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FSMA Major Rules Series

FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

Welcome and let's explore the final rule in this series under the Food Safety Modernization Act (FSMA), the Intentional Adulteration (IA) Rule.

This rule is designed to prevent intentional adulteration intended to cause widespread harm to public health, including potential terrorist attacks on the food supply. While such acts could also stem from disgruntled employees or economic motives, this rule specifically targets those aiming to cause widespread public health damage. Economic adulteration is separately addressed in the final preventive controls rules for human and animal foods which we covered in a previous article. *Read article*

Although the type of incidents considered are unlikely, they could lead to significant illness, death, and economic disruption if not mitigated. Instead of focusing on specific foods or hazards, this rule mandates the implementation of risk-reducing strategies for processes in certain registered food facilities[1].

Originally proposed in 2013, the Intentional Adulteration rule was finalized on May 27, 2016, and its compliance dates were phased in over several years, with full compliance required by July 26, 2019. The rule mandates that food facilities develop and implement food defense plans designed to prevent intentional adulteration. Interestingly, when creating this rule, the FDA collaborated with the intelligence community and analyzed vulnerability assessments with the food industry drawing on broad expertise.

Note: This rule is designed to cover large companies which are regulated by the FDA (US or abroad) and whose products reach many people, exempting smaller companies. It does not cover farms, animal feed and other small category exceptions which are explained in a flowchart on the FDA website[2] or within further guidance documents[3].

1. FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration | FDA
2. Does the final rule on intentional adulteration apply to me? Does the final rule on intentional adulteration apply to me? Does the final rule on international adulteration apply to me? (fda.gov)
3. Small Entity Compliance Guide: Mitigation Strategies to Protect Food Against Intentional Adulteration | FDA

Key Requirements:

Every applicable facility must develop a written food defense plan that includes vulnerability assessments, mitigation strategies, and monitoring procedures. This plan must be reviewed and updated regularly to ensure ongoing protection against intentional adulteration following and including as a minimum the items listed below.

1. Vulnerability Assessment:

Facilities must conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps. This includes evaluating potential risks in areas such as ingredient handling, mixing, and packaging.

Example: *A beverage manufacturer identifies the bulk liquid storage tanks as a vulnerable point. These are more vulnerable as they are outside with easier access and fewer people around to monitor, impact of tampering would also be widespread due to the bulk material being used in multiple products.*

2. Mitigation Strategies:

Based on the vulnerability assessment, facilities must implement mitigation strategies to address significant vulnerabilities. These strategies should be tailored to the specific risks identified and include measures like physical barriers, monitoring, and personnel controls.

Example: *A sports nutrition company installs tamper-evident seals on all ingredient containers and bulk silos. Ingredient use requires double verification or sign off for ingredient handling to prevent intentional contamination. Bulk silos are locked with strict access control and monitored by CCTV.*

3. Monitoring and Corrective Actions:

Facilities must establish and implement procedures to monitor the effectiveness of mitigation strategies. This includes regular inspections and immediate corrective actions if a strategy is found to be ineffective.

Example: *A large dairy processing plant uses electronic monitoring of access points to restricted areas through access codes, swipe-cards and CCTV recognition systems. This is tested regularly and if it fails or if an actual breach occurs, the system triggers an alarm and initiates an investigation protocol.*

4. Training and Records Keeping:

Personnel involved in implementing the food defense plan must receive adequate training. Facilities must also maintain records of vulnerability assessments, mitigation strategies, monitoring activities, and corrective actions.

Example: *A frozen food distributor conducts quarterly training sessions on food defense protocols and maintains detailed records of all training activities, monitoring results, and corrective actions for audit purposes. They also add food defense incidents into their BCP scenarios and test these annually using simulation exercises with a third party provider.*

Additional Considerations:

- **Reanalysis:** Specifically, the reanalysis requirement is detailed in the regulations as follows:
  - Every Three Years: A complete reanalysis of the food defense plan is mandated at least once every three years to ensure it continues to address current vulnerabilities and mitigation strategies effectively.
  - Upon Significant Changes: Reanalysis is also required when there are significant changes to the activities conducted at the facility, the production processes, or if new information about potential vulnerabilities becomes available. This includes changes in the production line, introduction of new ingredients, or alterations in the facility layout.
  - Failure of Mitigation Strategies: If any mitigation strategy is found to be improperly implemented or if it fails, a reanalysis must be conducted to address these issues and update the food defense plan accordingly

- **Integration with Food Safety Plans:**
  - While the food defense plan focuses on intentional adulteration, it should be integrated with other food safety plans to ensure a comprehensive approach to food protection.

Summary Food Defense Plan Contents – "What Good Looks Like":

- Identify Significant Vulnerabilities
- Tailored Strategies
- Monitoring Procedures & Checks
- Corrective Actions Well Defined
- Verification Performed and Documented
- Training in Place
- Records readily accessible for review by regulatory authorities.
- Review and Reanalysis is Routinely Evident.
- Integrated into Food Safety and Other Critical Plans.

Summary Requirements

The Intentional Adulteration rule under FSMA represents a proactive approach to food safety, emphasizing the importance of protecting our food supply from intentional harm. Implementing robust food defense plans fosters a culture of vigilance, accountability, and continuous improvement within the food industry.

Perigon clients can obtain funding towards RQA's services as part of a Contaminated Products Insurance policy.

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