

# FSIS DIRECTIVE

5100.4  
Rev. 1

5/22/15

## ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) PUBLIC HEALTH RISK EVALUATION (PHRE) METHODOLOGY

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

### I. PURPOSE

A. This directive provides instructions on how to schedule and assign the Public Health Risk Evaluation (PHRE) for the Enforcement, Investigations, and Analysis Officer (EIAO) and a Public Health Veterinarian (PHV) trained in the EIAO methodology.

B. This directive also provides instructions to an EIAO on how to conduct and document PHREs in the Public Health Information System (PHIS). This directive has been rewritten in its entirety to provide instructions for the new PHRE process.

#### KEY POINTS

- *Introduction of the PHRE*
- *Methodology of the PHRE*
- *Scheduling of PHREs*
- *Documenting PHREs*

### II. CANCELLATION

FSIS Directive 5100.4, Prioritized Scheduling of Food Safety Assessments (FSAs), 9/21/09  
FSIS PHIS Directive Prioritized Scheduling of Food Safety Assessments (FSAs) Using the Public Health Information System (PHIS) 4/11/11

### III. BACKGROUND

The PHRE is a new decision-making process that is to be used by an EIAO to determine whether the District Office (DO) needs to schedule an FSA. The PHRE is a distinct, separate activity from the Food Safety Assessment (FSA). The Office of Data Integration and Food Protection (ODIFP) provides to the DO a prioritized list of establishments for scheduling FSAs. The list is based on public health risk triggers, including whether an establishment has produced adulterated product, or whether an establishment has produced product associated with an outbreak. The remaining establishments included on the prioritized list from ODIFP are based on when an FSA was last performed. The DO is to review the list to schedule FSAs. It can also schedule an FSA at an establishment not on the list based on other reasons, such as in response to emergency incidents when the FSIS Emergency Management Committee (EMC) forms an Incident Investigation Team (IIT) (see [FSIS Directive 5500.3](#), *Incident Investigation Team Reviews*).

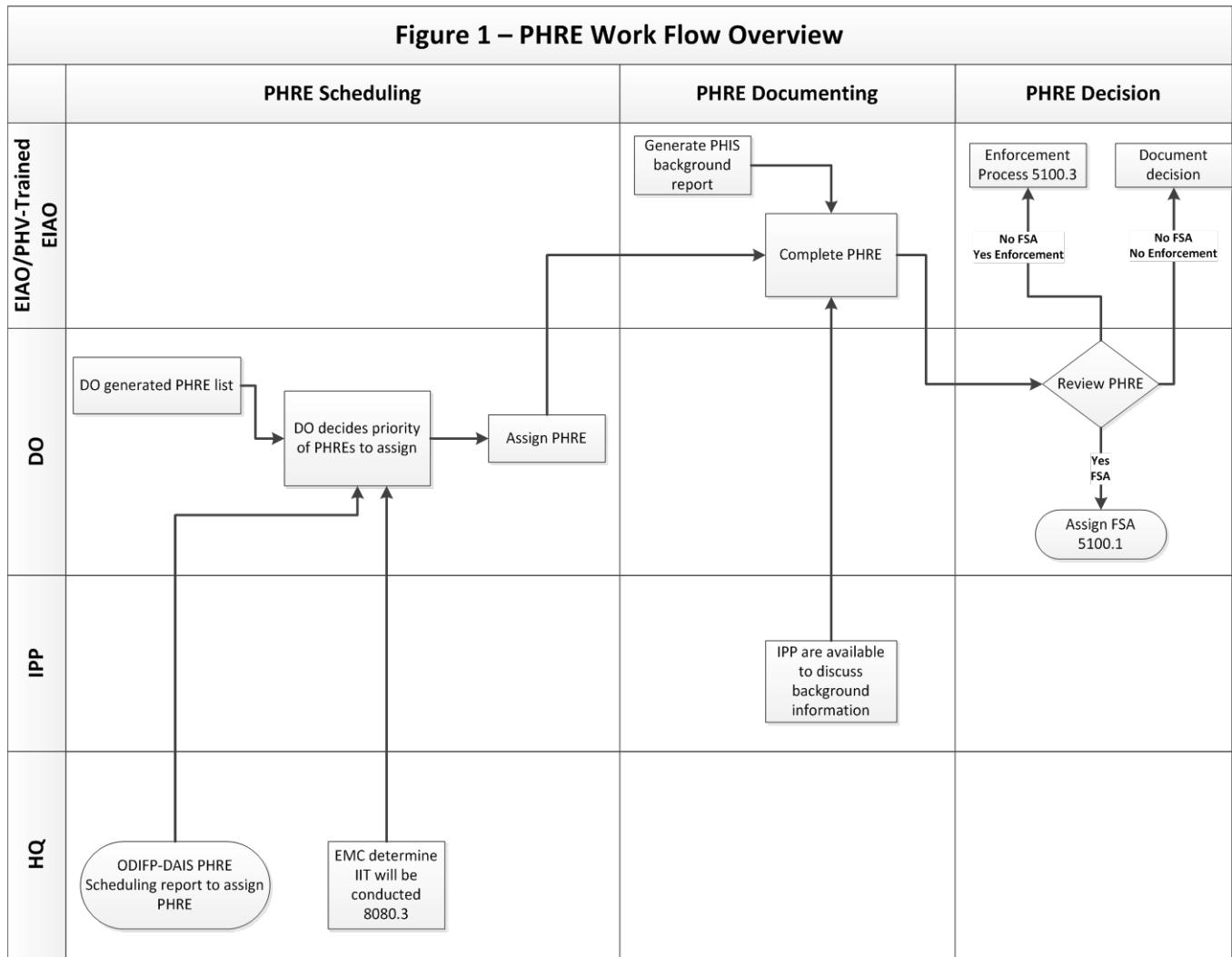
**IV. INTRODUCTION OF THE PHRE**

A. A PHRE will be conducted for each establishment scheduled for an FSA. The PHRE process has two parts, the PHRE Decision and the Assessment plan, if necessary.

1. Part 1: PHRE Decision: During the first part of the PHRE, an EIAO is to determine what action to take following the PHRE and document his or her recommendation. During the PHRE decision phase, an EIAO is to:
  - a. Evaluate the establishment's historical data using the PHIS PHRE report and other background information and correlate with inspection program personnel (IPP) assigned to the establishment and the Frontline Supervisor (FLS) to determine what action to take following the PHRE. The PHIS PHRE report replaces the pre-FSA report. An EIAO is to obtain the PHRE report in PHIS as part of his or her pre-FSA preparation. The PHRE report is further described in Section VII.
  - b. Document his or her recommendation to the District Manager (DM). An EIAO is to recommend whether to conduct an FSA as described in [FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#), to take an administrative enforcement action as described in [FSIS Directive 5100.3, Administrative Enforcement Reporting \(AER\) System](#), or to take no action because neither an enforcement action or an FSA is needed.
  - c. If an EIAO does not recommend either an FSA or enforcement at the time of the PHRE, he or she is to document his or her reasons why. Instructions are provided in this directive for how to perform the PHRE and how to make the evaluation.
2. Part 2: Assessment Plan: An EIAO is to develop an Assessment Plan prior to performing an FSA as described in [FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#). The development of an Assessment Plan helps to ensure that the assessment is thorough and well organized. Planning also promotes efficient use of limited resources. The Assessment Plan is to include the:
  - a. Apparent violations of the statutes – A brief statement of the apparent or possible food safety issue determined through the analysis. The plan is to cite the relevant statutes or regulations and state or paraphrase the language of the statutes or regulations (e.g., 21 U.S.C. 453 (g)(4) and 458 (a)(3), improperly stored poultry products, after transportation in commerce, under insanitary conditions, causing the products to become adulterated);
  - b. Scope of FSA – Briefly state the extent and range of the FSA, such as tools that will initially be used, regulatory issues, food safety issues or other matters, and any possible public health issues or concerns, and
  - c. Steps of the assessment – The steps necessary to develop facts and findings and to collect evidence to the apparent or possible food safety issues.

B. An EIAO is to document the PHRE outcomes using the PHRE tool in PHIS.

C. Figure 1 provides an overview of the PHRE scheduling, documenting and decision-making workflow.



## V. SCHEDULING OF THE PHRE

A. ODIFP generates a prioritized list of establishments for potential for cause or risk based FSAs based on public health risk triggers listed in Table 1. The triggers are based on public health decision criteria, risk-based criteria, and establishment demographic data (e.g., establishment with a history of public health-related noncompliance records and is in the highest percentile of health-related noncompliance record (NR) rates). Table 1 lists the public health risk determinations used to identify PHREs in priority order

B. ODIFP is to notify the DO to schedule FSAs. Every month, ODIFP will send each district a ranked list of eligible establishments that the DO is to review and use to schedule FSAs.

C. The DO is to schedule PHREs within 30 days of notification by ODIFP to determine whether an FSA needs to be conducted.

D. In addition, the DO may also schedule PHREs for establishments not included in the report generated by ODIFP. Examples include when an establishment produced product with *Salmonella* Pulsed-field Gel

Electrophoresis (PFGE) matches or at the request of an FLS or DO based on concerns at the establishment.

E. The DO is to use Table 1 to help decide which PHREs to perform in order to direct resources.

**TABLE 1: Public Health Risk Determinations for PHREs in Priority Order**

Public Health Risk Determinants	Data Sources	References	If needed, type of FSA to be scheduled
Human illness linked to FSIS-regulated product <sup>1</sup>	Coordination with Office of Public Health Science / Applied Epidemiology Staff (OPHS/AES) and Office of Investigation, Enforcement and Audit (OIEA)	<a href="#">FSIS Directive 8080.3</a>	For-cause
Emergency Management Committee (EMC) determines an IIT will be conducted <sup>2</sup>	EMC	<a href="#">FSIS Directive 5500.3</a>	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)	<a href="#">FSIS Directive 8080.1</a>	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	<a href="#">FSIS Directive 10,010.1</a>	For-cause
FSIS positive <i>Listeria monocytogenes (Lm)</i> or <i>Salmonella</i> in ready-to-eat (RTE) product	ODIFP-DAIS PHRE scheduling report	<a href="#">FSIS Directive 10,300.1</a>	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>	<a href="#">FSIS Directive 10,010.1</a>	<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	<a href="#">FSIS Directive 10,010.1</a>	For-cause

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	<a href="#">Public Health Regulations</a>	For-cause
Establishment in PR/HACCP <i>Salmonella</i> Category 3	ODIFP-DAIS PHRE scheduling report	<a href="#">FSIS Directive 10,250.1</a>	For-cause
Establishment produced product with repetitive <i>Salmonella</i> serotypes of public health concern <sup>1</sup>	Laboratory Information Management System (LIMS-Direct); <i>Salmonella</i> End-of-Set Letter	<a href="#">FSIS Directive 10,250.1</a>	For-cause
Establishment produced product with matching <i>Salmonella</i> PFGE patterns <sup>1</sup>	<i>Salmonella</i> End-of-Set Letter	<a href="#">FSIS Directive 10,250.1</a>	For-cause
Repeat residue violators from same supplier source <sup>1</sup>	<a href="#">Residue Repeat Violator List</a>	<a href="#">FSIS Directive 10,800.1</a>	For-cause
Documented change in an establishment's production process that may impact public health <sup>1</sup>	FLS requested	<a href="#">FSIS Directive 5000.6</a>	For-cause
Consumer complaints associated with meat or poultry products as reported through the Consumer Complaints Monitoring System (CCMS) <sup>1</sup>	Monthly CCMS monitoring	<a href="#">FSIS Directive 5610.1</a>	For-cause
New establishments coming under a permanent grant of inspection <sup>1</sup>	Grant application	<a href="#">FSIS Directive 5220.1</a>	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	<a href="#">FSIS Directive 5100.1</a>	Risk-based

<sup>1</sup> Criteria not automatically scheduled by the ODIFP-DAIS

<sup>2</sup> Results in a FSA performed as part of an IIT.

## VII. PERFORMING THE PHRE

A. Once the FSA has been scheduled, the SEIAO is to assign an EIAO to conduct a PHRE. The PHRE is to be completed by an EIAO as it is scheduled.

B. The PHRE is to be completed by the EIAO from his or her duty station.

C. The EIAO is to obtain the PHRE report in PHIS. The report is titled “Public Health Risk Evaluation for an Establishment” and is located in the report tab of PHIS. The report contains hyperlinks to information described below.

D. The EIAO is to review the data obtained from the PHRE Report through PHIS. The EIAO is to review all relevant data to determine whether there are patterns or trends that should be investigated. Types of data contained in the report include:

1. Any FSAs completed at the establishment;
2. Available enforcement data;
3. Establishment compliance history including all NRs issued to the establishment within a specified time period;
4. PHIS profile data;
5. Notes of Weekly Meetings;
6. IPP Memoranda of Interview (MOI); and
7. Recall information.

E. The EIAO is to also obtain the additional background information not included in the PHRE report below:

1. FSIS laboratory results (both regulatory and exploratory) – access from Laboratory Information Management System (LIMS);
2. Consumer complaints - access from Consumer Complaint Monitoring System (CCMS);
3. Previous FSAs – if the previous FSA is not in PHIS, the EIAO is to send a request to the SEIAO to retrieve the previous FSA from AssuranceNet;
4. Additional enforcement reports – the EIAO is to review the following from AssuranceNet if applicable: Notice of Intended Enforcement (NOIE) or Notice of Suspension (NOS), Verification Plan, Notice of Suspension (or Reinstatement; NROS) Held in Abeyance (NOSA/ROSA) or Letter of Warning (LOW) when a PHRE report shows that the establishment has an enforcement history; and
5. PFGE results for *Listeria monocytogenes* (*Lm*)-positive results. If there were previous *Lm* positive results, the EIAO is to email the Outlook mailbox “PFGE results”.

F. In addition, the EIAO is to contact the FLS and the IPP if necessary to discuss the background report and to gain an understanding of the establishment’s operating practices.

G. The EIAO is to complete the PHRE by evaluating the establishment’s historical data using the PHIS PHRE report and the other additional background information and by communicating with the FLS and IPP. The EIAO is to assess the information to gain a basic understanding of how the establishment is operating and of any issues needing particular attention.

## VII. DOCUMENTING THE PHRE

A. After reviewing the PHIS PHRE report and discussions with the FLS and IPP, the EIAO is to make one of following possible PHRE recommendations:

1. Conduct a FSA by following the instruction in [FSIS Directive 5100.1](#);
2. No need to conduct a FSA at this time, but the data obtained from the PHRE Report through PHIS and additional background information not included in the PHRE PHIS report establish the need for enforcement action. The PHRE shows that FSIS has sufficient support to pursue an enforcement action. If enforcement is the outcome of the PHRE, then the EIAO is to follow the instructions found in [FSIS Directive 5100.3](#);
3. No FSA is needed at this time because a review of the finding in the PHRE report does not show the trends that establish that a public health risk exists. There is nothing that would warrant spending the resources to conduct a FSA. For example, the PHRE Report obtained through PHIS identified no public health related noncompliance records, no positive sample results, and no recalls at the establishment within the specified time period; or
4. No FSA is needed at this time because the establishment had a recent FSA that assessed the same scope; thus, another FSA is not necessary. The PHRE Report obtained through PHIS identified no public health related noncompliance records, no positive sample results, and no recalls at the establishment within the specified time period since the last FSA.

B. The EIAO is to use the PHRE tool to document the rationale for why an FSA will or will not be conducted. If an FSA will be conducted, EIAO will use the PHRE Tool to document the Assessment plan. Instructions related to the development of the Assessment plan are provided in Section IV.A.2.

C. As part of the development of an Assessment Plan, the EIAO is to identify the type of sampling (e.g. RLm, IVT, IIT) to be performed during the FSA. An EIAO is also to coordinate with FSIS Labs and ODIFP so that FSIS sampling can be tentatively schedule.

D. FSAs are conducted as for-cause and risk-based. “For cause” FSAs are to be given a higher priority than risk-based FSAs and are to be scheduled first. As shown in Table 1, risk-based FSAs may be initiated at new establishments coming under a permanent grant of inspection, in response to a new policy issuance, or in establishments that produced post-lethality-exposed ready-to-eat (RTE) products. All other PHREs that result in the scheduling of an FSA will lead to a for cause FSA.

E. The PHRE is an internal document only and is NOT to be distributed to the establishment. The EIAO is to share the thought process verbally to the establishment during the entrance conference as described in [FSIS Directive 5100.1](#).

## VIII. DATA ANALYSIS

One year after the issuance of this directive and annually thereafter, ODIFP-DAIS, is to analyze the data collected and determine the frequency and outcomes of the PHRE as a result of completed FSAs and any associated sampling.

## IX. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff (RIMS) through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the information in the fields provided below.

Subject Field: Enter **Directive 5100.4**  
Question Field: Enter question with as much detail as possible.  
Product Field: Select **General Inspection Policy** from the drop-down menu.  
Category Field: Select **EIAO Methodology** from the drop-down menu.  
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

**NOTE:** Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator  
Office of Policy and Program Development