Hogan Lovells

california almonds
Almond Board of California

FSMA: What's Next & FDA's Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration

21st Annual Almond Quality & Food Safety Symposium

June 13, 2019

Agenda

- What's Next in FSMA
- Introduction and overview for the IA rule
- Review of specific requirements
- Compliance dates
- FDA inspection plans
- Questions and answe

FSMA: What's Next

- Revised farm definition?
- Rulemaking on "written assurances"
- Solution for co-manufacturers?
- Additional Guidance
  - App. 1
  - NRTE/RTE
  - *Salmonella*
- Intentional Adulteration rule compliance dates
- Escalating inspections and enforcement
  - States
  - 483s
  - Discussion points

Overview of the Intentional Adulteration Rule

- Purpose: To protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm
  - Focus is on preventing the actions of an inside attacker
- Uses a HACCP/HARPC framework, with terms modified for the food defense context (e.g., “food defense monitoring”)

→ This is a shift in thinking about food defense – what to protect against and how to do it

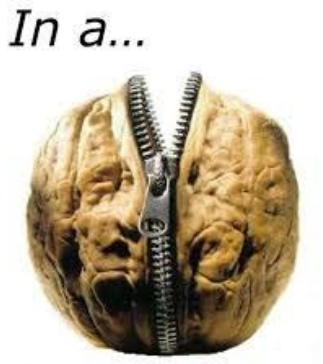
vs.

Who is Covered by the Rule?

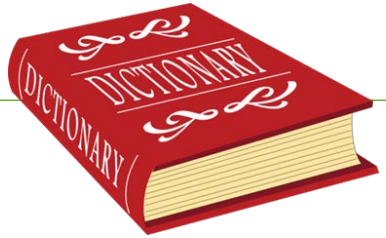
- Facilities that manufacture, process, pack or hold food for human consumption
  - Facilities that register with FDA
  - Foreign and domestic
  - Note: FDA enforcement discretion from PC for farm like facilities doesn't extend to this rule
- Key Exemptions:
  - **Very small businesses (those businesses, including affiliates and subsidiaries, averaging less than $10 million in sales of human food, plus the market value of human food manufactured, packed or held without sale)**
  - Holding food, except holding food in liquid storage tanks
  - Packing, re-packing, labeling, or re-labeling food where the container that directly contacts the food remains intact
  - Manufacturing, processing, packing or holding food for animals

Overview of the Requirements

- Create a Food Defense Plan
  - Conduct a written vulnerability assessment to identify significant vulnerabilities and actionable process steps
  - Develop and implement written mitigation strategies at actionable process steps
  - Develop and implement written food defense monitoring procedures
  - Develop and implement written food defense corrective action procedures
  - Develop and implement written food defense verification procedures
- Engage in reanalysis periodically
- Document everything in records
- Train employees



Definitions



- ***Food defense*** means, for purposes of this part, the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.
- ***Vulnerability*** means the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.
- ***Significant vulnerability*** means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (*e.g.*, severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.
- ***Actionable process step*** means a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.
- ***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.

Vulnerability Assessment

- Conduct a vulnerability assessment for each type of food at your facility using appropriate methods to evaluate each point, step, or procedure in your operation **to identify significant vulnerabilities and actionable process steps**
  - **Identify those points at highest risk**
- Must be written regardless of outcome
- Must include **an explanation** of why each point, step, or procedure either was or was not identified as an actionable process step

Vulnerability Assessment continued…

- Can use "any appropriate method, but it must include, at a minimum, an evaluation of:
  - (1) The **potential public health impact** (*e.g.*, severity and scale) if a contaminant were added;
    - Volume of product impacted
    - Number of risk servings generated
    - Number potential exposures
    - As appropriate and with sufficient scientific rigor: food velocity, agents of concern, infectious or lethal dose, morbidity/mortality rate
  - (2) The **degree of physical access** to the product; and
    - Ability of an attacker to attack at the particular processing step
    - Openness of the processing step to intentional adulteration based on physical barriers such as gates, railings, doors, lids, seals, shields
  - (3) The **ability of an attacker to successfully contaminate the product**
    - Ease of introducing an agent
    - Ability for agent to be uniformly mixed or evenly applied
    - Ability of an attacker to work unobserved
    - As appropriate and with sufficient scientific rigor: amount of agent required, downstream dilution, concentration or processing, and ability of attacker to successfully introduce sufficient volume of agent without being detected or interdicted
- You must consider the possibility of an **inside attacker**

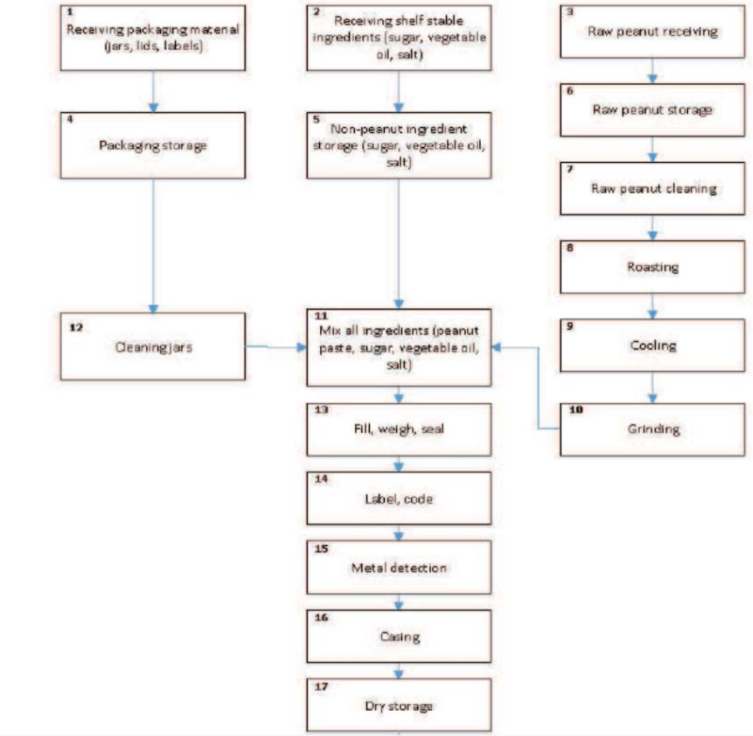
The Inside Attacker

- When evaluating the 3 elements for each point, step, or procedure, you must consider the possibility of the inside attacker
- Assume:
  - The inside attacker has legitimate access to the facility (e.g. an employee, contractor, driver, or visitor)
  - The inside attacker has a basic understanding of the facility's operations and the food being produced
  - The inside attacker has the intent to cause wide scale public health harm

Vulnerability Assessments: Recommended Preliminary Steps

- Assemble a Food Defense Team
- Describe the product under evaluation
- Develop a process flow diagram
- Describe the process steps
  - Makes it more accurate
  - Can assist with mitigation strategies
  - Example: Raw juice surge tanks –
    - what used for
    - capacity
    - typical volume
    - resident time
    - accessible points
    - cleaning, etc.

Figure 2a-1. Smooth Peanut Butter Process Flow Diagram[4]



One Appropriate Method for a VA = KAT Method

- Key Activity Types (KATs) – reflects consideration of criticality, accessibility and vulnerability from CARVER + Shock
  - (1)bulk liquid receiving and loading; (2) liquid storage and handling; (3) secondary ingredient handling; and (4) mixing and similar activities

KAT: Bulk Liquid Receiving and Loading

- Inbound/outbound
- Opening the transport vehicle
- Opening venting hatches or other access points
- Attaching pumping equipment, hoses
- Loading/unloading the bulk liquid
- Does NOT include:
  - Receiving loading sealed jugs, drums, jars, totes because liquid isn't using the vehicle as the bulk container

KAT: Liquid Storage and Handling

- Storage or holding of liquids (**bulk or non-bulk**)
  - Tanks
  - Silos
  - Totes and other containers where the tamper evident seals are opened, the container is used for storage, and the container is not resealed in a tamper-evident fashion
  - Handling, metering, surge or other types of intermediate processing tanks used to control flow or product
    - Can include totes or drums where seals are opened and the container is used as handling tank (attach a pump directly to a drum)

KAT: Secondary Ingredient Handling

- Any place where dry or liquid secondary ingredients are manipulated by human contact prior to or during addition to the product stream
  - Staging
  - Preparation (e.g., measuring, weighing, pre-mixing)
  - Addition to the product stream
  - Rework
  - Storage of partially used, open containers of secondary ingredients where tamper-evident packaging has been breached

KAT: Mixing and Similar Activities

- Mixing
- Homogenizing
- Grinding
- Coating
- Process steps not designed to evenly mix product, but where mixing is the result:
  - Nut roaster uses paddles to achieve an even roast

Identifying APS Using the KAT Method

- Process steps that fit within one or more KATs are actionable process steps (APS)
- Process steps that do not fit within any of the KATs are not actionable process steps and do not require mitigation strategies

Identifying APS Using the 3 Fundamental Elements

- Can use the 3 fundamental elements alone or in conjunction with the KAT method (“hybrid approach”)
- Need to be a “qualified individual” to use the 3 fundamental elements
  - In-person FSPCA training course
- Why do it this way?
  - More tailored VA
  - Allows you to conclude that certain steps are not APS, even though they are a KAT
- FDA explains how to use the 3 fundamental in the version of the Draft Guidance released March 2019

Written Explanations

- VA must include a written explanation as to why each point, step, or procedure was or was not identified as an APS
  - Can use abbreviations or footnotes
  - If it is an APS, should identify which KAT

Example

(1) #	(2) Process Step	(3) Process Description	(4) Vulnerability Assessment Method	(5) Explanation	(6) Actionable Process Step
3	Raw peanut receiving	Shelled peanuts are received on trucks from several sheller domestic locations in 2000 lb. super sacks.	Key Activity Type	This point, step, or procedure does not fit within any of the KATs.	**No**
4	Packaging storage	Corrugate, shrink film, plastic containers, plastic lids, and labels are stored in a dry storage area and segregated from raw food material. Packaging is used on a first-in-first-out basis.	Key Activity Type	This point, step, or procedure does not fit within any of the KATs.	**No**
5	Non-peanut ingredient storage	Sugar, hydrogenated vegetable oil, and salt are received and stored at ambient conditions in an area separate from raw peanuts. Ingredients are stored in tamper-evident sealed containers. These materials are used on a first-in-first-out basis. Open containers of partially used ingredients may be put back into storage for later use.	Key Activity Type	This point, step, or procedure fits within the KAT- Secondary Ingredient Handling since partially used ingredient containers are open containers that are accessible.	**Yes**

Mitigation Strategies

- Identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability will be minimized or prevented
  - Must be written
  - FDA's Mitigation Strategies Database can be a resource
- You must include a written explanation of how the mitigation strategy will be effective
  - Generally should address how the mitigation strategy affects
    - (1) the accessibility of the product to an attacker; and/or
    - (2) the opportunity for an attacker to successfully contaminate the product

Mitigation Strategies that Minimize Accessibility

- Personnel-Based
  - Restricting access to authorized employees (e.g., seniority, skill level, background checks)
  - Identify in some way (e.g., colored hats)
  - Train to identify, handle situations
- Operations-Based
  - Reducing staging time of ingredients and rework
  - Relocating partially used open containers to a secure location
- Technology-Assisted
  - Tamper evident seals
  - Locks
  - Key swipe entry systems
  - Barriers
  - Automated and enclosed equipment

MS that Reduce the Ability to Contaminate Product

- Personnel-Based
  - Peer monitoring
- Operations Based
  - Increased supervision
  - Requiring workers to check-in with a supervisor
  - Moving activities to increase observation
  - Requiring workers to wear uniforms without pockets or means of concealing items
  - Altering visual inspection procedures
  - Using CIP equipment of flushing equipment
  - Requiring driver check-in and identification
  - Accepting only scheduled deliveries from known suppliers

MS that Reduce the Ability to Contaminate Product contin.

- Technology-assisted
  - Alerts
  - Notifications
  - Alarms
  - Motion detection equipment
  - Sensors regarding product conditions
  - CCTV

Facility Wide Measures

- Facility wide measures: general, non-targeted protective measures implemented at the facility wide-level to protect personnel, property, or product
  - Physical security (perimeter fencing, locking doors)
  - Personnel security
  - Visitor management
  - Securing hazardous materials
  - Management practices
  - Crisis management planning

- Don't require a VA to inform identification and implementation
- May be MS if it specifically addresses a SV at an APS, needs management components

Role of Existing Measures

- Consider whether they can be mitigation strategies in current or altered form; do not consider them during the VA
  - VA is done 'in the absence of control'
- Examples:
  - Use of senior worker at a process step
  - Use of a buddy system for worker safety
  - Use of seals for product quality and integrity reasons
  - Inspection following cleaning procedures
  - Prohibition on personnel articles on the plant floor

- If functioning as a MS, management components are needed, but only at the APS (not throughout the facility)

Written Explanations

- FDP must include a written explanation of how the MS will significantly minimize or prevent each significant vulnerability
  - Abbreviations or footnotes can be used
  - Generally address accessibility, vulnerability, or both elements
  - Can be brief and straightforward, but may be lengthier if using multiple MS
- Explain thinking, ensure appropriate MS chosen, implementation, facilitates inspections

Examples of Written Explanations - Scenario 1

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Liquid ingredient storage tank	Use a lock to secure access hatch on ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator.	The lock on the hatch renders the food in the tank inaccessible to an attacker, including an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step.

Examples of Written Explanations – Part of Scenario 2

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Bulk liquid receiving	Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	Having the employee responsible for reviewing shipping documentation visually observe the opening of venting and sampling hatches as well as the hooking up of hoses and pumping equipment significantly reduces the ability of an attacker to introduce a contaminant either to the conveyance via the venting or sampling hatches, or into the hoses prior to unloading without being detected.

Examples of Written Explanations – Scenario 3

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Liquid food storage tank	Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning.	The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to ensure no contamination occurred. The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior.

Management Components

- Mitigation strategies are subject to the following management components, ***as appropriate*** to ensure the proper implementation of the mitigation strategies, ***taking into account the nature of each such mitigation strategy and its role in the facility's food defense system***:
  - Food defense monitoring
  - Food defense corrective actions
  - Food defense verification

Food Defense Monitoring

- Establish and implement written procedures, including the frequency with which they are to be performed, for food defense monitoring of the mitigation strategies.
- Monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed
- Document the food defense monitoring

What and How to Monitor

- Based on nature of the MS
  - Lock or seal in place
  - Inside of liquid storage tank
  - Shipment matches scheduled delivery information
- May be already being performed for another reason
- May occur concurrent with implementation
  - Inspecting tank
  - Authorized personnel observing whether unauthorized personnel are in the area
- Can be non-continuous
- May be at irregular intervals

Monitoring Records

- Must document monitoring, records subject to verification and records review
- Documentation can be “yes” or “no”
- Exception records: a record of when the MS is not functioning as intended
  - Alarm sounds and record generated when gate left open too long
  - Authorized personnel noting when unauthorized personnel in area
  - Personal items found in area around APS
- Exception records not appropriate where MS implemented to maintain a static situation that is not under constant monitoring (e.g., lock)

Examples

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action Procedures	(6) Food Defense Verification Procedures	(7) Food Defense Records
	Bulk liquid receiving	Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.	Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery.	*Guidance forthcoming*	*Guidance forthcoming*	Receiving/delivery paperwork that includes additional information to indicate monitoring was completed
	Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	After daily operations, supply chain supervisor confirms that the hose cap is on and taped.	*Guidance forthcoming*	*Guidance forthcoming*	Food defense monitoring log

Examples

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action Procedures	(6) Food Defense Verification Procedures	(7) Food Defense Records
	Bulk liquid receiving	Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	On a periodic basis (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	*Guidance forthcoming*	*Guidance forthcoming*	Food defense monitoring log

Food Defense Corrective Actions

- Must establish and implement written food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented
- The food defense corrective action procedures must describe the steps to be taken to ensure that:
  - Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and
  - Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur
- Corrective actions must be documented
- There is no provision for “corrections”

Food Defense Verification

- Must establish and implement written verification procedures, including the frequency for performing record reviews
- Verification activities must include:
  - Verification that food defense monitoring is being conducted
  - Verification that appropriate decisions about food defense corrective actions are being made
  - Verification of reanalysis
  - Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities, including:
    - Reviewing monitoring and corrective action records within appropriate timeframes
    - Other activities appropriate for verification of proper implementation of mitigation strategies (e.g., supervisor observing monitoring)
- Verification activities must be documented

Reanalysis

- Must conduct a reanalysis of the food defense plan, as a whole at least once every 3 years
- Must reanalyze part of or the whole plan:
  - (1) Whenever a significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability;
  - (2) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;
  - (3) Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and
  - (4) Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

Recordkeeping

- Records need to be:
  - Originals, true copies, or electronic records
  - Contain actual values and observations
  - Be accurate, indelible, and legible
  - Be created concurrently with performance of the activity documented
  - Be as detailed as necessary to provide history of the work performed
  - Include:
    - Information adequate to identify the facility (e.g., name and location)
    - Date and, when appropriate, the time of activity documented
    - Signature/initials of person performing the activity
    - Where appropriate the identity of the product and production code

Recordkeeping continued…

- Location:
  - Retained for 2 years
  - Food defense plan must always remain on-site and must be retained for 2 years after its use is discontinued
  - Electronic records considered on-site if accessible from onsite
- Electronic records are exempt from Part 11
- Access:
  - All required records must be made promptly available to FDA upon oral or written request
  - Records are subject to disclosure under the FOIA, but likely will be withheld from disclosure because they will fall under the standard disclosure exemptions
    - Food defense plans generally considered “trade secret” and “compiled for law enforcement purposes [and which production of] could reasonably be expected to endanger the life or physical safety of any individual”

Training Requirements

1. Each individual who performs activities required under the regulation (e.g., engages in food defense monitoring, food defense corrective actions) must be a "qualified individual"
   - Must have the education, training, or experience (or a combination thereof) necessary to perform the required activities, as appropriate to their assigned duties
2. Each individual assigned to an actionable process step and their supervisors must:
   - Be a "qualified individual" (i.e., have the appropriate education, training, and/or experience necessary to properly implement the mitigation strategy); and
   - Receive training in food defense awareness
3. Responsibility for ensuring compliance with the requirements under the rule must be assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities

Training Requirements

4. There are specialized training requirements for the following activities:
   - Preparation of the food defense plan;
   - Conducting a vulnerability assessment;
   - Identification and explanation of required mitigation strategies; and
   - Reanalysis

These individuals must:

- Be a “qualified individual” (i.e., have the appropriate education, training, and/or experience necessary to properly perform these activities); and
- Successfully complete training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities

Training Resources

- FDA has established an Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance to develop food defense training resources for industry (and regulators)
  - Module-based approach with certain modules varying based on the difficulty and skill level of the activity being performed

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Training Overview

Role of Individual	Method of Training
Employees assigned to Actionable Process Steps and their supervisors	Online course – Food Defense Awareness
Preparation of the Food Defense Plan	Online course – Food Defense Plan Preparation
Conducting the Vulnerability Assessment	In person- 1 day training
Conducting the Vulnerability Assessment Using Key Activity Types	Online course - KATs
Identification and explanation of mitigation strategies	Online course – mitigation strategies
Reanalysis	Online course - reanalysis

Compliance Dates

Business Type	Time Until Compliance	Compliance Date
Large Business (anyone who is not small or very small)	3 years	July 26, 2019
Small Businesses (including any affiliates and subsidiaries employing fewer than 500 full-equivalent employees)	4 years	July 27, 2020
Very Small Businesses (under $10 million) * Only requirement is to provide documentation upon request to show that they meet this exemption. This documentation must be retained for 2 years.	5 years	July 26, 2021

Inspectional Framework

- Staged implementation
  - Food Defense Plan Quick-Check
    - All covered facilities
    - Part of routine inspection
    - Training via webinar
  - Food Defense Plan Comprehensive Inspection
    - Limited number of priority facilities
    - Specialized training and inspection force
    - Regulator training in-person
- Event and need-based assignments continue

Conclusion

- IA is a first-of-its-kind regulation and will require careful focus for successful implementation
- Compliance will involve more than just revising and updating existing plans
- Review of Guidance is essential
  - Many things clarified and explained
  - Flexibility in some areas, more prescriptive in others
- Almond Board of California is here to help!
  - Vulnerability Assessment template?

Questions?

Contact Information

Elizabeth Fawell, Partner
(202) 637-6810
Elizabeth.Fawell@hoganlovells.com