

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

FSIS DIRECTIVE

5100.4
Revision 2

8/12/21

PUBLIC HEALTH RISK EVALUATION METHODOLOGY

I. PURPOSE

This directive provides instructions to Enforcement, Investigation, and Analysis Officers (EIAO) on how to schedule, conduct, and document the Public Health Risk Evaluation (PHRE) methodology in the Public Health Information System (PHIS). FSIS is revising this directive as described in [Section III](#).

NOTE: In this directive, the term EIAO also includes EIAO-trained Public Health Veterinarians and other EIAO-trained personnel.

KEY POINTS

- *PHRE Overview*
- *Scheduling of PHREs*
- *Documenting PHREs*
- *Scheduling Routine risk-based *Listeria monocytogenes* (RLm) Sampling, Intensified Verification Sampling (IVT), and Incident Investigation Team (IIT) Sampling*

II. CANCELLATION

FSIS Directive 5100.4, Revision 1, *Enforcement, Investigations, and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*, 05/22/15

III. SIGNIFICANT CHANGES

FSIS made the following changes to this directive by:

1. Updating Agency office names;
2. Adding new instructions on the scheduling of PHREs, including that District Offices (DOs) are not to wait for the PHRE Scheduling Spreadsheet;
3. Clarifying the PHRE process, including roles and responsibilities;
4. Explaining the types of sampling that may be performed during a PHRE or a Food Safety Assessment (FSA);
5. Revising Table 1 to reflect the FSA Workflow Category list available in PHIS; and

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6. Adding *RLm* sampling as an option to inform a PHRE.

IV. BACKGROUND

A. The PHRE is a decision-making analysis used by an EIAO to inform DO decisions. Based on PHRE findings, an EIAO may:

1. Conduct an FSA as described in [FSIS Directive 5100.1](#), *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*;
2. Take an administrative enforcement action as described in [FSIS Directive 5100.3](#), *Administrative Enforcement Action Decision-Making and Methodology*; or
3. Take no action because enforcement action or an FSA is not needed.

B. IPP are to be aware that PHIS will assign a random FSA Identification (FSA ID) number when the PHRE is assigned in the PHIS PHRE FSA module.

V. PHRE OVERVIEW

A. The PHRE is an analysis of establishment performance based on “For-cause” and “Routine risk-based” criteria. Specifically:

1. For-cause criteria:
 - a. The establishment produced product adulterated by pathogens [e.g., non-intact beef product found positive for Shiga toxin-producing *Escherichia coli* (STEC)];
 - b. The establishment produced product associated with an outbreak; or
 - c. The establishment may be associated with an increased risk of producing product of public health concern [e.g., failing performance standards or receiving a [public health-related](#) (PHR) noncompliance record (NR) alert].
2. Routine risk-based criteria (also known as not for-cause) encompass all other factors that may result in product posing an increased public health risk (e.g., new establishments with conditional Grants of Inspection, an establishment producing post-lethality exposed ready-to-eat (RTE) product).

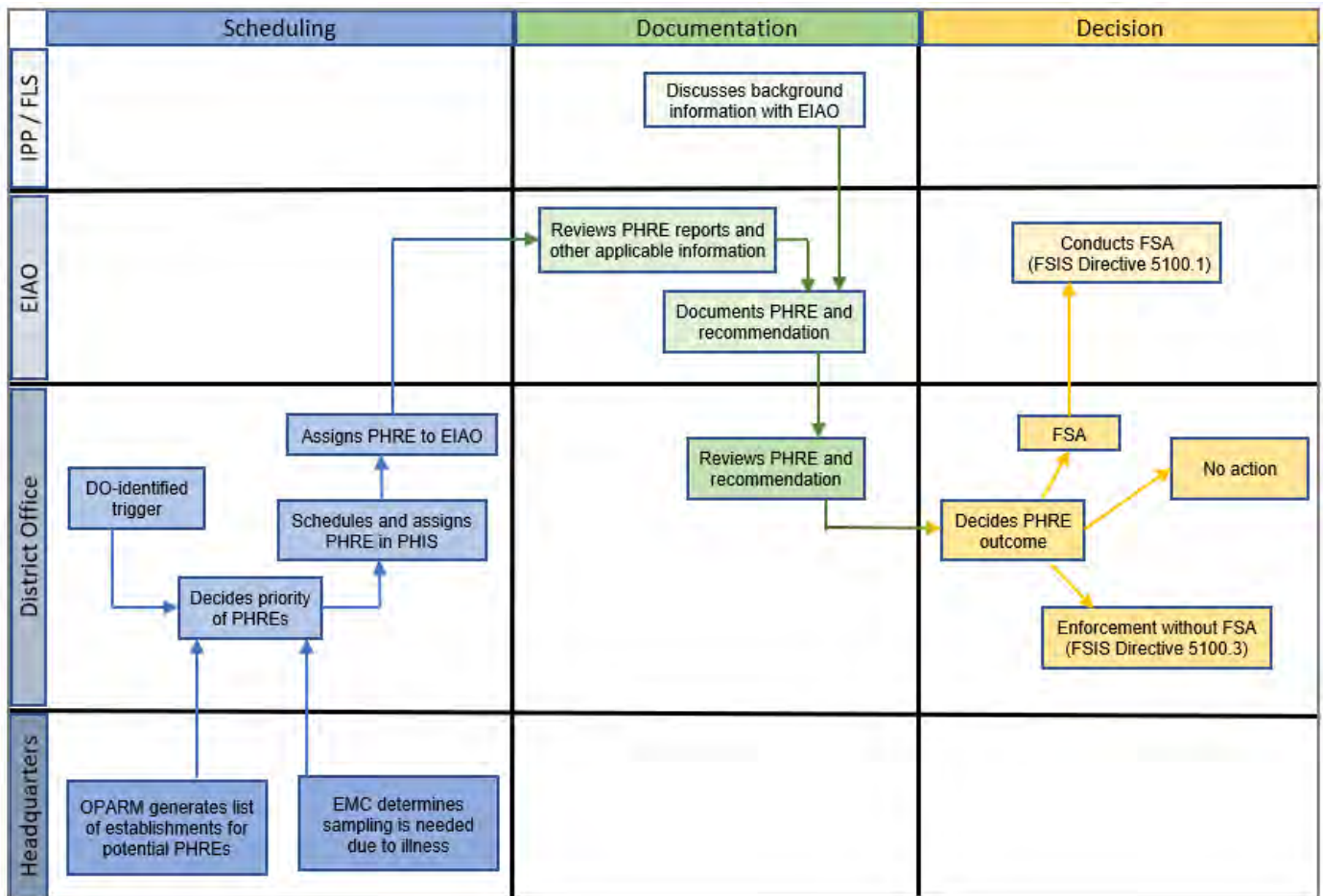
B. [Table 1](#) below identifies the for-cause and routine risk-based PHRE criteria that appear in the PHIS FSA Workflow Category.

1. PHIS is programmed to classify an FSA ID number as for-cause or routine risk-based depending on the FSA Workflow Category selected when the PHRE is assigned.
2. The District may schedule a single PHRE to include analyses for more than one category (including both for-cause and not-for-cause categories). Any for-cause category selection in the PHIS PHRE FSA module will result in the entire PHRE, and any subsequent FSA, being classified for-cause in PHIS, regardless of whether the subsequent FSA is ultimately performed for-cause or not-for-cause.

C. The DO is to schedule PHREs by assigning them to an EIAO through the PHIS PHRE FSA module, which is found under the PHIS left navigation menu option “Manage FSAs.” An EIAO is to add the PHRE tool, which is a series of questions, and complete the PHRE analysis. The DO is to review each PHRE and EIAO recommendation and determine the outcome. See [Figure 1](#) for an overview of the PHRE process.

1. A PHRE includes the PHIS PHRE FSA module tool, data field entry completion, and analysis performed of the data in the tool and data field entry. If the DO determines the PHRE outcome is to perform an FSA, the EIAO is to also develop the FSA plan as part of the PHRE.
2. If an FSA is to be performed, the DO may assign the FSA to a different EIAO other than the one who performed the PHRE.

Figure 1: Overview of the PHRE process: scheduling, documentation, and decision-making workflow



VI. SCHEDULING OF THE PHRE

A. The DO is to schedule PHREs as they become aware that an establishment’s performance data indicates one or more of the PHRE criteria are met (e.g., through PHIS alerts, sampling results, Biological Information Transfer E-mail System, PHRE spreadsheet, information from the frontline supervisor (FLS)).

1. Most of the for-cause risk criteria identified in [Table 1](#) result in a PHIS alert when the criterion threshold is met (e.g., failing a pathogen performance standard) or there are events that involve the Districts (e.g., Class 1 and 2 recalls of adulterated products).
2. Each month, the Office of Planning, Analysis, and Risk Management (OPARM) generates a list (PHRE Scheduling Spreadsheet) of establishments that meet one or more of the specified for-cause or select routine risk-based criteria in the prior month for the DO. The DO is not expected to perform PHREs for all establishments included on the PHRE Scheduling Spreadsheet, nor are they expected to perform PHREs in the exact order the establishments appear on the PHRE Scheduling Spreadsheet. In addition, the DO is not to wait for the PHRE Scheduling Spreadsheet to begin scheduling and performing the PHRE if they become aware that an establishment meets one or more criteria. OPARM is to e-mail the list to DO personnel.
3. In addition to the establishments identified in the PHRE spreadsheet, the DO is to consider other criteria that may warrant additional PHREs, including:
 - a. FLS identification of process control problems;
 - b. Recent or ongoing construction activities at the establishment;
 - c. A change in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan or the addition of a new HACCP plan;
 - d. Addition by the establishment of a new product;
 - e. Roof leaks, equipment breakdowns, condensation, or other events that could increase the possibility of product contamination at the establishment;
 - f. Findings of *Lm*, other pathogens, or an increase in indicator organism positives obtained through establishment sampling and testing; and
 - g. Anything indicating that the establishment may be having issues with sanitation that could increase the probability of contamination, including sanitation-related NRs, increased aerobic plate counts or adenosine triphosphate values, use of high-pressure hoses during cleaning in the RTE production area during operations, or operational conditions that move product debris into difficult to clean areas.
4. DOs are to be aware that due to the ranking algorithm for the routine section of the *RLm* tab of the PHRE Scheduling Spreadsheet, large establishments may no longer appear near the top of the routine section. As a result, DOs are also to consider scheduling routine, risk-based PHREs at large RTE establishments.
5. The FSIS Emergency Management Council (EMC) may request the DO to schedule a for-cause IIT PHRE, or other investigational sampling as appropriate for an emergency incident (as described in [FSIS Directive 5500.3](#), *Incident Investigation Team Reviews*), through the Office of Field Operations supervisory chain of command.
6. DOs are to also follow other Agency instructions (i.e., notices) concerning PHREs.

B. The DO may schedule a single PHRE for an establishment that meets multiple PHRE criteria. The DO is to select all appropriate PHRE criteria in PHIS under the FSA Workflow Category and may assign additional criteria to the PHRE as needed until the DO finalizes the outcome.

C. If sampling is required for a PHRE, the DO is to refer to [Section IX](#) for instructions on scheduling *RLm*, IVT, or IIT sampling through the PHIS PHRE FSA Module.

NOTE: Eligibility for the *RLm* project does not impact other for-cause or routine not-for-cause criteria that the DO are to consider when assigning a PHRE. DOs are to apply the same decisional process equally when assigning routine risk-based PHREs to both *RLm* and non-*RLm* eligible establishments.

TABLE 1: PHRE Criteria Triggers in Priority Order

PHIS PHRE FSA Module: FSA Workflow Category	Basis for Selection	FSIS Risk Type	References
Human illness linked to FSIS-regulated product	Establishment produced product linked to human illnesses through whole genome sequencing (WGS) and epidemiologically, or just epidemiologically ¹	For-cause	FSIS Directive 8080.3
Incident Investigation Team	Investigative sampling ²	For-cause	FSIS Directive 5500.3
Adulterated or misbranded product produced or shipped undergoing a Class I or Class II recall or Public Health Alert	Establishment produced or shipped adulterated or misbranded product that is subject to a Class I or Class II recall or Public Health Alert	For-cause	FSIS Directive 8080.1
Positive STEC test results in raw non-intact beef products by FSIS or other government entities' testing	Government (FSIS or other) testing in a raw non-intact beef product identified STEC positive	For-cause	FSIS Directive 10.010.1
FSIS positive <i>Listeria monocytogenes (Lm)</i> in ready-to-eat (RTE) product	FSIS testing in a RTE product identified <i>Lm</i> ; this criterion is only for FSIS testing, and not other government (i.e., Food and Drug Administration (FDA)) testing	For-cause	FSIS Directive 10.300.1
FSIS positive Salmonella in ready-to-eat (RTE) product	FSIS testing in a RTE product identified <i>Salmonella</i> ; this criterion is only for FSIS testing, and not other government (i.e., Food and Drug Administration (FDA)) testing	For-cause	FSIS Directive 10.300.1
Sole supplier of a positive STEC ground beef or patties or raw	Establishment is the sole supplier of beef product that was identified as STEC	For-cause	FSIS Directive 10.010.1

beef components	positive		
Repetitive STEC positives in the past 120 days	Establishment did not apply a full lethality treatment to raw beef product after repetitive STEC positives in that product in the past 120 days	For-cause	FSIS Directive 10.010.1
History of public health-related noncompliance records (PHR NR)	Establishment is in the highest percentile of PHR NR rates	For-cause	Public Health Regulations
Establishment failing performance standards	Failed one or more performance standards	For-cause	FSIS Directive 10.250.2
Repetitive serotypes of public health concern	Use will be directed by FSIS Headquarters ¹	For-cause	FSIS Directive 10.250.2
Product with matching WGS clusters	Use will be directed by FSIS Headquarters ¹	For-cause	FSIS Directive 10.250.2
Repeat residue violators from same supplier source	Same supplier source has repeat residue violations ¹	For-cause	FSIS Directive 10.800.1
Documented change in an establishment's production process that may impact public health	Establishment has made a documented change to the production process; this also includes positive test results (i.e., FDA testing in a dual jurisdiction establishment) indicating a potential food safety concern with the production process ¹	For-cause	FSIS Directive 5000.6
Consumer complaints reported through the Consumer Complaints Monitoring System (CCMS)	Establishment received consumer complaints through CCMS	For-cause	FSIS Directive 5610.1
New establishments coming under a permanent grant of inspection	New establishments	Routine/Risk-based	FSIS Directive 5220.1
Instructed in FSIS Notice or Directive	Agency instructs DO to schedule an ad hoc PHRE through updated instructions	Routine/Risk-based	
Post-lethality exposed ready-to-eat (RTE) products without positive sample results	Establishment produces post-lethality exposed RTE products, but FSIS testing has not identified positive product	Routine/Risk-based	FSIS Directive 10.240.5
Other Risk-Based	Any other risk criteria	Routine/Risk-based	

identified which is not
specified above

¹ Criteria not automatically scheduled by OPARM

² Including when product is linked through WGS, but not epidemiologically, to any human illness

VII. PERFORMING THE PHRE

A. The EIAO is to complete the PHRE as assigned from his or her duty station or another assigned location specified by the DO. The EIAO is not to complete the PHRE at the establishment, unless directed by the DO to do so.

B. For each assigned PHRE, the EIAO is to add and complete the PHRE tool. The PHRE tool is a series of analysis questions. The EIAO responds based on his or her findings. The historical performance period evaluated is based on the PHRE criterion reason and establishment operations. The DO is to provide EIAOs with guidance on the time periods evaluated.

1. The EIAO is to review all applicable PHIS Reports and data relevant to the establishment operations and FSA workflow categories as assigned. EIAOs may find that the *Public Health Risk Evaluation for an Establishment* and other available PHIS Reports have more specific data or filtering options that better correspond to the PHRE criteria to be analyzed. For example, EIAOs may assess the *Task Regulation Verified and Noncompliant Summary for an Establishment* report to help assess for any trends in PHR NRs for specific HACCP category tasks. EIAOs may also access the *Further Characterization of Positive Samples for an Establishment* tab of the *Public Health Risk Evaluation for an Establishment* report to assess WGS results for indications of harborage or cross-contamination.
2. The EIAO is to review customer complaints through the Surveillance, Complaints and Outbreaks Response Enterprise (SCORE)/CCMS module in PHIS. EIAOs are to access this module by changing the PHIS role to SCORE-CCMS Field Personnel.
3. The EIAO is to evaluate additional background information not in PHIS such as:
 - a. PulseNet Cluster Analysis: Obtain this data by submitting an [askFSIS](#) request using the title "PulseNet cluster analysis." This analysis includes the last year of *Salmonella* data from the establishment. Examples of when an EIAO would request this analysis includes criteria for failing a performance standard or product linked to human illness; and
 - b. Food and Drug Administration (FDA) sampling results for dual-jurisdiction establishments. EIAOs are to contact the DO to determine if any FDA *Lm* sampling results have been reported per [FSIS Directive 5730.1](#), *Responsibilities in Dual Jurisdiction Establishments*.
4. The EIAO is also to evaluate any additional enforcement reports from AssuranceNet or DO Q drive, if applicable, such as:
 - a. Notice of Intended Enforcement;
 - b. Notice of Suspension or Reinstatement;
 - c. Verification plans;
 - d. Notice of Suspension Held in Abeyance or Notice of Reinstatement of Suspension Held in Abeyance;

- e. Letter of Warning;
- f. Product recall information, including Recall Releases, Recall Notification Reports, and Public Health Alerts; and
- g. Previous FSAs, if not in PHIS.

C. The EIAO is to gain an understanding of the establishment's operating practices and product types produced through the information in PHIS. After reviewing PHIS information, the EIAO is to correlate with IPP assigned to the establishment. The EIAO is to assess the information to gain a basic understanding of how the establishment operates and identify any issues which may require further assessment.

VIII. DOCUMENTING THE PHRE

A. After reviewing the applicable reports and discussions with the FLS and IPP, and completing the PHRE tool, the EIAO is to make one of the following possible PHRE recommendations to the District Manager through the appropriate supervisory chain:

1. Conduct an FSA as described in [FSIS Directive 5100.1](#);
2. Take an administrative enforcement action as described in [FSIS Directive 5100.3](#). In this option, the EIAO is able to gather the appropriate support for enforcement action without conducting the FSA. Examples include adulterant STEC positive from FSIS testing, evidence of egregious insanitary conditions, or *Lm* harborage from whole genome sequencing in coordination with insanitary conditions in the establishment; or
3. Take no action because enforcement action or an FSA is not needed. The EIAO may recommend this option if the establishment had a recent FSA that assessed the same scope or the PHRE report does not find any noncompliances or risks (e.g., the establishment has implemented effective corrective actions, has no PHR NRs, has no positive sample results, and has no recalls).

B. The EIAO is to use the PHRE tool to document the rationale for their recommendation. If the EIAO recommends an FSA, the rationale is to support that the risk requires further assessment. It may include that any additional data required to complete the assessment may only be accessible in the establishment and not through discussions with the IPP and FLS.

C. If an FSA will be conducted, the EIAO is to use the PHRE tool to document the assessment plan. The development of an assessment plan helps to ensure thoroughness and organization. Planning also promotes efficient use of limited resources. The assessment plan is to include the:

1. Summary of Findings – Apparent violations of the statutes or regulations and a brief statement of the apparent or possible food safety issues determined through the analysis. The plan is to cite the relevant statutory or regulatory noncompliances and state or paraphrase the language of the statutes or regulations (e.g., 21 U.S.C. [453\(g\)\(4\)](#) and [458\(a\)\(3\)](#), poultry products stored under insanitary conditions during transportation, causing the products to become adulterated);
2. Scope of FSA – Briefly state the extent and range of the FSA, such as tools that will initially be used, and any possible public health issues or concerns;
3. Steps of the assessment – The steps necessary to gather facts, collect evidence relevant to the apparent or possible food safety issues, and develop findings; and

4. Sampling – The type of sampling to be conducted if applicable (e.g., *RLm*, IVT, IIT) in advance of the FSA. The EIAO is also to coordinate with FSIS laboratories and OPARM so that FSIS sampling can be tentatively scheduled.

D. Once the EIAO completes the PHRE and recommends an outcome, the DO is to review the PHRE and determine if the recommendation is supportable.

E. FSAs are conducted under the same FSA ID and the same FSA Workflow Category or categories as the PHRE.

F. The PHRE is an internal document only and is not to be distributed to the establishment. If an FSA is scheduled, the EIAO is to share the thought process verbally with the establishment during the entrance conference as described in [FSIS Directive 5100.1](#).

IX. SCHEDULING OF SAMPLING

A. When sampling is required to inform a PHRE or FSA, DOs are to select “Samples will be collected as part of the FSA” in PHIS. Scheduling of the *RLm* and IVT samples is only possible through the PHIS PHRE FSA module and as such, the DO has some flexibility when scheduling these samples.

B. DOs are to be aware that both *RLm* and IVT samples can be scheduled in PHIS depending on the FSA Workflow Category or categories initially selected. However, these samples are only to be collected under the appropriate FSA Workflow Category. *RLm* sampling is not to be scheduled to assess or verify known RTE for-cause criteria. IVT sampling is a for-cause verification to be used when there are existing for-cause criteria that relate to the RTE process.

C. *RLm* Sampling

1. EIAOs are to follow the instructions in [FSIS Directive 10.240.5](#), *Verification Procedures for Enforcement, Investigations and Analysis Officers for the Listeria monocytogenes (Lm) Regulation and Routine Risk-Based Listeria monocytogenes (RLm) Sampling Program*, to conduct *RLm* sampling.
2. The *RLm* sampling project is a routine, risk-based project for post lethality exposed, RTE-producing establishments. FSIS has incorporated a risk-based selection algorithm to prioritize establishments in each District for *RLm* sampling in the routine portion of the *RLm* tab of the spreadsheet.
 - a. The routine portion of the *RLm* tab of the PHRE Scheduling Spreadsheet ranks the establishments for the next month’s *RLm* product, environmental, and food contact projects using the algorithm.
 - b. The algorithm makes it possible that one establishment may be prioritized more than one time before another eligible establishment in the District.
 - c. DOs are not to wait for establishment selection for *RLm* sampling to schedule a PHRE for other routine risk-based criteria indicated by establishment performance. DOs are to continue to schedule *RLm* eligible establishments for routine risk-based PHREs as needed using the same decisional criteria they apply to non-*RLm* eligible establishments.
3. DO may assign the *RLm* sampling to occur when a PHRE is already assigned for another risk criterion, except any for-cause criteria involving the RTE operations represented by the *RLm*

sampling.

4. EIAOs are to select the FSA Workflow Category of the routine risk-based criteria “post-lethality exposed ready-to-eat (RTE) without positive sample results” if not already selected when the PHRE was assigned.

D. IVT Sampling

1. EIAOs are to follow the instructions in [FSIS Directive 10,300.1](#), *Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for Listeria monocytogenes (Lm) or Salmonella spp.*, for IVT sampling.
2. IVT sampling may occur only to support a for-cause PHRE or FSA in the applicable RTE HACCP category.
3. IVT sampling is only available if a for-cause criterion is selected when the PHRE is first assigned. When assigning the PHRE, select from the following FSA Workflow Categories:
 - a. “FSIS positive *Listeria monocytogenes* (*Lm*) in ready-to-eat RTE product;”
 - b. “FSIS positive *Salmonella* in ready-to-eat (RTE) product;”
 - c. “History of public health-related noncompliance records (PHR NR);” or
 - d. “Documented change in an establishment’s production process that may impact public health.”

E. IIT and other sampling

1. EIAOs are to follow the instructions in [FSIS Directive 5500.3](#) for IIT or other investigative sampling.
2. Select the FSA Workflow Category of “Incident Investigation Team” if not already selected when the PHRE was assigned.
3. Special sampling projects or tasks created for investigations may also be distributed through the PHIS Establishment Task List and Calendar. FSIS Headquarters will advise the DOs of how the samples are to be scheduled in PHIS for each IIT.
4. Collect products and food contact and environmental surface swabs for designated pathogens upon activation through the EMC or other means to respond to a nonroutine incident.

X. QUESTIONS

Refer questions regarding this directive to your supervisor and if needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select General Inspection Policy for the inquiry type.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is fluid and cursive, with the first name being the most prominent.

Assistant Administrator
Office of Policy and Program Development