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# **Intentional Adulteration Rule Compliance: Is Your Plant Ready?**

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## Food Safety

- Unintentional
- Ongoing
- “Real” threat
- Easier to anticipate
- Risk assessments identify severity of adverse health outcome
- May involve many illnesses but few deaths

## Commonality

- Minimize adulteration of food
- Risk-based decision making
- Similar sources of contamination
- Focus on prevention at local level
- Common tools, in some instances
- Liability for an event (?)

## Food Defense

- Intentional
- Sporadic
- Plausible, but unknown threat
- More difficult to anticipate
- Vulnerability assessments identify where hazards can be introduced
- Has potential to result in many deaths
- Human element
- Law enforcement involvement

# Critiques of the IA Rule

- Significantly different from current successful practices employed by food manufacturers
- Mitigation strategies FDA suggests lean towards those with large capital investments
- Not flexible enough account for the ever-changing nature of terrorism
- Need more time for food industry training and for FDA to issue final guidance on all elements
- Rule needs to better consider risk and likelihood or probability of IA event



# Challenges for Food Industry

- Intentional adulteration (IA) rule is the first of its kind in the world
- Not many food defense experts
- Most companies have food quality or regulatory manager
  - Job function usually specified to food safety and regulatory compliance
  - Not common to have food defense experts at each facility
  - Just because someone is a food safety expert does not mean that person is a food defense expert
- Agents used in acts of IA can include materials that are not naturally occurring or are not routinely tested for as part of food safety program
- Participating in global food safety schemes and programs such as Customs-Trade Partnership Against Terrorism or Chemical Facility Anti-Terrorism Standard does not substitute for compliance with regulation
- First compliance date is nearing without complete guidance

## Post 9/11 Food Defense Plans

- Voluntarily adopted, but recommended by FDA
- Focused facility wide measures:
  - Physical security (perimeter fencing, locking doors, guards)
  - Visitor management
  - Management practices
    - Employee vetting
    - HR management
  - Crisis management planning

## IA Rule Food Defense Plans

- Mandatory, written with required explanations
- Must cover each type of food produced at a facility
- More targeted than previous mitigation strategies
  - Focus on each actionable step, process, or procedure with a significant vulnerability
  - But can (and should) include facility wide measures
- More elements especially as strategies work to address vulnerabilities

# Building a Food Defense Team and Culture

- Team to conduct the Vulnerability Assessment and implement food defense plan
- Suggest multi-disciplinary team, which include individuals with expertise in day-to-day operations of facility
  - Food safety quality assurance or quality control
  - Supply chain or sourcing
  - Security
  - Maintenance
  - Human Resources
  - Engineering
  - Third-parties (i.e. consultants)
- Must have at least one individual that is Food Defense Qualified Individual
- Food defense awareness and training important for all employees to build a food defense culture within company – many companies are incorporating this training into annual cGMP training

# Choosing Mitigation Strategies

- Are very facility and process specific – what works in your facility might not work in all facilities
- Customized to the process step at which they are applied
- Tailored to existing facility practices and procedures
- Directed toward the actionable process step's vulnerability, including vulnerability to an insider attack
- Can layer many mitigation strategies together so long as significantly minimize or eliminate the vulnerability identified at that actionable process step
- Use your Vulnerability Assessment which provides with the reasons that the actionable process step was significantly vulnerable to help identify an appropriate Mitigation Strategy
- Balance with whether the mitigation strategy will introduce or present a food safety hazard or a workplace safety hazard



# Inside Attacker

- Must be considered in Vulnerability Assessment
- Individual with legitimate access to facility, has a basic understanding of operations and food processed, and **has intent to cause wide scale public health harm**
- Mitigation Strategies should be focused on minimizing the accessibility to and potential to contaminate product by an inside attacker
  - Access based (locks, hatches, alarms)
  - Personnel-management based (employee vetting, reduced accessibility, increased observation)
  - Operations based (relocate ingredient staging, secure open ingredient containers)

## Corrective Actions

- Steps taken when a Mitigation Strategy is not properly implemented
- Corrective Actions ensure that appropriate action is taken:
  - To identify and correct a problem that has occurred in implementing a Mitigation Strategy; and
  - To reduce the likelihood that the problem will reoccur

### Both

- Must be documented!
- Missing key guidance on corrective actions and verification

## Verification

- Methods, procedures or evaluation to verify:
  - Monitoring activities are conducted
  - Corrective actions are made as required
  - Mitigation strategies are properly implemented
- Unlike food safety plan, does not require validation, calibration, or testing

# Confidentiality of Plans and Inspection Outcomes

- Some concern that if Food Defense Plan (FDP) falls into wrong hands then it is a roadmap for a future attack
  - At minimum, the Vulnerability Assessment should be kept confidential
- Unclear how FDA will be handling confidential information during inspections
  - Concerns regarding FDP becoming public record if taken into FDA's possession
  - FOIA exemptions exist for trade secret and commercial confidential information
- How inspectors will document non-compliance?





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**Questions?**



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