Key Aspects of Inspections for Domestic Facilities

Collaborative Food Safety Forum

April 12, 2012

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

- **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
Types of Food Inspections

- Food Safety (sanitation)
- Cheese
- HACCP
- LACF/AF
- Interstate Travel Sanitation
- Labeling
- Medical Foods
- Infant Formulas
- Dietary Supplements
- Cosmetics
Areas of Concern/Risk

- Microbiological
- Chemicals/Pesticides
- Pests
- Storage Conditions
- Cross-Contact
- Cross-Contamination

- Employees/Operators
- Time/Temperature Abuse
- Incomplete/Inadequate Processing
- Equipment
- Facility
Food Safety Modernization Act (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
# DOMESTIC SEAFOOD HACCP REPORT (Form 3501)

## SECTION 1 - GENERAL INFORMATION

1. FEI
2. State Permit No. (optional)
3. Date of Inspection

4. Inspected by (First Name) (Middle) (Last Name)

5. Firm Name

Street Address

City State Zip

6. Inspection Basis
   - FDA
   - State Contractor
   - State Partnership

7. Establishment Type Information
   - a. Vessel
   - b. Establishment Type (Check one)
     - Yes Manufacturer
     - No Warehouse
     - Repacker
     - Relabeler

8. FDA Finished Product Code Information
   - (For the specific product listed in Block 9)
     - a. Industry
     - b. Class
     - c. Container
     - d. Process
     - e. Product ID

9. Description of the Finished Product covered by this form (One product per inspection form) include species and production form

10. Was the firm actively processing the product you listed in Block 9? Yes No

11. Does the firm deal only in intrastate commerce, i.e. no interstate? Yes No

12. Does the firm meet HACCP Training Requirements? Yes No

Investigator/Inspector

Date submitted

A. State Agency Code
B. Employee Phone Number (Area Code - Phone Number - Extension)
## SECTION II - HAZARD CONTROL

13. Is a HACCP plan needed to control a food safety hazard that is reasonably likely to occur in the product you selected?  
   (If the answer is NO, proceed to Section III - Sanitation Control)
   ( ) Yes ( ) No

14. Is there a HACCP plan for the product you selected?  (If the answer is NO, proceed to Section III - Sanitation Control)
   ( ) Yes ( ) No

INSTRUCTIONS: Identify hazard not controlled by checking the appropriate square(s) in the right-hand columns. (Please refer to "Hazard Guide, species and process Hazards tables" for guidance in determining hazards, if needed)

### Potential Hazards Not Controlled

<table>
<thead>
<tr>
<th>S</th>
<th>E</th>
<th>L</th>
<th>O</th>
<th>F</th>
<th>C</th>
<th>A</th>
<th>M</th>
<th>D</th>
<th>H</th>
<th>P</th>
<th>G</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>E</td>
<td>L</td>
<td>O</td>
<td>F</td>
<td>C</td>
<td>A</td>
<td>M</td>
<td>D</td>
<td>H</td>
<td>P</td>
<td>G</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>Y</td>
</tr>
<tr>
<td>S</td>
<td>E</td>
<td>L</td>
<td>O</td>
<td>F</td>
<td>C</td>
<td>A</td>
<td>M</td>
<td>D</td>
<td>H</td>
<td>P</td>
<td>G</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>Y</td>
</tr>
</tbody>
</table>

### HACCP Plan Documentation

15. Reasonably likely to occur hazard not identified: Specifically
   ( ) Yes ( ) No

16. Inadequate or no critical control point identified: Specifically for
   ( ) Yes ( ) No

17. Inadequate or no critical limit identified: Specifically for
   ( ) Yes ( ) No

18. Inadequate or no written monitoring procedure: Specifically for
   ( ) Yes ( ) No

19. Inadequate corrective action procedure: Specifically for (answer only when plan contains written corrective action procedures)
   ( ) Yes ( ) No

### HACCP Plan Implementation

20. Inadequate implementation of monitoring procedures: Specifically for
   ( ) Yes ( ) No

21. Inadequate or no monitoring records: Specifically for
   ( ) Yes ( ) No

22. Inadequate or no corrective action taken when there is a deviation from the critical limit: Specifically for
   ( ) Yes ( ) No

23. Inadequate or no corrective action records: Specifically for
   ( ) Yes ( ) No

### Verification

24. Were required processing monitoring instruments properly calibrated?
   ( ) Yes ( ) No ( ) Unknown

25. Does the HACCP Plan include "In-Processing Testing" as a verification activity?
   ( ) Yes ( ) No ( ) Unknown

26. Does the HACCP Plan include "End-Product Testing" as a verification activity?
   ( ) Yes ( ) No ( ) Unknown
## SECTION III - SANITATION CONTROL

INSTRUCTIONS: Identify sanitation deficiencies by blackening the appropriate square(s) in the right-hand columns.

<table>
<thead>
<tr>
<th>Sanitation Items</th>
<th>C</th>
<th>R</th>
<th>O</th>
<th>S</th>
<th>H</th>
<th>E</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sanitation Items

27. Sanitation deficiencies observed: Specifically for

28. Inadequate or no monitoring (when required): Specifically for

29. Inadequate or no monitoring records (when required): Specifically for

30. Inadequate or no corrections taken (when required): Specifically for

31. Inadequate or no correction records (when required): Specifically for

32. Sanitation records do not reflect conditions in the establishment: Specifically for

33. Although not required, is a written standard sanitation operating procedure (SSOP) in place?  
   - Yes
   - No
   - Unknown
### Component Selection Key

**Components:**
1) Adequacy of HACCP Plan (A)
2) Implementation of HACCP Plan (I)
3) Sanitation (S)

<table>
<thead>
<tr>
<th>Combination Type</th>
<th>HACCP Plan Needed</th>
<th>HACCP Plan Present</th>
<th>Deficiencies (VAI or OAI) found in</th>
<th>If same product(s) covered as previous inspection</th>
<th>If HACCP plan now needed when wasn’t before (allergen guidance)</th>
<th>If new product/process covered in current inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>no</td>
<td>N/A</td>
<td>N/A</td>
<td>no</td>
<td>S</td>
<td>A &amp; I</td>
</tr>
<tr>
<td>Type 2*</td>
<td>no</td>
<td>N/A</td>
<td>N/A</td>
<td>yes</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Type 3</td>
<td>yes</td>
<td>no</td>
<td>N/A</td>
<td>no</td>
<td>N/A</td>
<td>A &amp; I</td>
</tr>
<tr>
<td>Type 4*</td>
<td>yes</td>
<td>no</td>
<td>N/A</td>
<td>yes</td>
<td>Comprehensive</td>
<td>N/A</td>
</tr>
<tr>
<td>Type 5</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>N/A</td>
<td>A &amp; I</td>
</tr>
<tr>
<td>Type 6</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>S</td>
</tr>
<tr>
<td>Type 7</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>I</td>
</tr>
<tr>
<td>Type 8</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>I &amp; S</td>
</tr>
<tr>
<td>Type 9</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>A</td>
</tr>
<tr>
<td>Type 10</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>A &amp; S</td>
</tr>
<tr>
<td>Type 11</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>A &amp; I</td>
</tr>
<tr>
<td>Type 12*</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Comprehensive</td>
</tr>
</tbody>
</table>

* Not targeting combination type for component pilot. If previous inspection yielded compliance deficiencies in all possible components, then all possible components must be covered in subsequent inspections.
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