

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

FSIS DIRECTIVE

5100.5

9/25/19

PUBLIC HEALTH REGULATIONS AND FSIS RESPONSE TO ELEVATED PUBLIC HEALTH REGULATION NONCOMPLIANCE RATES

I. PURPOSE

This directive summarizes how FSIS determines the annual updated list of Public Health Regulations (PHRs). Based on FSIS data analysis, PHRs are associated with positive pathogen results or enforcement actions. PHR noncompliance rate data are used to inform FSIS as to when additional evaluation is necessary to assess an establishment's operational and compliance history. This directive also instructs in-plant FSIS inspection program personnel (IPP) and Frontline Supervisors (FLSs) on how to respond to the Public Health Information System (PHIS) Early Warning Alerts. Finally, this directive provides information on when the District Office (DO) is to schedule a Public Health Risk Evaluation (PHRE) to determine if a Food Safety Assessment (FSA) is necessary.

KEY POINTS:

- *Each year, FSIS updates a list of PHRs, based on data analysis, to allow FSIS to focus on specific public health related regulations that may best inform FSA prioritization*
- *FSIS uses the PHR noncompliance rate data to determine cut points for a PHR Early Warning Alert and PHRE*
- *When IPP receive a PHR Early Warning Alert through PHIS, they are to review and evaluate the establishment's noncompliance history, identify noncompliance trends, and work with their supervisors to determine what actions are necessary*
- *When the DO is informed that an establishment met or exceeded the cut point for PHRE scheduling, the DO is to assign an Enforcement, Investigations and Analysis Officer (EIAO) to perform a PHRE to aid the DO in determining whether a FSA is necessary*

II. BACKGROUND

A. Each year, the Office of Planning, Analysis, and Risk Management (OPARM) updates the PHR list based on analysis of data on regulatory noncompliances and their association with positive sample results and enforcement actions. FSIS makes these annual updates to better reflect noncompliance records (NRs) associated with public health hazards. The updated list includes regulations that have higher rates of noncompliance at establishments in the three (3) months before pathogen positive results or enforcement actions at those establishments.

DISTRIBUTION: Electronic

OPI: OPPD

B. FSIS uses the following three-step method to identify PHRs:

1. Define a set of evaluation criteria for selecting a candidate list of regulations;
2. Develop a list of candidate regulations that are relied upon to verify the effectiveness of establishments' food safety systems; and
3. Select a subset of the candidate regulations that have been determined (by OPARM) to be verified as noncompliant at an elevated rate in establishments that:
 - a. Have had a *Salmonella*, *E. coli* O157:H7, non-O157 Shiga Toxin-producing *E. coli* (STEC), *Listeria monocytogenes* (Lm) or *Campylobacter* positive, or
 - b. Without positive sample results, have had an enforcement action, specifically a public-health related Notice of Intended Enforcement or Suspension that resulted from a Sanitation Standard Operating Procedure (Sanitation SOP), Hazard Analysis and Critical Control Point (HACCP) or Sanitation Performance Standards (SPS) violation.

C. This data-driven approach identifies the PHRs with statistically higher individual noncompliance rates in establishments in the three (3) months prior to a microbiological positive result or a public-health related enforcement action when compared to establishments with no microbiological positive results or public-health related enforcement actions. This statistical association does not inherently imply that a particular regulation constitutes a more serious food safety concern but gives a statistical association to better align scheduling criteria and agency resources. PHRs are not the only important food safety and public health related regulations. Noncompliance with many other regulations are critical indicators of public health concern but may not be statistically associated with the outlined criteria.

D. Additional information on how the evaluation criteria for the PHRs are established is provided in the current [annual Public Health Regulations report](#).

III. ANNUAL CUT POINTS FOR PHRE SCHEDULING AND PHR EARLY WARNING ALERTS

A. Each year, OPARM sets Tier 1 and Tier 3 cut points for two broad categories of establishments: 1) Processing and 2) Combination (Slaughter and Processing). These cut points are based on PHR noncompliance rates. In general, Tier 1 is the higher threshold at which FSIS will consider the establishment for a PHRE and Tier 3 is the lower threshold at which IPP are notified through a PHIS Alert that an establishment is at an elevated PHR noncompliance level. For a detailed explanation on how FSIS determines these cut points, see the FSIS Data Analysis and Reporting: [Public Health Regulations webpage](#).

B. IPP are to familiarize themselves with the annual PHR list and cut points, which can be found on the aforementioned webpage.

IV. PHR NONCOMPLIANCE RATES

A. Each month, OPARM uses the PHIS inspection task result data to calculate a PHR noncompliance rate for each official meat and poultry establishment. This PHR noncompliance rate is compared to the annual cut points to consider whether IPP at the establishment will receive a PHR Early Warning Alert through PHIS or whether the DO will assign a PHRE based on PHR data.

B. The PHR noncompliance rate is intended to be a comparison between an establishment and similar establishments at the same point in time. FSIS personnel are not to use the PHR noncompliance rate for tracking trends in establishment performance from year-to-year because variation introduced by the PHR list changes each year makes year-to-year comparisons invalid.

V. PHRE SCHEDULING

A. Establishments with PHR noncompliance rates that are equal to or exceed the Tier 1 cut point for PHRE scheduling are listed on the monthly PHRE schedule report, which OPARM provides to the DOs. The DOs are to assign EIAOs to perform PHREs for these establishments to determine whether a FSA is necessary, as directed in [FSIS Directive 5100.4, Enforcement, Investigations and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#).

B. The DO is not to automatically assign a PHRE to an establishment that meets or exceeds the Tier 1 cut point if it has had an FSA within the past 6 months. In this situation, the DO is to determine whether the establishment should receive an additional PHRE or possible FSA on a case-by-case basis, depending on the specific facts of each situation.

VI. FSA

A. The DO is to determine whether a FSA is necessary based on the PHRE results.

B. When a FSA is deemed necessary, EIAOs are to inform the establishment that the elevated PHR noncompliance rate is the reason for the FSA, explain the current PHRs and cut points to the establishment and refer them to the Public Health Regulations webpage for more detailed information, during the FSA entrance meeting.

VII. PHR EARLY WARNING ALERT

A. A PHR Early Warning Alert is issued to IPP through PHIS when an establishment has a PHR noncompliance rate that is greater than or equal to the Tier 3 cut point for early warning, but less than the Tier 1 cut point, unless:

1. IPP have documented fewer than 20 PHR verifications in the prior 3-month inspection period; or
2. IPP have documented fewer than 2 PHR noncompliances (e.g., zero or one) in the prior 3-month inspection period; or
3. A PHR Alert was issued the previous month.

B. See the [Attachment](#) for a description of the PHR Alert information.

C. When IPP receive a PHR Early Warning Alert on their PHIS dashboard, they are to review the information in the Alert, and the past full 3 months of information in the PHIS “PHR Noncompliances for an Establishment” report, which provides information about the NRs associated with the PHR Alert. IPP are to analyze this information and identify any noncompliance trends.

D. To view the “PHR Noncompliances for an Establishment” report in PHIS, IPP are to click on the “View Report” tab in the left navigation menu. This will display the Inventory of Standard Reports page. IPP are to find the “PHR Noncompliances for an Establishment” report in the list and click on “Run” to select this report. In the user prompts, IPP are to enter the number of the current month (e.g., 5 for May), current year and the establishment number, and click on “Run” to display the past full 3 months of information. The tabs on the bottom of the report display the PHR status and PHR NRs.

NOTE: Information provided in the “PHR Noncompliances for an Establishment” report can be particularly useful to relief personnel and IPP who rotate to establishments. An FLS can also run the “PHR

Noncompliances for a Circuit” report in PHIS to review a summary of PHR noncompliances for all establishments in his or her circuit.

E. IPP are to discuss their analysis and ideas with their FLS to determine whether the information demonstrates a trend of repetitive NRs or the implementation of ineffective corrective actions at the establishment.

F. After this analysis and discussion with their FLS, IPP are to determine what actions are necessary, which may include performing additional directed verification tasks. IPP, at the direction of their FLS, may perform directed verification tasks to determine whether a negative trend is continuing or whether an establishment’s corrective actions have been effectively implemented. If IPP perform additional directed verification tasks in this situation, and this prevents them from completing some scheduled inspection tasks, they are to mark the scheduled tasks as “Not Performed”, as instructed in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System](#).

G. IPP are to discuss the information that caused the PHR Early Warning Alert, the results of their analysis of relevant information, and actions they intend to take in response to their analysis with the establishment at a weekly meeting. IPP are to document the weekly meeting as directed in [FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System](#).

H. As IPP continue to perform their scheduled verification tasks, as well as any additional directed verification tasks deemed necessary, they are to assess whether identified noncompliance trends are continuing or whether the establishment’s corrective actions are effective to resolve the noncompliance issues. IPP are to keep their FLS informed about the establishment’s progress in resolving the issues that resulted in the elevated PHR noncompliance rates.

I. FLSs are to review the PHR reports, applicable Memoranda of Interview (MOIs), and associated NRs in their establishments that receive PHR Early Warning Alerts and communicate with IPP to identify noncompliance trends and establishment failures to implement effective corrective actions. When the FLS, with input from the IPP, determines that the establishment has failed to implement effective corrective actions in response to noncompliance trends, he or she is to discuss the situation with the DO to determine whether to schedule a FSA.

VIII. DATA ANALYSIS

OPARM is to periodically analyze the PHR selection criteria and the results of the PHREs and FSAs performed to evaluate the effectiveness of the criteria. OPARM is also to analyze data gathered from this process to further refine the methods for selecting PHRs and prioritizing establishments for PHREs.

IX. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#), or by telephone at 1-800-233-3935. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5100.5**.

Question Field: Enter the question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Regulations/Agency Issuances** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.)** 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.

Robert J Wagner

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Office of Policy and Program Development

Attachment
Description of the PHR Alert Information

Alert Column Heading	Description
Establishment	Full establishment number
Circuit Number	Circuit of establishment
Establishment Type	Processing or Combination
Number of PHRs Verified	The number of PHR regulations cited while performing PHIS inspection tasks
Number of PHR Noncompliances	The number of noncompliances that cited regulations from the current PHR list
PHR Noncompliance Rate	This represents the current rate of PHR noncompliance, which is calculated as a percentage of PHR verifications that were cited as noncompliant. It is derived by dividing the number of PHR noncompliances by the number of PHRs verified and multiplied by 100. If this rate is higher than or equal to the cut point for early warning and below the Noncompliance Cut Point For PHRE/Food Safety Assessment (FSA) Scheduling, an alert is issued in PHIS.
Noncompliance Cut Point for Early Warning	When the PHR Noncompliance Rate is equal to or greater than this value, an alert is issued through PHIS. These rates usually change from year to year.
Noncompliance Cut Point for PHRE	When the PHR Noncompliance Rate is equal to or greater than this value, the DO may schedule a PHRE to determine if a FSA is necessary. These rates usually change from year to year.
Status	The "Elevated, but below PHRE cut point" status means that the PHR Noncompliance Rate is higher than or equal to the cut point for early warning and below the Noncompliance Cut Point for PHRE.
EstablishmentID	Establishment ID; unique numeric identifier