The FSA: Purpose

• Focus on certain processes based on the PHRE
• Assess and analyze a plant’s food safety system as a whole
• Prepare a written report with a supportable recommendation focusing on documenting vulnerabilities and noncompliance.

The FSA: Purpose

• FSA Methodology
  • Focus based approach.
  • Allows for EIAOs to focus time and resources on vulnerable portions of the Establishment’s Food Safety System.
  • Allows for EIAOs to focus their observations, review and analysis to focus on public health risk.
  • Increases consistency of FSA in time, analysis and documentation.
Process from PHRE to Finalizing FSA

Preparing for the FSA

- Define the scope and the tools to be completed.
- Develop a plan for conducting the FSA.
- Complete the General tool for every FSA.
- Any additional tools to complete will depend on the specific scenario.

Preparing for the FSA

- Situations when >2 tools are completed:
  - New establishments coming under inspection
  - All applicable tools
  - Criteria in Directive 5100.4 spans multiple HACCP categories
  - STEC positive in raw non-intact
  - Lm positive in RTE
  - Any issues identified during the FSA or PHRE
    - Add tool associated with the issue identified
### Tools

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HACCP Category</th>
<th>Tool to Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Poultry</td>
<td>Slaughter: Raw; Raw Non-Intact</td>
<td>Poultry Tool</td>
</tr>
<tr>
<td>Raw Meat</td>
<td>Slaughter: Raw; Raw Non-Intact</td>
<td>Meat Tool</td>
</tr>
<tr>
<td>NRTE Meat or Poultry</td>
<td>HT S; NHT S; HT NFC NSS;</td>
<td>RTE/NRTE Products Tool</td>
</tr>
<tr>
<td></td>
<td>Secondary Inhibitors NSS</td>
<td></td>
</tr>
<tr>
<td>RTE Meat or Poultry</td>
<td>HT S; NHT S; FC NSS; Secondary Inhibitors NSS</td>
<td>RTE/NRTE Products Tool</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermally Processed</td>
<td>Thermally Processed Commercially Sterile</td>
<td>Thermally Processed Commercially Sterile Tool</td>
</tr>
<tr>
<td>Meat or Poultry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Scope of the FSA

- Determine if pathogen sampling is to be performed.
  - **RLM**: sample during the week prior to the FSA and consider the results in the FSA outcome.
  - **IVT**: Intensified Verification Testing will be discussed later in this course.
  - **IIT**: If an Incident Investigation Team is formed, it will include subject matter experts who will focus on the unique issue of concern.

### RLM, IVT, or IIT

- Sampling is completed prior to an FSA.
- Not a part of the 5-7 day window.
- Provide the establishment with at least 1-week notice that RLM sampling will occur.
- Delay in results or sampling may extend FSA.
**Notifying Establishment of FSA**

- Give the establishment 1-2 weeks advance notice of the visit;

- Give the FLS and IPP 1-2 weeks advance notice of the establishment visit.

**Notifying Establishment of FSA**

- Exception to 1-2 week advance notice
  - “For Cause” FSA prompted by
    - Positive sample results
    - Shipment of adulterated product
    - Other high priority food safety incidents
  - See FSIS Directive 5100.4

**Notifying Establishment of FSA**

- During the Discussion with Est./FLS/IPP
  - Communicate documents needed
    - SSOPs, HACCP Plan, HA, PRP, Supporting Documents, Testing Records, etc.
    - At least the last 60 days of records
    - At least 13 productions days for very small plants.
  - Must express the need for these documents to be available to accomplish 5-7 day time frame.
  - May follow up discussions with a MOI to assure clear communication.
Objective Check-Up

• What is the overall purpose of an FSA?

Pre-FSA Correlation

• Prior to Visiting the Establishment

Prior to Visiting the Plant

• Review PHRE that contains
  • All relevant data available regarding the establishment including any previous FSAs
  • Review relevant agency issuances that pertain to plant processes, compliance guidelines, training and AskFSIS questions
  • Correlate with the Case Specialist about issues and discuss strategy
Prior to Visiting the Plant

- EIAO should also review relevant
  - Policy issuances
  - Guidance materials
  - Training materials

Professionalism reminder:
- Being prepared improves your credibility

Pre-Entrance Meeting

- EIAO should meet with FSIS personnel first to discuss the process and any issues
- Advise that EIAO role is not to resolve disputes
- EIAO assesses food safety systems and formulates an agency supportable recommendation based on findings

Professionalism reminder:
- Contact IIC and reach out as a team member

Entrance Meeting

- Conduct entrance meeting with management, in-plant inspection team, FLS and discuss:
  - Reason for and scope of the FSA
  - Discuss Public Health Regulations
  - How an FSA differs from day-to-day inspection verification
  - Typical work schedule
  - Accessing production areas and special rules
  - Where EIAO will work
  - Where records are stored and access to them
  - Photographs as an extension of inspection authority
Entrance Meeting

- Explain
  - EIAO role is not to resolve disputes
  - Communication with in-plant inspection team and establishment management about findings
  - Possible outcomes
  - Exit conference held upon completion of FSA
  - Draft copy of FSA report will be provided at exit conference.
  - Final copy provided by the EIAO or DO.
- EIAO Contact Information
- Document entrance meeting in the General Tool

Performing the Assessment

On-going Communication

- FSIS expects the EIAO to communicate with establishment management throughout the FSA process.
- Remain fair and objective.
- Bring attention to and discuss non-compliances and vulnerabilities as they are identified.
Ongoing Communication

• Do not predict the FSA outcome!

Ongoing Communication

• Noncompliances will be documented in the FSA even if the establishment comes into compliance after notification
  • NRs by IPP
  • NOIE or suspension letter

Ongoing Communication

• EIAO communicates with in-plant team and FLS throughout the FSA
• Describe noncompliances and vulnerabilities
• Discuss establishment production practices
• Document in the FSA report any information provided by FLS or in-plant team that may affect outcome if not already captured in NR or MOIs
Ongoing Communication

• The EIAO, in-plant inspection team, and FLS work collaboratively to ensure all noncompliances are communicated to plant management and documented for issuance at the exit meeting.

Ongoing Communication

• Example
  • EIAO recommends in-plant team issue NRs
  • Contacts DDM and SEIAO to discuss prior to sending draft FSA for review.
  • After concurrence EIAO contacts FLS and works with IIC and in-plant team to ensure NRs are issued

Ongoing Communication

• FSIS must provide due process to the plant through ongoing communication with plant officials throughout the course of the FSA.
Ongoing Communication

- EIAO provides frequent updates to SEIAO, DDM, or DM on FSA progress and strategy
- Frequent updates to IIC and FLS on findings and any recommendations
- DDM may request additional info or provide resources

Request, don't demand!

- Be able to explain statutory authority to examine facilities and copy records
- If EIAO encounters resistance
  - Contact SEIAO or DO to develop strategy
  - DO may contact EARO who may then contact OIEA to get administrative subpoena to obtain records

Objective Check-Up

- What are the reasons an FSA is scheduled at an establishment?
- What are the timeframes involved in preparing for, notifying other parties, conducting, and concluding an FSA.
FSA Methodology Overview

• Complete FSA in 5-7 days
• If additional time needed explain to DO
• If a delay is necessary, discuss reasons with establishment and when it will resume
• Possible reasons for an extension:
  • Enforcement
  • 3 or more tools

FSA Methodology

• Evaluate the HACCP System as a whole.
  • Use system-based approach to determine adequacy
• Focus on:
  • Vulnerabilities and noncompliances - their effect on the food safety system
  • The establishment’s ability to produce a safe and wholesome product

FSA Methodology Overview

• FSA is conducted by:
  • Records review
  • Direct observation of establishment operations
The FSA Tools

• Every FSA must have:
  • PHRE & General Tool
  • At least one of the processing category tools

• Function of FSA tools questions
  • Provide a structured format
  • Aid in gathering all necessary info
  • Aid in determining risk relative to other establishments

• Each tool is only completed once
  • For example, if an establishment produces products under multiple HACCP processing categories that fall under the same tool such as raw intact and raw non-intact the tool should be completed once with an assessment of both HACCP categories included throughout.
The FSA Tools

• Be familiar with the tool questions.
  - Enhances your ability to complete FSA in 5-7 days
  - Limits redundancy.
  - Document all noncompliance and vulnerability findings.
    - Vulnerability: a less than perfect finding that may lead to noncompliance if it is not addressed
  - Several questions could have similar responses
    - Do not “copy and paste”
      - Instead, reference the original response

The FSA Tools

• Limit responses in the tools to information related to the HACCP categories being evaluated
• Do not include information from other categories unless the information has a bearing on the category being evaluated as part of the focused FSA.

The FSA Tools - Overview

• General Tool:
  • The General Tool contains the following sections:
    - FSA Recommendation
    - General Sanitation
    - Other General Questions
The FSA Tools – Overview

• Meat Tool & Poultry Tool contains:
  • Hazard Analysis and HACCP System
  • Slaughter and Sanitary Dressing
  • Outside Source Materials for Further Processing
  • Antimicrobial Treatment for Slaughter and Further Processing
  • Sampling and Testing for Slaughter and Further Processing

The FSA Tools – Overview

• Ready-to-Eat (RTE) Processed Products FSA Tool:
  • Hazard Analysis and HACCP System
  • Lethality and Stabilization: Fully Cooked, Not Shelf Stable
  • Lethality and Stabilization for Fermentation, Drying, and Salt-curing
  • Non-meat Ingredients for RTE Products
  • Listeria Rule (9 CFR 430) for RTE Products

The FSA Tools – Overview

• Not Ready-To-Eat (NRTE) Processed Products:
  • Hazard Analysis and HACCP System
  • Design of the Heat Treatment, Fermentation, or Other Processes for NRTE Processed Products
  • NRTE Processed Products: Appearance
The FSA Tools – Overview

- Thermally Processed:
  - Hazard Analysis and HACCP System
  - Following Canning Regulations as Pre-Requisite Program to Prevent Biological Hazards
  - Chemical and Physical Hazards

The FSA Tools

- Use tools to document all findings
  - Do not keep outside notes
  - If an enforcement is recommended, any notes outside FSA Report must be forwarded to DCS

The FSA Tools – Analysis Sections

- EIAO analyzes findings to reach an agency supportable recommendation
- Summary documented as part of each tool
- Analysis is summarized in the Decision-Making Analysis Question in the General Tool
- The Executive Summary is documented in the General Tool
FSA Methodology Overview

- Use AskFSIS to obtain expert advice on scientific and technical issues.