



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

FSA Methodology Introduction

Condensed EIAO



Objectives:

1. Learn how to use Decision Making Analysis (DMA) to identify food safety vulnerabilities
2. Learn when to recommend performing an FSA
3. Learn how to complete FSA within the identified time frames involved in preparing for, notifying other parties, conducting, and concluding an FSA.
4. Write an executive summary that supports recommended outcomes of PHREs and FSAs.

Objectives continued:

5. Describe the distribution of the FSA Report and timeframe for completion.

Background

- FSIS Directives 5100.1 (Dec 17, 2024) & 5100.4 (Aug 12, 2021) outline EIAO workflows and processes for performing FSAs and PHREs
- EIAOs work closely with CSIs, FLSs, District Office staff, policy development staff, headquarters staff, compliance officers and other program employees
- TEAM Approach!



Background continued

- EIAOs will:
 - Complete Public Health Risk Evaluations (PHRE)
 - Conduct FSAs based on the PHRE results
 - 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

Background

- FSAs are a risk based, targeted, review of an establishment's food safety system based on PHRE and PHIS data
- The EIAO is to complete the in-plant portion of the FSA within seven production days
 - The time for sampling is not included in the seven days allotted for the FSA

FSA Methodology

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| Time in Plant | No more than 7 (Seven) days in plant |
| Public Health Risk Evaluation (PHRE) | Make a determination to conduct FSA, Enforcement or No Action. Pre-FSA analysis |
| Sampling | Occurs prior to start of FSA |
| FSA Tools | 9 tools with about ~400 questions However, in most cases only the General tool and one other tool may be conducted |
| Approach | Assessing overall design of program and food system |
| EIAO Responsibilities | Shorter time frame, focused approach, DO not remove EIAO during FSA |
| Review Process | Focus on recommendation, summary and supporting actions |

Importance of PHREs & FSAs

- Information evaluated during a PHRE and FSA assists the agency to ensure that consumers receive products that are safe, wholesome, and not adulterated



Overview of FSA Methodology

