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Food Safety and Inspection Service
FY2025 Public Health Regulations**

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SUMMARY

The Food Safety and Inspection Service (FSIS) public health regulations (PHR) are regulations¹ that have significantly higher individual noncompliance rates at establishments within 90 days of a pathogen-positive laboratory sample—*Salmonella*, *Escherichia coli* (*E. coli*), *Listeria monocytogenes* (*Lm*), or *Campylobacter*—or a public health-related enforcement action, compared to establishments with no pathogen-positive samples or enforcement actions.² Although correlation does not necessarily indicate a higher risk in food safety, it can be helpful for agencies in allocating resources. FSIS expects establishments to comply with all regulatory requirements.

This report describes the agency’s data-driven approach to selecting the PHRs that prioritize certain inspection activities for the 2025 fiscal year (FY) spanning October 1, 2024, to September 30, 2025. FSIS uses decision criteria, including PHRs, to prioritize establishments for public health risk evaluations³ (PHRE) through which FSIS determines the need for a food safety assessment (FSA) or enforcement action. In addition to exceeding an upper threshold for PHR noncompliance rate, other decision criteria used to prioritize establishments for PHREs include pathogen testing results, recalls, outbreaks, regulatory findings, and inspection results. The list of PHRs, as well as the upper and lower thresholds that inform PHREs and alert FSIS inspection program personnel of elevated PHRs noncompliance, are updated annually (around July 1) with targeted implementation in October.

The FY2025 PHRs list is based on calendar year (CY) 2023 FSIS verification data from January 1, 2023, to December 31, 2023. For inclusion in the FY2025 PHRs list, FSIS evaluated a curated list of candidate regulations from Title 9 of the Code of Federal Regulations (CFR) to determine whether noncompliance with each regulation occurred more frequently in establishments within 90 days of having pathogen-positive samples or enforcement actions compared to establishments without positives or enforcement actions.

The final list of FY2025 PHRs (see Appendix A) consists of 67 regulations that have a higher rate of noncompliance in the 90 days before a pathogen-positive sample or enforcement action. Of the 63 PHRs identified for FY2024, 50 remain on the FY2025 PHRs list.

The average noncompliance rate of FY2025 PHRs in the 90 days before a pathogen-positive sample or enforcement action is 16.01 times higher than the average FY2025 PHRs noncompliance rate for establishments with no pathogen-positive sample and no enforcement

¹ The term “regulation” is meant to include both regulations and the provisions of regulations. The Code of Federal Regulations (CFR) is composed of a set of regulations and the provisions of the regulations that define in greater detail the specific requirements of a regulation. The inclusion of provisions of regulations in the PHRs list allows FSIS to focus on specific health-related provisions of regulations that may be most informative for prioritizing public health risk evaluations (PHRE).

² Hereafter, the term “enforcement action” refers to a public health-related Notice of Intended Enforcement (NOIE) or Notice of Suspension (NOS) that results from a Sanitation Standard Operating Procedure (SSOP), Hazard Analysis and Critical Control Point (HACCP), or Sanitation Performance Standards (SPS) violation.

³ If an establishment is selected for a PHRE, the District Office first performs the evaluation as described in [FSIS Directive 5100.4](#) “Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology” to review the operational and compliance history of the establishment to decide if a Food Safety Assessment (FSA) or enforcement action is appropriate.

action. Noncompliance with a single FY2025 PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the 90-day rolling average noncompliance rate for all similar establishments. The aggregate FY2025 PHRs noncompliance rate by establishments is evaluated and compared to thresholds (also referred to as cut points) for two broad categories of establishment operations: “Processing” (processing only) and “Combination” (both slaughter and processing).

The FY2025 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2025 PHR rates for each of the four quarters in CY2023 (the log transformation of the non-zero FY2025 PHR rates is taken to obtain an approximately normal distribution). The mean and standard deviation are averaged over the four quarters, and the upper cut point is defined as the mean plus two times the standard deviation of the log transformed non-zero PHR rates. The antilog is then taken to obtain the upper cut point of the non-transformed PHRs noncompliance data. If an establishment’s PHRs noncompliance rates exceed the upper cut point for similar establishments, it is classified as “Upper” and may be subject to a for-cause PHRE if it has not had one in the last 180 days. The lower cut point is defined as the mean plus one and a half times the standard deviation of the log transformed non-zero PHR rates. Establishments that have PHRs noncompliance rates below the lower cut point for similar establishments are classified as “Lower.” As outlined in FSIS Directive 5100.5, establishments with a PHRs noncompliance rate between the upper and lower cut points will be notified by FSIS inspection program personnel that the establishment is at an elevated level of noncompliance. Tables S-1 and S-2 present the upper and lower FY2025 PHRs cut points for the non-transformed PHRs noncompliance data for each of the two establishment operation types. The FY2024 and FY2023 PHRs cut points are included for comparison (See Section 6 and Appendix D).

Table S-1 PHR Upper Cut Points

Operation Type	FY2025	FY2024	FY2023
Processing	3.50%	3.76%	3.65%
Combination	6.02%	7.17%	7.48%

Table S-2 PHR Lower Cut Points

Operation Type	FY2025	FY2024	FY2023
Processing	2.35%	2.49%	2.45%
Combination	3.71%	4.44%	4.59%

Table S-3 presents the number of establishments in each level from January 1, 2024, to March 31, 2024, based on the PHR criterion. The period used for calculating the noncompliance rate of the PHRs was January 1, 2024, to March 31, 2024. The number of for-cause PHREs for Upper cut point establishments is approximately the same as in previous years.

Table S-3 Number of Establishments in Levels Based Solely on the PHR Criterion

Level	Processing	Combination	Total
Upper	48	17	65
Mid	69	37	106
Lower	4,278	1,171	5,449
Total	4,395	1,225	5,620

1.0 INTRODUCTION

In January 2008, the Food Safety and Inspection Service (FSIS) published a decision tree methodology and a set of seven public health-based decision criteria for use in prioritizing establishments for Public Health Risk Evaluations (PHRE). The decision criteria include pathogen testing results, recalls, outbreaks, regulatory findings, and a record of noncompliance with certain regulations in Title 9 of the Code of Federal Regulations (CFR). The purpose of a PHRE is to review an establishment's food safety system to verify that the establishment can produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements. If an establishment is selected for a PHRE, the FSIS district office first performs the evaluation as described in [FSIS Directive 5100.4 \(Public Health Risk Evaluation Methodology\)](#) to review the operational and compliance history of the establishment to decide if a food safety assessment (FSA) or enforcement action is appropriate.

The purpose of this report is to update the list of PHRs for fiscal year (FY) 2025 based on FSIS verification inspection data from the FSIS public health information system (PHIS). The updated FY2025 PHRs list will prioritize certain inspection activities for the fiscal year spanning October 1, 2024, to September 30, 2025.

The CFR is composed of a set of regulations and the provisions of the regulations; therefore, the use of "regulation" in this report describes both regulations and their provisions. These provisions define the specific requirements of a regulation in greater detail. Including provisions in the PHRs list allows FSIS to focus on specific public health-related provisions that may be most informative for prioritizing PHREs.

FSIS used the same methodology to develop the FY2025 PHRs list as last year. For inclusion in the FY2025 PHRs list, each candidate 9 CFR regulation was evaluated to determine whether noncompliance with the verified regulation had occurred at a more frequent rate in establishments in the 90 days before *Salmonella*, *Escherichia coli* (*E. coli*), *Listeria monocytogenes* (*Lm*), or *Campylobacter* positives or enforcement actions than in establishments without positives or enforcement actions⁴. The analysis was based on one calendar year (CY) of FSIS verification inspection results recorded in PHIS, from January 1 to December 31, 2023 (CY2023).

The body of this report describes the agency's data-driven approach to selecting the PHRs. Sections Two and Three identify how the candidate regulations are selected and outline the analysis results for selecting the appropriate PHRs from those regulations; Section Four summarizes the final list of PHRs; and Section Five explains the calculation of the cut points used for notifying districts of establishments that need to be scheduled for an FSA or a PHRE. The final FY2025 PHRs list is presented in Appendix A; Appendix B lists the candidate regulations evaluated to determine PHRs; Appendix C describes the differences between the FY2025 PHRs list and FY2024 PHRs list; and Appendix D explains the methodology and calculations used to determine the PHRs cut points.

⁴ As noted above, the term "enforcement action" refers to a public health-related Notice of Intended Enforcement (NOIE) or Notice of Suspension (NOS) that results from a Sanitation Standard Operating Procedure (SSOP), Hazard Analysis and Critical Control Point (HACCP), or Sanitation Performance Standards (SPS) violation.

The FY2025 PHRs list, as well as the upper and lower thresholds that inform PHREs and alert FSIS inspection program personnel of elevated PHRs noncompliance, are anticipated to be implemented beginning October 2024.

2.0 SELECTION OF PHRS

The PHRs candidate list will consist of verified 9 CFR regulations with which noncompliance occurs at a more frequent rate in establishments in the 90 days before *Salmonella*, *E. coli* O157:H7, non-O157 STEC, *Lm*, or *Campylobacter* positives or enforcement actions than in establishments without positives or enforcement actions. Not all regulations are related to pathogen-positive samples or enforcement actions. Therefore, to facilitate the analysis and to focus on the most relevant regulations, the list of regulations is narrowed to those related to verifying HACCP food safety process control.

Thus, the selection of PHRs is a two-step process:

1. Develop a candidate list of 9 CFR regulations related to verifying food safety process control.
2. From this list, select the subset of regulations whose individual noncompliance rates are statistically higher in establishments in the 90 days before a *Salmonella*, *E. coli* O157:H7, non-O157 STEC, *Lm*, or *Campylobacter* positive or enforcement actions than in establishments without positives or enforcement actions.

Noncompliance with a single PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the 90-day rolling average noncompliance rate for all similar establishments.

2.1 Criteria for Selection of Candidate Regulations

The purpose of the list of candidate regulations is to identify a subset of 9 CFR regulations that are more directly related to a possible loss of process control. Process control refers to procedures designed by an establishment to control operating conditions necessary to produce safe, wholesome food.

Regulations are selected for the candidate list if noncompliance with the regulation provides evidence that establishments are *not* satisfying one of the four criteria:

1. Establish and maintain HACCP plan and critical control points (CCP),
2. Establish and maintain sanitary conditions,
3. Prevent adulteration, or
4. Implement effective corrective actions.

The following are examples of the types of regulations under each criterion that would be considered candidate regulations.

- **Establish and Maintain HACCP Plan and CCPs**
 - Failure to maintain an adequate HACCP plan.
 - Adequacy of the HACCP plan in controlling food safety hazards.
 - Critical factors specified in the process schedule shall be measured, controlled, and recorded.
 - CCPs are under control.

- **Establish and Maintain Sanitary Conditions**
 - Products are prepared, packed, or held under sanitary conditions.
 - Products do not contain any filthy, putrid, or decomposed substance.
 - Products do not contain foreign material.
 - Operates in a manner that does not deter inspection to determine sanitary conditions.
- **Prevent Adulteration**
 - No adulterated product enters commerce.
 - Product and ingredients rendered adulterated by polluted water shall be condemned.
 - Container composed of any poisonous or deleterious substance.
 - Dead, dying, disabled or diseased and similar livestock shall be condemned.
 - Lethality and stabilization requirements for cooked beef.
 - Time/temperature for heat-processing combinations of fully cooked meat patties.
 - Positive *E. coli* O157:H7 during FSIS verification testing.
- **Implement Effective Corrective Actions**
 - Select appropriate procedures and corrective actions.
 - Document corrective actions.
 - Identify and eliminate the cause.
 - Establish measures to prevent recurrence.
 - Reassess hazard analysis.

2.2 Relationship with Pathogen-Positive Samples and Enforcement Actions

The second step in selecting a list of PHRs is to determine which candidate regulations are related to a higher rate of noncompliance in the 90 days before the occurrence of a pathogen-positive sample during FSIS sampling or an enforcement action. The time period of 90 days is chosen as it is long enough to have sufficient FSIS verification data for analysis and short enough to indicate establishment operating conditions before a pathogen-positive sample or enforcement action. A candidate regulation will be included in the final list of PHRs if the noncompliance rate for the regulation is higher in establishments in the 90 days before a *Salmonella*, *E. coli*, *Lm*, or *Campylobacter* positive or an enforcement action than the average noncompliance rate in establishments that do not have a *Salmonella*, *E. coli*, *Lm*, or *Campylobacter* positive or an enforcement action.

3.0 CANDIDATE REGULATIONS

All regulations in 9 CFR were individually reviewed to determine if they satisfied any of the four criteria delineated in Section 2.1. A set of 185 9 CFR regulations were selected to indicate a potential loss of food safety process control. The list of 185 candidate regulations that are indicators of a potential loss of HACCP food safety process control is presented in Appendix B.

4.0 RELATIONSHIP BETWEEN CANDIDATE REGULATIONS AND PATHOGEN-POSITIVE SAMPLES AND ENFORCEMENT ACTIONS

The purpose of this section is to provide the results of the analysis between the list of candidate regulations and *Salmonella*, *E. coli*, *Lm*, or *Campylobacter* positives during FSIS verification testing or enforcement actions. The noncompliance rate of each of the FY2025 185 candidate regulations in establishments in the 90 days prior to a pathogen-positive sample or enforcement action was compared with the average noncompliance rate of establishments that received FSIS verification testing but had no positives or enforcement actions for CY2023. Regulations that received more than 30 verifications within a year and have a rates ratio of 3.0 or higher, along with a 95% probability (determined by a two-sided Fisher's Exact Test p -value of less than 0.05), indicating that the noncompliance rate of the regulation in establishments during the 90 days before a pathogen-positive sample or enforcement action is statistically higher than the noncompliance rate for establishments with no positives, are classified as PHRs. For FY2025 PHR rates, there was not sufficient data for Siluriformes or eggs to be considered separately. There was no Siluriformes testing done in 2023. Egg sampling data was included in the *Salmonella* and *Listeria* sections as there was only one positive in CY2023.

Candidate regulations with less than or equal to 30 verifications in the 90 days prior to a specific pathogen-positive sample or enforcement action are excluded from consideration for that specific pathogen or enforcement action since the noncompliance rate associated with these regulations is highly uncertain. The candidate regulation is still considered for pathogens or enforcement actions with more than the 30 verifications.

A rates ratio is one of several statistics useful as an effect-size measure, especially when statistical significance of dichotomous data is computed using the Fisher's Exact test. The odds of an event occurring is calculated as the number of events divided by the number of non-events. A rates ratio is calculated by dividing the odds of a test group (in this case, the odds of receiving a noncompliance of a candidate regulation for establishments with a pathogen-positive sample or enforcement action) by the odds in the control group (in this case, the odds of receiving a noncompliance of a candidate regulation for establishments without a pathogen-positive sample or enforcement action). There is no definitive rule for determining a meaningful rates ratio size. In this report, a rates ratio size of 3.0 is taken as the threshold for a meaningful rates ratio size.

4.1 *Salmonella*

The purpose of this section is to provide the results of the analysis between the list of candidate regulations and *Salmonella* positives. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 2,229 establishments with *Salmonella* testing data. There were 750 establishments that had 3,963 *Salmonella* positives. There were 1,479 establishments that did not have any *Salmonella* positives. There were 55,049 total *Salmonella* tests performed.

Table 4-1 presents the 26 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact Test *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments in the 90 days prior to a *Salmonella* positive is higher than the average noncompliance rate for establishments with no *Salmonella* positive for CY2023.

Table 4-1 Comparison of Noncompliance Rates 90 Days before a *Salmonella* Positive with Those for Establishments with No *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
301.2 Adulterated	Adulterated	No	0.37	0.08	6.85	2.07E-18
310.22(c)	Disposal of SRM	Yes	0.03	0.00	9.62	2.77E-37
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.11	0.02	7.64	4.43E-23
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.06	0.01	8.23	7.98E-12
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.03	0.00	17.60	1.07E-13
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.05	0.01	6.49	3.33E-11
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	0.01	0.00	6.35	1.81E-09
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.11	0.01	22.42	3.97E-29
416.13(a)	Conduct pre-op procedures	Yes	0.08	0.02	5.45	0.00E00

Regulation Verified	Description¹	On FY 2024 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i>-Value
416.13(b)	Conduct other procedures listed in the plan	Yes	0.01	0.00	5.58	0.00E00
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.04	0.01	5.28	0.00E00
416.15(b)	Corrective action, procedures for	Yes	0.08	0.01	6.73	3.93E-83
416.2(a)	Grounds and Pest Control	Yes	0.12	0.03	4.94	0.00E00
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	0.13	0.03	4.18	0.00E00
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.10	0.03	3.48	0.00E00
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.02	0.00	6.52	6.18E-58
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	0.01	0.00	3.57	2.83E-17
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.05	0.01	4.88	1.44E-70
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.12	0.03	4.50	0.00E00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.18	0.04	5.60	0.00E00
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	0.19	0.02	9.62	4.21E-18

Regulation Verified	Description ¹	On FY 2024 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
417.6	Inadequate HACCP systems	No	0.77	0.05	62.66	6.27E-32
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.01	0.00	27.45	4.73E-20
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	0.15	0.00	49.71	2.53E-18
310.18(c)(1)	Sampling locations	No	0.03	0.00	13.23	2.24E-05
310.26(b)	Carcass sorting and disposition	No	0.02	0.01	4.15	1.10E-03

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.1 *Salmonella* in Intact Chicken

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 214 establishments with intact chicken *Salmonella* testing data, of which 171 had 516 *Salmonella* positives, and 43 did not have *Salmonella* positives. There were 9,765 total intact chicken *Salmonella* tests performed.

Table 4-2 presents the five regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments in the 90 days prior to an intact chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no intact chicken *Salmonella* positive for CY2023.

Table 4-2 Comparison of Noncompliance Rates 90 Days before an Intact Chicken *Salmonella* Positive with Those for Establishments with No Intact Chicken *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
417.2(a)(1)	Hazard analysis	Yes	0.02	0.00	4.62	3.00E-06
417.5(a)(1)	Written hazard analysis	Yes	0.00	0.00	5.84	1.32E-24
417.5(a)(2)	Written HACCP plan	Yes	0.00	0.00	8.90	9.10E-03
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	0.09	0.02	5.37	5.34E-13
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	0.00	0.00	9.96	3.50E-03

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.2 *Salmonella* in Intact Turkey

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 43 establishments with intact turkey *Salmonella* testing data, of which three establishments had five *Salmonella* positives and 40 establishments did not have *Salmonella* positives. There were 1,331 total intact turkey *Salmonella* tests performed.

Table 4-3 presents the 14 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact Test *p*-value of less than 0.05) that the noncompliance rate of the regulations in establishments in the 90 days prior to an intact turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no intact turkey *Salmonella* positive for CY2023.

Table 4-3 Comparison of Noncompliance Rates 90 Days before an Intact Turkey *Salmonella* Positive with Those for Establishments with No Intact Turkey *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	0.12	0.01	14.71	2.69E-09
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.07	0.01	9.34	9.40E-16
416.15(a)	Appropriate corrective actions	Yes	0.21	0.04	7.13	3.57E-04
416.15(b)	Corrective action, procedures for	Yes	0.24	0.03	11.24	4.87E-06
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.03	0.00	8.60	6.09E-10
416.2(a)	Grounds and Pest Control	Yes	0.45	0.09	8.31	3.16E-05
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.36	0.09	5.96	4.98E-03
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.55	0.11	9.42	1.17E-06
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.68	0.17	10.36	6.64E-10
417.2(a)(1)	Hazard analysis	Yes	0.13	0.01	22.27	6.57E-03

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
381.65(f)	Procedures for controlling visible fecal contamination	Yes	0.04	0.01	3.19	1.19E-36
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	0.05	0.01	5.05	7.40E-04
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.02	0.00	8.28	7.80E-03
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	0.00	0.00	46.81	1.55E-11

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.3 *Salmonella* in Ground Beef

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 1,315 establishments with ground beef *Salmonella* testing data, of which 89 establishments had 124 *Salmonella* positives and 1,226 establishments did not have *Salmonella* positives. There were 11,586 total ground beef *Salmonella* tests performed.

Table 4-4 presents the 14 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact Test *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments in the 90 days prior to a ground beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no ground beef *Salmonella* positive for CY2023.

Table 4-4 Comparison of Noncompliance Rates 90 Days before a Ground Beef *Salmonella* Positive with Those for Establishments with No Ground Beef *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
301.2_Adulterated	Adulterated	No	0.46	0.13	5.76	4.65E-03
310.22(c)	Disposal of SRM	Yes	0.02	0.00	7.48	1.48E-08
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.09	0.01	6.92	3.02E-06

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
310.22(e)(2)	Appropriate corrective actions	Yes	0.03	0.01	6.47	2.03E-02
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.03	0.01	4.10	4.76E-02
318.2(a)	All products subject to reinspection by program employees	Yes	0.01	0.00	5.78	2.09E-02
416.15(b)	Corrective action, procedures for	Yes	0.08	0.01	6.97	3.88E-03
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.01	0.00	5.07	4.11E-04
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	0.03	0.00	6.69	3.32E-06
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.06	0.01	6.51	8.12E-10
417.2(c)(4)	List of procedures and frequency	Yes	0.01	0.00	4.45	2.29E-30
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.33	0.03	13.99	1.70E-02
417.4(a)(1)	Initial validation	Yes	0.55	0.11	10.17	5.19E-04
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.06	0.01	4.40	1.94E-65

¹ Refer to the [2021 Code of Federal Regulations](#) for complete regulation descriptions.

4.1.4 *Salmonella* in Intact Beef

FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There were 970 establishments with intact beef *Salmonella* testing data, of which 58 establishments had 102 *Salmonella* positives and 912 establishments did not have *Salmonella* positives. There were 5,999 total intact beef *Salmonella* tests performed.

Table 4-5 presents the 19 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact Test *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days prior to an intact beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no intact beef *Salmonella* positive for CY2023.

Table 4-5 Comparison of Noncompliance Rates 90 Days before an Intact Beef *Salmonella* Positive with Those for Establishments with No Intact Beef *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
301.2 Adulterated	Adulterated	No	0.28	0.09	3.90	2.97E-06
310.22(c)	Disposal of SRM	Yes	0.04	0.00	8.92	2.77E-26
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.13	0.02	6.84	8.20E-16
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.06	0.01	4.08	2.60E-05
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.04	0.00	20.13	7.60E-14
416.12(d)	Plan list frequency for each procedure and responsible individual	No	0.02	0.00	16.69	9.67E-03
416.13(b)	Conduct other procedures listed in the plan	Yes	0.01	0.00	5.65	9.75E-47
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.04	0.01	4.49	5.05E-165
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.01	0.00	5.22	1.44E-21

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.15(b)	Corrective action, procedures for	Yes	0.10	0.02	6.67	1.39E-05
416.2(a)	Grounds and Pest Control	Yes	0.10	0.03	3.86	1.81E-25
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.11	0.03	3.46	1.51E-48
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.17	0.05	3.97	1.72E-69
417.2(c)(4)	List of procedures and frequency	Yes	0.02	0.00	6.93	5.92E-87
417.3(a)(2)	CCP is under control	Yes	0.02	0.00	4.21	1.48E-04
417.3(b)(3)	No adulterated product enters commerce	Yes	0.02	0.00	8.48	3.52E-02
417.3(b)(4)	Reassessment	Yes	0.07	0.01	9.27	1.18E-04
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.50	0.04	26.32	1.79E-05
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.07	0.02	4.18	7.14E-168

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.5 *Salmonella* in Ground Chicken

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 150 establishments with ground chicken *Salmonella* testing data, of which 96 establishments had 622 *Salmonella* positives and 54 establishments did not have *Salmonella* positives. There were 2,011 total ground chicken *Salmonella* tests performed.

Table 4-6 presents the 15 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a ground chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no ground chicken *Salmonella* positive for CY2023.

Table 4-6 Comparison of Noncompliance Rates 90 Days before a Ground Chicken *Salmonella* Positive with Those for Establishments with No Ground Chicken *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
381.83	Septicemia or toxemia	No	0.00	0.00	3.27	5.37E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents	Yes	0.36	0.01	39.53	1.25E-60
416.15(b)	Corrective action, procedures for	Yes	0.23	0.05	5.47	5.89E-17
417.2(a)(1)	Hazard analysis	Yes	0.02	0.01	4.09	4.02E-08
417.3(a)(1)	Identify and eliminate the cause	Yes	0.12	0.00	286.45	4.08E-91
417.3(a)(2)	CCP is under control	Yes	0.01	0.00	50.25	4.98E-24
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.12	0.00	192.87	3.01E-69
417.3(b)(4)	Reassessment	Yes	0.01	0.00	59.61	7.98E-07
417.3(c)	Document corrective actions	Yes	0.01	0.00	24.02	6.58E-04
417.4(a)(1)	Initial validation	Yes	0.08	0.01	14.72	8.82E-04
417.5(a)(2)	Written HACCP plan	Yes	0.00	0.00	8.05	8.88E-08
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.00	0.00	3.70	2.97E-12
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	0.01	0.00	6.18	9.38E-30
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.02	0.00	11.11	2.82E-61
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	0.00	0.00	5.30	5.24E-05

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.6 *Salmonella* in Ground Turkey

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 49 establishments with ground turkey *Salmonella* testing data, of which 34 establishments had 263 *Salmonella* positives and 15 establishments did not have *Salmonella* positives. There were 1,331 total ground turkey *Salmonella* tests performed.

Table 4-7 presents the six regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a ground turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no ground turkey *Salmonella* positive for CY2023.

Table 4-7 Comparison of Noncompliance Rates 90 Days before a Ground Turkey *Salmonella* Positive with Those for Establishments with No Ground Turkey *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.13(a)	Conduct pre-op procedures	Yes	0.11	0.04	3.12	3.66E-29
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.04	0.01	6.74	1.80E-78
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.01	0.00	22.35	1.48E-15
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.18	0.04	5.70	6.93E-30
417.3(a)(2)	CCP is under control	Yes	0.11	0.00	67.79	1.17E-24
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.47	0.06	15.36	1.29E-07

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.7 *Salmonella* in Intact Pork

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 97 establishments with intact pork *Salmonella* testing data, of which 30 establishments had 134 *Salmonella* positives and 67 establishments did not have *Salmonella* positives. There were 1,903 total intact pork *Salmonella* tests performed.

Table 4-8 presents the six regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments

90 days before an intact pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no intact pork *Salmonella* positive for CY2023.

Table 4-8 Comparison of Noncompliance Rates 90 Days before an Intact Pork *Salmonella* Positive with Those for Establishments with No Intact Pork *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
310.3	Carcasses and parts in certain instances to be retained	Yes	0.66	0.22	6.87	2.54E-08
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	0.02	0.01	3.89	3.07E-02
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.00	0.00	6.61	2.16E-22
416.2(a)	Grounds and Pest Control	Yes	0.13	0.04	3.39	2.68E-15
417.3(b)(3)	No adulterated product enters commerce	Yes	0.08	0.01	12.55	1.59E-02
417.3(b)(4)	Reassessment	Yes	0.04	0.00	13.76	6.83E-03

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.8 *Salmonella* in Ground Pork

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 307 establishments with ground pork *Salmonella* testing data, of which 134 establishments had 917 *Salmonella* positives and 173 establishments did not have *Salmonella* positives. There were 5,107 total ground pork *Salmonella* tests performed.

Table 4-9 presents the nine regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that for which the noncompliance rate of the regulation in establishments 90 days before a ground pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no ground pork *Salmonella* positive for CY2023.

Table 4-9 Comparison of Noncompliance Rates 90 Days before a Ground Pork *Salmonella* Positive with those for Establishments with No Ground Pork *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
301.2_Adulterated	Adulterated	No	0.59	0.11	11.73	2.20E-02
310.22(c)	Disposal of SRM	Yes	0.03	0.00	43.98	2.41E-09
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.13	0.00	80.15	2.15E-03
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.04	0.01	5.79	9.65E-03
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.02	0.00	3.90	6.46E-157
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.01	0.00	6.50	4.11E-08
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.07	0.02	3.35	1.89E-46
416.6	Only FSIS program employee may remove “U.S. Rejected” tag	Yes	0.30	0.02	26.33	1.13E-06
417.3(a)(2)	CCP is under control	Yes	0.01	0.00	3.87	1.11E-05

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.9 *Salmonella* in Chicken Parts

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 487 establishments with chicken parts *Salmonella* testing data, of which 384 establishments had 1,280 *Salmonella* positives and 103 establishments did not have *Salmonella* positives. There were 14,630 total chicken parts *Salmonella* tests performed.

Table 4-10 presents the five regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a chicken parts *Salmonella* positive is higher than the average noncompliance rate for establishments with no chicken parts *Salmonella* positive for CY2023.

Table 4-10 Comparison of Noncompliance Rates 90 Days before a Chicken Parts *Salmonella* Positive with Those for Establishments with No Chicken Parts *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.01	3.81	3.05E-124
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.19	0.06	3.94	3.09E-108
416.6	Only FSIS program employee may remove “U.S. Rejected” tag	Yes	0.11	0.01	10.85	1.25E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.03	0.00	8.43	5.82E-03
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	0.24	0.02	17.55	2.10E-38

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.1.10 *Salmonella* in Ready-to-Eat Products

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 2,361 establishments with RTE *Salmonella* testing data, of which eight establishments had eight *Salmonella* positives and 2,353 establishments did not have *Salmonella* positives. There were 15,742 total RTE *Salmonella* tests performed.

Table 4-11 presents the one regulation that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a RTE *Salmonella* positive is higher than the average noncompliance rate for establishments with no RTE *Salmonella* positive for CY2023.

Table 4-11 Comparison of Noncompliance Rates 90 Days before a RTE *Salmonella* Positive with Those for Establishments with No RTE *Salmonella* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.13(a)	Conduct pre-op procedures	Yes	0.05	0.01	3.89	2.14E-04

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.2 *E. coli*

The purpose of this section is to provide the results of the analysis between the candidate regulations and *E. coli* positives in the following products: MT43 (raw ground beef and veal), MT60 (beef or veal trim), MT64 (raw ground beef or beef patty components, other than trim), and MT65 (bench trim for further use in any raw, non-intact beef products). Routine *E. coli* testing was expanded on February 1, 2023 to include six additional STECs. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 1512 establishments with *E. coli* testing data, of which 52 establishments had 56 positives and 1460 establishments did not have *E. coli* positives. There were 17,585 total *E. coli* tests performed.

Table 4-12 presents the nine regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before an *E. coli* positive is higher than the average noncompliance rate for establishments with no *E. coli* positive for CY2023.

Table 4-12 Comparison of Noncompliance Rates 90 Days before an *E. coli* Positive with Those for Establishments with no *E. coli* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>E. coli</i> Positive	Noncompliance Rate for Establishments with no <i>E. coli</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
310.22(b)	Inedible and prohibited SRM for use as human food	No	0.14	0.00	103.08	1.68E-02
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	0.02	0.00	42.00	3.56E-02
416.15(a)	Appropriate corrective actions	Yes	0.06	0.02	3.66	1.57E-02
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	0.02	0.00	5.24	8.98E-03

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>E. coli</i> Positive	Noncompliance Rate for Establishments with no <i>E. coli</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
417.2(c)(4)	List of procedures and frequency	Yes	0.01	0.00	4.50	7.08E-18
417.3(a)(1)	Identify and eliminate the cause	Yes	0.62	0.05	33.93	2.82E-08
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.83	0.12	35.76	5.22E-08
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.06	0.02	3.43	2.30E-02
311.14	Abrasions, bruises, abscesses, pus, etc.	No	0.01	0.00	130.81	4.51E-05

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.3 *Listeria monocytogenes*

The purpose of this section is to provide the results of the analysis between the candidate regulations and *Lm*. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 2,361 establishments with *Lm* testing data, of which 37 establishments had 39 *Lm* positives and 2,324 establishments did not have *Lm* positives. There were 16,007 total *Lm* tests performed.

Table 4-13 presents the four regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a *Lm* positive is higher than the noncompliance rate for establishments with no *Lm* positive for CY2023.

Table 4-13 Comparison of Noncompliance Rates 90 Days before a *Lm* Positive with Those for Establishments with No *Lm* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Lm</i> Positive	Noncompliance Rate for Establishments with no <i>Lm</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	0.01	0.00	3.00	1.56E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.04	0.01	5.26	2.21E-02

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Lm</i> Positive	Noncompliance Rate for Establishments with no <i>Lm</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
430.4(c)(6)	Lm, prerequisite program requirements	No	0.25	0.01	42.29	3.19E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.05	0.01	6.02	4.96E-06

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4 *Campylobacter*

The purpose of this section is to provide the results of the analysis between the candidate regulations and *Campylobacter* positives. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 614 establishments with *Campylobacter* testing data, of which 495 establishments had 4,884 *Campylobacter* positives and 119 establishments did not have *Campylobacter* positives. There were 20,885 total *Campylobacter* tests performed.

Table 4-14 presents the 11 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2023.

Table 4-14 Comparison of Noncompliance Rates 90 Days before a *Campylobacter* Positive with Those for Establishments with No *Campylobacter* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.13(b)	Conduct other procedures listed in the plan	Yes	0.03	0.01	4.89	2.51E-230
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.00	0.00	4.98	2.06E-51
416.2(a)	Grounds and Pest Control	Yes	0.23	0.04	8.00	1.71E-197
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	0.22	0.05	5.15	2.38E-119
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.19	0.04	5.41	6.53E-150

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.04	0.01	6.94	7.15E-23
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	0.04	0.01	6.01	2.75E-11
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.12	0.01	10.51	1.58E-43
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.22	0.04	6.31	3.96E-248
417.2(c)(4)	List of procedures and frequency	Yes	0.01	0.00	4.31	5.79E-52
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	0.18	0.03	7.02	2.28E-10

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4.1 *Campylobacter* in Intact Chicken

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 213 establishments with intact chicken *Campylobacter* testing data, of which 208 establishments had 2,092 *Campylobacter* positives and five establishments did not have *Campylobacter* positives. There were 8,422 total intact chicken *Campylobacter* tests performed.

Table 4-15 presents the seven regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2023.

Table 4-15 Comparison of Noncompliance Rates 90 Days before a *Campylobacter* Intact Chicken Positive with Those for Establishments with No *Campylobacter* Intact Chicken Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	0.01	0.00	3.76	3.95E-02
416.13(b)	Conduct other procedures listed in the plan	Yes	0.03	0.00	16.23	8.92E-33
416.2(a)	Grounds and Pest Control	Yes	0.28	0.07	4.98	1.07E-12
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	0.28	0.04	8.36	4.42E-12
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.24	0.02	13.19	2.88E-15
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.25	0.04	7.18	7.18E-18
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.35	0.10	4.90	1.14E-20

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4.2 *Campylobacter* in Intact Turkey

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 43 establishments with intact turkey *Campylobacter* testing data, of which eight establishments had 12 *Campylobacter* positives and 35 establishments did not have *Campylobacter* positives. There were 1,331 total intact turkey *Campylobacter* tests performed.

Table 4-16 presents the four regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulations in establishments 90 days before an intact turkey *Campylobacter* positive is higher than the noncompliance rate for establishments with no intact turkey *Campylobacter* positive for CY2023.

Table 4-16 Comparison of Noncompliance Rates 90 Days before a *Campylobacter* Intact Turkey Positive with Those for Establishments with No *Campylobacter* Intact Turkey Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	0.20	0.05	4.31	5.96E-03
417.2(c)(4)	List of procedures and frequency	Yes	0.03	0.00	6.76	6.00E-18
417.3(c)	Document corrective actions	Yes	0.67	0.09	19.60	2.83E-02
381.76(a)	Post-mortem inspection, when required, extent	Yes	0.05	0.00	15.58	4.15E-04

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4.3 *Campylobacter* in Ground Chicken

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 98 establishments with ground chicken *Campylobacter* testing data, of which 47 establishments had 194 *Campylobacter* positives and 51 establishments did not have *Campylobacter* positives. There were 1,923 total ground chicken *Campylobacter* tests performed.

Table 4-17 presents the one regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a ground chicken *Campylobacter* positive is higher than the average noncompliance rate for establishments with no ground chicken *Campylobacter* positive for CY2023.

Table 4-17 Comparison of Noncompliance Rates 90 Days before a Ground Chicken *Campylobacter* Positive with Those for Establishments with No Ground Chicken *Campylobacter* Positives

Regulation Verified	Description ¹	On FY2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	0.24	0.07	3.99	4.21E-20

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4.4 *Campylobacter* in Ground Turkey

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 49 establishments with ground turkey *Campylobacter* testing data, of which 18 establishments had 39 *Campylobacter* positives and 31 establishments did not have *Campylobacter* positives. There were 1,314 total ground turkey *Campylobacter* tests performed.

Table 4-18 presents the seven regulations that had more than 30 verifications in a year in total, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulations in establishments 90 days before a ground turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no ground turkey *Campylobacter* positive for CY2023.

Table 4-18 Comparison of Noncompliance Rates 90 Days before a Ground Turkey *Campylobacter* Positive with those for Establishments with No Ground Turkey *Campylobacter* Positives

Regulation Verified	Description ¹	On FY2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents	Yes	0.13	0.03	4.72	6.84E-05
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.05	0.01	3.75	1.37E-53
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.02	0.00	16.34	4.06E-37
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.01	0.00	3.75	1.27E-10
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.20	0.07	3.45	1.53E-11
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.16	0.05	3.36	6.14E-08
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.01	0.00	4.22	3.79E-08

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.4.5 *Campylobacter* in Chicken Parts

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 487 establishments with chicken parts *Campylobacter* testing data, of which 416 establishments had 2,547 *Campylobacter* positives and 71 establishments did not have *Campylobacter* positives. There were 12,779 total chicken parts *Campylobacter* tests performed.

Table 4-19 presents the 12 regulations which had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher’s Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before a chicken parts *Campylobacter* positive is higher than the average noncompliance rate for establishments with no chicken parts *Campylobacter* positive for CY2023.

Table 4-19 Comparison of Noncompliance Rates 90 Days before a Chicken Parts *Campylobacter* Positive with Those for Establishments with No Chicken Parts *Campylobacter* Positives

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.13(a)	Conduct pre-op procedures	Yes	0.11	0.03	3.66	8.96E-145
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.00	8.37	7.18E-157
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.00	0.00	3.03	4.48E-11
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.00	0.00	3.93	2.50E-24
416.2(a)	Grounds and Pest Control	Yes	0.20	0.05	4.95	8.05E-70
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	0.16	0.05	3.77	1.85E-53
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.03	0.01	4.08	2.19E-06
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	0.02	0.01	3.90	4.10E-04
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.10	0.01	9.74	1.04E-22
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.19	0.05	4.20	4.29E-87

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positives	Rates Ratio	Two-Sided Fisher Exact <i>p</i> -Value
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.25	0.06	5.50	1.94E-168
417.2(c)(4)	List of procedures and frequency	Yes	0.01	0.00	9.04	1.46E-40

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

4.5 Enforcement Actions

The purpose of this section is to investigate the relationship between the candidate regulations and public health-related enforcement actions at meat and poultry establishments. FSIS enforcement actions, as defined in the Rules of Practice ([9 CFR 500.1](#)), include regulatory control actions, withholding actions, and suspensions. A regulatory control action is taken by FSIS inspectors when immediate correction of a deficiency is required. Establishment management does not have to be notified in advance. When a deficiency does not pose an imminent threat to public health, a notice of intended enforcement (NOIE) is issued to an establishment indicating that FSIS is considering withholding the marks of inspection or suspending the assignment of inspectors if not corrected. The establishment is requested to provide immediate corrective action and to specify preventive measures to prevent recurrence. FSIS determines further action based on the response provided. Only public health related NOIEs or suspensions are included in this analysis. These are NOIEs or suspensions that result from a sanitation standard operating procedure (SSOP), HACCP, or sanitation performance standards violation.

The enforcement action list of regulations is selected from the same list of candidate regulations used to select all other FY2025 PHRs. The enforcement action list consists of candidate 9 CFR regulations in which noncompliances occur at a more frequent rate in establishments 90 days prior to an NOIE or suspension than in establishments without an NOIE or suspension for CY2023. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 5,917 active meat and poultry establishments, of which 67 establishments had 72 enforcement actions and 5,850 establishments did not have any enforcement actions.

Table 4-20 presents the 36 regulations that had more than 30 verifications in a year, a rates ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher's Exact *p*-value of less than 0.05) that the noncompliance rate of the regulation in establishments 90 days before an enforcement action is higher than the noncompliance rate for establishments with no enforcement action for CY2023.

Table 4-20 Comparison of Noncompliance Rates 90 Days before an Enforcement Action with Those for Establishments with No Enforcement Actions

Regulation Verified	Description¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Actions	Rates Ratio	Two-Sided Fisher Exact p-Value
301.2_Adulterated	Adulterated	No	0.75	0.04	72.46	2.57E-04
310.22(c)	Disposal of SRM	Yes	0.02	0.01	3.67	2.65E-02
310.22(e)(4)(i)	Maintain daily records	No	0.03	0.00	18.57	9.16E-05
310.25(a)	Verification criteria for E. coli testing meat	No	0.04	0.01	4.24	8.18E-03
318.2(a)	All products subject to reinspection by program employees	Yes	0.02	0.00	10.94	1.61E-02
381.1_Adulterated	Adulterated	No	0.33	0.01	33.35	4.49E-02
416.1	Operate in a manner to prevent insanitary conditions	Yes	0.03	0.01	6.03	2.79E-18
416.12(c)	Plan identifies procedures for pre-op	Yes	0.04	0.00	21.88	4.36E-03
416.13(b)	Conduct other procedures listed in the plan	Yes	0.01	0.00	3.34	3.10E-14
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	0.01	0.00	6.28	2.81E-17
416.15(a)	Appropriate corrective actions	Yes	0.18	0.02	13.55	3.90E-09
416.15(b)	Corrective action, procedures for	Yes	0.24	0.02	14.77	1.32E-08
416.2(a)	Grounds and Pest Control	Yes	0.25	0.03	9.98	5.40E-70
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.08	0.01	7.09	1.00E-03
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	0.18	0.04	5.79	1.98E-32
417.2(a)(1)	Hazard analysis	Yes	0.06	0.01	6.90	7.33E-10

Regulation Verified	Description¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Actions	Rates Ratio	Two-Sided Fisher Exact <i>p</i>-Value
417.3(a)(1)	Identify and eliminate the cause	Yes	0.12	0.02	8.07	5.38E-05
417.3(a)(2)	CCP is under control	Yes	0.01	0.00	3.19	8.71E-05
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.15	0.02	8.23	4.36E-07
417.3(b)(1)	Segregate and hold the affected product	No	0.08	0.00	55.17	7.84E-04
417.3(b)(2)	Determine the acceptability of the affected product	No	0.08	0.00	63.11	6.10E-04
417.3(b)(3)	No adulterated product enters commerce	Yes	0.14	0.00	141.43	2.47E-06
417.3(b)(4)	Reassessment	Yes	0.03	0.00	12.55	1.22E-02
417.3(c)	Document corrective actions	Yes	0.20	0.01	41.91	1.56E-03
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.10	0.03	3.66	9.18E-03
417.4(a)(1)	Initial validation	Yes	0.19	0.06	3.68	3.53E-02
417.5(a)(1)	Written hazard analysis	Yes	0.02	0.00	6.87	1.74E-24
417.5(a)(2)	Written HACCP plan	Yes	0.01	0.00	9.80	4.90E-13
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.01	0.00	4.70	1.41E-10
430.4(b)(3)	Alternative 3	Yes	0.09	0.01	8.73	1.19E-04
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	0.00	0.00	8.65	2.39E-02
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Yes	0.07	0.00	45.21	2.67E-02

Regulation Verified	Description ¹	On FY 2024 PHRs List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Actions	Rates Ratio	Two-Sided Fisher Exact p-Value
418.3	Recall Plans	No	0.04	0.00	42.87	1.32E-03
381.65(f)	Procedures for controlling visible fecal contamination	Yes	0.05	0.01	7.85	5.70E-42
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	0.05	0.00	11.41	4.65E-08
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.29	0.01	67.52	9.18E-15

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

5.0 LIST OF FY2025 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2025 PHRs list. Table 5-1 presents the complete list of the 63 FY2025 PHRs. These 67 PHRs were selected since they were verified more than 30 times in a year, had a rates ratio of 3.0 or greater, and had higher noncompliance rates in establishments 90 days before *Salmonella*, *E. coli*, *Lm*, *Campylobacter* positives or enforcement actions than in establishments with no positives or enforcement actions.

Table 5-1 List of FY2025 PHRs

Regulation Verified	Description ¹	On FY 2024 PHRs List	Average Rates Ratio	Average of Two-Sided Fisher Exact p-Value
301.2_Adulterated	Adulterated	No	20.14	5.37E-03
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.76	1.46E-03
310.18(c)(1)	Sampling locations	No	13.23	2.24E-05
310.22(b)	Inedible and prohibited SRM for use as human food	No	103.08	1.68E-02
310.22(c)	Disposal of SRM	Yes	14.73	5.30E-03
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	25.39	5.39E-04
310.22(e)(2)	Appropriate corrective actions	Yes	6.47	2.03E-02
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	5.47	1.59E-02
310.22(e)(4)(i)	Maintain daily records	No	18.57	9.16E-05

Regulation Verified	Description¹	On FY 2024 PHRs List	Average Rates Ratio	Average of Two-Sided Fisher Exact p-Value
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	18.87	9.16E-14
310.25(a)	Verification criteria for E. coli testing meat	No	4.24	8.18E-03
310.26(b)	Carcass sorting and disposition	No	4.15	1.10E-03
310.3	Carcasses and parts in certain instances to be retained.	Yes	6.87	2.54E-08
311.14	Abrasions, bruises, abscesses, pus, etc.	No	130.81	4.51E-05
318.2(a)	All products subject to reinspection by program employees	Yes	8.36	1.85E-02
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	6.14	4.82E-03
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	3.89	3.07E-02
381.1_Adulterated	Adulterated	No	33.35	4.49E-02
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	24.17	1.78E-02
381.65(f)	Procedures for controlling visible fecal contamination	Yes	5.52	5.96E-37
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	7.55	2.47E-04
381.76(a)	Post-mortem inspection, when required, extent	Yes	15.58	4.15E-04
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	28.59	1.95E-03
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	20.69	1.19E-03
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	19.91	5.71E-11
381.83	Septicemia or toxemia	No	3.27	5.37E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents	Yes	22.22	2.28E-05
416.1	Operate in a manner to prevent insanitary conditions	Yes	6.87	1.03E-02
416.12(c)	Plan identifies procedures for pre-op	Yes	21.88	4.36E-03
416.12(d)	Plan list frequency for each procedure & responsible individual	No	16.69	9.67E-03
416.13(a)	Conduct pre-op procedures	Yes	4.03	5.35E-05
416.13(b)	Conduct other procedures listed in the plan	Yes	6.84	4.43E-15
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.83	2.74E-54
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	10.43	7.46E-12
416.15(a)	Appropriate corrective actions	Yes	8.11	5.34E-03

Regulation Verified	Description¹	On FY 2024 PHRs List	Average Rates Ratio	Average of Two-Sided Fisher Exact p-Value
416.15(b)	Corrective action, procedures for	Yes	8.64	6.50E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	5.58	1.47E-10
416.2(a)	Grounds and Pest Control	Yes	6.05	3.95E-06
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	5.20	1.19E-03
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	5.88	8.30E-04
416.2(b)(4)	Inedible from edible separated by time or space	Yes	5.82	8.26E-05
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.08	1.88E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	7.33	3.85E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	5.39	1.23E-07
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	5.61	1.11E-10
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	15.60	4.16E-03
417.2(a)(1)	Hazard analysis	Yes	9.47	1.64E-03
417.2(c)(4)	List of procedures & frequency	Yes	6.00	2.18E-18
417.3(a)(1)	Identify and eliminate the cause	Yes	109.48	1.79E-05
417.3(a)(2)	CCP is under control	Yes	25.86	4.92E-05
417.3(a)(3)	Establish measures to prevent recurrence	Yes	63.05	1.54E-07
417.3(b)(1)	Segregate and hold the affected product	No	55.17	7.84E-04
417.3(b)(2)	Determine the acceptability of the affected product	No	63.11	6.10E-04
417.3(b)(3)	No adulterated product enters commerce	Yes	54.15	1.71E-02
417.3(b)(4)	Reassessment	Yes	23.80	4.79E-03
417.3(c)	Document corrective actions	Yes	28.51	1.02E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	11.85	1.23E-02
417.4(a)(1)	Initial validation	Yes	9.52	1.22E-02
417.5(a)(1)	Written hazard analysis	Yes	6.36	1.53E-24
417.5(a)(2)	Written HACCP plan	Yes	8.92	3.03E-03
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	4.20	1.27E-08
417.6	Inadequate HACCP systems	No	62.66	6.27E-32
418.3	Recall Plans	No	42.87	1.32E-03
430.4(b)(3)	Alternative 3	Yes	8.73	1.19E-04
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	8.65	2.39E-02

Regulation Verified	Description ¹	On FY 2024 PHRs List	Average Rates Ratio	Average of Two-Sided Fisher Exact p-Value
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Yes	45.21	2.67E-02
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	No	42.29	3.19E-02

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

In FY2024 there were 63 PHRs, 50 of which are FY2025 PHRs. There are 13 regulations on the FY2024 PHRs list that are not on the FY2025 PHRs list (see Appendix C). There are 17 regulations that are on the FY2025 PHRs list that were not on the FY2024 PHRs list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2025 PHRs list. Most regulations were triggered by multiple events. Similar to the FY2024 PHRs list, *Salmonella* pathogen-positive samples and enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2025 PHRs List

Product	Number of Regulations
<i>Campylobacter</i>	11
<i>Campylobacter</i> Chicken Parts	12
<i>Campylobacter</i> Ground Chicken	1
<i>Campylobacter</i> Ground Turkey	7
<i>Campylobacter</i> Intact Chicken	7
<i>Campylobacter</i> Intact Turkey	4
Enforcements	36
<i>Listeria</i>	4
<i>E. coli</i>	9
<i>Salmonella</i>	26
<i>Salmonella</i> Chicken Parts	5
<i>Salmonella</i> Ground Beef	14
<i>Salmonella</i> Ground Chicken	15
<i>Salmonella</i> Ground Pork	9
<i>Salmonella</i> Ground Turkey	6
<i>Salmonella</i> Intact Beef	19
<i>Salmonella</i> Intact Chicken	5
<i>Salmonella</i> Intact Pork	6
<i>Salmonella</i> Intact Turkey	14
RTE <i>Salmonella</i>	1

There were 22 regulations triggered by a single type of event: 10 were from Enforcement Actions, three were from *Salmonella*, two were from *E. Coli*, two were from *Salmonella* intact pork, one was from *Listeria*, one was from *Salmonella* in ground beef, one was from *Campylobacter* in intact turkey, one was from *Salmonella* in ground chicken, and one was from

Salmonella in intact beef. Table 5-3 presents the regulations triggered for inclusion in the FY2025 PHRs list by only a single pathogen product or enforcement action type (event).

Table 5-3 Regulations Triggered for Inclusion in the FY2025 PHRs List by Only a Single Event

Regulation Verified	Description ¹	Event
310.18(c)(1)	Sampling locations	<i>Salmonella</i>
310.22(b)	Inedible and prohibited SRM for use as human food	E. coli
310.22(e)(2)	Appropriate corrective actions	<i>Salmonella</i> Ground Beef
310.22(e)(4)(i)	Maintain daily records	Enforcements
310.25(a)	Verification criteria for E. coli testing meat	Enforcements
310.26(b)	Carcass sorting and disposition	<i>Salmonella</i>
310.3	Carcasses and parts in certain instances to be retained.	<i>Salmonella</i> Intact Pork
311.14	Abrasions, bruises, abscesses, pus, etc.	<i>E. coli</i>
318.24	Product prepared using advanced meat/bone separation machinery; process control	<i>Salmonella</i> Intact Pork
381.1_Adulterated	Adulterated	Enforcements
381.76(a)	Post-mortem inspection, when required, extent	<i>Campylobacter</i> Intact Turkey
381.83	Septicemia or toxemia	<i>Salmonella</i> Ground Chicken
416.12(c)	Plan identifies procedures for pre-op	Enforcements
416.12(d)	Plan list frequency for each procedure & responsible individual	<i>Salmonella</i> Intact Beef
417.3(b)(1)	Segregate and hold the affected product	Enforcements
417.3(b)(2)	Determine the acceptability of the affected product	Enforcements
417.6	Inadequate HACCP systems	<i>Salmonella</i>
418.3	Recall Plans	Enforcements
430.4(b)(3)	Alternative 3	Enforcements
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Enforcements
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Enforcements
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	<i>Listeria</i>

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

6.0 CUT POINTS FOR FY2025 PHRS

The FY2025 PHRs are one of seven public health-based decision criteria that are used in prioritizing PHREs. Other decision criteria include pathogen testing results, recalls, outbreaks, regulatory findings, and inspection results. The decision criteria are intended for use in identifying establishments that may pose a greater risk to public health than other establishments and thus warrant certain prioritized inspection activities by FSIS inspection program personnel.

Noncompliance with a single FY2025 PHRs may not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the 90-day rolling average noncompliance rate for all similar establishments. The rate is calculated as

the number of times PHRs regulations are cited as non-compliant divided by the number of times the PHRs regulations are verified. This combines the verifications for all the PHRs regulations in a 90-day period together into a single aggregate ratio. The aggregate FY2025 PHRs noncompliance rate by establishments is compared to cut points that have been set for two broad categories of establishment operations: processing and combination). Only establishments with 20 or more verifications and at least two noncompliances were considered when developing cut points.

The aggregate non-zero PHRs noncompliance rates are approximately log normally distributed, so the rates can be log transformed to obtain an approximately normal distribution (see Appendix D). Then to determine a set of annual FY2025 cut points, the mean and standard deviation of the log transformed rates (for establishments having more than 20 verifications in the past 90 days and at least two noncompliances) for each of the four quarters and each of the two types of establishment operation are computed. These results are given in Table 6-1. Notice that the means are negative since they are the means of the natural log of a number between zero and one (the non-zero PHRs noncompliance rates).

Table 6-1 Mean and Standard Deviation of Quarterly FY2025 PHR rate

CY2023	Mean of Natural Log PHR rate		Standard Deviation PHR rate	
	Processing	Combination	Processing	Combination
Jan-Mar	-4.94	-4.74	0.80	0.97
Apr-Jun	-4.97	-4.76	0.79	0.96
Jul-Sept	-4.91	-4.69	0.81	0.96
Oct-Dec	-4.99	-4.80	0.81	0.98
Average	-4.95	-4.75	0.80	0.97

The mean and standard deviation are averaged over the four quarters, and the annual upper cut point is defined as the mean plus two standard deviations. Establishments with PHRs noncompliance rates higher than the upper cut point for similar establishments are classified as the Upper level and are candidates to receive a for-cause PHRE. For example, the upper cut point for the log transformed data for Combination establishments is $-4.74827 + 2 * 0.9691177 = -4.74827 + 1.938235 = -2.81003$. The cut point of the original, non-transformed PHRs noncompliance data is the antilog of -2.81003 or $\text{Exp}(-2.81003) = 6.02\%$. Establishments that are below the upper-level threshold but meet or exceed the lower-level threshold will be notified by FSIS inspection program personnel of an elevated level of noncompliance.

The PHRs cut points are defined as follows for each of the two establishment types: (1) processing and (2) slaughter/processing combination:

- Any establishment with a PHR rate less than the lower cut point for all establishments with the same type would continue receiving routine inspection procedures. These establishments are performing better on average than their peers with respect to compliance with the PHRs.
- Establishments with a PHR rate greater than or equal to the lower cut point but less than the upper cut point for all establishments with the same establishment type would

continue to receive routine inspection procedures and be alerted through FSIS inspection program personnel of elevated PHRs noncompliance levels.

- Establishments with a PHR rate greater than the upper cut point for establishments with the same establishment type that have not had an FSA in the last 180 days are prioritized for a PHRE.

Tables 6-2 and 6-3 present the FY2025 PHRs upper and lower cut points for each of the two establishment operation types. The FY2024 and FY2023 PHRs cut points are included for comparison. (see Appendix D). The cut points are determined once a year. The next update to the cut points is planned for October 2025.

Table 6-2 FY2025 PHRs Upper-Level Cut Points

Operation Type	FY2025 PHRs Cut Points	FY2024 PHRs Cut Points	FY2023 PHRs Cut Points
Processing	3.51%	3.76%	3.65%
Combination	6.02%	7.17%	7.48%

Table 6-3 FY2025 PHRs Lower-Level Cut Points

Operation Type	FY2025 PHRs Cut Points	FY2024 PHRs Cut Points	FY2023 PHRs Cut Points
Processing	2.35%	2.49%	2.45%
Combination	3.71%	4.44%	4.59%

Table 6-4 presents the number of establishments in each level based solely on the FY2025 PHRs criterion and the cut points in Tables 6-2 and 6-3. Establishments that qualify for the upper level but have less than 20 verifications or only one noncompliance are moved to the mid-level classification. Sixty-five establishments are in the upper level, and candidates are to receive a recommendation for a for-cause PHRE. Table 6-4 is based on regulatory noncompliances from January 1 to March 31, 2024.

Table 6-4 Classification of Establishments Based Solely on the PHRs Criterion

Classification	Processing	Combination	Total
Upper	48	17	65
Mid	69	37	106
Lower	4,278	1,171	5,449
Total	4,395	1,225	5,620

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2025 PHRs used to prioritize certain FY2025 FSIS inspection activities. This process involves:

- (1) Selecting a list of candidate regulations related to food safety process control.
- (2) Selecting a subset of these regulations whose noncompliance rates are higher in establishments 90 days prior to a pathogen-positive sample or enforcement action.
- (3) Using this subset to determine cut points to determine which establishments should be flagged for a PHRE or an alert throughout the year.

The list of FY2025 PHRs has 67 regulations whose individual noncompliance rates are higher in establishments 90 days before *Salmonella*, *E. coli*, *Lm*, or *Campylobacter* positives or enforcement action than in establishments without positives or enforcement actions. Fifty regulations on the FY2024 PHRs list are also on the FY2025 PHRs list.

Establishments that have PHRs noncompliance rates higher than the antilog of the mean plus two standard deviations of the log transformed distribution of the non-zero PHR rates for similar establishments are recommended to receive a PHRE. Upon completion of a PHRE, the FSIS district office may perform an FSA or take enforcement actions as appropriate based on its analysis of establishment performance as described in [FSIS Directive 5100.4](#).

APPENDIX A: FY2025 PHRS

Table A-1 presents the list of 67 FY2025 Public Health Regulations (PHRs). On average, these PHRs have noncompliance rates 90 days prior to a pathogen-positive sample or enforcement action that is 16.01 times higher than the PHRs noncompliance rates for establishments with no pathogen-positive sample or enforcement action.

Table A-1 List of FY2025 PHRs

Regulation	Description ¹
301.2_Adulterated	Adulterated
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(c)	Disposal of SRM
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
310.22(e)(2)	Appropriate corrective actions
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
310.22(e)(4)(i)	Maintain daily records
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
310.25(a)	Verification criteria for E. coli testing meat
310.3	Carcasses and parts in certain instances to be retained.
318.2(a)	All products subject to reinspection by program employees
318.2(d)	Removal of U.S. retained by authorized Program employees only
318.24	Product prepared using advanced meat/bone separation machinery; process control
381.1_Adulterated	Adulterated
381.65(a)	Clean and sanitary practices; products not adulterated
381.83	Septicemia or toxemia
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
416.1	Operate in a manner to prevent insanitary conditions
416.12(c)	Plan identifies procedures for pre-op
416.12(d)	Plan list frequency for each procedure & responsible individual
416.13(a)	Conduct pre-op procedures
416.13(b)	Conduct other procedures listed in the plan
416.13(c)	Plant monitors implementation of SSOP procedures
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.15(a)	Appropriate corrective actions

416.15(b)	Corrective action, procedures for
416.16(a)	Daily records required, responsible individual, initialed and dated
416.2(a)	Grounds and Pest Control
416.2(b)(1)	Sound construction, good repair & sufficient size
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized
416.2(b)(4)	Inedible from edible separated by time or space
416.3(b)	Constructed, located & operated in a manner that does not deter inspection
416.3(c)	Receptacles for storing inedible material must identify permitted use
416.4(a)	Food contact surface, cleaning & sanitizing as frequency
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
416.6	Only FSIS program employee may remove "U.S. Rejected" tag
417.2(a)(1)	Hazard analysis
417.2(c)(4)	List of procedures & frequency
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(b)(1)	Segregate and hold the affected product
417.3(b)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions
417.4(a)	Adequacy of HACCP in controlling food safety hazards
417.4(a)(1)	Initial validation
417.5(a)(1)	Written hazard analysis
417.5(a)(2)	Written HACCP plan
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
417.6	Inadequate HACCP systems
430.4(b)(3)	Alternative 3
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
418.3	Recall Plans

381.65(f)	Procedures for controlling visible fecal contamination
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation
381.76(a)	Post-mortem inspection, when required, extent
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia
311.14	Abrasions, bruises, abscesses, pus, etc.
310.18(c)(1)	Sampling locations
310.26(b)	Carcass sorting and disposition

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

APPENDIX B: FY2025 CANDIDATE REGULATIONS

Table B-1 presents the list of candidate regulations. Of the 180 candidate regulations, two regulations did not have any verifications for the time period as they were replaced with a new regulation or removed from possible verifications prior to this analysis. The noncompliance rates in Table B-1 are based on Public Health Information System (PHIS) data from January 1 through December 31, 2023.

Table B-1 FY2025 List of Candidate Regulations

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
301.2_Adulterated	Adulterated	No	No	2916	140	4.80%
304.3(a)	Develop written SSOP	No	No	351	0	0.00%
304.3(c)	Conduct hazard analysis and develop HACCP plan for new product	No	No	204	5	2.45%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	88	1	1.14%
309.3	(Modernized ONLY) Dead, dying, disabled or diseased and similar livestock	No	No	65	2	3.08%
309.4	(Modernized ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases	No	No	35	2	5.71%
309.5	(Modernized ONLY) Swine; disposal because of hog cholera	No	No	13	0	0.00%
309.9	(Modernized ONLY) Swine erysipelas	No	No	15	0	0.00%
310.22(b)	Inedible and prohibited	No	No	2250	7	0.31%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	SRM for use as human food					
310.22(c)	Disposal of SRM	Yes	Yes	54789	235	0.43%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar US products	No	No	37	0	0.00%
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	9796	171	1.75%
310.22(e)(2)	Appropriate corrective actions	Yes	No	2495	27	1.08%
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	7126	83	1.16%
310.22(e)(4)(i)	Maintain daily records	No	No	64255	133	0.21%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	No	13132	34	0.26%
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	No	1012	2	0.20%
310.22(g)(4)	Maintain records of official establishment showing proper	No	No	3080	15	0.49%

Regulation ¹	Description ²	FY 2024 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	disposition of vertebral columns					
310.25(a)	Verification criteria for E. coli testing meat	No	No	29056	340	1.17%
310.25(b)	Pathogen reduction performance standards; Salmonella	No	No	159	0	0.00%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	29	2	6.90%
310.3	Carcasses and parts in certain instances to be retained	Yes	No	1875	240	12.80%
311.16	(Modernized ONLY) Carcasses so infected that consumption of the meat may cause food poisoning	No	No	236	27	11.44%
311.17	(Modernized ONLY) Necrobacillosis , pyemia, septicemia	No	No	254	5	1.97%
311.24	(Modernized ONLY) Hogs affected with tapeworm cysts	No	No	38	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	35	0	0.00%
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	No	11535	49	0.42%
317.24(a)	Packaging materials	No	No	1192	10	0.84%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	composed of poisonous or deleterious substances					
318.1(b)	Only inspected and passed poultry product to enter official establishment	No	No	103347	10	0.01%
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	170	0	0.00%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	510	0	0.00%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision	No	No	109	0	0.00%
318.16(b)	Pesticides chemicals and other residues in products not to exceed Federal Food, Drug, and Cosmetic Act levels - Meat ingredients	No	No	116	0	0.00%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	1782	2	0.11%
318.17(b)	Lethality and Stabilization processes other	No	No	363	0	0.00%

Regulation ¹	Description ²	FY 2024 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	than HACCP for cooked beef					
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	35	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	40192	51	0.13%
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	6066	50	0.82%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully-cooked meat patties	No	No	424	0	0.00%
318.23(b)(3)	Heat deviations for meat patties	No	No	89	0	0.00%
318.23(c)(1)	Stabilization requirements for meat patties	No	No	259	0	0.00%
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	75	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	194	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	37	0	0.00%
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2776	11	0.40%
318.6(b)(1)	Requirements for use of	No	No	1819	0	0.00%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	casings, used as containers					
318.6(b)(4)	Detached spinal cords	No	No	8873	0	0.00%
318.6(b)(6)	Tonsils	No	No	9605	0	0.00%
318.6(b)(8)	Intestines as ingredients	No	No	147	0	0.00%
319.5(b)	Mechanically separated (beef) - prohibited for use in human food	No	No	266	0	0.00%
381.1_Adulterated	Adulterated	No	No	2263	35	1.55%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	1796	2	0.11%
381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	No	492	5	1.02%
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry	No	No	36	0	0.00%
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	5	0	0.00%
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	310	0	0.00%
381.22(a)	Develop written SSOP	No	No	162	1	0.62%
381.22(b)	Conduct hazard analysis and develop and	No	No	1102	1	0.09%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	validate HACCP plan					
381.22(c)	Conduct hazard analysis and develop HACCP plan for new product	No	No	203	3	1.48%
381.37(a)	Product not produced under supervision of program employee	No	No	1452	12	0.83%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	23577	92	0.39%
381.71(a)	Condemnation on ante-mortem inspection	Yes	No	760	9	1.18%
381.72(a)	Poultry	No	No	118	0	0.00%
381.72(b)	Ratites	No	No	10	0	0.00%
381.83	Septicemia or toxemia	No	No	1367333	44	0.00%
381.85	Special Diseases (organisms or toxins dangerous to the consumer)	No	No	72	0	0.00%
381.91(a)	Certain contaminated carcasses to be condemned	Yes	No	2929	7	0.24%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents	Yes	No	6689	207	3.09%
416.1	Operate in a manner to prevent insanitary conditions	Yes	Yes	654590	3528	0.54%
416.12(c)	Plan identifies procedures for pre-op	Yes	No	37347	65	0.17%
416.12(d)	Plan list frequency for	No	No	53427	73	0.14%

Regulation ¹	Description ²	FY 2024 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	each procedure and responsible individual					
416.13(a)	Conduct pre-op procedures	Yes	Yes	803535	15392	1.92%
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	2015679	7146	0.35%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2849726	27014	0.95%
416.14	Evaluate effectiveness of SSOP's and maintain plan	Yes	Yes	1790292	2603	0.15%
416.15(a)	Appropriate corrective actions	Yes	Yes	60811	636	1.05%
416.15(b)	Corrective action, procedures for	Yes	Yes	38516	616	1.60%
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	Yes	3026935	4053	0.13%
416.2(a)	Grounds and Pest Control	Yes	No	188165	5952	3.16%
416.2(b)(1)	Sound construction, good repair and sufficient size	Yes	No	151395	5874	3.88%
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned and sanitized	Yes	No	206149	7475	3.63%
416.2(b)(4)	Inedible from edible separated by time or space	Yes	No	114891	399	0.35%
416.3(b)	Constructed, located and operated in a manner that does not deter inspection	Yes	No	77139	374	0.48%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	63750	729	1.14%
416.4(a)	Food contact surface, cleaning and sanitizing as frequency	Yes	No	257399	9234	3.59%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	234801	10760	4.58%
416.5(c)	Any person who appears to have any abnormal source of microbial contamination	No	No	29995	8	0.03%
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2357	75	3.18%
417.2(a)(1)	Hazard analysis	Yes	Yes	132491	1401	1.06%
417.2(c)	Contents of HACCP Plan	Yes	No	26997	38	0.14%
417.2(c)(4)	List of procedures and frequency	Yes	Yes	1399633	4261	0.30%
417.3(a)(1)	Identify and eliminate the cause	Yes	Yes	30083	537	1.79%
417.3(a)(2)	CCP is under control	Yes	Yes	143523	613	0.43%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	Yes	27077	617	2.28%
417.3(a)(4)	No adulterated product enters commerce	Yes	Yes	46969	128	0.27%

Regulation ¹	Description ²	FY 2024 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
417.3(b)(1)	Segregate and hold the affected product	No	Yes	23771	50	0.21%
417.3(b)(2)	Determine the acceptability of the affected product	No	Yes	23183	45	0.19%
417.3(b)(3)	No adulterated product enters commerce	Yes	Yes	33535	48	0.14%
417.3(b)(4)	Reassessment	Yes	Yes	48971	163	0.33%
417.3(c)	Document corrective actions	Yes	Yes	24572	188	0.77%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	6332	204	3.22%
417.4(a)(1)	Initial validation	Yes	No	5037	275	5.46%
417.4(b)	Reassessment of hazard analysis	Yes	Yes	28834	60	0.21%
417.5(a)(1)	Written hazard analysis	Yes	Yes	1495411	3499	0.23%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1331441	1147	0.09%
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1435877	3291	0.23%
417.5(f)	Official Review	No	No	89933	76	0.08%
417.6	Inadequate HACCP systems	No	No	502	92	18.33%
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	Yes	309677	85	0.03%
430.4(b)(1)	Alternative 1	No	No	726	2	0.28%
430.4(b)(2)	Alternative 2	No	No	11830	49	0.41%
430.4(b)(3)	Alternative 3	Yes	No	16292	265	1.63%
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	Yes	Yes	303401	108	0.04%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	Yes	301810	92	0.03%
430.4(c)(4)	<i>Lm</i> , validate and verify control measures in HACCP plan	No	No	3058	11	0.36%
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Yes	No	4606	9	0.20%
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	No	No	4221	45	1.07%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	378973	5258	1.39%
310.18(b)	Brains, cheek meat, head trimmings from animals slaughtered by gunshot	No	No	21484	3	0.01%
590.422	Condemnation of adulterated product	No	No	1344	0	0.00%
418.2	Notification of adulterated or misbranded product in commerce	Yes	No	2232	63	2.82%
418.3	Recall Plans	No	No	22708	28	0.12%
354.242(b)	All equipment and utensils clean and sanitary	No	No	109	1	0.92%
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	62	0	0.00%
354.243(a)	No handling or storage of objectionable materials	No	No	33	0	0.00%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
381.193(a)	Poultry not intended for human food in commerce	No	No	182	13	7.14%
590.510(c)(1)	Checks and eggs with a portion of the shell missing	No	No	3616	117	3.24%
590.510(c)(2)	Eggs with clean shells damaged in candling or transfer	No	No	3363	10	0.30%
590.510(c)(3)	Eggs with meat or blood spots	No	No	2581	4	0.15%
590.510(d)	Loss or inedible eggs placed in dedicated container	No	No	3262	6	0.18%
381.65(f)	Procedures for controlling visible fecal contamination	Yes	No	1624376	11350	0.70%
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	No	114852	586	0.51%
381.65(h)	Recordkeeping requirements	Yes	No	22382	26	0.12%
381.76(a)	Post-mortem inspection, when required, extent	Yes	No	6708	41	0.61%
381.94(a)	Verification criteria for E. coli testing ratites	No	No	1102	3	0.27%
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	No	68583	432	0.63%
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	No	4612	464	10.06%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	No	1477877	53	0.00%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Yes	No	82275	57	0.07%
537.1	Basic Requirements	No	No	24750	74	0.30%
537.2	Hazard Analysis and HACCP plan	No	No	111	0	0.00%
540.1	Dead fish	No	No	241	0	0.00%
548.2	Requirements concerning ingredients and other articles used in the preparation of fish products	No	No	1530	0	0.00%
548.8	Polluted water contamination at establishment	No	No	1202	0	0.00%
311.14	Abrasions, bruises, abscesses, pus, etc.	No	No	28194	14	0.05%
539.1(c)	Fish found to be in a state of spoilage or decomposition	No	No	226	0	0.00%
548.1(a)	Clean and sanitary fish preparation, fixtures or appliances	No	No	3281	52	1.58%
309.3(e)	Establishment notify IPP of non-ambulatory livestock; Prompt condemnation and disposal	No	No	45	1	2.22%
431.4	Critical factors and the application of the process schedule	No	Yes	10201	20	0.20%
431.9(b)	Procedures for handling of process deviations	No	Yes	9168	1	0.01%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
431.9(c)(1)	Process deviations identified in-process	No	No	92	1	1.09%
431.9(c)(2)	Process deviations identified through record review	No	No	31	5	16.13%
431.9(d)	Process deviation file	No	No	114	1	0.88%
431.11	Personnel and training	No	No	50	0	0.00%
431.12	Recall procedure	No	No	40	0	0.00%
309.19(a)	Market hog sorting activities	No	No	1700	5	0.29%
309.19(c)	Sorted and removed hogs identified; written procedures	No	No	1313	0	0.00%
309.19(d)	Records of animals disposed of per day	No	No	5548	3	0.05%
309.19(e)	Notifiable animal disease	No	No	102	0	0.00%
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	No	9984	25	0.25%
310.18(c)(1)	Sampling locations	No	No	1825	3	0.16%
310.18(c)(1)(i)	Very low volume establishments	No	No	3329	0	0.00%
310.18(c)(2)(i)	Sampling frequency	No	No	3180	2	0.06%
310.18(c)(2)(ii)	Sampling frequency for very low volume establishments	No	No	2072	6	0.29%
310.18(c)(2)(iii)	Records of test results for sampling program	Yes	No	26668	19	0.07%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	No	40719	21	0.05%
310.26(b)	Carcass sorting and disposition	No	Yes	3884	49	1.26%
310.26(d)(2)	Document number of carcasses disposed of per day	No	No	2893	0	0.00%
590.504(e)	Permit shipment of egg products pending lab results	No	No	186	0	0.00%
590.720	Disposition of restricted eggs	No	No	1303	0	0.00%
590.580(b)	Sampled and analyzed from the final package form	No	No	2006	0	0.00%
590.504(a)	Operations involving the processing, storing, and handling of eggs, ingredients, and egg products must be done in a sanitary manner	No	No	7347	36	0.49%
590.504(b)(1)	Eggs and egg products are subject to inspection in each official plant processing egg products for commerce	No	No	3833	1	0.03%
590.504(b)(2)	Any eggs and egg products not processed in accordance	No	No	3394	10	0.29%

Regulation ¹	Description ²	FY 2024 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	with the regulations in this part or part 591 or that are not otherwise fit for human food must be removed and segregated					
590.516(a)	Cleaning of eggs prior to packaging, breaking, or pasteurizing	No	No	5154	60	1.16%
590.522	Each egg used in processed egg product must be broken in a sanitary manner and examined to ensure contents are acceptable for human consumption	No	No	4662	17	0.36%
590.570	Control of pathogens in pasteurized egg products	No	No	616	0	0.00%
590.580(b)(2)	Samples must be analyzed for the presence of Salmonella spp. with such frequency and using such laboratory methods as is sufficient to ensure that product is not adulterated. For each category of product, sampling should be conducted on a rotating basis	No	No	2042	0	0.00%

Regulation¹	Description²	FY 2024 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
591.1	Basic requirements	No	No	2687	1	0.04%
590.580(b)(1)	Pasteurized liquid, frozen, and dried egg products, and heat treated dried egg whites must be sampled and analyzed for the presence of Salmonella spp.	No	No	2090	0	0.00%

¹Regulations 417.3(a) and 417.4(a)(3) are not included in this table as they had zero regulations verified in CY2023.

²Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

³Mandatory Regulations are the regulatory requirements that must be verified each time IPP perform the task.

APPENDIX C: COMPARISON OF FY2024 PHRS LIST WITH FY2025 PHRS LIST

There are 13 regulations from the FY2024 PHRs list that no longer appear in the FY2025 PHRs list. These are shown in Table C-1.

Table C-1 Regulations on the FY2024 PHRs List No Longer on the FY2025 PHRs List

FY2024 PHRs	Description¹
381.71(a)	Condemnation on ante mortem inspection
381.91(a)	Certain contaminated carcasses to be condemned
417.2(c)	Contents of HACCP Plan
417.3(a)(4)	No adulterated product enters commerce.
417.4(b)	Reassessment of hazard analysis
430.4(a)	<i>Lm</i> , post-lethality exposed RTE
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis
418.2	Notification of adulterated or misbranded product in commerce
381.65(h)	Recordkeeping requirements
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage
310.18(c)	Written procedures to prevent contamination; all swine slaughter
310.18(c)(2)(iii)	Records of test results for sampling program
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures

¹ Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

There are 17 regulations on the FY2025 PHRs list that were not on the FY2024 PHRs list.

Table C-2 Regulations on the FY2025 PHRs List That Were Not on the FY2024 PHRs List

FY2025 PHRs	Description¹
301.2 Adulterated	Adulterated
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(e)(4)(i)	Maintain daily records
310.25(a)	Verification criteria for E. coli testing meat
318.24*	Product prepared using advanced meat/bone separation machinery; process control
381.1 Adulterated	Adulterated
381.83	Septicemia or toxemia
416.12(d)	plan list frequency for each procedure & responsible individual
417.3(b)(1)	Segregate and hold the affected product
417.3(b)(2)	Determine the acceptability of the affected product
417.6	Inadequate HACCP systems
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements
418.3	Recall Plans
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia
311.14	Abrasions, bruises, abscesses, pus, etc.
310.18(c)(1)*	Sampling locations
310.26(b)	Carcass sorting and disposition

¹Refer to the [Code of Federal Regulations](#) for complete regulation descriptions.

*Indicates first time regulation qualified for PHRs list.

APPENDIX D: METHODOLOGY AND CALCULATION OF PHRS CUT POINTS

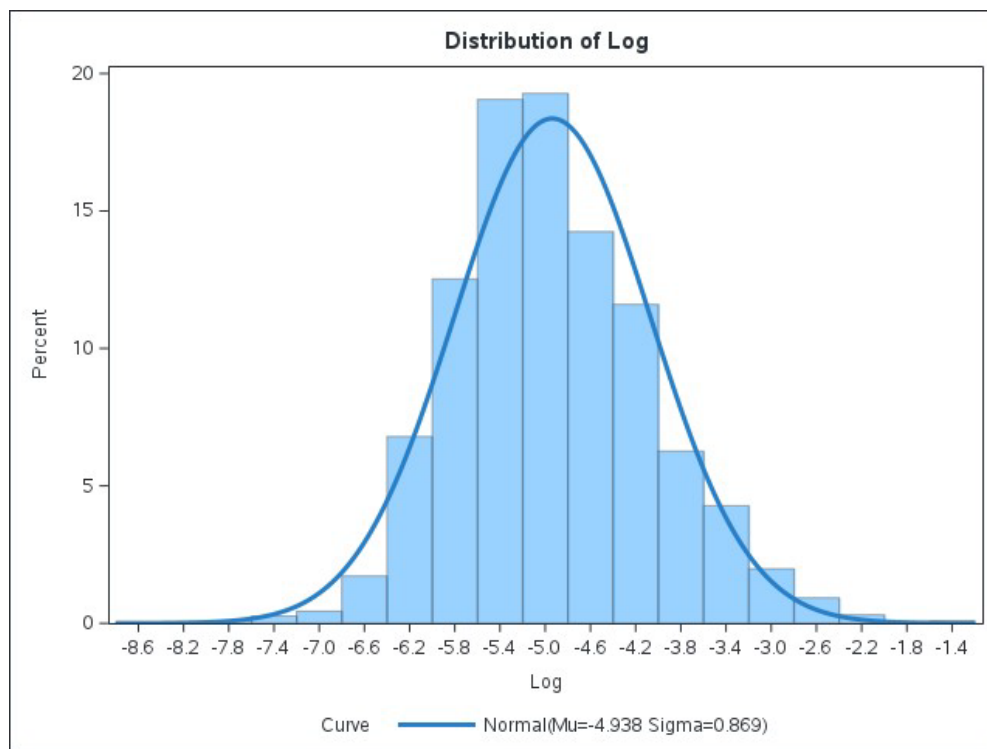
The purpose of this appendix is to explain the methodology and calculations used to develop the PHRs cut points. The PHRs noncompliance rate is calculated by the following formula using the most recent 90 days of establishment verification inspection data:

$$sPHR \text{ Noncompliance Rate} = \frac{\text{Total Noncompliant PHRs}}{\text{Total PHRs Verified}}$$

Establishments are categorized into one of two establishment types: (1) processing only and (2) slaughter/processing; named processing, and combination in the main body of the report. The establishment type is determined by the type of HACCP inspection task codes performed at each establishment. If an establishment has only 03A through 03I codes, it is classified as a processing only establishment. If an establishment has a combination of 03A through 03J codes, it is classified as a slaughter/processing establishment.

The aggregate non-zero PHRs noncompliance rates are approximately log normally distributed. That means that the natural logarithm of the non-zero PHRs noncompliance rates is approximately normally distributed. Figure D-1 presents a histogram for the log transformed non-zero PHRs noncompliance data. Only establishments with greater than or equal to 20 verifications and at least 2 noncompliances are considered.

Figure D-1 Log Transformed Non-Zero Noncompliance Rates of PHRs with 20 or More Verifications 90 Days before a Pathogen-Positive Sample or Enforcement Action



This distribution is approximately normally distributed. Three goodness of fit tests, shown in Figure D-2, indicate near-normality.

Figure D-2 Goodness of Fit for Normal Distribution of the Log Transformation

Goodness-of-Fit Tests for Normal Distribution				
Test	Statistic		p-Value	
Kolmogorov-Smirnov	D	0.04621964	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.15925194	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	6.83733311	Pr > A-Sq	<0.005

The final list of log-transformed cut points is derived from the average of the mean and standard deviation of the log transformed non-zero PHR rate from four quarters of PHRs data. (The antilog of these cut points is taken to obtain the cut points of the non-transformed PHRs noncompliance data). Table D-1 shows the number of establishments, mean and standard deviation for each establishment type, as well as the level distribution (based only on PHRs noncompliances) using the quarterly cut points.

Table D-1 Quarterly PHRs Mean, Standard Deviation and Level Distribution

Quarter/ Establishment Type	Number of Establish- ments	Mean	Standard Deviation	Level	Tier Distribution (Number of Establishments)
Q1CY2023					
				Upper	68
Combination	1,160	-4.74631	0.966794	Mid	108
Processing	4,370	-4.94156	0.795851	Lower	5,354
Q2CY2023					
				Upper	69
Combination	1,202	-4.75661	0.962888	Mid	109
Processing	4,381	-4.96941	0.789097	Lower	5,405
Q3CY2023					
				Upper	87
Combination	1,223	-4.69452	0.963164	Mid	95
Processing	4,418	-4.90836	0.807980	Lower	5,459
Q4CY2023					
				Upper	68
Combination	1,230	-4.79833	0.983625	Mid	106

Processing	4,422	-4.99123	0.810477	Lower	5,478
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Table D-2 shows the average mean and standard deviation of the log transformed non-zero PHR rate over four quarters for each establishment type based on the quarterly data in Table D-1. Table D-3 shows the upper and lower cut points for FY2025 PHRs. Table D-4 show the distribution of establishments using data from January to March 2024 utilizing the proposed FY2025 PHRs.

Table D-2 Average Mean and Standard Deviation of Log Transformed Non-Zero PHR rates by Establishment Type

Statistic	Combination	Processing
Mean	-4.74827	-4.9526415
Standard Deviation	0.9691177	0.8008517

Table D-3 FY2025 PHRs Upper and Lower Cut Points

Operation Type	Upper Cut Points	Lower Cut Points
Processing	3.51%	2.35%
Combination	6.02%	3.71%

Table D-4 March 2024 Level Distribution Based on the Previous Year's (FY2024) PHRs Cut Points

(Note: Establishments that qualify for the upper level but with less than 20 verifications or only one noncompliance are moved to the mid-level classification).

Classification	Establishments
Upper	48
Mid	92
Lower	5,480
Total	5,620