One Team, One Purpose

Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Public Health Risk Evaluation (PHRE) and Food Safety Assessment (FSA) Methodology at Egg Products Plants

*Drive Compliance With Food Safety Statutes and Regulations*
Food Safety and Inspection Service: Objectives

- FSIS Authority
- EIAO Background and Role
- Vision for Phased Roll-out
- Egg Products FSA Process
- FSA Overview and Plan
- Next Steps
The Egg Products Inspection Act (EPIA) provides FSIS personnel the authority to examine facilities, inventory, and records at FSIS regulated plants, warehouses, distribution centers and other in-commerce facilities subject to the statutes (21 U.S.C 1034 and 1040).

- similar to FMIA (460) and PPIA (642)
Similar to meat and poultry FSAs, the Egg Product FSAs will broadly follow:
FSIS Directive 5100.4 – PHRE Methodology
FSIS Directive 5100.1 – FSA Methodology

The EIAO position was first introduced in FSIS in 2002.

EIAOs are trained to assess the design and validity of food safety systems, possess scientific and technical expertise relating to food safety controls, and provide food safety outreach material to industry. District manager is responsible for ensuring all personnel, including EIAOs conducting FSAs are properly training to perform their assigned duties.

FSAs are conducted by EIAOs in a manner that protects the confidentiality of the information gathered, particularly commercially sensitive and proprietary information.
Food Safety and Inspection Service:
Roll-out Plan – Vision for Phased Roll-Out

Approximately 80 Inspected Egg Products Plants
FSIS will start with 4 locations, prior to conducting FSAs nationally.

- 4 locations are: To be determined

The red square show the phased roll-out area
FSIS Directive 5100.4 – PHRE Methodology

The PHRE is a decision-making process that is used by an EIAO to determine whether the District Office (DO) needs to schedule an FSA based on public health risk triggers (noncompliances, sample history, etc.)

- When an FSA is warranted, based on the outcome of the PHRE, the district will schedule an FSA.
- One of the “risk based” triggers is for new plants coming under a permanent grant of inspection. For egg products, FSIS will take the more literal approach, and consider plants without a previous FSA to be eligible for this option.

- Establishments will be selected based on PHRE factors, and likely include different plant sizes and processing practices.

- For the phased roll-out only, FSIS will select the first 4 plants from the Des Moines District, the district with the largest concentration of egg products plants.

- The 4 plants will be notified within two weeks of starting the FSA, that an FSA has been scheduled.
The EIAO completes PHRE by:

- Evaluating the plant’s historical data including:
  - Available enforcement data,
  - Compliance history,
  - FSIS laboratory results,
  - Weekly meeting notes,
  - Memoranda of Interview (MOI),
  - Recall information, and
  - Consumer complaints.

- Correlating with inspection program personnel (IPP) and the Frontline Supervisor (FLS) assigned to the plant.
The EIAO is to document their PHRE recommendation to the District Office management (same as for meat and poultry PHRE).

The possible outcomes of the PHRE include:
- Recommendation of an administrative enforcement action,
- Recommendation that no action be taken because neither an enforcement action nor an FSA is needed, or
- Recommendation for an FSA as described in FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology.
Pre-FSA, the EIAO will:
- Provide IPP and plant personnel 1-2 weeks advance notice of the FSA.
- Become familiar with the plant’s operations, restrictions, and controls.

Entrance meeting, the EIAO and plant management will discuss:
- Differences between IPP role and EIAO role,
- Access and examination authority and how observations will be made,
- Communicating findings,
- Possible FSA outcomes, and
- Delivery of the completed report.
Food Safety and Inspection Service:  
Egg Products FSA Process - FSA Methodology

The FSA may be conducted by one EIAO, or multiple EIAOs.

**When Initiating FSAs, the EIAO will:**
- Begin assessing and analyzing the plant’s food safety system to verify the production of safe and wholesome egg products in accordance with FSIS statutory and regulatory requirements.
- Review ~60 days of records and make observations.

**Importance of Proper Communication:**
- EIAOs are to carry out their duties in a fair, firm, professional, and courteous manner; treat in-plant and establishment personnel with respect; and keep them informed as to their actions by maintaining open lines of communication.
Time to Complete FSAs:
  - The EIAO will complete the FSA within 5-7 production days.
  - Only under rare situations will the FSA extend beyond 5-7 days.

General FSA Methodology:
  - The EIAO conducts the assessment by direct observation of the plant’s implemented food safety system and review of plant records.
  - The EIAO is to focus on the overall design of the food safety system, from a regulatory, statutory, and science-based perspective.
  - The EIAO is not to focus on verifying whether individual regulatory requirements are in compliance.
  - HACCP requirements will not be verified, the EIAO can be available to answer any theoretical HACCP principle questions, if asked.
Answering FSA Egg Products Tool questions:
- The EIAO is to complete the General Tool (Background, demographics, compliance history, etc.).
- The EIAO is to document all relevant noncompliance and vulnerability findings in the Egg Products Tool.

The FSA Egg Products Tool covers the following:

- General Sanitation
- Shipping and Receiving
- Formulation/Blending
- Cooling, Freezing, Defrosting, and Holding
- Egg Product Stabilization (De-sugaring)
- Miscellaneous
- Receiving, Washing, and Breaking
- Pasteurization
- Egg Drying
- Salmonella Sampling
- Packaging

- Only applicable sections of the Tool are completed
- Some FSAs will be short, while others may take 5-7 days
Food Safety and Inspection Service:
Egg Products FSA Process - FSA Methodology

The FSA Egg Products Tool is not a regulatory document, it is designed to assist the EIAO in evaluating, organizing, and documenting their observations and review of the food safety system.

Executive Summary:
- The EIAO is to draft a brief overview of the FSA report to give the readers a quick summary of the FSA results.
- This summary focuses on the most essential and significant food safety information.
- This summary is to be concise, and include an analysis of the background, applicable sample results, and the observations made throughout the FSA support the recommendation.
The EIAO must receive District Office concurrence before taking an enforcement action.

Note: The egg products plant can follow the procedures in 9 CFR 590.300 for the appeal of an inspection or decision.
Exit Conference, the EIAO will:

- Provide the plant with a copy of the report,
- Discuss the results of the FSA, including any noncompliances observed,
- Issue any NRs or enforcement documents,
- Answer questions, and
- Thank everyone for their cooperation.
As part of the phased roll-out, FSIS will consider:
Acceptability of the tool to cover all plant operations,
The FSA findings and any vulnerability trends and trends of noncompliance,
Identification and classification of best practices,
Available avenues for outreach assistance, and
Issuance of policy documents.

FSIS will analyze whether new or revised guidance materials are needed to outline best practices.
Resources:

FSIS Website: https://www.fsis.usda.gov/

Egg Products Inspection Act

FSIS Directive 5100.4 – PHRE Methodology

FSIS Directive 5100.1 – FSA Methodology

- General FSA Tool
- The Egg Products Tool will be added to FSIS’ website at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/food-safety-assessments

Questions can be submitted to askFSIS, at https://askfsis.custhelp.com/, using the subject “Egg Products FSA”
Food Safety and Inspection Service: Questions?