FSMA Food Defense: Mitigation Strategies to Protect Food Against Intentional Adulteration

Marie Limoges PhD, RDN

The Intentional Adulteration (IA) Rule

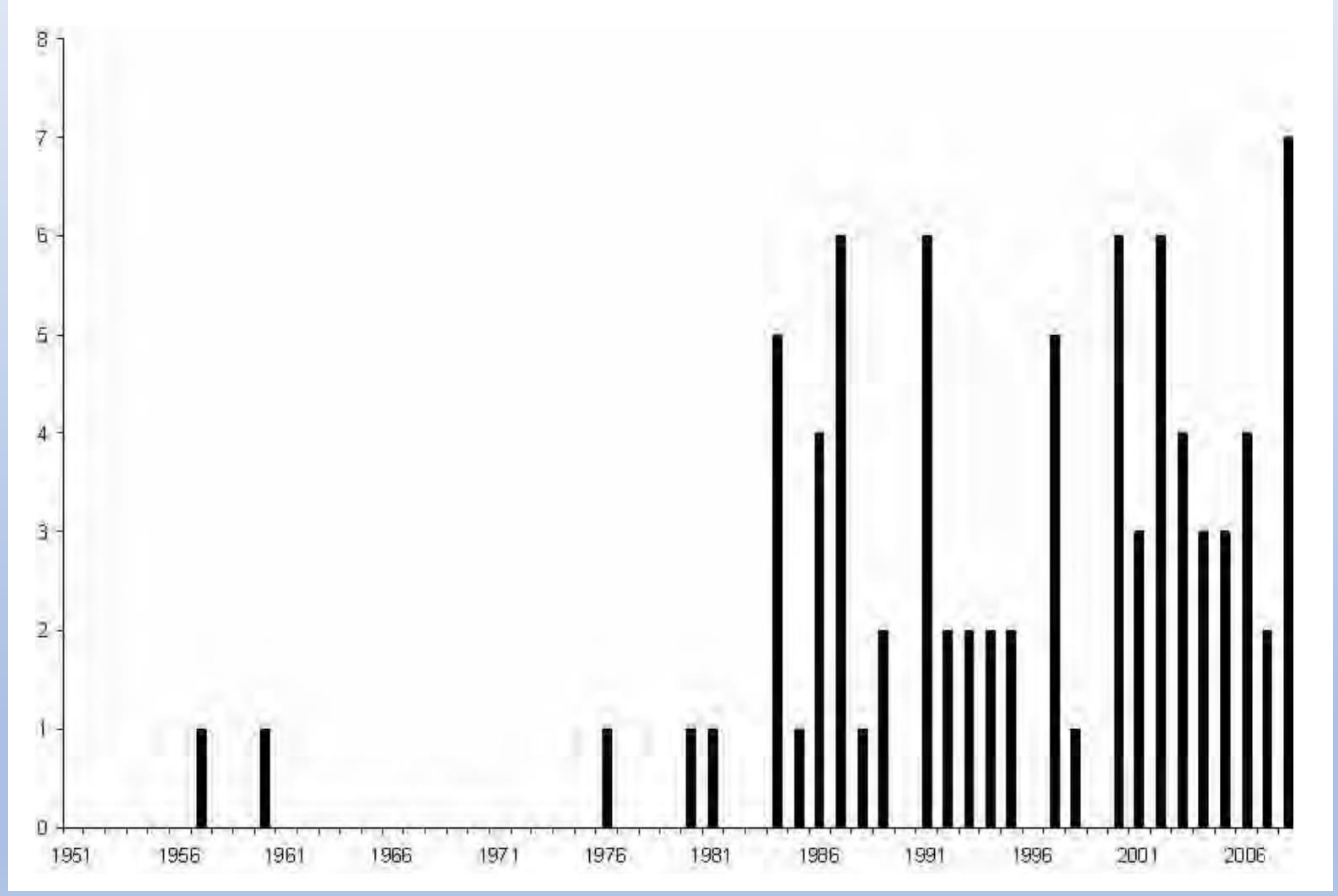
- On May 27th, 2016, the FDA issued the final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration under FSMA with requirements for covered facilities to prepare and implement food defense plans.

- Purpose: to protect food from tampering or other malicious, criminal, or terrorist action which would lead to public health harm.

- Uses a similar HACCP framework with a focus on prevention.

Malicious Acts: Trends (1960-2008)

- 85 cases worldwide
- Agents: Acetone; Arsenic; Atropine; Cyanide; Herbicide; Insecticide; Pesticide; Physical contaminates (various); Rat poison; Rohypnol; Salmonella Typhimurium; Thallium
- Fatalities: 123
- Injuries: 3304



Who Falls Under the Rule?

- All other “domestic or foreign facility that manufactures/processes, packs or holds food for consumption in the United States that is required to register with the FDA” (**compliance deadline was on July 26th, 2019**)
- **Small Businesses**: defined as a “business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees”. **Must comply by July 27, 2020.**

Exemptions:

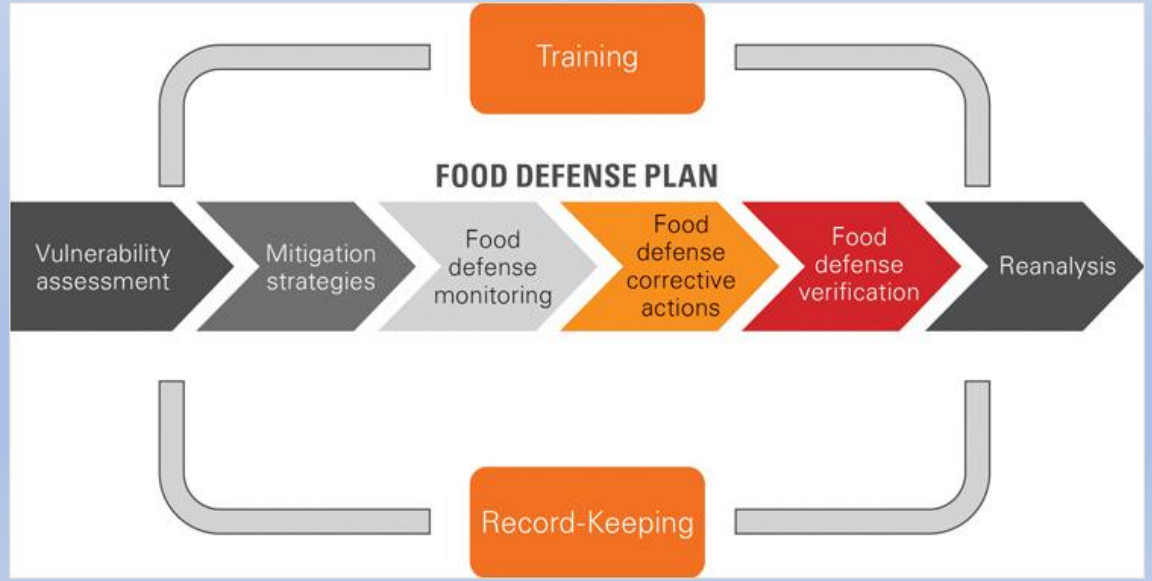
- **Very Small Businesses:** defined as “a business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).”
  - Need to provide documents upon request that demonstrate status as very small business. Such documentation must be retained for two years. **Compliance is expected by July 26, 2021** otherwise.

Other Exemptions

- The establishment does not hold food, except the holding of food in liquid storage tanks.
- The facility packs, re-packs, labels, or re-labels food where the container that directly contacts the food remains intact.
- The facility is a farm mixed-type facility that conducts activities that fall within FDA's "farm" definition.
- The facility manufactures, processes, packs, or hold food for animals.

Requirement Overview

1. Written Food Defense Plan
   - Information adequate to identify the facility (e.g., the name and, when necessary, location of the facility).
   - Vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps.
   - Mitigation strategies, including required explanations.
     - Food defense monitoring procedures
     - Food defense corrective actions procedures
     - Food defense verification procedures
   - Appropriate signature(s)
2. Training for supervisors and personnel
3. Records
4. Periodical reanalysis



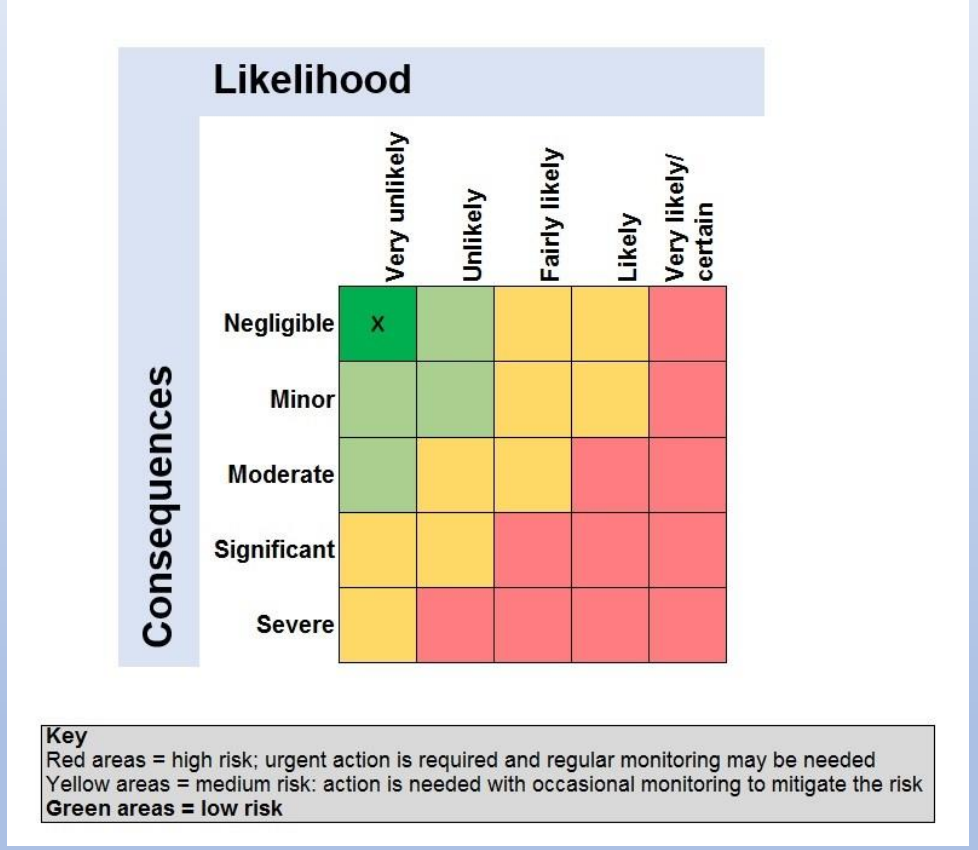
Preliminary Actions

- A **Food Defense Team** must be assembled; a designated coordinator should be responsible for delegating tasks.
- Describe the product(s) under evaluation.
- Use a process flow diagram to describe the process steps.
  - Can assist with implementation of mitigation strategies:
    - What equipment is used for
    - Capacity
    - Volume
    - Access points
    - When does cleaning/routine maintenance occur

Vulnerability Assessment (VA): Risk Mitigation

Objective is to identify significant **vulnerabilities** and **actionable process steps (APS)** for each food item manufactured.

- The severity and scale of the possible impact on public health needs to be evaluated for each point, step, or procedure if IA were to occur.
  - An explanation must be provided as to why a point, step, or procedure was or was not identified as an actionable process step.
  - A written explanation for how each strategy significantly minimizes or prevents the significant vulnerability at that actionable process step is required.
  - FDA's Mitigation Strategy Database
- The degree of physical access to the product.
- The ability of an attacker to successfully contaminate the product.



Vulnerability Assessment (VA): Risk Mitigation

Evaluation must, at least, include the following:

1. The **severity and scale of a public health impact** if a product were contaminated.
   - Volume of product that could be impacted (scale)
     - Number of possible exposures
     - Number of servings impacted at any point
   - The infectious or lethal dose of one contaminant, morbidity/mortality rate- based upon scientific investigation (severity)

2. The **degree of physical accessibility to** product.
   - How likely is it for an intruder to have access to product at any given step.
   - Consider physical barriers such as gates, railings, doors, lids, seals, etc.

3. The **ability of an intruder to successfully contaminate product(s)**
   - Accessibility of introducing a adulterant into product
   - Opportunity for an adulterant to be mixed in successfully
   - How likely an intruder's actions will go unnoticed
   - Consider dilution as processing commences and initial concentration

- Must consider the possibility of an inside attacker (e.g. an employee, contractor, driver, or visitor).

VA Key Activity Types (KAT): Examples

1. Bulk Tank Receiving/Loading

- Inbound/outbound is needed
- Transport vehicle access
  - Main access point and alternates
- Attaching pumping equipment, hoses
- Unloading and loading bulk tank milk

2. Liquid Storage and Handling

3. Secondary Ingredient Handling (process point where dry or liquid secondary ingredients are altered before or during the inclusion step of product processing)

- Staging
- Preparation of ingredients (measuring, weighing, pre-mixing)
- Adding ingredients throughout the product line
- Rework
- Storage of partially used ingredients, where packaging is already opened- easy to breach

4. Mixing, rework, staging, and other like activities (homogenization etc.)

Process Step #	Process Step	Process Description	Vulnerability Assessment Method	Explanation	Actionable Process Step
1	Bulk Tank Milk Receiving	Milk is received from a truck and pumped into a bulk milk tank for storage prior to use.	Key Activity Type	This point, process, or step does fit within a KAT: Bulk Tank Receiving	Yes
2	Packaging Storage	Corrugated boxes and plastic film are stored in a dry storage away from raw and finished foods. The FIFO method is applied when using packaging.	Key Activity Type	This point, process, or step does not fit in with KAT	No

Mitigation Strategies (MS) for Accessibility

Personnel

- Restricting access to authorized employees (e.g., seniority, skill level, background checks)
- Maintaining an updated list of plant personnel with open or restricted access to the establishment should be maintained at the security office
- Easy identification of personnel in the facility (colored hats, garments, etc.)
- Incoming and outgoing vehicles (both private and commercial) should be inspected for unusual cargo or activity

Visitors

- Parking areas for visitors or guests should be designated at a secure distance from the main facility
- Vehicles of authorized visitors, guests and employees should have clear signage (placards, decals etc.)

Mitigation Strategies for Accessibility cont'd

Operations

- Minimize the amount of time ingredients and rework are staged
- Ensure that partially used containers and ingredients are stored in a secure location

Other

- Tamper evident seals
- Locks (auto-lock is preferred if possible)
- Key swipe systems
- Physical barriers (gates, etc.)
- Automated and self-closing equipment

Mitigation Strategies to Reduce IA of Product

Personnel

- Provide an appropriate level of supervision to all staff (cleaning and maintenance staff, contract workers, computer support staff, and new staff)

Operations

- Secondary supervision
- Workers need to check-in with their supervisor
- Ensuring that all activities are moved to areas where supervision can be maintained
- Garments should not have pockets
- Use CIP processing to flush systems if possible
- Truck deliveries should be verified using a roster of scheduled deliveries as well as identification. Any unscheduled deliveries should be held outside the plant premises when possible until verification of the shipper and cargo is completed

Other

- Alerts when gates are left open etc.
- Notifications and alarms
- Motion detectors
- Sensors for when product conditions do not meet spec
- CCTV

Facility-Based Mitigation Strategies

- Conducting routine security checks of the premises, including utilities and critical computer data systems (at a frequency appropriate to the operation)
- Visitor management
- Management and secured storage of hazardous materials
- Crisis management planning
  - Evacuation Plan
- Monitoring of outside storage tanks for hazardous materials and potable water supply to protect from unauthorized access.
- Have procedures in place to notify law enforcement and public health officials

VA are not required to implement mitigation strategies at the facility level

Mitigation Strategies: Management Practices

- An initial assessment of food security procedures and operations should be conducted and kept confidential.
- Crisis management strategy to respond to threats of and events of tampering and other malicious activity, which includes removing and securing impacted product.
  - Identify analytical lab services to use in case of an issue.
- Have access to 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies.
- Staff should be aware of what individual(s) in management should be contacted regarding potential malicious or tampering activity- contacts should be 24 hours.
- Encourage employees to report possible signs of tampering or breaks in the food safety plan.
- Establish an internal communication system to inform and update staff about relevant security issues.
- Ensure that a spokesperson is appointed with addressing the public.
- Perform a mock incident regularly to test the efficacy of the Food Defense plan.

Process Step #	Actionable Process Step	Mitigation Strategy	Explanation
	Bulk Tank Milk Storage	A lock secure access hatch on the tank. Keys can only be accessed by authorized personnel (owner, food defense coordinator).	Milk cannot be accessed with the lock. This reduced the vulnerability and risk at this actionable process step.

Food Defense Monitoring

- Monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed as intended.
- Monitoring can be conducted along with the MS:
  - Inspection of the bulk tank
  - Observation of personnel in the area
- Monitoring does not need to be a continuous practice, can be done at scheduled intervals as needed.
  - FDA does not specify any specific monitoring frequencies for mitigation strategies.

Food Defense Monitoring: Records

- Records: All food defense monitoring activities must be documented which must be verified and reviewed.
  - Checks can be “yes” or “no”.
- Records may be affirmative records or exception records.
  - Exception records are used when the mitigation strategy is not working as expected.
- Records do not have to be in electronic format.
- Records must be created concurrently with performance of the activity documented.
- Records must be retained for at least 2 years after they were prepared. Food defense plans must be retained for 2 years after they have stopped being used.
- Records, with the exception of the Food Safety Plan, can be held offsite.
- All records must be available for official review and copying at the request of FDA.

Food Defense: Corrective Actions

- For each mitigation strategy, corrective actions must be implemented if they are not executed properly.
- The corrective action must describe the proper steps taken to ensure that:
  - Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy
  - Appropriate action is taken, when necessary, to reduce the likelihood that the problem will reoccur
- Records: all food defense corrective actions taken must be documented in records and are subject to verification requirements and records review.

Process Step #	Actionable Process Step	Mitigation Strategy	Food Defense Monitoring Procedure and Frequency	Food Defense Corrective Action Procedures	Food. Defense Verification Procedures	Food Defense Records
	Bulk Tank Milk Receiving	A lock secures the access hatch on the tank. Keys can only be accessed by authorized personnel (owner, food defense coordinator).	Person in charge reviews who milk is being received from.	Guidance TBD	Guidance TBD	Receiving paperwork-checked all necessary information along with monitoring activities.

Food Defense Reanalysis

- A reanalysis of the entire Food Defense Plan must be conducted at least once every 3 years.
- Or a reanalysis of the food defense plan or applicable parts:
  - Before change in activities (including mitigation strategy) at the facility are operative
  - Or within 90-calendar days after production
  - Or within a another reasonable timeframe is also acceptable as long as a written justification is prepared
- If a significant change in the activities conducted at your facility creates a reasonable need for revision after reanalysis, then the Food Defense plan must be updated.
  - Learn from previous activity and threats

Food Defense Verification

- Verify that monitoring is conducted as required.
- Verify that appropriate decisions about corrective actions are being made.
- Verify that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities.
- Verify that a reanalysis of the food defense plan has been conducted, as appropriate
- Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records
- Frequency of which verification activities are to be performed must be established and implemented.
- At least annually, the effectiveness of the security program must be verified (ensure that security contactors are doing the job well).

Record Requirements

- Identification of the facility (e.g., the name, and when necessary, the location of the facility).
- The date and, when appropriate, the time of the activity documented.
- The signature or initials of the person performing the activity (verification, reanalysis, etc.).
- Where appropriate, the identity of the product and the lot code, if any.
- Records must be kept as original records (photocopies or other accurate reproductions of the original records are acceptable) or electronic records.
- Contain the actual values and observations obtained during food defense monitoring.
- Be accurate, indelible, and legible.
- Actions must be documented at time of performance.
- Be as detailed as necessary to provide history of work performed.

Training Requirements

- A qualified individual is defined as “a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity within the IA rule, as appropriate to the individual’s assigned duties.”
  - Individuals assigned to an actionable process step (including temporary and seasonal personnel)
  - Supervisors of those individuals who are assigned to actionable processes
  - Supervisors who are responsible for ensuring compliance
  - Individuals over see the Food Defense Plan, vulnerability assessment, mitigation strategies, and reanalysis
- Training records need to include:
  - Date of training
  - Type of training
  - Individuals who were trained
  - Signatures

Training Tools

- FDA has created an Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance who have developed resources for food defense training.
- Modules based on specialized training requirements.
- Online training:
  - Food Defense Awareness
    - For those who are directly involved in action process steps and their supervisors
  - Food Defense Plan Preparation
  - KATs (Hybrid Vulnerability Assessment)
  - Mitigation Strategies
  - Reanalysis
- 1 day in-person training:
  - Vulnerability Assessment

Conclusion

- IA is an preventative measure that requires thorough assessment for successful implementation.
- In order to get the best results, IA requires individualized plans for each facility.

Resources

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-mitigation-strategies-protect-food-against-intentional-adulteration
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-mitigation-strategies-protect-food-against-intentional-adulteration
- The Food and Drug Administration (FDA) Food Defense website: http://www.fda.gov/food/fooddefense/
- Guidance for Industry: Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (2007) - http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm082751.htm
- "If You See Something, Say Something" Campaign:http://www.fda.gov/downloads/Food/FoodDefense/UCM245306.pdf (English Version)
- Active Shooter Preparedness: http://www.dhs.gov/active-shooter-preparednessCommercial Facilities Resources: http://www.dhs.gov/commercial-facilities-resources
- Counter-Improvised Explosive Device (IED) Training & Awareness:http://www.dhs.gov/bombing-prevention-training
- The U.S. Postal Service has prepared guidance for identifying and handling suspicious mail. It is available at: http://www.usps.com/news/2001/press/mailsecurity/postcard.htm.
- The Federal Anti-Tampering Act (18 USC 1365) makes it a federal crime to tamper with or taint a consumer product, or to attempt, threaten or conspire to tamper with or taint a consumer product, or make a false statement about having tampered with or tainted a consumer product. The Act is available at: Federal Anti-Tampering Act (PDF).
- https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials
    - https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder
    - https://www.fda.gov/food/food-defense-tools-educational-materials/mitigation-strategies-database

Marie Limoges PhD, RDN Contact Info

- Email: mlimoges12@gmail.com
- Cell: 347-416-3761