FSPCA Webinar Series on the FSMA IA Rule

Vulnerability Assessment Overview

June 20, 2017
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
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
Background – FDA Vulnerability Assessments

• 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
History of FDA Vulnerability Assessments

- 2001: Operational Risk Management
- 2003: FDA/USDA begin using CARVER+Shock
- 2005: HSPD-9
- 2007: WHWG approves using CARVER+Shock
- 2009: Interagency SPPA Initiative
- 2011: Food Safety Modernization Act
- 2015: FDA Key Activity Type analysis begins
- 2017: IA Final Rule

FDA Vulnerability Assessment Program Continues
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
CARVER + Shock Method

• Simplifies and standardizes the process of evaluating a food operation’s susceptibility to acts of intentional adulteration
  – Seven CARVER+Shock “factors” assess different aspects of overall vulnerability
  • Adapted from a military targeting tool by a White House chaired interagency commission as an appropriate tool to evaluate vulnerability of the food system
  • Replaced ORM as FDA’s assessment method in 2003
  – Identifies and characterizes processing steps where intentional adulteration vulnerability is highest
CARVER + Shock Method

• Considers seven factors that affect the desirability of a target:
  - **Criticality** – Public health and economic impacts to achieve the attacker’s intent
  - **Accessibility** – Physical access to the target
  - **Recuperability** – Ability of the system to recover from the attack
  - **Vulnerability** – Ease of accomplishing the attack
  - **Effect** – Amount of direct loss from an attack
  - **Recognizability** – Ease of identifying a target
  - **Shock** – Psychological effects of an attack
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
• We believe that 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
  – Informed by our interactions with the intelligence community and law enforcement
  – Consider how people with different roles can move around within your facility and who works at APS

• Outcome of assessment must be written

• Key Activity Types are considered an appropriate method to conduct a vulnerability assessment
  – Future webinar will focus on using Key Activity Types
Food Defense Plan – Vulnerability Assessment

• Consideration of Inherent characteristics and existing measures
  – Characteristics that are inherent to the process (i.e., the process could not operate properly in their absence) 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