



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

**Public Health Risk Evaluation (PHRE)
and Food Safety Assessment (FSA)
Methodology at Egg Products Plants**

*Drive Compliance With Food Safety
Statutes and Regulations*

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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

Food Safety and Inspection Service:
FSIS Authority - Access and Examination



We are the public health agency in the USDA and are responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970

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)

Food Safety and Inspection Service:
EIAO Background and Role

The Agency believes it can better protect public health by assigning an Enforcement Investigations & Analysis Officer (EIAO) to perform PHREs and FSAs at Egg Products plants.



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.

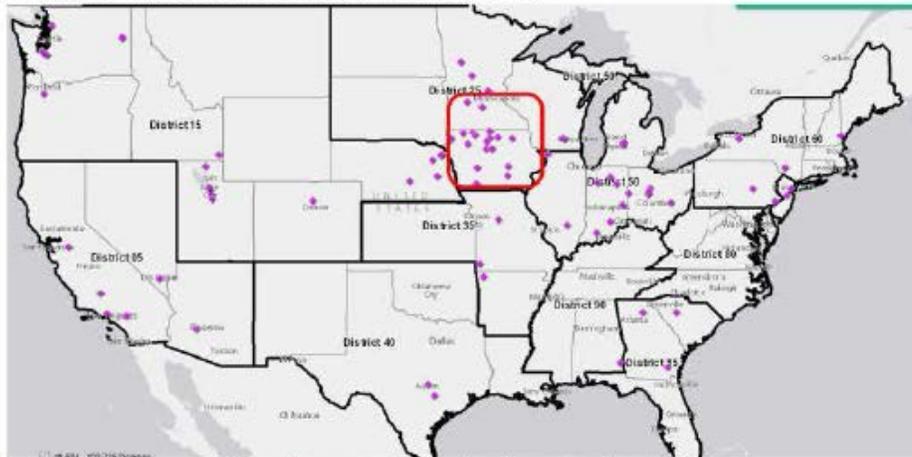
FSAs are conducted by EIAOs in a manner that protects the confidentiality of the information gathered, particularly commercially sensitive and proprietary information.

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

Food Safety and Inspection Service:
Egg Products FSA Process - PHRE

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.

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Food Safety and Inspection Service:
Egg Products FSA Process - PHRE

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.

Food Safety and Inspection Service:
Egg Products FSA Process - PHRE

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.

Food Safety and Inspection Service:
Egg Products FSA Process - FSA Methodology

[FSIS Directive 5100.1](#) – FSA 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.

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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.

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Food Safety and Inspection Service:
Egg Products FSA Process - FSA Methodology

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.

Food Safety and Inspection Service:
Egg Products FSA Process - FSA Overview

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

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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.

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Food Safety and Inspection Service:
Egg Products FSA Process - FSA Methodology

Recommendation, the EIAO will recommend:

- No action
- Issuance of NRs by IPP
- Suspension *with* prior notification, or
 - FSIS may provide prior notification to allow the plant opportunity to take corrective actions and avoid suspension
- Suspension *without* prior notification
 - FSIS may not provide prior notification when it is essential in the interest of public health, and as listed in [9 CFR 590.160\(f\)\(1\)](#)



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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.

Food Safety and Inspection Service:
Egg Products FSA Process - FSA Methodology

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.

Food Safety and Inspection Service:

Take the
NEXT STEPS



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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.

Food Safety and Inspection Service: Resources

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?

