Human Food Program
- Work Planning 101 -

February 10-13, 2020
AFDO-MFRPS meeting, Spokane, WA
Topics To Be Covered

• Work Planning Overview
  • Timeline
  • Inputs
  • Process Flow
• Domestic Inspections
  • Mandate
  • Frequency
  • Risk Algorithm
  • Prioritizing beyond the Risk Algorithm
• Sampling
  • Types of Sampling
  • Sampling Prioritization Process
  • Timeline
• Responsive Resources
• State Resources
  • Contract
  • Non-Contract
When and how is the fiscal year Work Plan for the Human Food developed annually?
General overarching process & timeline

**ORA forecasts inspection and laboratory programmatic resources for CFSAN to plan into the upcoming FY* work cycle**

- **Feb/Mar**

**CFSAN builds the plan, shares with ORA, and together a final plan is achieved through an iterative and collaborative process**

- **Mar/Aug**

**ORA issues final Work Plan to the implementing Divisions and CFSAN issues the accompanying Sample Collection Operation Planning Effort (SCOPE)**

- **Sept**

* Federal fiscal year runs October 1 through Sept 30 annually
Work Plan Inputs

- Compliance Programs
- Inspections
- State Contracts
- Food and Cosmetics Work Plan
- Sampling Prioritization
- FSMA Activities
- Policy Driven Activities
- Emergency Response/Emerging Issues (For Cause)

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Conversion Factor
CFSAN’s Work Planning Process Flow

Receive upcoming FY human resource Forecast

Pre-planned Resources
(Prior Notice, Food Specialists, Foreign Food Cadre)

Sampling Prioritization

Compliance Program Resources

Responsive Resources

Proposed CFSAN Workplan

• Inspections Frequency
• Regulatory Compliance Initiatives
• FSMA Activities
• Congressional Mandates
CFSAN’s Work Planning Process Flow

Receive FY Call for Forecast Memo

Pre-planned Resources
(Prior Notice, Food Specialists, Foreign Food Cadre)

Sampling Prioritization

Responsive Resources

Compliance Program Resources

Proposed CFSAN Workplan

- Inspections Frequency (421)
- Regulatory Compliance Initiatives
- FSMA Activities
- Congressional Mandates
FD&C Act 421 (FSMA SEC. 201) - TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY

(a) Identification and Inspection of Facilities.--

(1) Identification.--The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:

   (A) The known safety risks of the food manufactured, processed, packed, or held at the facility.
   (B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.
   (C) The rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls.
   (D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 801(h)(1).
   (E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) or 806, as appropriate.
   (F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.
FD&C Act 421 (FSMA SEC. 201) – Frequency Mandate

High Risk (every 3 years)
- 5 years for initial inspection following FSMA implementation
- Completed first cycle in 3 years

Non-high Risk (every 5 years)
- 7 years for initial inspection following FSMA implementation
- Completed first cycle in 7 years
FSMA Domestic Human Food Facility Risk Categorization

Step 1: Required to register under Sec. 415 (Bioterrorism Act)

- Yes
  - Step 2: Identify known safety risks of food
    - Commodity categories associated with OAI inspections, class I recalls, class 3 samples, outbreaks
    - No
    - Step 3: Compliance history of specific facility
      - OAI inspections, class I recalls, class 3 samples, outbreaks, compliance actions

- No
  - Not a FSMA facility

- No
  - Step 2: Identify known safety risks of food
    - Commodity categories associated with OAI inspections, class I recalls, class 3 samples, outbreaks
    - No
    - Step 3: Compliance history of specific facility
      - OAI inspections, class I recalls, class 3 samples, outbreaks, compliance actions

- Yes
  - High Risk

- No
  - Non-High Risk
How does FDA prioritize inspection and sampling work in any given year?
Further Inspectional Prioritization

**Priority 1**
- Immediate, for-cause inspections
- Outbreak, Class 1 Recall,
- Compliance Follow up (OAI)

**Priority 2**
- HR
- NHR

**Priority 3**
- Non-FSMA 201

**Inspections Priorities**
- Outbreaks
- Compliance History
- Class 1 Recall
- Frequency
- Assignments
- Egg Rule
- ITP
CFSAN’s Work Planning Process Flow

- Receive FY Call for Forecast Memo
- Pre-planned Resources (Prior Notice, Food Specialists, Foreign Food Cadre)
- Sampling Prioritization
- Compliance Program Resources
- Responsive Resources
- Proposed CFSAN Workplan

- Inspections Frequency
- Regulatory Compliance Initiatives
- FSMA Activities
- Congressional Mandates
Sampling

Assignments
Large/Small (Prioritization)

SCOPE (Sample Collection Operation Planning Efforts)
Compliance Programs

PREDICT Import Sampling

Sampling Types
Overall Work Plan
Sampling Request Process

Request Received
Through a submission portal
Includes information on the basis of sampling (background, number of samples requested, locations and other information to help in the scoring process)
Submissions accepted from across FDA and State Partners

Requests Scored based on Public Health and Other Decision Criteria
Public Health Criteria includes: historical outbreaks and incident data, manufacturing and process contamination probability
Other Decisions Criteria includes: urgency, policy imperative and feasibility
Hazard Commodity Pairs are ranked amongst the requests received

Management Briefings and Decision Points
Office of Compliance (management personnel within the office)
Senior Management

Communication and Outreach
Internal (Office wide communication requesting feedback on proposed large scale commodities)
External Stakeholders (Associations, academia, states, other foreign/domestic agencies)
Work Plan Prioritization Process & Timeline

- **Nov/Dec**: Request Period Opened for Planned Requests for upcoming FY
- **Feb/Mar**: Request Period Closes for Planned Requests for upcoming FY
- **Oct/Sept**: Unplanned Requests Accepted through the Request Tool for current FY
CFSAN’s Work Planning Process Flow

Receive FY Call for Forecast Memo

Pre-planned Resources (Prior Notice, Food Specialists, Foreign Food Cadre)

• Inspections Frequency
• Regulatory Compliance Initiatives
• FSMA Activities
• Congressional Mandates

Sampling Prioritization

Compliance Program Resources

Responsive Resources

Proposed CFSAN Workplan
Responsive Resources

For cause inspections

Emerging issues

Environmental sampling follow up

Outbreaks – tracebacks & root cause investigations (RCI)

Laboratory operations
Receive FY Call for Forecast Memo → Pre-planned Resources (Prior Notice, Food Specialists, Foreign Food Cadre) → Sampling Prioritization → Responsive Resources → Proposed CFSAN Workplan

CFSAN’s Work Planning Process Flow

- Inspections Frequency
- Regulatory Compliance Initiatives
- FSMA Activities
- Congressional Mandates

Responsive Resources

Compliance Program Resources

Sampling Prioritization

Pre-planned Resources (Prior Notice, Food Specialists, Foreign Food Cadre)
How does FDA leverage State resources to minimize duplication and provide broader coverage?
Integrated Operations

- **State Training/MFRPS Cert.**
- **Contracted Inspections**
- **Non-Contracted Inspections**
- **PC Rule**
- **FSMA Frequency**
- **MFPRS Conformance**
- **Labs Strategic Planning/State Coop Agreements**
- **Sample Collection**
- **Lab Testing**
- **FDA Sampling**

**Legend:**
- Current
- Future State

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State Inspections Leverage –
Non-contracted inspection data

• FDA has initiated a pilot with Florida to accept non-contract inspection’s of NHR, NAI firms to meet FSMA inspection frequency mandates.
  – 69 submitted inspections thus far have changed FSMA frequency cover by dates.

• 28 Full-Conformance MFRPS States are eligible to participate in this data exchange.
Leveraging State Inspections

• Goal: To utilize state data for non-high risk, non-contract, NAI inspections from states in full conformance with MFRPS

• **13,479** NHR firms with NAI last inspection in the 28 MFRPS Full Conformance States

• Represents approximately **392 FTEs** worth of work in ORA Surveillance terms; around **78 FTEs** on an annualized basis

• If FDA adopted this approach, our current gap could be eliminated, assuming we have a mechanism to receive/confirm state data

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Questions & Answers