Inspections Under Food Safety Modernization Act (FSMA)

Collaborative Food Safety Forum

April 5, 2012

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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)

Definitions[1]

- **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