FDA’s Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration

Webinar for the American Frozen Food Institute

June 27, 2016
Agenda

• Introduction and Overview
• Highlights from the Final Rule
• Review of specific requirements
• Compliance dates
• Questions and answers
Every company should conduct its own detailed review of the final rule

This presentation provides an overview and uses shorthand, so it should not be relied on as a substitute for reading the final rule, obtaining legal advice, or as a summary of all regulatory requirements.
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

• Applies to:
  – Registered Food Facilities: Domestic and foreign facilities engaged in the manufacturing, processing, packing, or holding of food for human consumption in the United States
    – Unless covered by a specific exemption

• Uses a HACCP/HARPC framework, with terms modified for the food defense context (e.g., “food defense monitoring”)

• Extended compliance dates (earliest is 3 years)
Exemptions

• The rule does not apply to:
  – 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
  – Farm activities at farm mixed-type facilities
  – Manufacturing, processing, packing or holding food for animals
  – On-farm manufacturing, processing, packing or holding the following foods on a farm mixed type facility when conducted by a small business if they are the only activities conducted:
    – Eggs (in shell, pasteurized)
    – Game meats (whole or cut, not ground or shredded, without secondary ingredients)
  – Pre-packaged foods and alcoholic beverages at certain alcoholic beverage facilities
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 for 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
Highlights of the Final Rule

• Removes Key Activity Types (KATs) from the regulation, but still permissible to rely on KATs to conduct a vulnerability assessment and they will be discussed in guidance

• Specifies 3 elements that must be considered during vulnerability assessment

• Requires consideration of each point, step, or procedure in the food operation as part of the vulnerability assessment

• Adds requirement to consider the possibility of an inside attacker

• Removes the distinction between “broad” and “focused” mitigation strategies
Highlights of the Final Rule

• Additional requirements to provide written explanations of the reasoning behind certain conclusions

• Makes mitigation strategy management components more flexible

• Renames mitigation strategy management components to emphasis role for “food defense”

• Provides for the use of “exception records”

• Exempts electronic records from compliance with Part 11

• Adds training requirements for employees conducting activities under the rule, including FSPCA-IA training
What’s a Food Defense Plan?

• The written food defense plan must include:
  – (1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps, as required by § 121.130(c);
  – (2) The written mitigation strategies, including required explanations, as required by 121.135(b);
  – (3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies, as required by 121.140(a);
  – (4) The written procedures for food defense corrective actions, as required by 1221.145(a)(1); and
  – (5) The written procedures for food defense verification, as required by 121.150(b).
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.

• 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.

• You can use any appropriate method.
  – Can identify actionable process steps using the four Key Activity Types (KATs), which will be in guidance.
    – KATs: (1) bulk liquid receiving and loading; (2) liquid storage and handling; (3) secondary ingredient handling; and (4) mixing and similar activities.
Vulnerability Assessment continued...

- Must include 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**
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
Broad vs. Focused Mitigation Strategies

- The proposed rule only required “focused” mitigation strategies because “broad” mitigation strategies, such as a fence around the entire facility, did not protect specific points from being attacked by an insider.

- The final rule does not distinguish between “broad” and “focused” mitigation strategies.

- FDA continues to believe that general facility-level protections are not adequate because they do not address an inside attacker who has legitimately obtained access to the facility.
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
  – May be affirmative or exception records (demonstrating the mitigation is not functioning as intended)
  – Example: key card entry systems vs. adequate lighting
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

• 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.
Reanalysis continued...

• Complete the reanalysis and implement any additional mitigation strategies:
  – Before the change in activities at the facility is operative
  – When necessary within 90 days after production
  – Within a reasonable time frame, provided a written justification is prepared

• Revise the food defense plan if appropriate or document the basis for concluding no changes are needed
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”
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 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
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
Role of Existing Food Defense Plans

- Existing food defense plans that were built in reliance on FDA’s existing tools are “not adequate” to substitute for meeting the requirements of this rule.

- Participation with global food safety schemes and programs such as C-TPAT, CFATS, or FSIS also is not a substitute for compliance with this rule. However, these programs decrease a facility’s vulnerability to intentional adulteration and can work in concert with the requirements of the final rule.
  - A facility’s participation in such programs may be considered by FDA as it prioritizes risk-based inspections.

“We recognize that some facilities have already voluntarily developed and implemented food defense plans. These facilities likely have a head start on compliance with this rule.”

81 Fed. Reg. 34166, 34195 (May 27, 2016)
Guidance & Resources

- Existing FDA tools will be updated (e.g., Food Defense Plan Builder)

- FDA will develop fact sheets, FAQ documents, guidance, and other informational materials to support compliance
## Compliance Dates

<table>
<thead>
<tr>
<th>Business Type</th>
<th>Time Until Compliance</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Business (anyone who is not small or very small)</td>
<td>3 years</td>
<td>July 26, 2019</td>
</tr>
<tr>
<td>Small Businesses (including any affiliates and subsidiaries employing fewer than 500 full-equivalent employees)</td>
<td>4 years</td>
<td>July 27, 2020</td>
</tr>
<tr>
<td>Very Small Businesses (under $10 million)</td>
<td>5 years</td>
<td>July 26, 2021</td>
</tr>
</tbody>
</table>

* Only requirement is to provide documentation upon request to show that they meet this exemption. This documentation must be retained for 2 years.
1. The rule affects most food manufacturing facilities, but note the broad exemption for “very small businesses” (under $10 million)

2. FDA revised the rule in some respects to make it more flexible (e.g., management components)...

3. ...but in other places the rule is more prescriptive (e.g., the vulnerability assessment)

4. Key Activity Types are not in the regulation, but will be in guidance

5. Detailed requirements for the vulnerability assessment and mitigation strategies (and explanations) will require careful attention
10 Key Takeaways, continued...

6. Employee training is an integral part of implementation

7. As always, recordkeeping matters

8. Records generally will be exempt from FOIA disclosure

9. Companies with existing food defense plans will be on their way to compliance, but still have significant work to do

10. Extended compliance dates of at least 3 years
Conclusion

• This is the 7th, and final, major FSMA regulation
• Issuing all 7 regulations by the court-ordered deadlines is a major accomplishment
• FDA will now focus efforts to the implementation phase
• Guidance development will be a significant undertaking
  – Opportunity to provide comments on draft guidance
• There are open questions about how food defense plans will be inspected, but FDA has built in time to figure this out
• Food defense is a first-of-its-kind regulation and will require careful focus for successful implementation
Questions?
Contact Information

Maile Hermida, Partner
(202) 637-5428
Maile.Hermida@hoganlovells.com

Elizabeth Fawell, Counsel
(202) 637-6810
Elizabeth.Fawell@hoganlovells.com
FDA’s Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration

Webinar for the American Frozen Food Institute

June 27, 2016