

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

FSIS NOTICE

15-18

3/20/18

PUBLIC HEALTH REGULATIONS AND ALERTS FOR USE IN DETERMINING INSPECTION PROGRAM PERSONNEL ACTIONS AND PUBLIC HEALTH RISK EVALUATION SCHEDULING IN MEAT AND POULTRY ESTABLISHMENTS

I. PURPOSE

A. This notice is issued yearly with the annually updated list of Public Health Regulations (PHRs).

B. This notice defines the Public Health Regulation (PHR) alerts in the Public Health Information System (PHIS) and instructs inspection program personnel (IPP) on how to review and respond to the alert.

C. The notice also instructs Frontline Supervisors (FLSs) to provide guidance to IPP about findings and trends in the establishment when an alert is generated.

D. This notice also includes instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) on sharing PHR information with establishments at Food Safety Assessment (FSA) entrance meetings.

II. BACKGROUND

A. The Office of Data Integration and Food Protection (ODIFP) analyzes noncompliance data in PHIS from establishments that have received noncompliance records (NRs) that cite the regulations on the PHR list. ODIFP annually reviews the regulations designated as PHRs, which are listed on the FSIS Data Analysis and Reporting: [Public Health Regulations Webpage](#), and makes updates as needed to better reflect NRs associated with public health hazards.

B. FSIS uses a three-step method to identify PHRs. The Agency:

1. Defines a set of evaluation criteria for selecting a candidate list of regulations;
2. Develops a list of candidate regulations that are relied upon in verifying food safety process control; and
3. Selects a subset of the candidate regulations that ODIFP determined to be out of compliance at an elevated rate in establishments:

- a. That have had *Salmonella*, *E. coli* O157:H7, non-O157 Shiga Toxin-producing *E. coli* (STEC), *Listeria monocytogenes* (*Lm*), or *Campylobacter* positives, or

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- b. Without positives that had another deficiency that resulted in an enforcement action.

C. Details on how the evaluation criteria for the PHRs were established are explained in the [FY2018 Public Health Regulations](#) report. The final list of FY2018 PHRs consists of 57 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action.

III. RECEIPT OF A PHR ALERT

A. Each month ODIFP will use the results of IPP inspection tasks to calculate a PHR noncompliance rate for each meat and poultry official establishment. ODIFP will use the PHR noncompliance rate to determine whether the establishment will be issued a PHR alert or whether the establishment will be assigned for a Public Health Risk Evaluation (PHRE).

B. A PHR alert will be issued to IPP through PHIS when an establishment has a PHR noncompliance rate that is at the Noncompliance Cut Point for Early Warning as described in the table in paragraph E, unless the establishment meets the exceptions listed below.

C. A PHR alert will not be issued if:

1. IPP documented fewer than 20 PHRs in the prior 3 month inspection period;
2. IPP documented fewer than two noncompliances in the prior 3 month inspection period; or
3. A PHR alert was issued the previous month.

D. IPP will receive a PHR alert on the IPP dashboard in PHIS with a list of reference numbers for the NRs that caused the alert to be generated.

E. The information in the PHR alert is to be used by IPP to identify trends in noncompliance. The following describes each column of the alert:

| 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 regulations cited while performing tasks in PHIS |
| Number of PHR Noncompliances | The number of noncompliances from the PHR list |
| PHR Noncompliance Rate | The number shown in this column is the current rate. 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, the alert is issued in PHIS. It is derived by dividing the number of PHR noncompliances by the number of PHRs verified and multiplied by 100 (to show as a percentage). |
| Noncompliance Cut Point for Early Warning | When the PHR Noncompliance Rate reaches the value in this field the alert is triggered. The Noncompliance Rate Cut Point for Early Warning for FY18 is set at 5.38% in Combination establishments and at 2.82% in Processing establishments. |

| | |
|---|---|
| | These rates will change from year to year. |
| Noncompliance Cut Point For PHRE | If the PHR Noncompliance Rate is higher than or equal to the Noncompliance Cut Point For Public Health Risk Evaluation (PHRE) Scheduling, a PHRE is to be scheduled. The Noncompliance Rate Cut Point for PHRE Scheduling for FY18 is set at 8.73% in Combination establishments and at 4.22% in Processing establishments. These rates likely will change from year to year. |
| Status | “Elevated, but below PHRE cut point” |
| Establishment ID | Establishment ID; unique numeric identifier |

F. Establishments with a PHR noncompliance rate that is equal to or exceeds the Noncompliance Cut Point for PHRE Scheduling will be listed in the monthly PHRE schedule report, which is provided by ODIFP to the Office of Field Operations (OFO) District Offices. A District Office is to assign an EIAO to perform a PHRE and make a decision on scheduling an FSA at the establishment as directed in [FSIS Directive 5100.4, Enforcement, Investigations, and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#).

IV. IPP RESPONSIBILITIES IN RESPONSE TO PHR ALERTS

A. IPP are to familiarize themselves with the FY2018 PHRs so that they can be aware of how FSIS determines the public health-related NR rates. The PHR noncompliance rate is based on the 57 regulations listed on the FY2018 PHR list. IPP can find the FY2018 PHR list and cut points on the [Public Health Regulations webpage](#).

B. Once IPP in meat and poultry establishments receive a PHR alert, they are to:

1. Review the PHR alert and review NRs that have been linked or associated with the alert by running the PHIS Report titled “PHR Noncompliances for an Establishment” located in the report tab of PHIS. The PHIS Report provides more specific information about the NRs associated with the PHR alert;

NOTE: This information is particularly useful to relief personnel and IPP who rotate to the establishment. FLSs can run a summary of all establishments in their circuit from the “PHR Noncompliance for a Circuit” report.

2. Discuss their analysis of the PHR alert, the PHIS Report, and the associated NRs with supervisory personnel to determine whether a trend of ineffective corrective actions or repetitive NRs exists at the establishment;
3. Discuss what actions to take based upon their analysis, including developing a plan with targeted additional directed tasks. IPP, at the direction of supervisory personnel, may perform directed tasks to determine whether a trend is continuing, and whether an establishment’s corrective actions performed are effective. If additional directed tasks are performed, IPP could mark scheduled tasks as “Not Performed” by following the instructions in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System](#); and
4. Discuss with the establishment at a weekly meeting the findings and information that underlie the PHR alert and any actions that the IPP intends to take based on their analysis of the findings and information. Once the establishment implements its corrective actions, IPP are to assess whether a trend of noncompliance is continuing, and whether the establishment’s corrective actions have proven to be effective or

ineffective; IPP are to inform the supervisor of their determination.

V. FLS RESPONSIBILITIES IN RESPONSE TO PHR ALERTS

Supervisory personnel are to review the PHR reports, Memoranda of Interview (MOIs), and associated NRs and communicate with the inspection teams to identify establishments that have PHR noncompliance or failure to implement effective corrective actions.

VI. FSA ENTRANCE MEETINGS

A. When a PHRE results in a for-cause FSA due to PHR noncompliance, EIAOs are to discuss the PHRs as the reason for the FSA with the establishment.

B. At the entrance meeting, EIAOs are to meet with establishment management as described in [FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#) and refer establishment management to the FY2018 PHR list and cut points on the FSIS Data Analysis and Reporting: [Public Health Regulations Webpage](#), for more detailed information regarding the PHRs review criteria.

C. Information pertaining to the IPP alerts and instructions will not need to be discussed.

VII. DATA ANALYSIS

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

VIII. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff 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 **Notice 15-18**
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.



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