FSPCA Webinar Series on the FSMA IA Rule

Mitigation Strategies

Oct 24, 2017
Key Terms

• **Vulnerability** – means the susceptibility of a point, step, or procedure in a facility’s food process to IA

• **Significant Vulnerability** – means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A SV is identified by a vulnerability assessment.

• **Actionable Process Step** – a point, step, or procedure in a food process where a significant vulnerability exists
Key Terms

- **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.
IA Rule – What Is Required?

• Food defense plan
  – Vulnerability assessment
  – **Mitigation strategies**
  – Procedures for food defense monitoring
  – Food defense corrective action procedures
  – Food defense verification procedures

• Training

• Reanalysis

• Records

www.fda.gov
Requirements for Mitigation Strategies

• Mitigation Strategies must exist for each Actionable Process Step

• Must be identified and written in the food defense plan

• Must include an explanation of how the mitigation strategy(ies) sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step
Mitigation Strategies

• Identified in response to a significant vulnerability present in the food system – Actionable Process Step
• Implemented to significantly minimize or prevent the significant vulnerability that was evaluated during the Vulnerability Assessment – including significant vulnerabilities posed by inside attackers
Mitigation Strategies are informed by the vulnerability assessment’s evaluation of the nature of the significant vulnerability at an actionable process step.

Mitigation strategies can only be properly identified after the vulnerability assessment is conducted.

Identify and explain mitigation strategy for this actionable process step.
Mitigation Strategies

• Based on our vulnerability assessments, we believe that adequate mitigation strategies will be designed to address

Element 2: Degree of physical access to the product
  • Locks on hatches
  • Restrict access to only a limited number of authorized personnel
  • Gates, rails, seals, shields, and other barriers

Element 3: The ability of an attacker to successfully contaminate the product
  • Increased observation
  • Peer monitoring

• Mitigation Strategies Database can support facility identification of mitigation strategies
Mitigation Strategies

• Consideration of Inherent characteristics and existing measures
  – Characteristics that are inherent to the process should be included in the VA
  – Existing measures that are applied to the process for various reasons (e.g., occupational safety, food safety, quality control, etc.) should be considered after the VA when mitigation strategies are identified
Flexibility for Mitigation Strategies

- Facilities have flexibility to identify and implement mitigation strategies that are most appropriate for the circumstances
  - Tailored to existing facility practices and procedures
  - Designed to address the unique nature of the significant vulnerability
  - Existing facility-wide security measures or other practices may be foundational to a mitigation strategy
  - Existing measures may already be serving as mitigation strategies - document in food defense plan
Mitigation Strategies Explanation

• Mitigation Strategies must have an explanation in the food defense plan for how the strategy is protective of the actionable process step
  – Can be straightforward and simple, common sense
  – Will facilitate common understanding with inspectors
  – Can inform the development of mitigation strategies management components
  – Integral to the determination of proper and consistent implementation
Managing Mitigation Strategies

• To ensure their consistent and proper implementation, mitigation strategies must have accompanying management components
  – Food Defense Monitoring
  – Food Defense Corrective Actions
  – Food Defense Verification

• Facilities have flexibility in identifying these procedures and determining appropriate frequency
  – A future webinar will focus on Mitigation Strategies Management Components
www.fda.gov/fsma