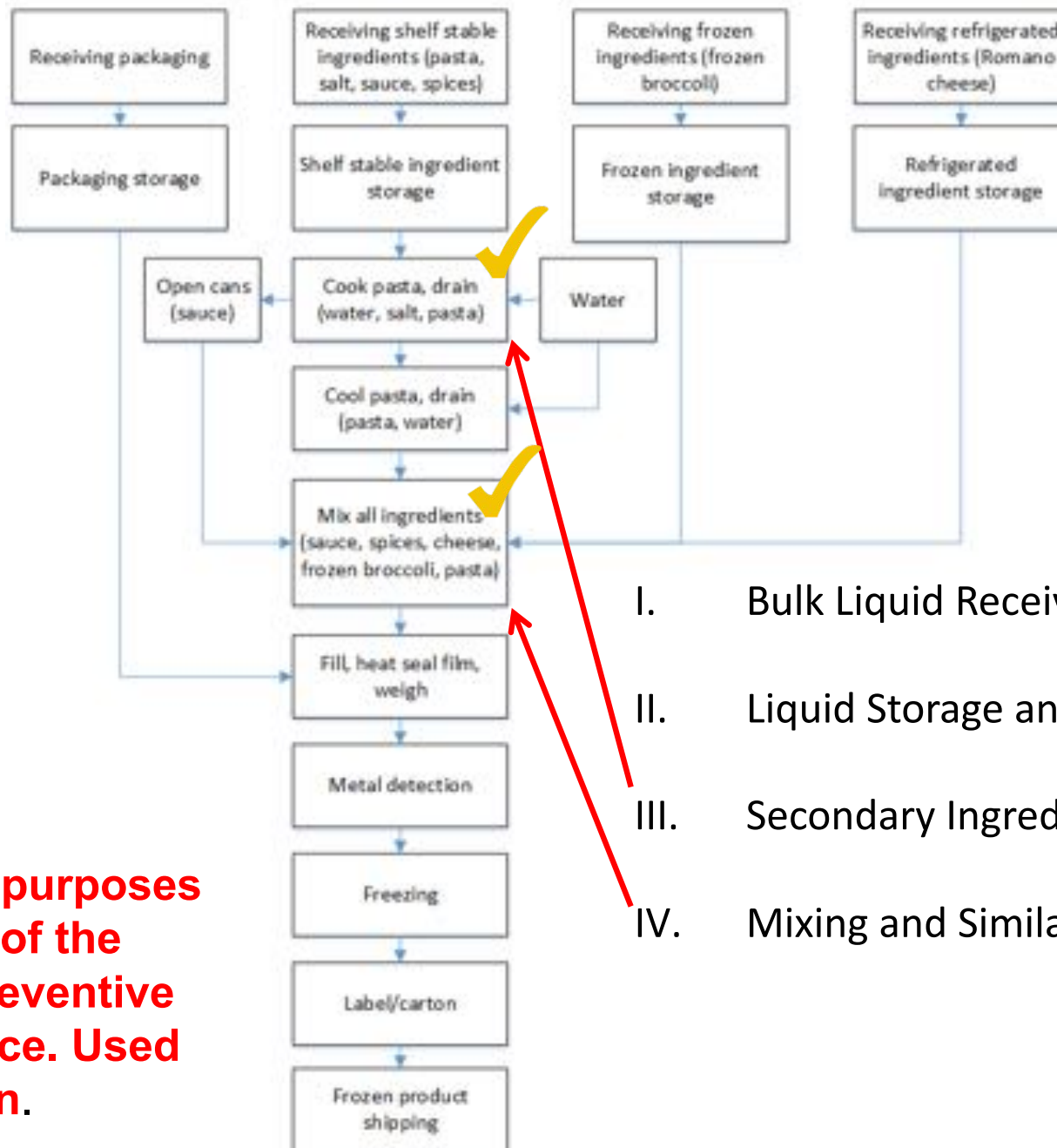
# Key Activity Types

- I. Bulk Liquid Receiving and Loading
  - II. Liquid Storage and Handling
  - III. Secondary Ingredient Handling
  - IV. Mixing and Similar Activities
- High volume of food (Element 1)
  - Increased access (Element 2)
  - Increased vulnerability (Element 3)
- 



# Key Activity Types as a Vulnerability Assessment Method

# Fettuccini Marinara with Broccoli



- I. Bulk Liquid Receiving and Loading
- II. Liquid Storage and Handling
- III. Secondary Ingredient Handling
- IV. Mixing and Similar Activities

**For illustrative purposes only. Courtesy of the Food Safety Preventive Controls Alliance. Used with permission.**

# Mitigation Strategies Requirement

# Key Terms

- **Mitigation Strategies** – mean those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis.



# Requirements for Mitigation Strategies

- Mitigation Strategies must exist for each Actionable Process Step
- Must be identified and written in the food defense plan
- Must include an explanation of how the mitigation strategy(ies) sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step

# Mitigation Strategies



- Based on our vulnerability assessments, we believe that adequate mitigation strategies will be designed to address

Element 2: Degree of physical access to the product

- Locks on hatches
- Restrict access to only a limited number of authorized personnel
- Gates, rails, seals, shields, and other barriers

Element 3: The ability of an attacker to successfully contaminate the product

- Increased observation
- Peer monitoring

- Mitigation Strategies Database can support facility identification of mitigation strategies

# Flexibility for Mitigation Strategies

- Facilities have flexibility to identify and implement mitigation strategies that are most appropriate for the circumstances
  - Tailored to existing facility practices and procedures
  - Designed to address the unique nature of the significant vulnerability
  - Existing facility-wide security measures or other practices may be foundational to a mitigation strategy
  - Existing measures may already be serving as mitigation strategies - document in food defense plan



# Mitigation Strategies Explanation

- Mitigation Strategies must have an explanation in the food defense plan for how the strategy is protective of the actionable process step
  - Can be straight forward and simple, common sense
  - Will facilitate common understanding with inspectors
  - Can inform the development of mitigation strategies management components
  - Integral to the determination of proper and consistent implementation



# 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 – published Aug. 2017

# 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)

Food Defense Plan Quick-Check continues for all firms

Final IA Rule  
May 27, 2016

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

Facility prioritization method development

Facility Food Defense Inspection Workplanning

Food Defense Inspections (Initial Phase)

Food Defense Inspections

# Training Update

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 course – Food Defense Awareness
Supervisors of those individuals assigned to an actionable process step (including temporary and seasonal personnel)	Online course – 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 course – 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 course – 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 course – Mitigation Strategies
Individual(s) conducting or overseeing: <ul style="list-style-type: none"> <li>• Reanalysis</li> </ul>	Online course – Reanalysis

# FDA Food Defense Tools & Resources

