



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

Public Health Risk Evaluation Condensed EIAO



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 the FSA.
- PHRE's are an internal FSIS Document and is NOT shared with the establishment.

Public Health Risk Evaluation (PHRE)

Office of Planning, Analysis and Risk Management (OPARM) provides a prioritized list to DO for scheduling PHREs.

For-Cause Criteria

- Product adulterated by pathogens
- Product associated with illness outbreak
- Failing performance Standards
- PHR noncompliance rate alert

Routine Risk-Based Criteria

- New establishments with Conditional Grants of Inspection
- Establishment produces post-lethality exposed ready-to-eat (RTE) product

PHRE/ FSA Scheduling

- 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.
- Many establishments are on the PHRE list based on noncompliance with Public Health Regulations (PHR).

PHRE/ FSA Scheduling

- 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.

<https://www.fsis.usda.gov/science-data/scientific-reports/public-health-regulations-phr/fsis-data-analysis-and-reporting-5>

- PHR Methodology:

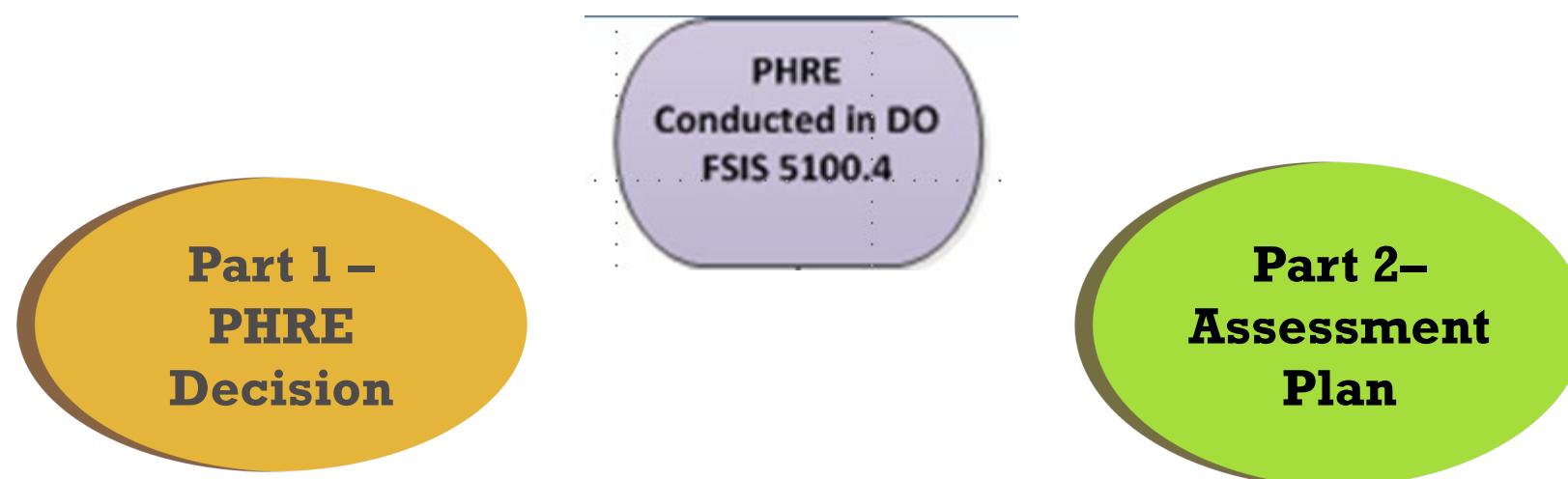
- <https://www.fsis.usda.gov/science-data/scientific-reports/public-health-regulations-phr>

PHRE/ FSA Scheduling

- FSIS is actively working to better use data generated from the tasks to drive inspection decisions.
- The list isn't the only way the Agency identifies establishments. Districts may schedule for other reasons including:
 - Recommendations from field personnel
 - In response to changes in policy based on new or emerging public health-based information

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

Part 1 –
PHRE
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



Part 1 –
PHRE
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 MOIs
 - Recall Information
 - Sampling Results
 - STEPs Information



A screenshot of a web-based application interface for the USDA Food Safety and Inspection Service (FSIS) Public Health Information System (PHIS). The top navigation bar includes the USDA logo, the text 'United States Department of Agriculture Food Safety and Inspection Service', and links for 'Home', 'About PHIS', 'My Profile', 'Help', and 'Sign Out'. The main content area is titled 'Inventory of Standard Reports'. On the left, a sidebar menu lists 'Establishment Profile', 'Manage FSAs', 'Inspection Verification', 'Sample Management', 'Create Recall', and 'View Report', with 'View Report' currently highlighted. The main table displays a list of standard reports with columns for 'Title', 'Category', 'Inspection Task', 'Slaughter', 'Inspection Task', 'Inspection Task', 'Inspection Task', 'Establishment Profile', 'Lab Sampling', 'Lab Sampling', and 'Lab Sampling'. Each row includes 'View' and 'Run' buttons. The table shows items 31 to 40 of 55, with a page size of 10 and links for 'First', 'Prev', 'Page: 4 of 6', 'Next', and 'Last'.

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
 - Discuss compliance with:
 - FLS, CSI, DDM

Analyze PHRE Data

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

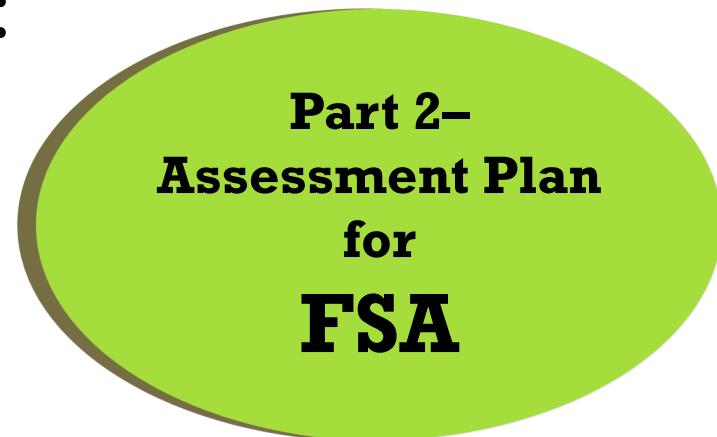
PHRE- Decision

- Possible PHRE Recommendations:
 - Enforcement Action
 - Perform Food Safety Assessment (FSA)
 - No Action
- The rationale and explanation for the recommendation should 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 with planning of the FSA.
- PHRE 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 Contents

- 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 Question 1

1. What is the overall purpose of the PHRE?



Objective Check-Up Question 2

1. What are the two parts of the PHRE?

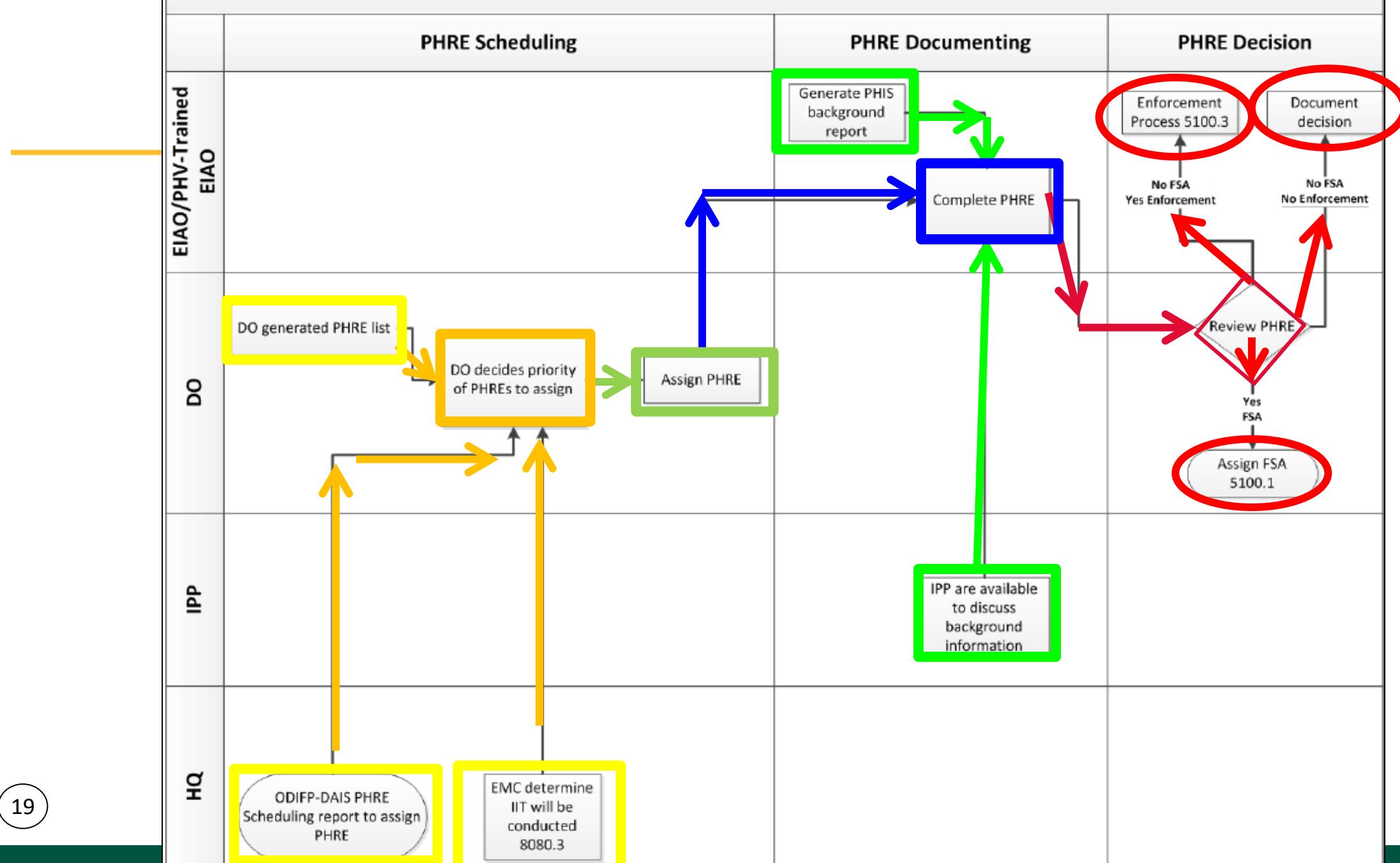


Objective Check-Up Question 3

1. When is the PHRE tool to be completed.



Figure 1 – PHRE Work Flow Overview



PHRE Tool

1. Now let's look at the PHRE Tool

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

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 \(ELAO\) 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)

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

PHRE Tool Example

PHRE Example

PHRE Workshop

