

EIAO Work Methods

EIAO Training



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.

Objectives:

5. Write an executive summary that supports recommended outcomes of PHREs and FSAs.
9. Describe the distribution of the FSA Report and timeframe for completion.
10. Given a scenario, perform an FSA using records only and complete the required tools and document a supportable enforcement recommendation.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5100.1
Rev. 4

5/29/15

ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) FOOD SAFETY
ASSESSMENT (FSA) METHODOLOGY

Implementation of new FSA procedures in PHIS will be 6-10-15. For FSAs scheduled prior to this date, the EIAO is to record his or her FSA reports using Word versions of the modified tools. Updated tools will be available on the EIAO SharePoint site on 6-1-15.

CHAPTER I – GENERAL

I. PURPOSE

The purpose of this directive is to provide instructions to EIAOs on how to conduct FSAs using a new work methodology, so an EIAO can complete the in-plant portion of most FSAs in 5 to 7 production days. This directive also provides instructions on how to document FSAs using the FSA tools that are a series of questionnaires that an EIAO is to use to gather information. The new work methodology is designed to focus the FSAs on public health risk and to increase consistency in how EIAOs conduct FSAs. For the purposes of this directive, the term "EIAO" also refers to EIAO-trained Public Health Veterinarians (PHVs) when they are conducting EIAO activities. The term "District Office (DO)" includes the District Manager (DM); the Deputy District Manager (DDM); the Supervisory Enforcement, Investigations and Analysis Officer (SEIAO); and the District Case Specialist (DCS).

II. CANCELLATION

FSIS Directive 5100.1, Revision 3, Enforcement, Investigation and Analysis (EIAO) Comprehensive Food Safety Assessment Methodology, 8/23/11

III. SIGNIFICANT CHANGES

1. Establishment of a timeline for the completion of most FSAs from 2 to 4 weeks to 5 to 7 production days;
2. FSAs are to be performed after the EIAO derives results from a Public Health Risk Evaluation (PHRE);
3. The EIAO is to focus on certain processes during the FSA based on the PHRE;
4. Any Routine *Listeria monocytogenes* (RLm) sampling is to be conducted before the start of an FSA; and

Background

- FSIS directives outline EIAO workflows and processes for performing PHREs and FSAs.
- EIAOs work closely with CSIs, FLSs, District Office staff, policy development staff, headquarters staff, compliance officers and other program employees.
- TEAM Approach!



Background

- 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 in-plant part of the FSA should take 5-7 production days to complete.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
	1	2	3	4	5	6	7
	[Red bar spanning days 1-6]						
	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				

FSA Methodology

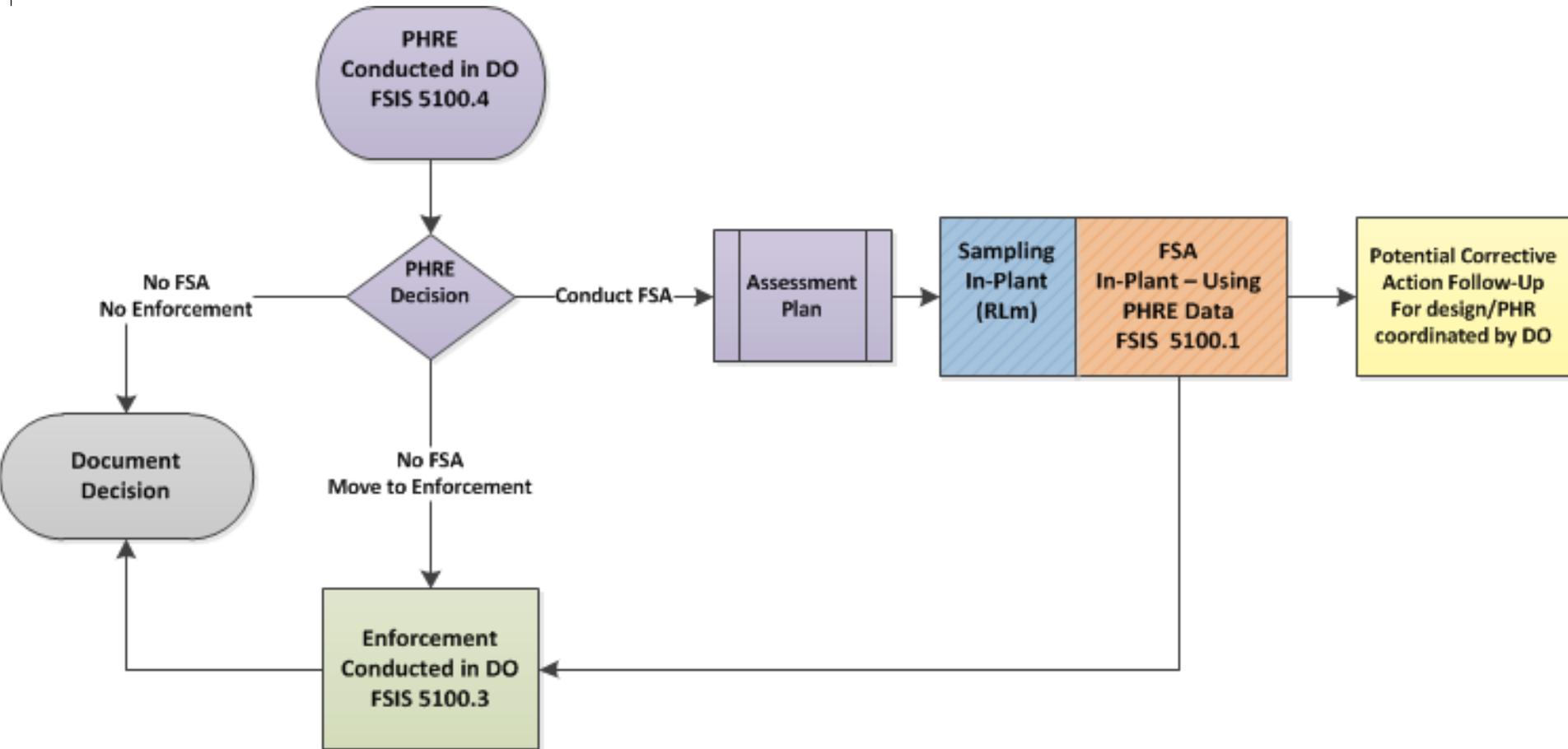
Time in Plant	5-7 In-plant production days
Public Health Risk Evaluation (PHRE)	Make a determination to conduct FSA, Enforcement or No Action. Pre-FSA analysis
Sampling	Occurs prior to start of FSA.
FSA Tools	6 tools with about ~400 questions. However, in most cases only the General tool and one other tool may be conducted.
Approach	Assessing overall Design of Program and Food System
EIAO Responsibilities	Shorter time frame, focused approach, DO not to 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.
- Supports the FSIS Strategic Plan.



Overview of FSA Methodology



Public Health Risk Evaluation (PHRE) Background

- A decision making process utilized to determine if the District Office (DO) needs to schedule an FSA or take enforcement action.
- PHRE is a separate activity from the FSA and will be completed prior to scheduling FSAs

Public Health Risk Evaluation



PHRE/ FSA Scheduling

- Office of Planning, Analysis and Risk Management (OPARM) provides a prioritized list to DO for scheduling FSAs.
- The list is generated based upon available inspection data:
 - Public Health Triggers
 - Trends in Noncompliance Records/ Public Health Regulations
 - Recalls and Outbreaks
 - Production of adulterated product = positive FSIS sample results

PHRE/ FSA Scheduling

- OPARM is responsible for developing ways to use data in inspection and enforcement decisions. The Agency is actively working to better use inspection data to inform inspection activities.
- The establishment's inspection data needs to be assessed. But it's only one part of the picture – here's where you come in to assess the establishment and make a recommendation.

PHRE/ FSA Scheduling

- Many establishments are on the PHRE list based on noncompliance with Public Health Regulations (PHR).
 - PHR non-compliance rates are calculated for each establishment monthly, and IPP will get an Early Warning alert when rates exceed the cut point
 - Establishments with a PHR NR rate exceeding the cut point will be included in the proposed “for cause” list
 - The list of PHRs is updated annually
 - PHR Methodology:
 - <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting/public-health-regulations>

PHRE/ FSA Scheduling

- FSIS is actively working to better use data generated from to tasks to drive inspection decisions
- The list isn't the only way the Agency uses to identify establishments. Districts may schedule for other reasons to include:
 - Recommendations from field personnel
 - In response to changes in policy based on new or emerging public health based information
 - Response to emergency incidents.
 - See Directive 5500.3, Incident Investigation Team

Public Health Risk Determinations for PHRE Priority Order

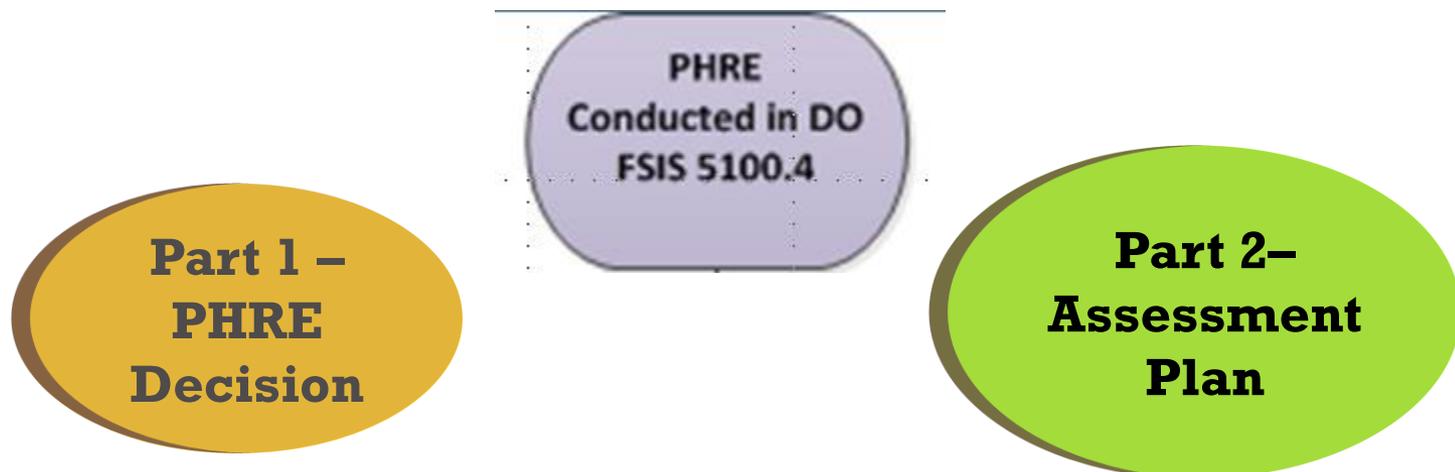
Public Health Risk Determinants	Data Sources	References	If needed, type of FSA to be scheduled
Human illness linked to FSIS-regulated product ¹	Coordination with Office of Public Health Science / Applied Epidemiology Staff (OPHS/AES) and Office of Investigation, Enforcement and Audit (OIEA)	FSIS Directive 8080.3	For-cause
Emergency Management Committee (EMC) determines an IIT will be conducted ²	EMC	FSIS Directive 5500.3	For-cause
Establishment that produced and shipped adulterated or misbranded product, undergoing a Class I or Class II recall	Coordination with Office of Field Operations of (OFO) Resource Management and Technical Analysis Staff (RMTAS)	FSIS Directive 8080.1	For-cause
Positive STEC test results on ground beef or patties or raw beef components through testing by FSIS or other government entities' testing (such as AMS or state public health labs) (see Section V. F.)	ODIFP-DAIS PHRE scheduling report	FSIS Directive 10,010.1	For-cause
FSIS positive <i>Listeria monocytogenes</i> (Lm) or <i>Salmonella</i> in ready-to-eat (RTE) product	ODIFP-DAIS PHRE scheduling report	FSIS Directive 10.300.1	For-cause
<i>Establishment identified as a sole supplier of a positive STEC ground beef or patties or raw beef components</i>	<i>ODIFP-DAIS PHRE scheduling report</i>	FSIS Directive 10,010.1	<i>For-cause</i>
Establishment with more than one STEC positive in the past 120 days identified as a multiple supplier, except if the establishment applied a full lethality treatment to the implicated raw beef product	ODIFP-DAIS scheduling report	FSIS Directive 10,010.1	For-cause

Public Health Risk Determinations for PHRE Priority Order

Public Health Risk Determinants	Data Sources	References	If needed, type of FSA to be scheduled
Establishment with a history of public health-related noncompliance records and is in the highest percentile of health-related NR rates	ODIFP-DAIS PHRE scheduling report	Public Health Regulations	For-cause
Establishment in PR/HACCP <i>Salmonella</i> Category 3	ODIFP-DAIS PHRE scheduling report	FSIS Directive 10.250.1	For-cause
Establishment produced product with repetitive <i>Salmonella</i> serotypes of public health concern ¹	Laboratory Information Management System (LIMS-Direct); <i>Salmonella</i> End-of-Set Letter	FSIS Directive 10.250.1	For-cause
Establishment produced product with matching <i>Salmonella</i> PFGE patterns ¹	<i>Salmonella</i> End-of-Set Letter	FSIS Directive 10.250.1	For-cause
Repeat residue violators from same supplier source ¹	Residue Repeat Violator List	FSIS Directive 10.800.1	For-cause
Documented change in an establishment's production process that may impact public health ¹	FLS requested	FSIS Directive 5000.6	For-cause
Consumer complaints associated with meat or poultry products as reported through the Consumer Complaints Monitoring System (CCMS) ¹	Monthly CCMS monitoring	FSIS Directive 5610.1	For-cause
New establishments coming under a permanent grant of inspection ¹	Grant application	FSIS Directive 5220.1	Risk-based
Instructed in FSIS Notice or Directive	Policy issuance		Risk-based
Establishment producing post-lethality exposed ready-to-eat (RTE) products without positive sample results	ODIFP PHRE scheduling report	FSIS Directive 5100.1	Risk-based

The PHRE- *Directive 5100.4*

- PHRE has two parts:
 1. A decision process to determine which action to take.
 2. An Assessment Plan, if an FSA is recommended.



Part 1-Decision

- There are three possible decisions based on the PHRE
- The decisions must be documented in the PHRE tool
 1. Enforcement can be taken immediately based on the establishment's history
 2. An FSA should be performed to address vulnerabilities that can lead to adulterated or misbranded product
 3. No issue at the time

Part 1-Decision

- Utilizing the PHRE Tool, you will:
 - Perform a PHRE review and evaluate relevant data. The tool is designed to help you gather and access the data gathered from all parts of the Agency (lab data, inspection data, IPP input).
 - Document recommendation
 - Conduct FSA (*5100.1*)
 - Do not conduct FSA, but take enforcement action (*5100.3*)
 - Do not conduct FSA, do not take enforcement action (*5100.4*)



Part 1-Decision-Data Review



- Performing the PHRE Review
 - Evaluate PHIS PHRE Report
 - Report generated from PHIS
 - Past FSAs
 - Enforcement Data
 - Compliance History
 - PHIS Profile Data
 - Weekly Meeting MOI
 - IPP MOIs
 - Recall Information
 - Sampling Results
 - STEPs Information

USDA United States Department of Agriculture
Food Safety and Inspection Service

Public Health Information System

EIAO/S EIAO Home About PHIS My Profile Help Sign Out

You are here: Home > Reports Inventory

Inventory of Standard Reports

Show Description

Page size: 10 First Prev Page: 4 of 6 Next Last Displaying page 4 of 6, Items 31 to 40 of 55

Title	Category		
Noncompliance Records for an Establishment	Inspection Task	View	Print
NR Search by NR Number	Inspection Task	View	Print
NRs from PHIS and PBIS for an Establishment	Inspection Task	View	Print
Pending Dispositions for an Establishment	Slaughter	View	Print
PHR Noncompliances for a Circuit	Inspection Task	View	Print
PHR Noncompliances for an Establishment	Inspection Task	View	Print
Public Health Risk Evaluation for Establishment	Establishment Profile	View	Print
Salmonella - Campylobacter Sampling Task Status and List for an Establishment	Lab Sampling	View	Print
Sample Collection Status for a Circuit	Lab Sampling	View	Print
Sample Collection Status for an Establishment	Lab Sampling	View	Print

Part 1-Decision-Data Review

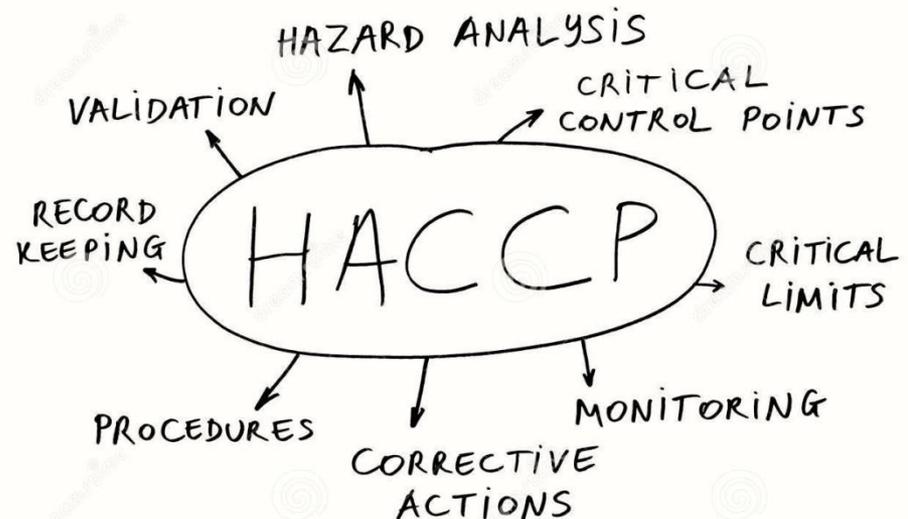
- Performing the PHRE Review
 - Investigate and gather data and other background information
 - Use PHIS to generate the PHRE report
 - Testing Data from LIMS Direct
 - Consumer Complaints from CCMS
 - Previous FSAs not in PHIS
 - Additional Enforcement Records (AssuranceNet)
 - Whole Genome Sequence and PFGE results for previous LM positives (Labs)
 - Discuss compliance with:
 - FLS, CSI, DDM

Analyze PHRE Data

- Analyze and identify any trends in sampling results or in NRs.
- Evaluate data looking for:
 - Poor or worsening performance
 - Evidence the establishment is not maintaining process control
 - Insanitary conditions

Part 1-Decision

- Documenting No Action:
 - The third outcome is that there is no action at this time. The rationale and explanation should also be documented on the PHRE. Support your decision with documentation from the PHRE.



Part 2- Assessment Plan

- The PHRE, by design, is the first step needed to formulate the assessment plan. It is formulated prior to performing an FSA to help inform the planning of the FSA.
- Assists the EIAO develop a plan to:
 - Ensure the FSA is thorough
 - Well organized
 - Promotes timeliness

**Part 2–
Assessment Plan
for
FSA**

Part 2- Assessment Plan

- Assessment Plan Contains



- Apparent Violations

- Statement of possible food safety issues found.
- Should contain relevant Statutes, regulations, etc.

- Scope of FSA

- The extent and range of the FSA such as:
 - Tools, regulatory issues, food safety issues or other issues that will be addressed.

- Steps of assessment:

- Steps to gather facts, findings and evidence to explore apparent/ possible food safety issues. The plan can change based on in-plant findings during the FSA



Objective Check-Up

- What is the overall purpose of the PHRE?



Objective Check-Up

- What are the two parts of the PHRE?

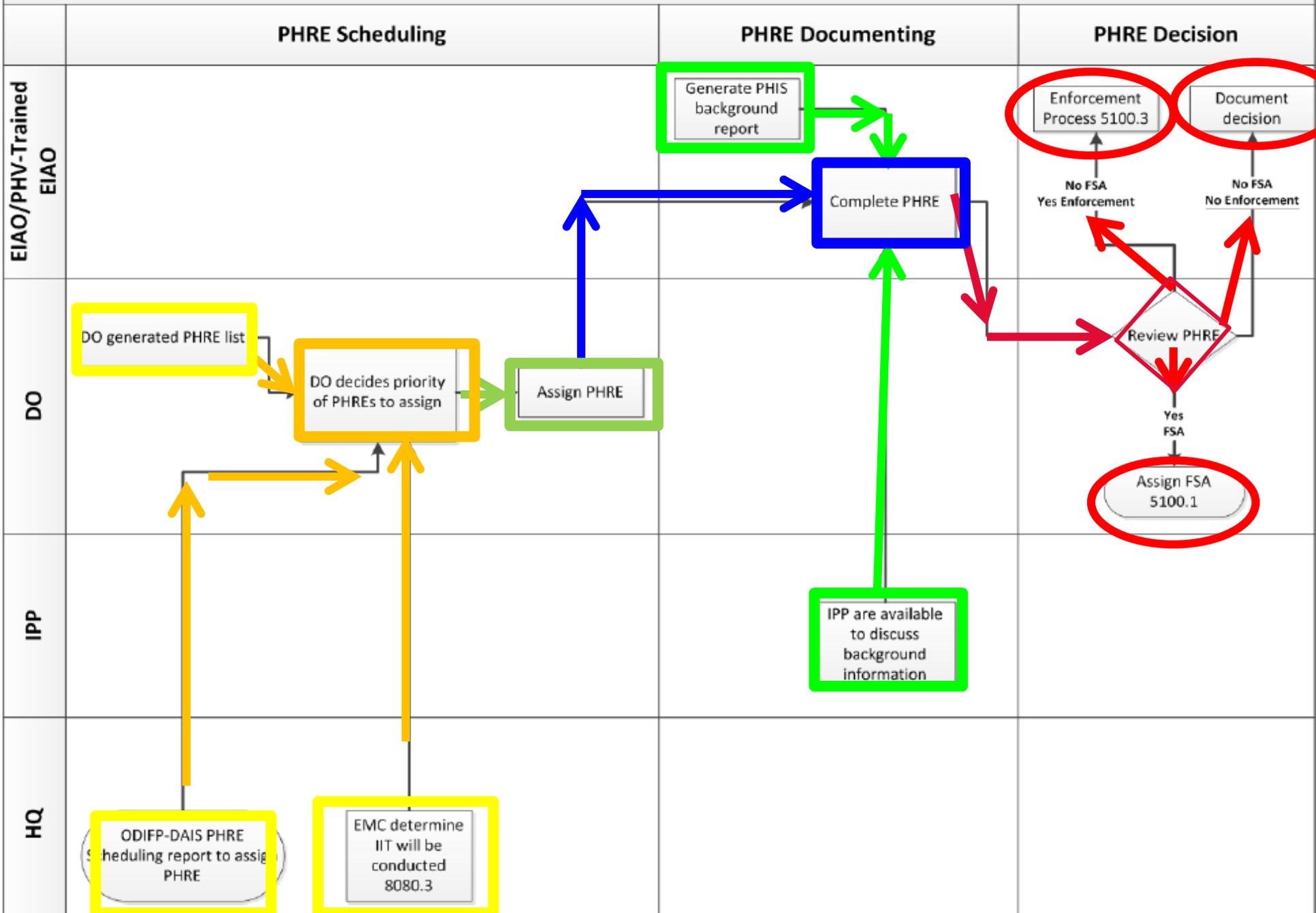


Objective Check-Up

- When is the PHRE tool to be completed.



Figure 1 – PHRE Work Flow Overview



PHRE Tool

- Now let's look at the PHRE Tool

Public Health Risk Evaluation (PHRE) vs2

** For Internal Use Only – Do Not Distribute to Establishment **

The PHRE is a decision-making process that is to be used to determine whether the District Office needs to schedule a Food Safety Assessment (FSA).

***References:**

[FSIS Directive 5100.4](#) *Enforcement, Investigations and Analysis Officers (EIAO) Public Health Risk Evaluation (PHRE) Methodology*

[FSIS Directive 5100.1](#), *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology*.

Establishment Information: (Name, Est. Number, Location, Email, Corporate Structure, and District/Circuit)

PHRE1 Based on the analysis of the PHRE PHIS report (see [FSIS Directive 5100.4](#)), can the Agency take a supportable enforcement action immediately?

NOTE: If enforcement action will be taken, no FSA is necessary.

Yes

No

IMPORTANT NOTE:
THE PHRE IS AN INTERNAL DOCUMENT
AND IS **NOT** TO BE PROVIDED TO
ESTABLISHMENTS

PHRE Workshop



Food Safety Assessment-FSA

EIAO Training



THE FSA

Directives 5100.1 Rev. 4

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ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) FOOD SAFETY ASSESSMENT (FSA) METHODOLOGY

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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
- Focus on documenting vulnerabilities and noncompliance.

The FSA: Purpose

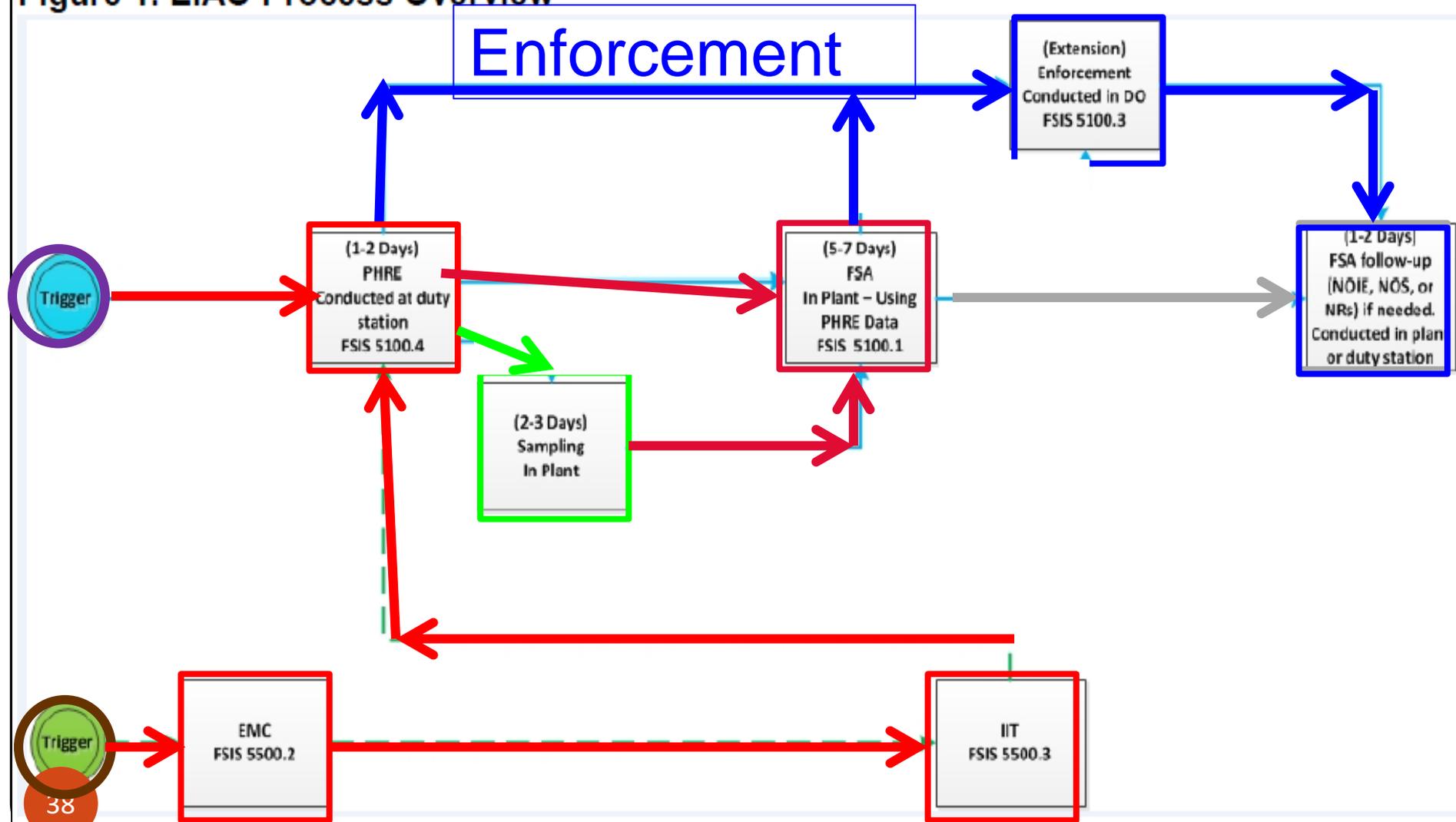
- FSA Methodology

- Focus based approach.

- Allows for EIAOs to focus time and resources on vulnerable portions of the Establishment's Food Safety System.
- Allows for EIAO's 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

Figure 1. EIAO Process Overview



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

Product Types	HACCP Category	Tool to Use
Raw Poultry	Slaughter; Raw Intact; Raw Non Intact	Poultry Tool
Raw Meat	Slaughter; Raw Intact; Raw Non Intact	Meat Tool
NRTE Meat or Poultry	HT SS; NHT SS; HT NFC NSS; Secondary Inhibitors NSS	RTE/NRTE Products Tool
RTE Meat or Poultry	HT SS; NHT SS; FC NSS; Secondary Inhibitors NSS	RTE/NRTE Products Tool
Thermally Processed Meat or Poultry	Thermally Processed Commercially Sterile	Thermally Processed Commercially Sterile Tool

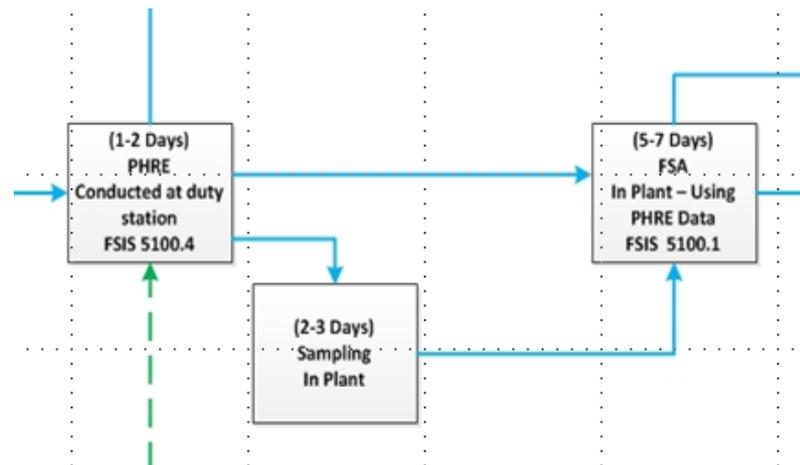
Scope of the FSA



- 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 apart of the 5-7 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; and
- 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 d 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

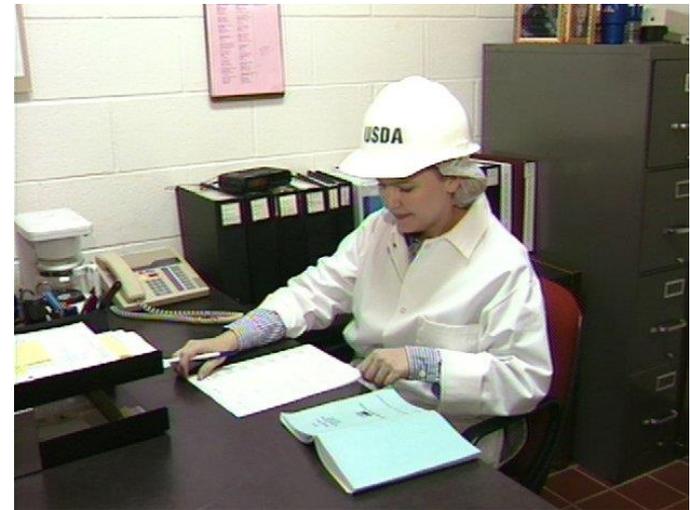


Prior to Visiting the Plant

- 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 DCS.
- EIAO Contact Information



Entrance Meeting

- Document entrance meeting in the
 - General Tool



Performing the Assessment



On-going Communication

Ongoing Communication

- FSIS expects the EIAO to communicate with establishment management throughout the FSA process.
- Remain fair and objective



Ongoing Communication

- Bring attention to and discuss noncompliances and vulnerabilities as they are identified
- 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

IMPORTANT

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.

Teamwork!



Ongoing Communication

- Example
 - EIAO recommends in-plant team issue NRs
 - Contacts DDM and SEIO 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

Teamwork!



Ongoing Communication

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

Due Process



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



Ongoing Communication

- 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

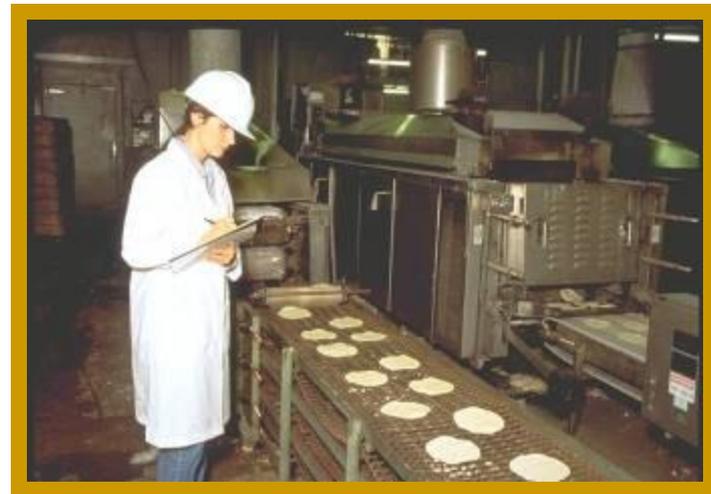


FSA Methodology

- 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

Public Health Risk Evaluation (PHRE) vs2

The PHRE is a decision-making process that is to be used to determine whether the District Office needs to schedule a Food Safety Assessment (FSA).

*References:
[FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officers \(ELAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#)
[FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer \(ELAO\) Comprehensive Food Safety Assessment \(FSA\) Methodology](#)

Establishment Information: (Name, Est. Number, Location, Email, Corporate Structure, and District/Circuit)

General FSA Tool vs3

This is the General FSA Tool. This tool is to be completed as part of all Food Safety Assessments.

The General Tool contains the following sections:
 FSA Recommendation (Questions G1 - G13)
 General Sanitation (G14 – G28)
 Other General Questions (G29 – end)



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Food Safety and Inspection Service

Meat FSA Tool vs2

This FSA tool is for establishments that produce RAW MEAT PRODUCTS that are considered to fall under the following HACCP processing categories:

MEAT SLAUGHTER
 INTACT MEAT
 NON-INTACT MEAT

The FSA Tool contains the following:

- Hazard Analysis and HACCP System
- Slaughter and Sanitary Design
- Outside Source Materials for Slaughter
- Antimicrobial Treatment
- Sampling and Testing for Slaughter

United States Department of Agriculture
Food Safety and Inspection Service

Not Ready-To-Eat (NRTE) Processed Products FSA Tool vs2

This FSA tool is for establishments that produce NOT READY-TO-EAT (NRTE) MEAT OR POULTRY PRODUCTS that are considered to fall under the following HACCP processing categories:

HEAT TREATED, SHELF STABLE;

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Poultry FSA Tool vs2

This FSA tool is for establishments that produce RAW POULTRY PRODUCTS that are considered to fall under the following HACCP processing categories:

HEAT TREATED, SHELF STABLE;

The FSA Tool contains the following:

- Hazard Analysis and HACCP System
- Slaughter and Sanitary Design
- Outside Source Materials for Slaughter
- Antimicrobial Treatment
- Sampling and Testing for Slaughter

United States Department of Agriculture
Food Safety and Inspection Service

Ready-to Eat (RTE) Processed Products FSA Tool vs2

This FSA tool is for establishments that produce READY-TO-EAT (RTE) MEAT OR POULTRY PRODUCTS that are considered to fall under the following HACCP processing categories:

HEAT TREATED, SHELF STABLE
 NOT HEAT TREATED, SHELF STABLE
 FULLY COOKED, NOT SHELF STABLE
 SECONDARY INHIBITORS, NOT SHELF STABLE

The FSA Tool contains the following main sections:

- Hazard Analysis and HACCP System (Questions RTE1 – RTE6)
- Lethality and Stabilization: Fully Cooked, Not Shelf Stable (RTE7- RTE40)
- Lethality and Stabilization for Fermentation, Drying, and Salt-curing RTE Processing in the Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; Secondary Inhibitors, Not Shelf Stable HACCP Processing Categories (Questions RTE41- RTE73)
- Non-meat Ingredients for RTE Products (Question RTE72- RTE73)
- *Listeria* Rule (9 CFR 436) for RTE Products (Questions RTE74- RTE98)

The FSA Tools

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

FSA Tools

The FSA Tools

- **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.

The FSA Tools

- 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 to 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 (Questions G1 - G13)
 - General Sanitation (G14 – G28)
 - Other General Questions (G29 – end)

United States Department of Agriculture
Food Safety and Inspection Service



General FSA Tool vs

This is the General FSA Tool. This tool is to be completed as part of all Food Safety Assessments.

The General Tool contains the following sections:

FSA Recommendation (Questions G1 - G13)

General Sanitation (G14 – G28)

Other General Questions (G29 – end)

The FSA Tools - Overview

- Meat Tool

- Hazard Analysis and HACCP System (Questions M1 – M23)
- Slaughter and Sanitary Dressing (M24 -M48)
- Outside Source Materials for Further Processing (M49 – M60)
- Antimicrobial Treatment for Slaughter and Further Processing (M61 – M67)
- Sampling and Testing for Slaughter and Further Processing (M68 – M89)



The FSA Tools - Overview

- Poultry Tool

- Hazard Analysis and HACCP System (Questions P1 – P19)
- Slaughter and Sanitary Dressing (P20 –P39)
- Outside Source Materials for Further Processing (P40 – P47)
- Antimicrobial Treatment for Slaughter and Further Processing (P48 – P55)
- Sampling and Testing for Slaughter and Further Processing (P56 – end)



The FSA Tools - Overview

- Ready-to Eat (RTE) Processed Products FSA Tool
 - Hazard Analysis and HACCP System (Questions RTE1 – RTE6)
 - Lethality and Stabilization: Fully Cooked, Not Shelf Stable (RTE7 - RTE40)
 - Lethality and Stabilization for Fermentation, Drying, and Salt-curing RTE Processing in the Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; Secondary Inhibitors, Not Shelf Stable HACCP Processing Categories (Questions RTE41- RTE71)
 - Non-meat Ingredients for RTE Products (Question RTE72 - RTE73)
 - Listeria Rule (9 CFR 430) for RTE Products (Questions RTE74- RTE98)



The FSA Tools- Overview

- Not Ready-To-Eat (NRTE) Processed Products
 - Hazard Analysis and HACCP System (Questions NRTE1 – NRTE6)
 - Design of the Heat Treatment, Fermentation, or Other Processes for NRTE Processed Products (NRTE7 - RTE41)
 - NRTE Processed Products: Appearance (NRTE42 – NRTE44)



The FSA Tools - Overview

- **Thermally Processed**
 - Hazard Analysis and HACCP System (Questions TP1 –13)
 - Following Canning Regulations as Pre-Requisite Program to Prevent Biological Hazards (TP14 -50)
 - Chemical and Physical Hazards (TP50 – end)



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

 **PHIS**
FSA TOOLS

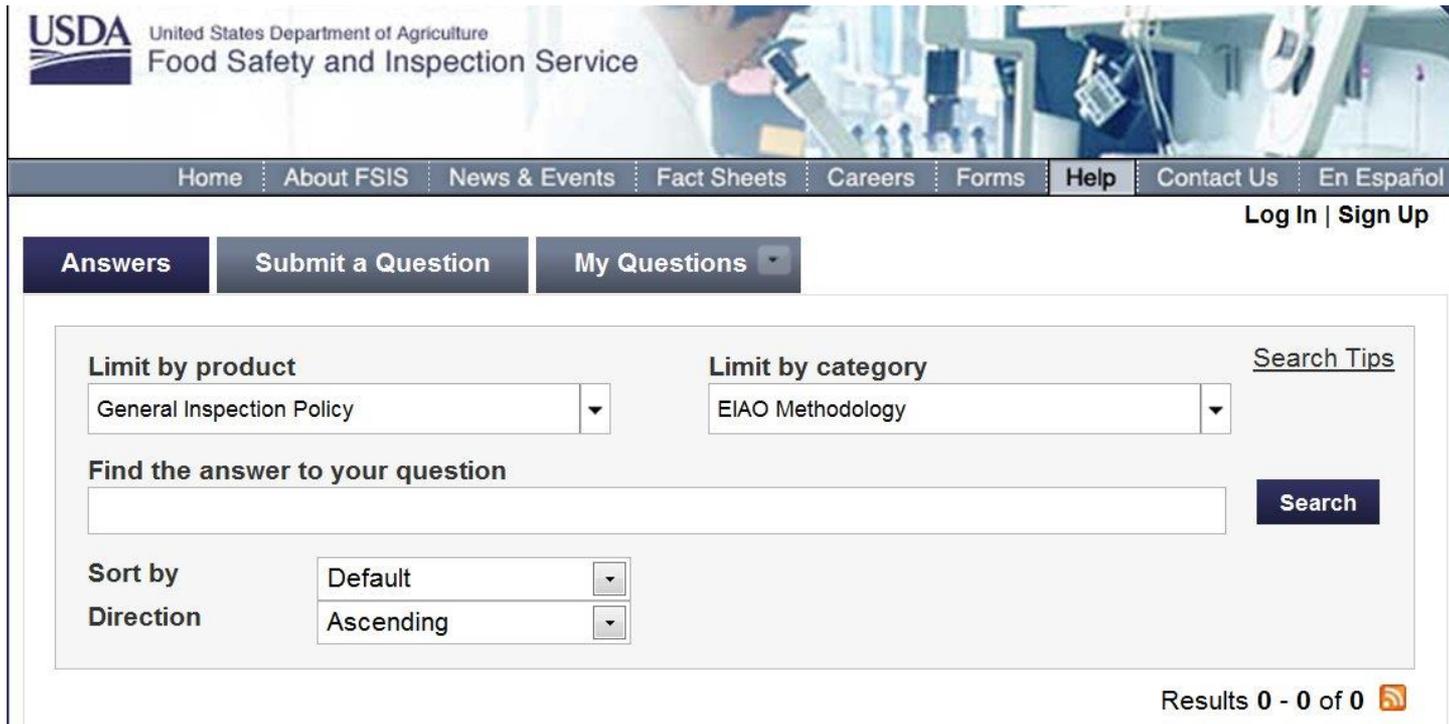


The FSA Tools – Analysis Sections

- 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.



The screenshot displays the AskFSIS website interface. At the top left is the USDA logo with the text "United States Department of Agriculture" and "Food Safety and Inspection Service". A navigation bar contains links for Home, About FSIS, News & Events, Fact Sheets, Careers, Forms, Help, Contact Us, and En Español. On the right side of the navigation bar are "Log In" and "Sign Up" links. Below the navigation bar are three buttons: "Answers", "Submit a Question", and "My Questions". The main content area features a search interface with two dropdown menus: "Limit by product" (set to "General Inspection Policy") and "Limit by category" (set to "EIAO Methodology"). A "Search Tips" link is located to the right of the category dropdown. Below these is a text input field with the placeholder "Find the answer to your question" and a "Search" button. At the bottom left of the search area are two more dropdown menus: "Sort by" (set to "Default") and "Direction" (set to "Ascending"). At the bottom right, it shows "Results 0 - 0 of 0" with a small RSS icon.

Assessment Strategies

EIAO Training



General Sanitation SPS/SSOP

- Review



Sanitation SOP Regulations

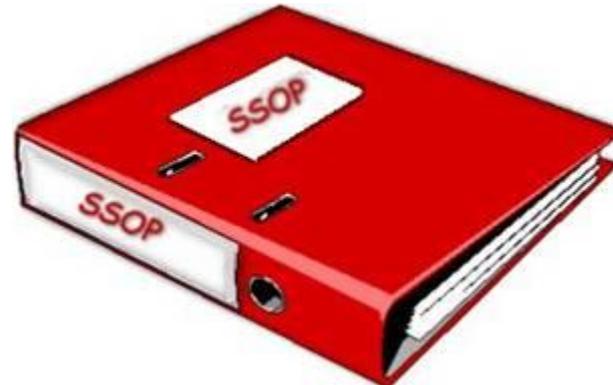
- Development of SSOP (416.12)
- Implementation / Monitoring (416.13)
- Maintenance / Effectiveness (416.14)
- Corrective Action (416.15)
- Recordkeeping (416.16)
- Agency Verification (416.17)

Sanitation SOP Development 416.12

- Sanitation SOP must contain:
 - Procedures to prevent direct contamination of product, or product contact surfaces
 - Procedures they will conduct daily
 - Procedures conducted prior to operations

Sanitation SOP Development 416.12

- Sanitation SOP must:
 - Specify a frequency for each procedure
 - Identify the responsible establishment employee
 - Be signed and dated



Sanitation SOP Implementation 416.13

- Each official establishment shall:
 - a. Conduct pre-operational procedures before start of operations
 - b. Conduct all other procedures at frequencies specified
 - c. Monitor daily the implementation of procedures in the Sanitation SOPs



Effectiveness 416.14

- The establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and procedures therein.
- The establishment shall revise both as necessary to keep them effective and current.

Corrective Action 416.15

- Corrective action must be taken when there is failure to prevent direct contamination of product or product contact surfaces



Corrective Actions 416.15

- **Must:**
 - Ensure appropriate **disposition** of product
 - **Restore** sanitary conditions
 - **Prevent** recurrence of direct product or product contact surface contamination and adulteration



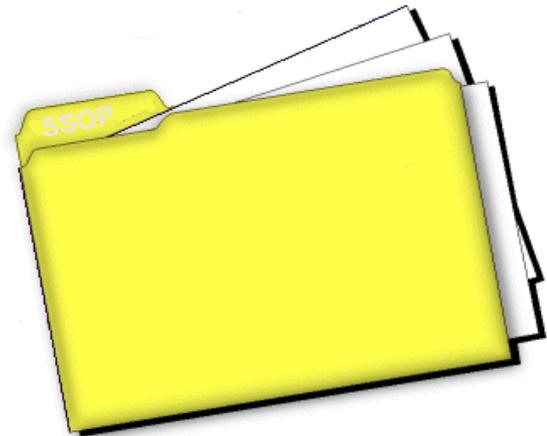
Product or Food Contact Surfaces

- When FSIS finds direct contamination or adulteration of product or food contact surfaces:
 - Take regulatory control action,
 - Verify establishment's proposed corrective actions meet regulatory requirements, and
 - Remove the regulatory control action only when proposed corrective actions meet requirements.



Recordkeeping 416.16

- Establishment must document:
 - Monitoring of Sanitation SOP
 - Any corrective action taken



Recordkeeping 416.16 (c)

- Records are kept
 - For 6 months
 - On-site for 48 hours following completion.
 - May be stored offsite after 48 hours, if they can be given to FSIS within 24 hours of a request



Performing the Assessment - Sanitation

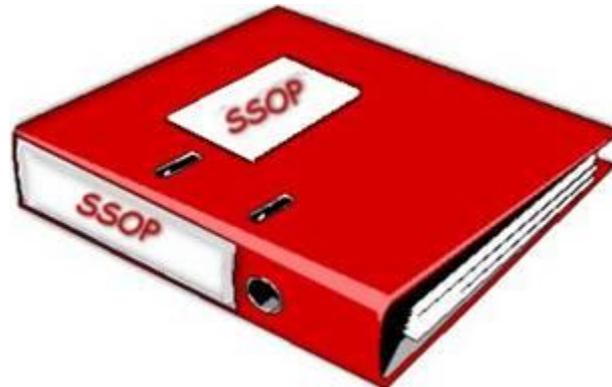
- Use FSIS Directive 5000.1 as guidance
- Answer questions from the General Tool
 - Additional questions may be contained in specific tools. i.e. Sanitary Dressing/ RTE Sanitation.
 - Review appropriate records
 - Make direct observations

Performing the Assessment - SPS

- The EIAO reviews and considers
 - Sanitation NRs
 - *Salmonella* Performance Standards results
 - Impact of SPS findings on food safety
 - Impact on the HACCP system
 - View entire operation
 - Determine if adequate level of sanitation is maintained to prevent product adulteration

Performing the Assessment - SSOP

- The EIAO will
 - Review SSOP design
 - Observe SSOP implementation
 - Randomly review 13 days of SSOP records from the last 60 production days
 - Answer questions from tools



Performing the Assessment - SSOP

- The EIAO will
 - Assess whether the SSOP and its routine procedures are designed and implemented to prevent direct product contamination
 - Analyze how the SSOP design and implementation impacts the ability to support decisions in the Hazard Analysis and HACCP plan implementation

Performing the Assessment - SSOP

- The EIAO should analyze the information collected relating to sanitation requirements and document a supportable agency position.



General Tool – Dual Jurisdiction

- When establishments produce both FDA and FSIS regulated products, gather info about how establishments address production
- Directive 5730.1
- Assess how the food safety system prevents contamination of FSIS products from insanitary conditions in FDA areas, especially for PLE RTE products

Other Information - Recalls

- 418.2 Notification
 - Establishment must notify FSIS within 24 hours if reason to believe adulterated product entered commerce
- 418.3 Written Recall Procedures
 - Establishment must maintain written procedures specifying how to decide on recall and how it would be carried out
- 418.4 Records
- Verification methods covered in Directive 5000.8

Other Information - Recalls

- Directive 5000.8 Verifying Compliance with Requirements for Written Recall Procedures
- Use Methods from Directive 5100.1
- General tool updated to address
- If EIAO determines noncompliance with 418
 - Work with supervisor to get NR issued under Other Inspection Requirements

Methods Group Exercise I

- A cattle slaughter plant has had multiple instances of rail dust contamination on carcasses the last 2 months.
- What would your regulatory & statutory thought process be for taking a possible enforcement action?



HACCP

EIAO Training



Performing the Assessment - HACCP

- Use Directive 5000.1 for policy guidance
- Answer the questions in the FSA Tool appropriate for the processing category
- Assess design and implementation

Hazard Analysis

9 CFR 417.2(a)(1)

- Each establishment must have a hazard analysis conducted to determine the food safety hazards reasonably likely to occur in the production process and identify preventive measures the plant can apply to control those hazards.

Hazard Analysis

Hazard Analysis – 417.2(a)(1)

- The Establishment must:
 - Consider all potential biological, chemical, and physical food safety hazards
 - Determine the food safety hazards reasonably likely to occur in its process
- Provides the basis for an establishment's food safety system

Hazard Analysis – 417.2(a)(1)

- HA involves:
 - Hazard identification
 - Hazard evaluation
- An adequate HA ensures the level of risk to the consumer is acceptable
- The HA must be supported according to 417.5(a)(1)

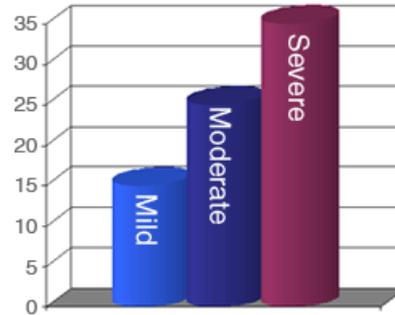
Hazard Identification



- Meat and Poultry Hazards and Controls Guide
[https://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat and Poultry Hazards Controls Guide 10042005.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES)
- FSIS Microbiological Hazards Guide
<http://www.fsis.usda.gov/Oa/haccp/higuide.pdf?redirecthttp=true>
- Appendices C & D of the HACCP Final Rule FR Notice
www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf
- FSIS HACCP Guidance
<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp>

Evaluating Hazards

- Based on:
 - Severity
 - Likelihood



- Arbitrary decisions can lead to:
 - CCPs unrelated to product safety
 - No CCP for controlling a high risk hazard



Hazard Analysis Decisions

- Reasonably Likely To Occur
 - CCP somewhere in the process
 - Support and validation for CCP
- Not Reasonably Likely To Occur
 - Supporting documentation
 - Prerequisite programs to prevent the hazard from occurring



Hazard Analysis

- If HA conducted incorrectly and does not identify significant hazards - HACCP plan will be ineffective
 - If cannot support decisions - 417.5(a)(1)
 - Noncompliance with 417.2(a) because of an inadequate hazard analysis
 - As a result an inadequate system may exist – 417.6

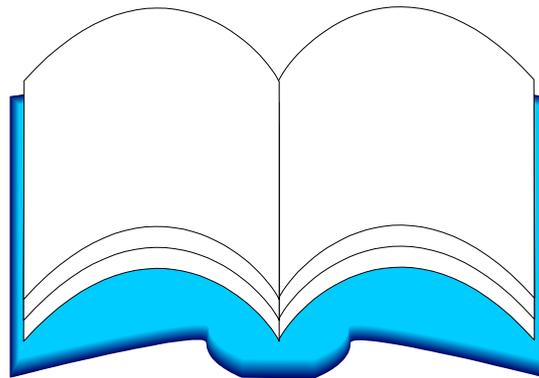
Performing the Assessment - HACCP

- Begin review of the HACCP system
- Verify the design of the hazard analysis
- Assess whether appropriate hazards have been addressed
- Use the questions from the Hazard Analysis and HACCP system section of each tool.

Performing the Assessment - HACCP

- Let's look at some of the questions from the FSA Tools in your notebook that deal with the hazard analysis and HACCP system.

FSA Tools



Performing the Assessment - HACCP



Supporting
Documentation
Workshop

Performing the Assessment - Prerequisite Programs (PRP)

- PRPs are often used to support decisions in hazard analysis
- Decisions often involve these programs preventing a hazard from being reasonably likely to occur (RLTO) or significant
 - Example: Purchase specifications for incoming materials



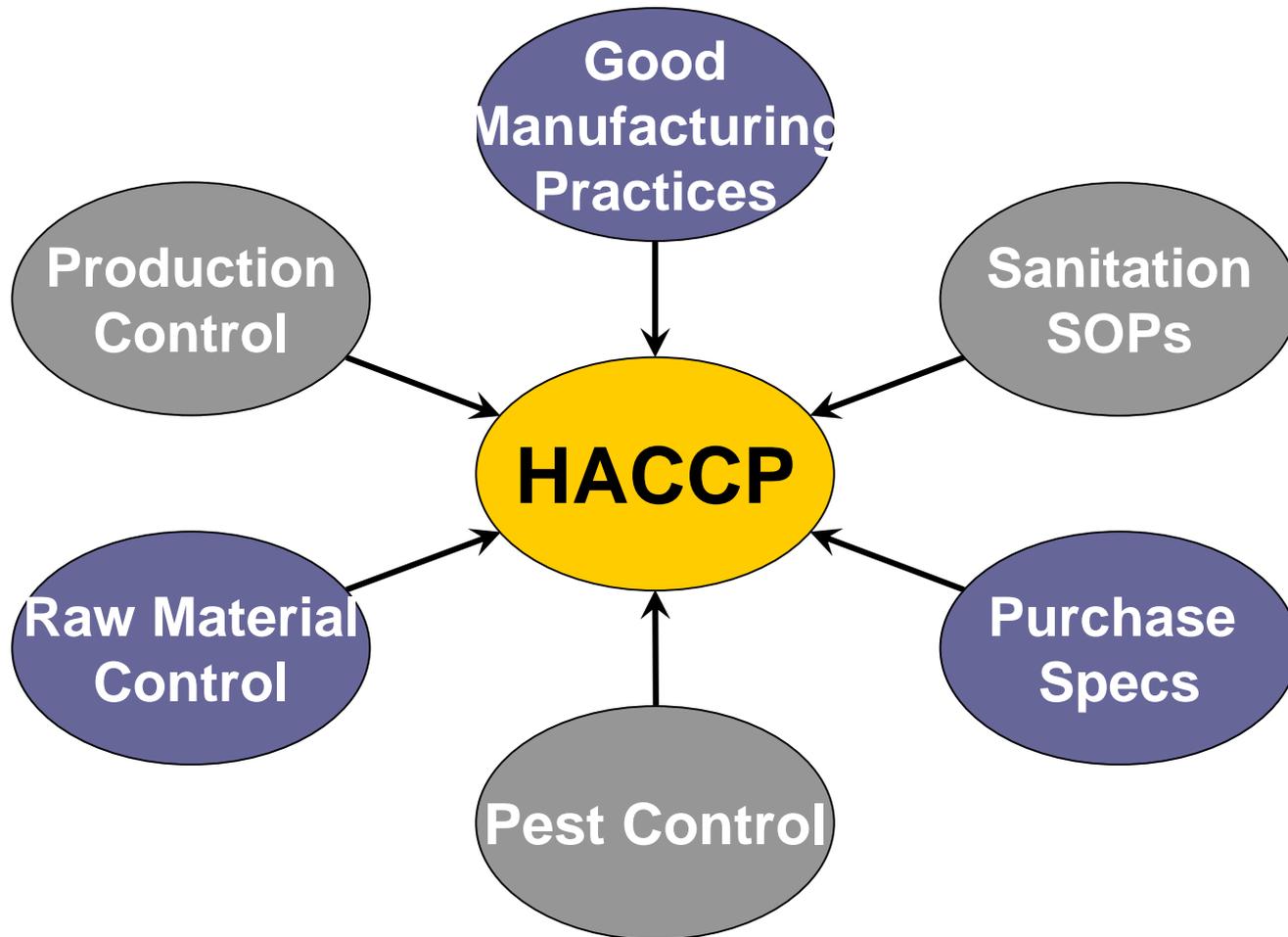
Performing the Assessment - Prerequisite Programs (PRP)

- Provide basic environmental and operating conditions necessary for the production of safe and wholesome food
- Foundation for an effective HACCP system
- Frequently function facility wide

Performing the Assessment - Prerequisite Programs

- PRPs may have unique names that do not incorporate the actual term “prerequisite program”
- Examples
 - Purchase Specification Program
 - Allergen Control Program
 - Temperature Control Program

Prerequisite Program Examples



Performing the Assessment - PRPs

- Plant may determine a hazard is not significant because of ongoing execution of a PRP



Prerequisite
Program
Records

Performing the Assessment Prerequisite Programs

- The EIAO will look closely at programs used in hazard analysis decisions
 - Determine if the design and implementation of the programs actually support the decision



Performing the Assessment - Prerequisite Programs

- PRPs cannot be used to directly control a hazard
- Nonconformance with a PRP may not create a food safety concern or call for product action
- Nonconformance with the PRP may call into question support for decisions in the HA

Prerequisite vs. CCP?

- Prerequisite Program
 - Cannot be used to directly control a hazard
 - May prevent a hazard from being likely to occur
 - Deviations from program may not create direct food safety concerns, BUT may call into question hazard analysis decisions
- Critical Control Point
 - Directly control specific hazards
 - Prevents, eliminates, or reduces a likely to occur hazard
 - Deviations from controls in a HACCP plan cause food safety concerns and generally require action on affected product

Performing the Assessment

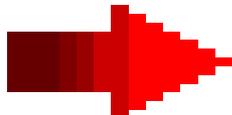
Inappropriate Use of PRPs

- The EIAO will seek info such as:
 - If criteria of the PRP are not met, are there questions about the safety of the food?
 - If criteria of the PRP are not met, does the establishment implement corrective actions that meet 417.3?
 - Is the only support for the PRP use historical info showing that the program is the primary means of control?

Performing the Assessment

Inappropriate Use of PRPs

- If the answers are “yes” to such questions then it is probable that the program is being used to directly control the hazard.

PR Program  **Control**

Performing the Assessment

Inappropriate Use of PRPs

- The EIAO will discuss such finding with the establishment and inform them that they need to:
 - Reassess its HACCP plan to reconsider use of the programs
 - Properly address the hazard

Performing the Assessment

Inappropriate Use of PRPs

- Failure to reassess and properly use the programs may result in the issuance of a **NOIE**



Performing the Assessment Prerequisite Programs

- The EIAO will review
 - Features of the written PRP
 - Supporting documents
 - Program data over a period of time
- Observe employees implementing the PRP



Prerequisite Programs

- The standard of performance for prerequisite programs records is different from the expectations of HACCP records

Prerequisite

HACCP

Performing the Assessment Prerequisite Programs

- Single instance of nonconformance may not represent noncompliance
 - If decisions in the HA are still supported
- PRP Records must continue to support the not reasonably likely to occur hazard analysis decision.

Performing the Assessment Prerequisite Programs

- If EIAO determines the prerequisite program is ineffective or not being executed as designed and there are no food safety concerns
 - The establishment will need to reassess the hazard analysis to determine whether there is continued support for the decisions.

Reassess

Evaluating Sampling that is part of a Prerequisite Program

- FSIS website resources to help EIAOs evaluate sampling and testing done by an establishment:
 - Foodborne Pathogen Test Kits Validated by Independent Organizations
 - <http://www.fsis.usda.gov/wps/wcm/connect/909c8279-6865-424d-ab7a-e1f165646c63/Validated-Test-Kit-Spreadsheet.xls?MOD=AJPERES>
 - FSIS Guidance for Evaluating Test Kit Performance
 - [http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation Studies Pathogen Detection Methods.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES)
 - Establishment Guidance for Selecting a Lab
 - <http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>
- AskFSIS

Prerequisite Programs - Example

- Raw ground beef operation has a PR program based on purchase specifications
 - The EIAO will review the records from the program to verify that it supports the decision made in the hazard analysis that *E. coli* O157:H7 is not likely to occur



Prerequisite Programs

Example

- Establishment producing post-lethality exposed RTE products has product or environmental testing in a PR program
 - The EIAO will review the program, results, and decision documents to verify it is science based
 - Assess the total system to verify design of the testing and implementation effectively addresses Listeria

Prerequisite Programs

- 
- Example of Regulatory Thought Process
 - Ineffective PR Program
 - Hazard likely to occur(?)
 - No support for NRLTO decision in HA
 - 417.5(a)(1) noncompliance
 - HA Inadequate (hazard unaccounted for)
 - 417.2(a)(1)
 - 417.4 HACCP system not valid (lack of support)
 - 417.6 Inadequate HACCP system

Performing the Assessment Prerequisite Programs

- The EIAO should analyze the information and document a supportable agency position related to the plants' use of prerequisite programs.



Performing the Assessment - HACCP

- Monitoring
 - Assess the design and frequency of monitoring procedures
 - Review the HACCP plan, supporting documentation and at least 60 days of records

Monitoring

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with monitoring.



Performing the Assessment - HACCP

- Verification
 - Review the HACCP plan and at least 60 days of verification records
 - Determine whether verification procedures comply with requirements
 - Look at the design and implementation of the procedures

Verification

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with verification.



Performing the Assessment - HACCP

- Recordkeeping
 - From the 60 days of records, summarize what happened related to safe and wholesome product production.
 - 417.5(a)(3)
 - Review supporting documentation
 - 417.5(a)(1)(2)

Performing the Assessment - HACCP

- Recordkeeping
 - Randomly select 13 production days from the 60 days
 - Assess whether the HACCP System design is implemented and whether it meets regulatory requirements.
 - If an establishment has operated less than 13 days in last 60 days, review minimum 13 days.
- Note: Only review more records if, larger food safety issue is observed.

Recordkeeping

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with recordkeeping

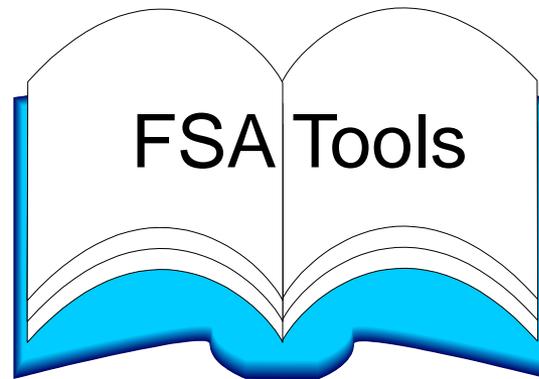


Performing the Assessment - HACCP

- Corrective Actions (CA)
 - Review the HACCP plan and at least 60 days of records
 - Assess design of CA and determine if they meet 417.3 requirements
 - If no CA taken in that timeframe attempt to find the last instance where CA was taken.
 - Answer questions in the tools

Corrective Actions

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with corrective actions.



Performing the Assessment - HACCP

- Reassessment
 - Review at least 60 days of records
 - Determine if reassessment should have occurred
 - Review reassessment decisions and any actions taken as a result
 - Verify annual requirement is met
 - Verify reassessment documentation

Performing the Assessment - HACCP

- Reassessment
 - 417.4(a)(3)(ii)
 - Requires documentation of all reassessments
 - Requires documentation of reasons for changes or no changes
 - For annual reassessment if there are no changes a reason is not required



Reassessment

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with reassessment.



Performing the Assessment

- Analyze, formulate and document a supportable Agency position about whether regulatory requirements have been met for:
 - Monitoring
 - Verification
 - Corrective Action
 - Reassessment
 - Recordkeeping



Performing the Assessment Validation

- Now let's review the validation requirements and key points to look for in the assessment.

validation

Performing the Assessment Validation 417.4(a)(1)

- When a HACCP plan is implemented, the establishment must:
 - Conduct activities designed to determine that the HACCP plan is functioning as intended
 - Repeatedly test CCPs, CLs, monitoring, recordkeeping, corrective action
 - Review records to ensure proper functioning of the HACCP system

Performing the Assessment - Validation

- Initial validation = first 90 days
 - 9CFR 304.3(b) and 381.22(b)
- Validation has **2 parts**:
 - Scientific or technical support for the HACCP system
 - In-plant demonstration proving the HACCP system can perform as expected

Part 1 Scientific or Technical Support

- Historical data
- Scientific journal articles
- Plant generated data
- Other regulatory requirements
- Pathogen modeling program
- Processing authority
- Agency Issuances

Historical Data as Support

- Records must be available
- Verify historical records reflect current establishment operations



Scientific Documents as Support

- Conditions in the study are representative of those in the establishment's process
- Document describes how and why the data support the conclusion

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***Escherichia coli* O157 Prevalence and Enumeration of Aerobic Bacteria, Enterobacteriaceae, and *Escherichia coli* O157 at Various Steps in Commercial Beef Processing Plants¹**

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²MS 05-315, Received 10 July 2003/Accepted 21 November 2003

ABSTRACT

The effectiveness of current antimicrobial interventions used in reducing the prevalence or load of *Escherichia coli* O157 and indicator organisms on cattle hides and carcasses at two commercial beef processing plants was evaluated. Spore sampling of beef carcasses was performed at five locations from the initial entry of the animals to the slaughter floor to the exit of carcasses from the "hotbox" cooler. For each sample, *E. coli* O157 prevalence was determined and total aerobic bacteria, Enterobacteriaceae, and *E. coli* O157 were enumerated. *E. coli* O157 was found on 70% of animal hides coming into the plants, but no carcasses leaving the cooler were identified as contaminated with *E. coli* O157. A positive relationship was seen between the incidence of *E. coli* O157 on hide samples and that in preservation samples. Aerobic plate counts and Enterobacteriaceae counts averaged 7.8 and 6.2 log CFU/100 cm², respectively, on hides, and 1.4 and 0.4 log CFU/100 cm², respectively, on chilled carcasses. Aerobic plate counts and Enterobacteriaceae counts on preservation carcasses were significantly related to the respective levels on the corresponding hides; the carcasses of animals whose hides carried higher numbers of bacteria were more likely to carry higher numbers of bacteria. Implementation of the sampling protocol described here would allow processors to evaluate the efficacy of on-line antimicrobial interventions and allow industry-wide benchmarking of hygiene practices.

Escherichia coli O157:H7 has been a pathogen of concern to the meat processing industry for two decades. Cases of hemolytic, uremic, and thrombotic thrombocytopenic syndrome associated with consumption of undercooked ground beef in the early 1990s (26). In the United States during 1992 and 1993, an outbreak of *E. coli* O157:H7 infections associated with consumption of ground beef caused hundreds of illnesses and four deaths (11). These events led the Food Safety and Inspection Service (FSIS) to declare the *E. coli* O157:H7 organism an adulterant in ground beef and to require that meat processors establish hazard analysis and critical control point (HACCP) plans for their plants (12). Since that time, numerous intervention strategies focusing on prevention of carcass contamination and disinfection of carcasses have been designed, tested, and put into practice at commercial processing plants.

Recent studies have demonstrated that combinations of antimicrobial interventions are more effective at reducing surface contamination on beef tissue than are individual interventions alone (5, 21, 24). Many commercial beef processing plants presently employ several interventions (i.e., trimming, steam vacuuming, steam pasteurization, water washing, and organic acid washes) in combination to achieve large reductions in carcass contamination in accordance with their individual HACCP plans (1).

In 2002, the FSIS required all raw beef processors to reassess their HACCP plans to ensure that their critical control points were adequately addressing *E. coli* O157:H7 contamination (13). In verifying process control, testing for pathogens is generally not useful because of the low numbers of bacterial cells (6, 7). Therefore, indicator organisms, present in sufficiently high numbers throughout the processing line, are monitored to ensure that intervention systems are functioning properly. To adequately interpret these data, the relationships between the indicator organisms and the pathogens of interest must be established (15).

In this study, counts of indicator organisms (aerobic bacteria and Enterobacteriaceae) and *E. coli* O157 and the prevalence of *E. coli* O157 were assessed at various steps in processing to identify relationships that may be exploited to monitor process control. The objectives of this study were twofold: (i) to determine the effectiveness of current interventions used in reducing the prevalence or level of *E.*

Scientific Support Characteristics

- Identify hazard and pathogen
- Level of reduction
- Identify critical parameters
- Sufficient relationship to hazard
- Implemented in the establishment as documented
- Otherwise additional research data needed

Plant Generated Data as Support

- Challenge studies
- Pathogen modeling programs
- Microbiological test results
 - Frequency of sampling
 - Sample selection
 - Sampling method
 - Sample handling
 - Analytical method

Other Regulations as Support

- May use regulations or other agency issuances to support a NRLTO decision
- Must follow or have additional support



Part 2 Initial In-Plant Validation

- In-plant observations
- Measurements
- Microbiological test results
- Other information demonstrating control measures can be implemented to achieve the intended food safety objective

Initial In-Plant Validation Characteristics

- Based on critical parameters identified in scientific support
- Intensified data collection during first 90 days “repeatedly testing” NOT recreating entire scientific support

Initial In-Plant Validation Characteristics

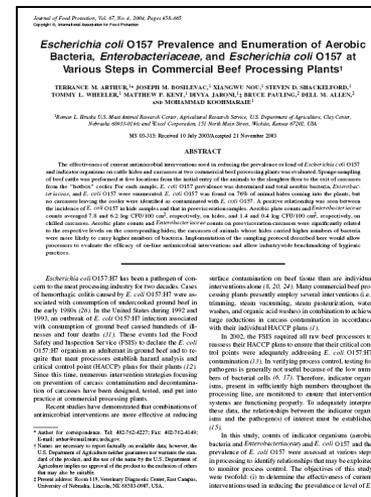
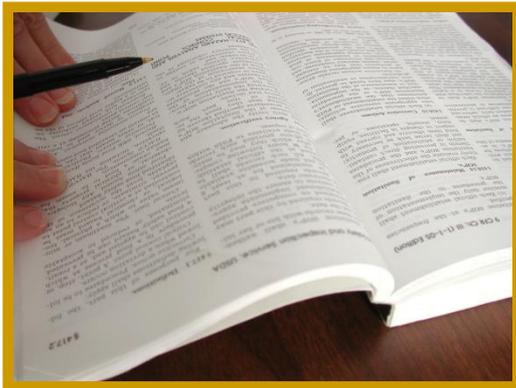
- EIAO may see microbial before/after testing used to demonstrate log reductions documented in scientific support
 - Indicators and pathogen of concern
 - Not required by regulation
 - No deliberate introduction of pathogens allowed

In-plant Validation Data Uses

- “Repeatedly testing” data often used as supporting documentation for frequencies
- Establish a baseline of performance
- Data can show which critical parameters are most important and give the first signs the system is “out of control”

Validation

- Scientific support documentation and 90 day initial validation data become records under 9 CFR 417.5(a)(1) supporting documentation



Validation

- 9 CFR 417.4(a)(1)
 - Includes review of HACCP system records
- 9 CFR 417.1 HACCP System Defined
 - The HACCP plan in operation including the HACCP plan itself
- Entire system must be validated
 - Includes any interventions or processes used to support decisions in the hazard analysis

Validation Update

- FR Docket No. FSIS–2009–0019
- Clarification of Requirements for Validation
- Compliance Guideline updated April 2015



Validation

- Now turn to the HACCP Tools portion of your notebook and look at some questions dealing with validation.



Questions?



Methods Group Exercise II

- Look at the Hazard Analysis for pepperoni
- Discuss any concerns
- Report out



Category Specific Hazards and Issues

EIAO Training



Category Specific Issues

- There are category specific food safety issues that must be addressed in the FSA
- Examples
 - Lm controls in PLE RTE products
 - *E. coli* 0157:H7 in raw beef products
 - SRMs in beef slaughter
 - NRTE comminuted poultry
 - Ingredients of Public Health Concern

Ingredients of Public Health Concern

Allergens

- Milk
- Eggs
- Fish
- Shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans

Other food additives

- Sulfites
- FD&C No. 5
- Monosodium glutamate (MSG)
- Gluten
- Nitrates/nitrites

FSIS Expectations for Ingredients of Public Health Concern

- An establishment must consider the controls necessary to ensure:
 1. Appropriate use of ingredients in its processes.
 2. All ingredients are appropriately declared in labeling.
- Procedures must be effectively implemented to ensure adequate control.

FSA Tool Questions Related to Ingredients of Public Health Concern

- EIAO will gather info about how establishments address the presence and control of allergens
 - Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling
 - EIAOs are to review this prior to FSAs

Raw Processes

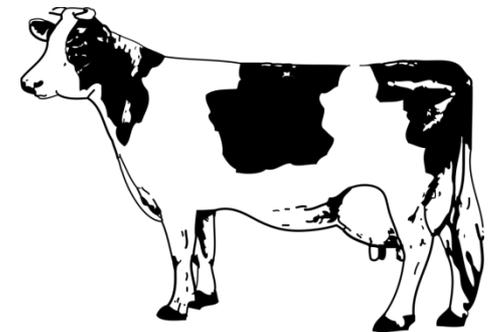
- Sanitary dressing and process control are crucial to producing a safe product
 - Provide the basis for CCPs being effective
- EIAO will observe and assess sanitary dressing and process control
 - Discuss with IIC and FLS
 - Document information gathered

Meat Slaughter

- Sanitary Dressing in Cattle Slaughter
 - 9 CFR 310.18(a)
 - FSIS Directive 6410.1
- Controlling fecal, ingesta, milk
 - FSIS Directive 6420.2
- Use the meat slaughter tool to seek information to verify establishment controls are working

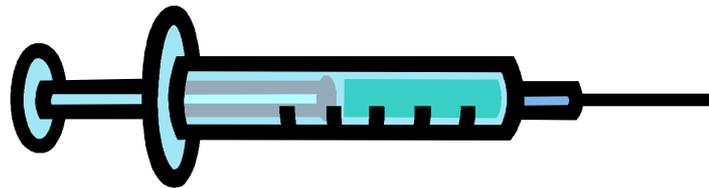
Meat Slaughter

- Beef has unique issues:
 - *E. coli* O157:H7
 - Non O157 STEC
 - SRMs – 9 CFR 310.22
- Use FSIS Directives:
 - 6410.1 Beef Sanitary Dressing
 - 10,010.3 Traceback Methodology
 - 6100.4 SRMs



Meat Slaughter

- Residues
 - Beef Primarily
 - Animal Drug and Biological Residue section



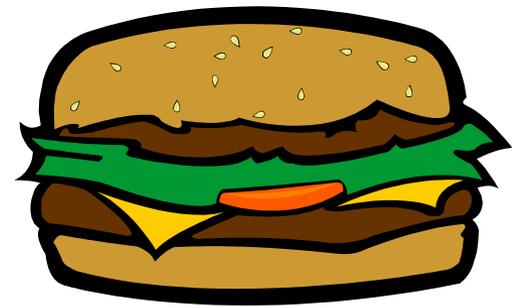
Raw Meat Processes

- Process control is crucial here as well
- Use these tools to verify:
 - *E. coli* 0157:H7 is properly addressed in raw beef
 - SRMs are properly addressed in raw beef
 - HACCP systems are effective



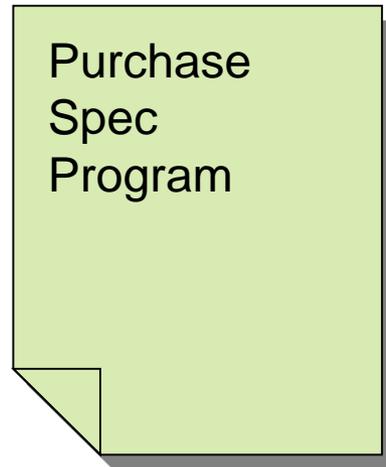
Raw Meat Processes

- For establishments producing non-intact raw beef products:
 - Use information in Directive 10010.1 Rev 4 and the FRN - 64 FR 2803 1/19/1999
 - If mechanically tenderized, are validated cooking instructions used?
 - Answer questions in the tool



Raw Meat Processes

- Critically assess the use of purchase specification programs
 - Determine if there is support for the decision in the hazard analysis



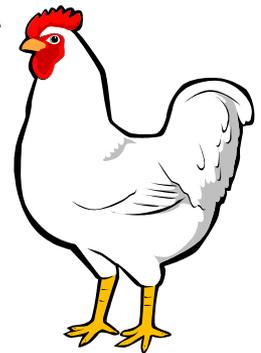
Raw Meat Processes

- Observe establishment operations and consider how the following relate to the raw products HACCP system's effectiveness:
 - Sanitary practices
 - Antimicrobial interventions
 - Testing effectiveness
 - Employee practices and training
 - PR programs, GMPs
 - Labeling practices



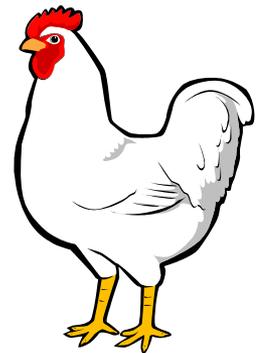
Poultry Slaughter Procedures for Preventing Contamination with Feces and Enteric Pathogens

- Poultry Sanitary Dressing
 - Directive 6420.5
 - 9 CFR 381.65(f) & (g)
- EIAO will
 - Observe each step of operations from live hang
 - Observe any incoming product
 - Assess process control including any PR programs and SSOPs



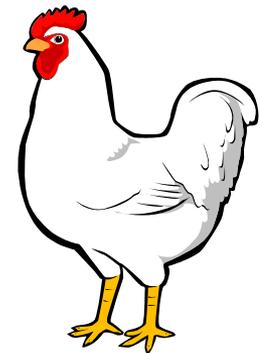
Poultry Antimicrobial Treatments

- Review support for antimicrobial treatments
 - Expected reduction
 - All critical operating parameters incorporated in HACCP system (CCP, PRP)



Slaughter and Raw Poultry

- Assess testing done by the establishment
 - Verify sampling and analysis methods are appropriate
 - Verify how the establishment responds to results
 - If failing to meet the moving window criteria, ask what changes were made to improve process control and if they were effective



Process Verification for Slaughter

Generic *E. coli* (Livestock and Ratite)

&

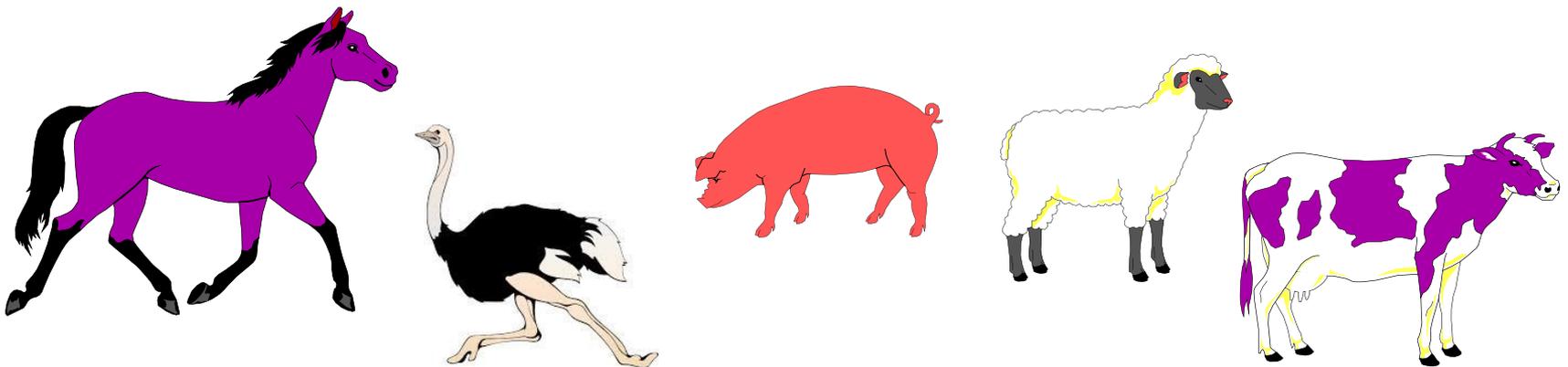
Sampling to Demonstrate Process Control in Poultry Slaughter



Generic *E. coli* Verification

310.25(a)(1), 381.94(a)(1)

- Slaughter establishments must test for generic *E. coli*:
 - Livestock and Ratites
- Criteria are guidelines – not enforceable
- Test species slaughtered in greatest number



Generic *E. coli* Verification

Sampling requirements

- 310.25(a)(2)(ii), 381.94(a)(2)(ii) -
 - Collect samples
 - Analyze results
 - Maintain records

Generic *E. coli* Verification Written Procedures

- 310.25(a)(2)(i), 381.94(a)(2)(i) –
 - Identify employee
 - Location of sampling
 - Sampling randomness
 - Sample integrity



Generic *E. coli* Verification

Sampling requirements

- 310.25(a)(2)(ii), 381.94(a)(2)(ii) –
 - Samples taken from chilled carcasses, except hot boning
 - Sponging/excision for meat



Generic *E. coli* Verification

Sampling frequency

- 310.25(a)(2)(iii), 381.94(a)(2)(iii) -

**Cattle, sheep,
goats, horses, mules,
other equine**
1/300
carcasses

Swine
1/1,000
carcasses

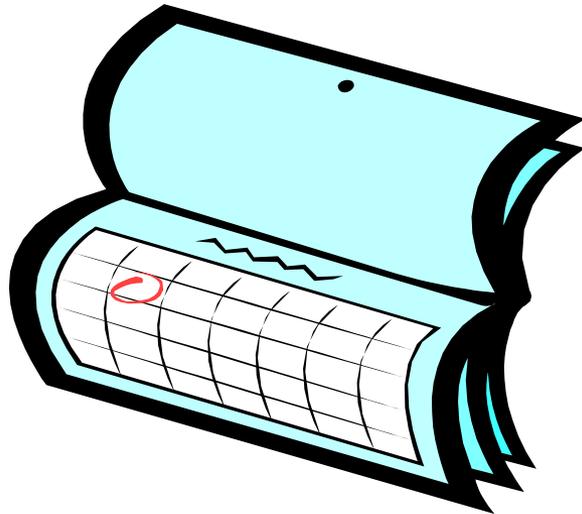
Ratite
1/3,000
carcasses

**Or a Minimum 1/week
whichever is greater**

Generic *E. coli* Verification

VLV frequency

- 310.25(a)(2)(v), 381.94(a)(2)(v) –
 - 1/week for 13 tests
 - Begins first full week after June 1st each yr.



Generic *E. coli* Verification Recording Test Results

- 310.25(a)(4), 381.94(a)(4) –

CFU/cm²

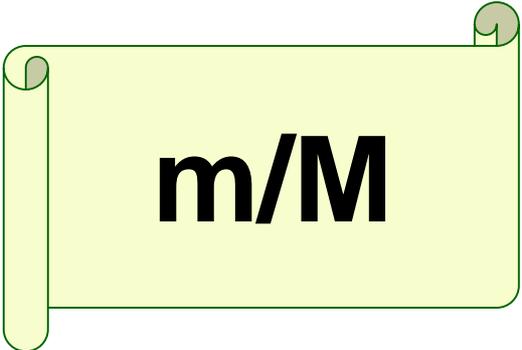
**Table
Chart**

**Keep
12 months**

Generic *E. coli* Verification

Criteria for evaluation

- 310.25(a)(5)(i), 381.94(a)(5)(i) –
- 13 test moving window
- Criteria not met if:
 - >3 tests above m
(marginal)
 - 1 test above M
(maximum)



m/M



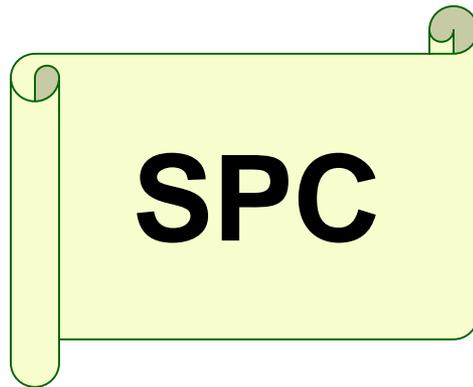
Cattle: Excision

Swine: Excision

Generic *E. coli* Verification

Criteria for evaluation

- 310.25(a)(5)(ii), 381.94(a)(5)(ii) -



Cattle: Sponge

Swine: Sponge

All Goats

All Sheep

All Equine

All Ratite

Generic *E. coli* Verification

Failure to meet criteria

- 310.25(a)(6), 381.94(a)(6) -

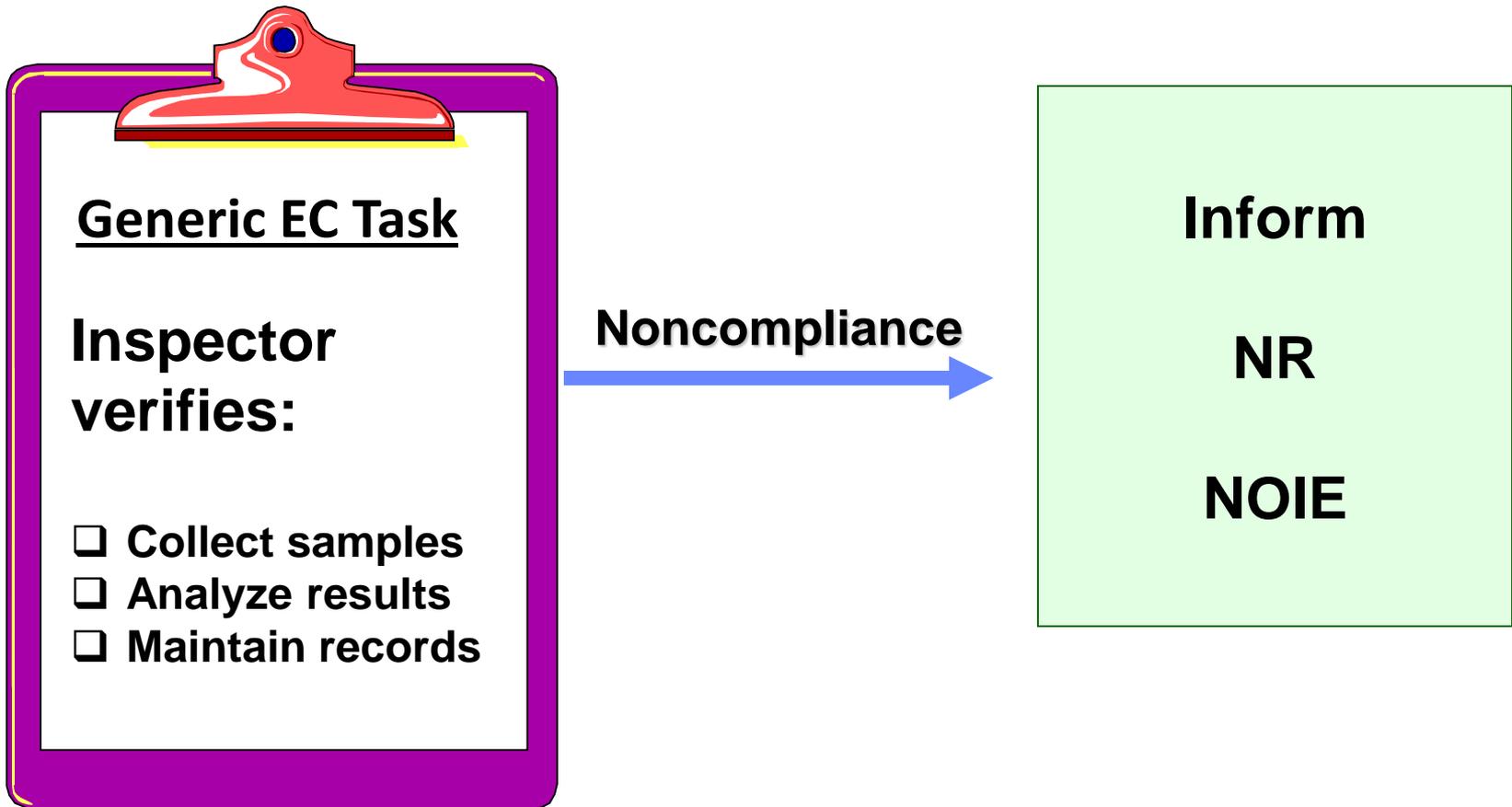
**Plant takes corrective action
if criteria are not met**



Generic *E. coli* Verification

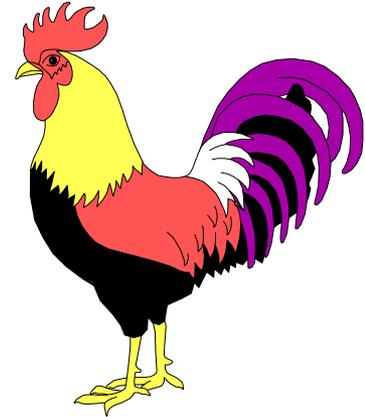
Failure to test & record

- 310.25(a)(7), 381.94(a)(7) -



Poultry Slaughter Operations - Required Testing

- 381.65 (g) requires:
 - Written procedures
 - HACCP
 - SSOP
 - Prereq programs
 - Sampling program for micro testing
 - Support for design of the program
 - Maintain daily records



Performing the Assessment

Slaughter Sampling Verification

- EIAO should first collect information on:
 - Establishment's written sampling procedures
 - Justification for any alternative sampling procedures
 - Laboratory assurances about methodology
 - Records of recent test results

Performing the Assessment

Slaughter Sampling Verification

- EIAO should:
 - Verify elements of sampling procedures by observing establishment employees performing them, if the samples are being taken
 - Verify that the regulatory requirements are met
 - Verify test results for a recent period of at least 60 days

Performing the Assessment

Slaughter Sampling Verification

- EIAO should:
 - Verify that the slaughter sanitary dressing process is in control for prevention of fecal contamination
 - Review fecal NRs or deviations from the zero tolerance CL for the same time period; look at corrective actions/preventive measures.

Performing the Assessment

Slaughter Sampling Verification

- EIAO should discuss the sampling results that do not meet criteria with establishment officials to see:
 - If they have any particular views about what might have caused them, and
 - Anything they may have done to improve the situation.

Other testing

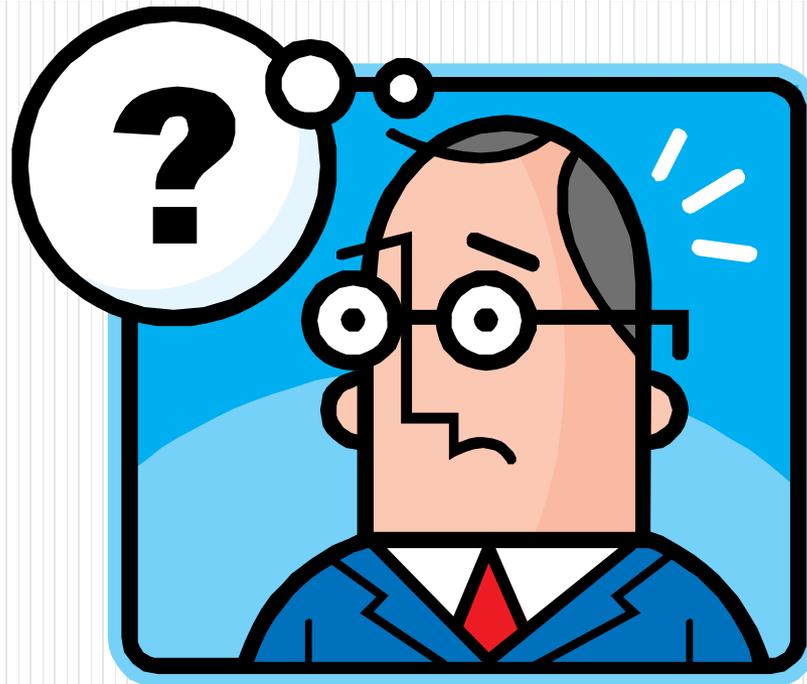
- If, by chance, the Agency was sampling and testing for *Salmonella* during the 60-day period, the EIAO should seek those results.
- If, by chance, the establishment's product was sampled and tested for *E. coli* O157:H7 or implicated in a recall during the same 60-day period, the EIAO should seek those results.

Other testing

- If there are significant correlations, the EIAO needs to analyze them further to be sure regulatory requirements are met.

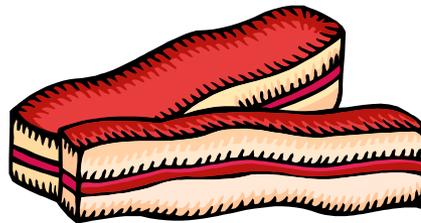


Questions?



Not Ready-to-Eat Tool

- EIAO will assess:
 - Support for decision product is NRTE
 - Stabilization process design
 - Allergen controls
 - Label approvals and any validated cooking instructions
 - Cooking instructions are crucial for these products



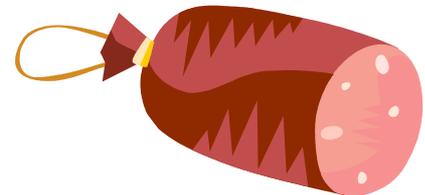
Processed Products

- EIAO will verify
 - Validated lethality processes are used
 - Stabilization is effective
 - Supporting documentation is present
 - Proper HACCP implementation
 - Allergen controls
 - Post-lethality exposed products meet the 9CFR 430 regulations



Not Heat Treated Shelf Stable

- EIAO will verify
 - Validated lethality processes are used
 - *E. coli* 0157:H7, *Salmonella*, and Lm
 - Sampling and testing programs
 - Processing practices including allergen controls
 - Post-lethality exposed products meet the 9CFR 430 regulations
 - Supporting documentation



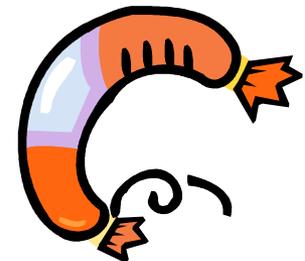
Heat Treated Shelf Stable

- EIAO will verify
 - Validated lethality processes are used
 - *E.coli* 0157:H7, *Salmonella*, and *Lm*
 - Sampling and Testing programs
 - Processing Practices including allergen controls
 - Post-lethality exposed products meet the 9CFR 430 regulations
 - Supporting documentation



Fully Cooked Not Shelf Stable

- EIAO will verify
 - Validated cook step and stabilization step
 - *E. coli* 0157:H7, *Salmonella*, and *Lm*
 - *Clostridium botulinum* and *perfringens*
 - Sampling and Testing procedures
 - Processing Practices including allergen controls
 - Post-lethality exposed products meet the 9CFR 430 regulations
 - Supporting documentation



Post-Lethality Exposed RTE Products

- June 6, 2003 Interim Final Rule
 - Required establishments producing PLE RTE products to control *Listeria monocytogenes (Lm)*
 - RTE product is adulterated if it contains *Lm* or has come into direct contact with a food surface with *Lm*
 - Affected establishments have 3 alternatives from which to control *Lm*

Post-Lethality Exposed RTE Products

- EIAO will verify compliance with 9 CFR 430
- Refer to Directives 10240.4 and 10240.5
- For Alternative 1
 - Complete PLT (post lethality treatment) tool section
 - AMAP (antimicrobial agent or process) tool section
- For Alternative 2
 - Complete either PLT or AMAP plus Sanitation as appropriate for Choice 1 and Choice 2
- For Alternative 3
 - Complete Sanitation section of tools

Post-Lethality Exposed RTE Products

- Testing Design section
 - Assess food contact surface testing data

Post-Lethality Exposed RTE Products

- PLT section (post lethality treatment)
 - Review the validation documentation for the PLT and its function in the HACCP plan
- AMAP section (antimicrobial agent/process)
 - Review supporting documents for the AMAP and its function in the HACCP system

Post-Lethality Exposed RTE Products

- Now turn to the RTE Tool and look at some questions dealing with Testing Design, PLT, and AMAP from the RTE tool.



Thermally Processed Commercially Sterile

- EIAO will verify
 - How biological hazards were addressed
 - Canning Regulations as a PR program or HACCP plan?
 - Processing procedures



workshop



Analysis and Recommendations



EIAO Recommendations

- EIAO recommendations from FSAs vary:
 - No action necessary
 - NRs issued by in-plant inspectors (500.1)
 - NOIE with or without NRs (500.4)
 - Notice of Suspension (NOS) (500.3)

**No
Action NRS NOIE NOS**

Tool Summaries

- At the end of the each tool, you summarize the findings as such.
-

Instruction: RTE Tool Summary:

This question is designed to focus on the most significant noncompliance or vulnerability findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Summarize the findings that bear most directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The answer to this question is to be used to construct the Executive Summary.

RTE99 Summarize in up to three bullets of any vulnerability or noncompliance findings identified in the RTE Processed Products Tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine a FSA recommendation. Describe the impact the findings have on the establishment's food safety system.

[Click here to enter text.](#)

Decision Making Analysis- General Tool

- Length is 1 to 2 pages
- Provide an overall analysis of findings and the thought process used to arrive at the recommendation
- Support the recommendation with:
 - sampling results
 - PHRE
 - in-plant observations
 - HACCP system design and implementation
- Show how the findings impact establishment's ability to produce safe product
- Show how recommendation is supported by FSIS statutory and regulatory requirements
- Summarize the analysis in an Executive Summary
- State whether follow up is necessary

Analysis -

Questions to help the analysis process

- Is there a relationship between past and current noncompliances?
- Do the current findings indicate that repetitive, sustained, or persistent food safety problems continue?
- Is supporting documentation adequate to support decisions in the hazard analysis?
- Has additional information arisen that calls hazard analysis decisions into question?
- Are there flaws in system design or implementation?
- Does the HACCP system prevent the production of adulterated, unsafe products?
- Is there a correlation between test results and findings related to sanitary practices?

Analysis and Recommendations

- Once analysis has been performed and a supportable recommendation determined
 - EIAO formulates and documents a regulatory rationale to support the recommendation
 - Example
 - The establishment's Raw Non-Intact process is inadequate under 9 CFR 417.6 because the establishment cannot support the decision in its hazard analysis that *E. coli* O157:H7 is not likely to occur.
 - Discuss significant findings and what lead to this conclusion using the regulations and statutes

Analysis and Recommendations

- FSA report must describe in detail so reader has a clear understanding of the information considered and how that supports the recommendation.
 - Identify all documents that had a bearing on the recommendation.

Analysis and Recommendations

- Describe in detail how past noncompliances relate to any present noncompliances
- Describe the public health significance
- If an enforcement action is recommended without evidence of multiple recurring noncompliances clearly document the findings which indicate serious threat to public health

Analysis and Recommendations

- Many establishments will address noncompliances as they are identified during the FSA
 - EIAO will still document those in the FSA and recommend NRs and/or enforcement actions as warranted

Analysis and Recommendations

- Additional points when writing analysis
 - Directives, Notices, and Guides are not support for enforcement
 - Analysis is not a simple repeating or listing of individual findings

- Analysis is an explanation of the rationale and support for the enforcement based upon regulations, statutes, and public health

Analysis and Recommendations

- Items to include in the analysis
 - For the recommendation of no further action
 - Describe facts that indicate compliance and that no food safety concerns exist
 - For the recommendation of NRs written
 - Describe noncompliance(s) and why this recommendation is being made. NRs issued if not in support of NOIE

Analysis and Recommendations

- Items to include in the analysis
 - For the recommendation of NOIE
 - Clearly describe noncompliances that meet one of the provisions of 9 CFR 500.4
 - Describe how noncompliances resulted in adulterated product or created insanitary conditions
 - Clearly describe the analysis and regulatory thought process that lead to the determination

Analysis and Recommendations

- Items to include in the analysis
 - Recommendation of Notice of Suspension without prior notice
 - Clearly describe noncompliances that meet one of the provisions of 9 CFR 500.3
 - Describe how noncompliances resulted in an imminent threat to public health
 - Clearly describe the analysis and regulatory thought process that lead to the determination

Executive Summary

- Emphasize the recommendation - include only the essential or most significant supporting information
- Show how you arrived at the recommendation.
- Make the summary **concise**
- Do **not duplicate** the Decision Making Analysis. Use **the summary question from each tool to construct the executive summary.**
- **TIP FOR SUCCESS:** imagine that the Executive Summary is the only part of the FSA that anyone can see - Does this summary adequately explain and support the recommendation?

Executive Summary

- Good Executive Summary contains:
 - 1-2 sentences describing establishment/products
 - 1-2 sentences describing compliance history
 - 2 sentences describing findings leading to recommendation
 - 2 sentences discussing analysis of findings and their significance

Executive Summary

- Emphasizes recommendation and essential support for it
- Organized in coherent manner
- No more than 350 words in most cases
 - Up to 500 words for complex cases

Executive Summary

- First and last sentence of Analysis section often contains key information
- Review summary and remove unnecessary words or sentences
- Do not introduce any “new” information not contained in the FSA Report.

Executive Summary

- How can an EIAO know that enough information has been included?
 - Imagine that the summary is the only part of the FSA report that anyone can see and then ask the question:
 - Does this summary adequately explain and support the recommendation?

Decision Making Analysis Workshop

- Turn back to the workshop from “Finding and Using Technical and Scientific Support” module
- What was the most food safety significant finding that you identified?
- Write one paragraph of analysis of that finding. Include all elements of the definition of “analysis.” Include an opening sentence, several supporting ideas, and a summary sentence.

Documenting the FSA



PHIS

USDA FSIS PHIS | Profile | - Windows Internet Explorer provided by FSIS

http://kcwebprod03.fsis.usda.gov/FSISDashboard/default.aspx

File Edit View Favorites Tools Help

USDA FSIS PHIS | Profile |

Consumer Safety Inspector (2) Home About PHIS My Profile Help Sign Out

You are here: Home

Home

My Dashboard My Establishments My Inspections and Samples

Alerts

[Show All Alerts](#)

Date	Title	Read?
6/22/2011 4:11 AM	DAIG-Sampling Tasks Recently Assigned-Targeted-Establishment	No
6/22/2011 4:05 AM	DAIG-Sampling Tasks Recently Assigned-Targeted-Establishment	No
6/22/2011 4:04 AM	DAIG-Sampling Tasks Recently Assigned-Targeted-Establishment	No
6/22/2011 4:04 AM	DAIG-Sampling Tasks Recently Assigned-Targeted-Establishment	No
6/22/2011 4:04 AM	DAIG-Sampling Tasks Recently Assigned-Targeted-Establishment	No

Page: 1 of 16 Go Page size: 5 Change Item 1 to 5 of 79

My Tasks

Name	Establishment	Type	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

No records to display.

Smart Links

FSA Documentation

- Use appropriate FSA tools in PHIS
- If Word version needed, obtain from Advanced EIAO SharePoint site to ensure current version
- Do not keep notes outside tools as they may be evidence

Noncompliance

- Noncompliance observed during the FSA will always be documented in the FSA report.
- Additionally, noncompliance will be documented in either an NR or it may be included in an enforcement letter (NOIE or NOS).

Noncompliance

- Example:
 - EIAO determines the establishment failed to identify a step in the flow chart.
 - This is regulatory noncompliance, but it may not pose an immediate health risk.
 - It would be prudent to complete the assessment process to determine how the matter should be addressed (NR or part of an enforcement letter if other noncompliance exists).

Noncompliance

- If additional noncompliance is observed during the FSA and an NOIE is warranted:
 - The NOIE documents noncompliance findings supporting the proposed action.
 - Other noncompliances that are not in support of the NOIE would be documented on NRs.
 - All enforcement letters and NRs are presented to the establishment at the exit meeting.

Noncompliance

- If no enforcement is warranted, any noncompliance would be documented on NRs.
- Work with the FLS and IPP to assure NRs are presented at the exit meeting.

Noncompliance

- FSIS must first stop the practice and take a RCA immediately if an establishment is:
 - shipping or producing adulterated product,
 - operating without a HACCP plan
 - treating animals inhumanely
 - engaging in any other type of noncompliance that supports taking action under the Rules of Practice
- A NR should be issued to the plant ASAP (MOI for humane egregious noncompliance)

Noncompliance

- For immediate enforcement, correlate with the IPP, the FLS, and the District Office.
- If a suspension without notice is warranted, the NR (or MOI for humane handling) can serve as a basis to support the action .
- The Food Safety Assessment can be completed later during the enforcement process.

Noncompliance

- Anytime noncompliance is observed, it is important to bring it to the establishment's attention and discuss it as soon as possible.



Noncompliance

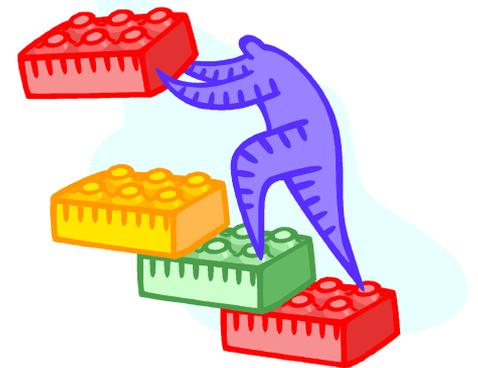
- Whenever noncompliance is discussed with the establishment:
 - Document what was discussed, including when the discussion took place and who was present.
 - The written summary can be part of the FSA or a separate memorandum for the record.
 - It is important in the administrative record to support that noncompliance was brought to the establishment's attention in a timely manner.

Noncompliance

- When notified of noncompliance that is not part of an enforcement action:
 - The establishment may take action to bring themselves back into compliance
 - An NR will still be documented and presented at the exit meeting
- This is why it is important to document that the establishment was notified, in the FSA or in an MOI.

Noncompliance

- NRs are fundamental “building blocks” to effective enforcement.
- They assure establishments have been provided the opportunity to correct situations before enforcement becomes necessary.



Noncompliance

- EIAO should reiterate with inspection team importance of documenting noncompliance, associating NRs, and building a case
- Being able to show history of multiple, recurring noncompliances is an important factor to support issuing a NOIE
- When suspending the assignment of inspectors without notice, documentation must exist to support action is warranted.

Follow-up

- Work with FLS to determine whether noncompliances require a follow-up
- Document need for follow-up in General Tool
- Contact the FLS within 30 days of the exit meeting to determine status of the NR

Exit Conference

EIAO Training



Performing the Assessment

- Prior to exit conference
 - Discuss findings with SEIAO and DO to ensure all issues are resolved
 - Meet with FLS, IIC, and IPP
- Hold Exit Conference within the 5-7 Day in-plant time frame.



Exit Conference

- EIAO schedules exit conference
- IIC, FLS, and plant management should attend the exit meeting
- Document meeting in the General tool



Exit Conference



- EIAO will provide a “Draft” marked copy of the report to the establishment
- If an Agency letter such as NOIE is issued, it should be presented and discussed
- Any NRs documenting noncompliances not in support of a NOIE should be presented and discussed

Exit Conference



- Thank the establishment for their cooperation
- Describe FSA findings including any recommendations made to the DO
- Describe the basis for all NRs and any enforcement recommendations made to the DO. Enforcement action documents are to be given at the exit conference.

Exit Conference



- Advise that a final copy will be provided through the DCS
- Answer questions
- Provide business card for contact info

Exit Conference



- For small /very small establishments, direct them to resources to meet SBREFA obligations

USDA United States Department of Agriculture
Food Safety and Inspection Service

Home About FSIS News & Events Fact Sheets Careers Forms Help Contact Us En Español

You are here: Home / Small & Very Small Plants

Small & Very Small Plants

Small plant owners and operators can use this page to find information about FSIS policies, technical assistance, and answers to common questions from small plants across the country.

Small & Very Small Plants

- Small & Very Small Plant Outreach
- Small Plant News
- Compliance Assistance
- askFSIS
- Export Information
- FSIS Directives Index
- FSIS Notices

I Want To...

- Apply for a Federal Grant of Inspection
- Order Small/Very Small Plant Resource Materials
- View FSIS Workforce Training Resources
- Import Meat, Poultry, or Egg Products
- Create a Food Defense Plan
- Review Guidance Material in Support of New Technology

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All FSIS

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- A to Z Index

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- Science
- Regulations & Policies
- FSIS Recalls
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- Codex Alimentarius

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Have you visited askFSIS lately? New questions are added weekly. RSS feeds available.

FSIS PHIS Directives
Access the new series of PHIS Directives which provide instructions on performing inspection duties using the Public Health Information System (PHIS). You can also askFSIS about PHIS.

Compliance Guides Index
Your first resource in maintaining compliance with FSIS policies.

Small & Very Small Plant Outreach

Questions?



Objective Checkup



- What are the key components to performing an FSA?
- What is “analysis”?
- What forms are completed by the EIAO during the FSA?
- What is the purpose of the executive summary?
- List and describe the possible FSA outcomes.
- What is the distribution of the FSA Report and timeframe for completion?