Inspections Under Food Safety Modernization Act (FSMA)

Collaborative Food Safety Forum

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Karyn M. Campbell, Director
Investigations Branch
Philadelphia District Office
FDA/Office of Regulatory Affairs
Authority to Inspect

• Section 704 of the Federal Food, Drug & Cosmetic Act (the Act)
• Credentials and written Notice of Inspection (form FDA 482)
• Enter and inspect at reasonable times, within reasonable limits, and in a reasonable manner
Authority to Inspect

- Establishments or vehicles used to manufacture, process, pack, hold, or transport food
- All pertinent equipment
- Finished and unfinished materials, containers, labeling
Authority to Inspect

• Extends to records under certain circumstances
  – Reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to human or animals
  – Infant formulas
  – Low Acid Canned Foods/Acidified Foods (LACF/AF)
  – Hazard Analysis and Critical Control Points (HACCP)
Definitions¹

- **Inspection** – careful, critical, official examination of a facility to determine its compliance with laws administered by FDA

- **Comprehensive Inspection** – directs coverage to everything in the firm subject to FDA jurisdiction to determine the firm’s compliance status

- **Directed Inspection** – directs coverage to specific areas to the depth described in the program, assignment, or other instructions
FSMA

• Inspection Frequency Mandates
  – **Domestic High Risk**: Not less often than once in the 5 year period following FSMA enactment and not less often than once every 3 years thereafter
  – **Domestic Non-High Risk**: Not less often than once in the 7 year period following FSMA enactment and not less often than once every 5 years thereafter
  – **Foreign**: Not fewer than 600 facilities in the 1 year period following FSMA enactment and not fewer than twice the number of facilities inspected during the previous year for each of the 5 years following
Component Inspection

• **Concept**: a subset (slice) of a comprehensive inspection designed to cover one or more components of a facility’s food safety system to assess compliance with applicable laws and regulations

• **Precedents**: pharmaceutical systems-based inspections; medical device QSIT (Quality System Inspection Technique)
Draft Proof of Concept (PoC) Pilot

• Objectives
  – To conduct component inspections at a sampling of firms to determine if component inspections provide a time savings in inspectional hours without forfeiting FDA’s ability to adequately assess a given firm’s compliance status during the inspection
  – To gather data about how component inspections compare to comprehensive inspections in efficiency, inspectional coverage, and time spent
  – To determine what confidence exists that a plant is producing a safe food after a component inspection
Draft PoC Pilot

• HACCP-regulated firms (seafood and juice)
• Three Components
  – Plan Adequacy
  – Plan Implementation
  – Sanitation
• Component selection to be driven by previous inspection coverage/findings as well as current conditions in the facility
Draft PoC Pilot

- Three FDA District Offices
- Test Group vs. Control Group
- Metrics
- Training
References

¹ Investigations Operations Manual (IOM) 2012, Section 5.1.2