FSPCA Webinar Series on the FSMA IA Rule

Key Activity Types

August 22, 2017
Background

• Homeland Security Presidential Directive (HSPD)#9 requires FDA to conduct vulnerability assessments of the food system and identify mitigation strategies (issued Jan 2004)

• FDA has conducted assessments on a wide variety of products/processes

• Form the foundation of FDA’s food defense program

• FDA issued the IA Final Rule which identifies Vulnerability Assessments as a component of the required Food Defense Plan (issued May 2016).
Examples of FDA Vulnerability Assessments

- Yogurt
- Bottled water
- Baby food (jarred)
- Apple juice
- Lettuce (bagged)
- Infant formula (pwdr)
- Fluid milk
- Retail milk (1 gal size)
- Animal feed
- Flour
- Ice Cream
- Chocolate
- Bakery
- Fast food restaurant

- Breakfast Cereal
- Grocery store - rotisserie chicken
- High fructose corn syrup
- Export grain elevator - corn
- Frozen pizza
- Refrigerated food distribution – lettuce
- Pet Food
- Breaded Fish & RTE Seafood
- Coffee Shop
- Deli Salads
- Transportation (OJ/Milk)
- Concessions & Catering
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
Food Defense Plan - Vulnerability Assessment

• Identification of those points at highest risk, i.e., actionable process steps

• For each point, step, or procedure, a facility must consider, at a minimum:
  – Potential public health impact
  – Degree of physical access to product
  – Ability of an attacker to successfully contaminate the product

• These 3 elements are fundamental and required for a food defense vulnerability assessment
Food Defense Plan - Vulnerability Assessment

• Must consider the possibility of an inside attacker

• Outcome of assessment must be written
Lessons Learned from Vulnerability Assessments

• What information can we share with industry stakeholders?

• Are there process steps that consistently ranked high in FDA-led vulnerability assessments regardless of the commodity?
Analysis of Vulnerability Assessments

• Results of this analysis show
  – Certain processing steps repeatedly ranked high across VAs, regardless of food
  – Focus on the activity being conducted at high ranking processing steps
  – Common vulnerabilities can be organized into generalized activity groups
    = FDA Identified Key Activity Types

https://www.fda.gov/food/guidanceregulation/fsma/ucm347023.htm
Key Activity Types

I. Bulk Liquid Receiving and Loading
   • High volume of food (Element 1)

II. Liquid Storage and Handling
   • Increased access (Element 2)

III. Secondary Ingredient Handling
   • Increased vulnerability (Element 3)

IV. Mixing and Similar Activities
Key Activity Types

• Based on vulnerability assessments conducted with many stakeholder groups
• Derived from robust VA data
• These vulnerability assessments include:
  – 3 required elements
  – Consideration of an inside attacker
• KATs represent an efficient, science-based approach that companies may use to identify actionable process steps
Key Activity Types

“The four identified key activity types are processes, steps, or procedures that consistently ranked as the most vulnerable, regardless of the commodity being assessed, and reflect significant vulnerabilities to intentional adulteration caused by acts intended to cause wide scale public health harm. Therefore, using the key activity types is an appropriate method to conduct a vulnerability assessment.” (Comment response 71; 81 FR 34195-34196)
Key Activity Types as a Vulnerability Assessment Method
Ground Black Pepper

I. Bulk Liquid Receiving and Loading
II. Liquid Storage and Handling
III. Secondary Ingredient Handling
IV. Mixing and Similar Activities

For illustrative purposes only. Courtesy of the Food Safety Preventive Controls Alliance. Used with permission.
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Cold Pressed Almond Cranberry Energy Bar

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www.fda.gov/fsma