

**U.S. Department of Agriculture/
Food Safety and Inspection Service
FY2024 Public Health Regulations**

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SUMMARY

The Food Safety and Inspection Service (FSIS) “public health regulations” (PHRs) 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*) O157:H7, non-O157 Shiga toxin-producing *E. coli* (STEC), *Listeria monocytogenes* (*Lm*), or *Campylobacter*—or a public health-related enforcement action, compared to establishments with no pathogen positives 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 select the PHRs that will prioritize certain inspection activities for the 2024 fiscal year (FY) spanning October 1, 2023, to September 30, 2024. FSIS uses decision criteria, including PHRs, to prioritize establishments for “public health risk evaluations”³ (PHREs) through which FSIS determines the need for a “food safety assessment” (FSA) or enforcement action. In addition to exceeding an upper threshold for PHRs noncompliance rate, other decision criteria 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 FY2024 PHRs list is based on calendar year (CY) 2022 FSIS verification data from January 1, 2022, to December 31, 2022. For inclusion in the FY2024 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 FY2024 PHRs (see Appendix A) consists of 63 regulations that have higher rate of noncompliance in the 90 days before a pathogen positive or enforcement action. Of the 71 PHRs identified for FY2023, 56 remain on the FY2024 PHRs list.

The average noncompliance rate of FY2024 PHRs in the 90 days before a pathogen positive or enforcement action is 5.64 times higher than the average FY2024 PHRs noncompliance rate for establishments with no pathogen positive and no enforcement action. Noncompliance with a

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 (PHREs).

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.

single FY2024 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 FY2024 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 FY2024 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2024 PHRs rates for each of the four quarters in CY2022 (the log transformation of the non-zero FY2024 PHRs 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 PHRs 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 PHRs 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 FY2024 PHRs cut points for the non-transformed PHRs noncompliance data for each of the two establishment operation types. The FY2023 and FY2022 PHRs cut points are included for comparison (See Section 6 and Appendix D).

Table S-1 PHRs Upper Cut Points

Operation Type	FY2024	FY2023	FY2022
Processing	3.76%	3.65%	3.63%
Combination	7.17%	7.48%	7.33%

Table S-2 PHRs Lower Cut Points

Operation Type	FY2024	FY2023	FY2022
Processing	2.49%	2.45%	2.44%
Combination	4.44%	4.59%	4.60%

Table S-3 presents the number of establishments in each level from January 1, 2023, to March 31, 2023, based on the PHRs criterion. The period used for calculating the noncompliance rate of the PHRs was January 1, 2023, to March 31, 2023. 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 PHRs Criterion

Level	Processing	Combination	Total
Upper	43	14	57
Mid	64	25	89
Lower	4,213	1,117	5,330
Total	4,320	1,156	5,476

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 (PHREs). 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) 2024 based on FSIS verification inspection data from the FSIS public health information system (PHIS). The updated FY2024 PHRs list will prioritize certain inspection activities for the fiscal year spanning October 1, 2023, to September 30, 2024.

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 in greater detail the specific requirements of a regulation. 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 FY2024 PHRs list as last year. For inclusion in the FY2024 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*) O157: H7, non-O157 Shiga toxin-producing *E. coli* (STEC), *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, 2022 (CY2022). Candidate regulations related to egg products are not included in this report because hazard analysis and critical control point (HACCP) implementation was not required in egg establishments until October 2022.

The body of this report describes the agency's data-driven approach to select 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 FY2024 PHRs list is presented in Appendix A; Appendix B lists the candidate regulations evaluated to determine PHRs; Appendix C describes the differences between the FY2024 PHRs list and

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.

FY2023 PHRs list; and Appendix D explains the methodology and calculations used to determine the PHRs cut points.

The FY2024 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 2023.

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 positives 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; and
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 (CCPs),
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 Positives 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 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 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* O157:H7, non-O157 STEC, *Lm*, or *Campylobacter* positive or an enforcement action than the average noncompliance rate in establishments that do not have a *Salmonella*, *E. coli* O157:H7, non-O157 STEC, *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 159 9 CFR regulations were selected to indicate a potential loss of food safety process control. The list of 159 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 POSITIVES 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* O157:H7, non-O157 STEC, *Lm*, or *Campylobacter* positives during FSIS verification testing or enforcement actions. The noncompliance rate of each of the FY2024 159 candidate regulations in establishments in the 90 days prior to a pathogen positive 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 CY2022. 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 or enforcement action is statistically higher than the noncompliance rate for establishments with no positives, are classified as PHRs

Candidate regulations with less than or equal to 30 verifications in the 90 days prior to a specific pathogen positive 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 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 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 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 2,166 establishments with *Salmonella* testing data. There were 777 establishments that had 4,000 *Salmonella* positives. There were 1,389 establishments that did not have any *Salmonella* positives. There were 55,359 total *Salmonella* tests performed.

Table 4-1 presents the 24 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 CY2022.

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 2023 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
310.22(c)	Disposal of specified risk materials (SRM)	Yes	0.04	0.00	8.40	2.10E-61
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.12	0.03	5.03	5.50E-27
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.19	0.01	17.84	5.12E-68
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	No	0.01	0.00	3.50	9.31E-04
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.04	0.01	3.85	1.07E-06
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	0.01	0.00	3.46	2.33E-08
381.71(a)	Condemnation on ante-mortem inspection	Yes	0.06	0.01	8.17	8.31E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.16	0.00	39.07	2.19E-108
416.13(a)	Conduct pre-op procedures	Yes	0.08	0.02	5.25	0.00E+00

Regulation Verified	Description¹	On FY 2023 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	4.80	0.00E+00
416.13(c)	Plant monitors implementation of sanitation standard operating procedures (SSOP) procedures	Yes	0.04	0.01	4.63	0.00E+00
416.15(b)	Corrective action, procedures for	Yes	0.10	0.02	4.68	2.06E-74
416.2(a)	Grounds and Pest Control	Yes	0.13	0.03	5.21	0.00E+00
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	0.12	0.03	3.68	0.00E+00
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.11	0.04	3.23	0.00E+00
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.02	0.00	6.11	4.56E-60
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	0.01	0.00	3.21	3.56E-19
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.03	0.01	3.43	4.11E-41
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.11	0.03	3.42	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.15	0.05	3.46	0.00E+00
417.2(c)(4)	List of procedures & frequency	Yes	0.01	0.00	3.09	3.79E-219
417.3(a)(2)	CCP is under control	Yes	0.01	0.00	3.68	6.13E-44
381.76(b)(6)(ii)(A)	New poultry inspection system (NPIS) Sorting,	Yes	0.01	0.00	12.17	7.58E-25

Regulation Verified	Description ¹	On FY 2023 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
	Trimming, and Reprocessing					
310.18(c)	Written procedures to prevent Contamination; all swine slaughter	Yes	0.01	0.00	6.91	8.20E-06

¹ Refer to the [2021 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 207 establishments with intact chicken *Salmonella* testing data, of which 154 had 427 *Salmonella* positives, and 53 did not have *Salmonella* positives. There were 9,676 total intact chicken *Salmonella* tests performed.

Table 4-2 presents the two 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 CY2022.

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 2023 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
381.91(a)	Certain contaminated carcasses to be condemned	No	0.01	0.00	15.09	2.00E-03T
381.76(a)	Post-mortem inspection, when required, extent	Yes	0.01	0.00	8.14	2.00E-02

¹ Refer to the [2021 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 42 establishments with intact turkey *Salmonella* testing data, of which four establishments had four *Salmonella* positives and 38 establishments did not have *Salmonella* positives. There were 1,598 total intact turkey *Salmonella* tests performed.

Table 4-3 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 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 CY2022.

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 2023 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 p Value
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.18	0.01	32.71	3.26E-04

¹ Refer to the [2021 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 1,246 establishments with ground beef *Salmonella* testing data, of which 117 establishments had 182 *Salmonella* positives and 1,129 establishments did not have *Salmonella* positives. There were 11,028 total ground beef *Salmonella* tests performed.

Table 4-4 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 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 CY2022.

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 2023 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 p Value
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	0.11	0.03	4.04	4.94E-09

Regulation Verified	Description ¹	On FY 2023 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
318.2(a)	All products subject to reinspection by program employees	Yes	0.01	0.00	3.76	9.48E-03
416.12(c)	Plan identifies procedures for pre-op	Yes	0.02	0.00	10.63	2.00E-02
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.03	0.01	3.47	8.65E-136
417.2(c)(4)	List of procedures & frequency	Yes	0.02	0.00	9.47	7.49E-119
417.3(a)(2)	CCP is under control	Yes	0.03	0.00	11.00	4.33E-13
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.22	0.04	6.96	5.49E-07
417.3(a)(4)	No adulterated product enters commerce.	Yes	0.05	0.00	17.04	1.72E-04
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.37	0.03	19.26	1.25E-06
417.4(b)	Reassessment of hazard analysis	No	0.01	0.00	6.50	1.74E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.06	0.01	5.25	1.02E-139

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 956 establishments with intact beef *Salmonella* testing data, of which 71 establishments had 138 *Salmonella* positives and 885 establishments did not have *Salmonella* positives. There were 6,348 total intact beef *Salmonella* tests performed.

Table 4-5 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 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 CY2022.

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 2023 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	Yes	41.55%	3.00%	23.00	6.32E-56
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.22%	1.13%	4.82	8.37E-227
310.22(c)	Disposal of SRM	Yes	6.55%	0.46%	15.00	3.37E-79
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	10.77%	2.59%	4.54	2.23E-15
310.22(e)(2)	Appropriate corrective actions	Yes	16.13%	5.50%	3.30	4.31E-04
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	15.75%	1.33%	13.82	7.41E-35
310.3	Carcasses and parts in certain instances to be retained.	Yes	39.55%	13.53%	4.18	4.48E-11
311.14	Abrasions, bruises, abscesses, pus, etc.	No	0.26%	0.01%	29.38	2.97E-03
381.65(f)	Procedures for controlling visible fecal contamination	Yes	4.19%	0.80%	5.45	2.14E-03
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.75%	0.94%	5.23	0.00E+00
416.14	Evaluate effectiveness of SSOPs & maintain plan	Yes	0.82%	0.16%	5.04	5.18E-38

Regulation Verified	Description¹	On FY 2023 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)	Procedures for corrective action	Yes	8.82%	2.58%	3.66	7.75E-05
416.2(a)	Grounds and pest control	No	14.46%	3.54%	4.61	3.35E-35
416.2(b)(4)	Inedible from edible separated by time or space	No	2.20%	0.24%	9.50	1.55E-07
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.70%	0.47%	8.15	5.21E-07
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	2.61%	0.77%	3.44	1.09E-02
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	17.38%	4.37%	4.61	1.40E-141
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	38.46%	3.98%	15.09	1.75E-04
417.2(c)(4)	List of procedures & frequency	Yes	2.33%	0.27%	8.75	3.08E-154
417.3(a)(1)	Identify and eliminate the cause	Yes	19.79%	3.63%	6.55	1.49E-08

Regulation Verified	Description ¹	On FY 2023 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 p Value
417.3(a)(2)	CCP is under control	Yes	1.58%	0.33%	4.87	5.08E-06
417.3(a)(3)	Establish measures to prevent recurrence	Yes	32.86%	8.49%	5.27	3.53E-08
417.3(a)(4)	No adulterated product enters commerce	Yes	2.04%	0.38%	5.50	2.18E-02
417.3(b)(1)	Segregate and hold the affected product	Yes	6.58%	1.45%	4.78	1.50E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	70.00%	2.41%	94.62	6.97E-18
418.2	Notification of adulterated or misbranded product in commerce	Yes	71.43%	4.02%	59.72	6.02E-10

¹ Refer to the [2021 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 135 establishments with ground chicken *Salmonella* testing data, of which 86 establishments had 537 *Salmonella* positives and 49 establishments did not have *Salmonella* positives. There were 2,002 total ground chicken *Salmonella* tests performed.

Table 4-6 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 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 CY2022.

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	Description¹	On FY 2023 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)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.89	0.27	22.00	1.63E-04
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.34	0.01	73.09	3.74E-151
416.15(a)	Appropriate corrective actions	Yes	0.18	0.04	5.75	4.62E-21
417.3(a)(1)	Identify and eliminate the cause	Yes	0.09	0.00	32.16	1.67E-22
417.3(a)(2)	CCP is under control	Yes	0.01	0.00	8.66	2.20E-11
417.4(a)(1)	Initial validation	No	0.08	0.00	31.27	1.17E-02
417.5(a)(2)	Written HACCP plan	Yes	0.00	0.00	5.08	3.33E-07
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.02	0.00	4.59	2.33E-17
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Yes	0.00	0.00	9.76	7.05E-11

¹ Refer to the [2021 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 46 establishments with ground turkey *Salmonella* testing data, of which 34 establishments had 234 *Salmonella* positives and 12 establishments did not have *Salmonella* positives. There were 1,345 total ground turkey *Salmonella* tests performed.

Table 4-7 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 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 CY2022.

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 2023 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	0.15	0.05	3.35	1.34E-32
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.05	0.02	3.57	1.30E-44
416.2(a)	Grounds and Pest Control	Yes	0.12	0.04	3.80	7.52E-12
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.16	0.02	8.76	2.57E-35
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.25	0.04	7.24	5.55E-31
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.20	0.05	4.56	1.66E-16
417.3(a)(2)	CCP is under control	Yes	0.24	0.00	251.20	8.50E-78

¹ Refer to the [2021 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 102 establishments with intact pork *Salmonella* testing data, of which 32 establishments had 177 *Salmonella* positives and 70 establishments did not have *Salmonella* positives. There were 2,347 total intact pork *Salmonella* tests performed.

Table 4-8 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 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 CY2022.

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 2023 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	0.60	0.25	4.51	1.80E-05
416.15(b)	Corrective action, procedures for	Yes	0.33	0.07	6.43	4.00E-15
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.00	0.00	3.60	1.86E-09
417.2(c)(4)	List of procedures & frequency	Yes	0.01	0.00	3.55	1.42E-19
417.3(a)(1)	Identify and eliminate the cause	Yes	0.33	0.07	6.84	2.77E-04
417.3(a)(2)	CCP is under control	Yes	0.05	0.00	18.01	4.91E-13
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.38	0.06	8.93	2.25E-07
417.3(a)(4)	No adulterated product enters commerce.	Yes	0.07	0.01	8.45	2.83E-03
417.3(c)	Document corrective actions	Yes	0.26	0.01	33.53	1.77E-04

¹ Refer to the [2021 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 310 establishments with ground pork *Salmonella* testing data, of which 133 establishments had 1,166 *Salmonella* positives and 177 establishments did not have *Salmonella* positives. There were 6,357 total ground pork *Salmonella* tests performed.

Table 4-9 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 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 CY2022.

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 2023 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(c)	Disposal of SRM	Yes	0.11	0.00	30.53	1.14E-26
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	0.41	0.01	46.59	1.82E-18
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.04	0.01	3.08	2.46E-02
416.13(a)	Conduct pre-op procedures	Yes	0.04	0.01	3.53	2.18E-93
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	0.13	0.03	5.53	1.49E-02
417.2(c)	Contents of HACCP Plan	Yes	0.01	0.00	12.33	3.96E-04
417.2(c)(4)	List of procedures & frequency	Yes	0.01	0.00	4.30	3.28E-43
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.21	0.05	5.57	1.79E-06
417.3(b)(3)	No adulterated product enters commerce	Yes	0.13	0.00	44.62	4.99E-12
417.5(a)(2)	Written HACCP plan	Yes	0.00	0.00	3.85	1.10E-11
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	0.02	0.01	4.31	6.44E-70

¹ Refer to the [2021 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 491 establishments with chicken parts *Salmonella* testing data, of which 377 establishments had 1,135 *Salmonella* positives and 114 establishments did not have *Salmonella* positives. There were 14,520 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 CY2022.

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 2023 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 p Value
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.16	0.02	11.20	7.06E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.02	0.00	9.98	9.61E-08
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.01	3.15	1.22E-112
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.03	0.01	3.06	1.66E-07
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.01	0.00	3.07	5.81E-11

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

4.1.10 *Salmonella* in Siluriformes

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 64 establishments with siluriformes *Salmonella* testing data, of which 3 establishments had three *Salmonella* positives and 61 establishments did not have *Salmonella* positives. There were 308 total siluriformes *Salmonella* tests performed.

Table 4-11 presents the 1 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 siluriformes *Salmonella* positive is higher than the average noncompliance rate for establishments with no siluriformes *Salmonella* positive for CY2022.

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

Regulation Verified	Description ¹	On FY 2023 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 p Value
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.55	0.05	21.65	9.69E-06

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

4.1.11 *Salmonella* in Ready-to-Eat Products

The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 2,240 establishments with RTE *Salmonella* testing data, of which nine establishments had 10 *Salmonella* positives and 2,231 establishments did not have *Salmonella* positives. There were 14,787 total RTE *Salmonella* tests performed.

There were 0 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 for which the noncompliance rate of the regulation in establishments 90 days before an RTE *Salmonella* positive is higher than the average noncompliance rate for establishments with no RTE *Salmonella* positives for CY2022.

4.2 *E. coli*

4.2.1 *E. coli* O157:H7

The purpose of this section is to provide the results of the analysis between the candidate regulations and *E. coli* O157:H7 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). The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 1,435 establishments with *E. coli* O157:H7 testing data, of which 17 establishments had 17 *E. coli* O157:H7 positives and 1,418 establishments did not have *E. coli* O157:H7 positives. There were 17,207 total *E. coli* O157:H7 tests performed.

Table 4-12 presents the 10 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* O157:H7 positive is higher than the average noncompliance rate for establishments with no *E. coli* O157:H7 positive for CY2022.

Table 4-12 Comparison of Noncompliance Rates 90 Days before an *E. coli* O157:H7 Positive with Those for Establishments with no *E. coli* O157:H7 Positives

Regulation Verified	Description ¹	On FY 2023 PHRs List	Noncompliance Rate 90 Days before a <i>E. coli</i> O157:H7 Positive	Noncompliance Rate for Establishments with no <i>E. coli</i> O157:H7 Positives	Rates ratio	Two-Sided Fisher Exact <i>p</i> Value
318.2(a)	All products subject to reinspection by program employees	Yes	0.02	0.00	11.26	1.59E-02
416.13(b)	Conduct other procedures listed in the plan	Yes	0.01	0.00	3.25	8.21E-04
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.03	0.01	3.57	1.68E-20
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.01	0.00	5.24	1.45E-05
416.15(a)	Appropriate corrective actions	Yes	0.20	0.02	13.17	1.44E-02
416.15(b)	Corrective action, procedures for	Yes	0.67	0.03	63.42	2.79E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	0.03	0.00	6.14	4.56E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.09	0.01	8.77	6.21E-03
417.2(c)(4)	List of procedures & frequency	Yes	0.02	0.00	7.84	1.61E-17
417.3(a)(2)	CCP is under control	Yes	0.06	0.00	15.81	8.17E-03

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

4.2.2 Non-O157 STEC

The purpose of this section is to provide the results of the analysis between the candidate regulations and non-O157 STEC positives in MT60 (beef or veal trim). FSIS has declared six non-O157 STEC adulterants in raw non-intact beef products and product components. On June 4, 2012, FSIS began testing for these six non-O157 STECs in beef manufacturing trimmings. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 549 establishments with non-O157 STEC testing data, of which 16 establishments had 16 non-O157 STEC positives and 533 establishments did not have non-O157 STEC positives. There were 3,615 total non-O157 STEC tests performed.

Table 4-13 presents the three 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 non-O157 STEC positive is higher than the average noncompliance rate for establishments with no non-O157 STEC positive for CY2022.

Table 4-13 Comparison of Noncompliance Rates 90 Days before a non-O157 STEC Positive with Those for Establishments with No non-O157 STEC Positives

Regulation Verified	Description ¹	On FY 2023 PHRs List	Noncompliance Rate 90 Days before a non-O157 STEC Positive	Noncompliance Rate for Establishments with no non-O157 STEC Positives	Rates ratio	Two-Sided Fisher Exact p Value
416.13(a)	Conduct pre-op procedures	Yes	0.07	0.02	3.21	1.91E-0
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.00	4.79	6.34E-0
416.2(a)	Grounds and pest control	Yes	0.25	0.06	4.77	1.14E-0

¹ Refer to the [2021 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 2,240 establishments with *Lm* testing data, of which 42 establishments had 46 *Lm* positives and 2,198 establishments did not have *Lm* positives. There were 15,059 total *Lm* tests performed.

Table 4-14 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 *Lm* positive is higher than the noncompliance rate for establishments with no *Lm* positive for CY2022.

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

Regulation Verified	Description ¹	On FY 2023 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 p Value
416.15(a)	Appropriate corrective actions	Yes	0.13	0.02	9.85	1.74E-05

Regulation Verified	Description ¹	On FY 2023 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
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.11	0.03	3.74	1.17E-09
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.33	0.03	14.44	3.02E-03
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	0.00	0.00	5.81	4.90E-02
430.4(b)(3)	Alternative 3	Yes	0.10	0.01	8.34	1.55E-04
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	No	0.00	0.00	6.45	4.07E-02
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	No	0.00	0.00	5.80	4.90E-02

¹ Refer to the [2021 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 609 establishments with *Campylobacter* testing data, of which 478 establishments had 4,737 *Campylobacter* positives and 131 establishments did not have *Campylobacter* positives. There were 29,089 total *Campylobacter* tests performed.

Table 4-15 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 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 CY2022.

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

Regulation Verified	Description ¹	On FY 2023 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
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	0.02	0.01	3.55	8.06E-08
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.03	0.01	4.32	5.05E-08
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.01	4.48	1.68E-202
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.01	0.00	5.37	1.79E-46
416.15(b)	Procedures for corrective action	Yes	0.12	0.02	6.97	2.67E-15
416.2(a)	Grounds and pest control	Yes	0.24	0.03	8.79	1.34E-282
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	0.25	0.06	5.36	2.70E-167
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.23	0.04	6.71	2.15E-252
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.05	0.01	6.74	6.41E-28
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	0.05	0.02	3.16	6.45E-08
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	0.10	0.03	3.76	1.97E-19
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.20	0.04	5.35	1.81E-228
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.26	0.06	5.74	6.44E-302
417.2(c)(4)	List of procedures & frequency	Yes	0.01	0.00	3.63	2.55E-52

Regulation Verified	Description ¹	On FY 2023 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
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.01	0.00	11.93	4.32E-08

¹ Refer to the [2021 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 207 establishments with intact chicken *Campylobacter* testing data, of which 199 establishments had 2,025 *Campylobacter* positives and eight establishments did not have *Campylobacter* positives. There were 9,659 total intact chicken *Campylobacter* tests performed.

Table 4-16 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 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 CY2022.

Table 4-16 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 2023 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	4.54	5.43E-22
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	0.33	0.09	4.98	2.14E-11
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.27	0.07	4.96	1.35E-13
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.23	0.08	3.50	8.59E-13
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.32	0.13	3.09	2.66E-15

¹ Refer to the [2021 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 42 establishments with intact turkey *Campylobacter* testing data, of which seven establishments had nine *Campylobacter* positives and 35 establishments did not have *Campylobacter* positives. There were 1,596 total intact turkey *Campylobacter* tests performed.

Table 4-17 presents the 4 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 CY2022.

Table 4-17 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 2023 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 p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.01	0.00	3.16	4.99E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.01	0.00	4.37	1.86E-06
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.04	0.01	5.20	3.50E-02
417.2(c)(4)	List of procedures & frequency	Yes	0.04	0.00	13.18	1.67E-31

¹ Refer to the [2021 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 87 establishments with ground chicken *Campylobacter* testing data, of which 48 establishments had 192 *Campylobacter* positives and 48 establishments did not have *Campylobacter* positives. There were 1,907 total ground chicken *Campylobacter* tests performed.

Table 4-18 presents the three 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 CY2022.

Table 4-18 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 FY2023 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
310.22(c)	Disposal of SRM	Yes	0.26	0.02	16.80	2.43E-03
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.00	6.52	7.65E-55
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	0.24	0.07	4.26	2.82E-21

¹ Refer to the [2021 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 46 establishments with ground turkey *Campylobacter* testing data, of which 11 establishments had 41 *Campylobacter* positives and 35 establishments did not have *Campylobacter* positives. There were 1,344 total ground turkey *Campylobacter* tests performed.

Table 4-19 presents the 11 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 CY2022.

Table 4-19 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 FY2023 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	0.18	0.05	4.09	1.57E-56
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.01	0.00	5.42	5.04E-10
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.01	0.00	3.13	1.72E-08

Regulation Verified	Description ¹	On FY2023 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 p Value
416.2(a)	Grounds and pest control	Yes	0.13	0.04	3.20	1.80E-06
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.17	0.04	4.88	1.64E-15
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.03	0.00	6.50	2.72E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	0.08	0.02	3.68	1.70E-02
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.25	0.08	3.93	1.21E-10
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.26	0.10	3.23	1.49E-14
417.3(a)(2)	CCP is under control	Yes	0.25	0.02	15.66	3.18E-66
381.76(a)	Post-mortem inspection, when required, extent	Yes	0.10	0.01	13.40	2.53E-04

¹ Refer to the [2021 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 497 establishments with chicken parts *Campylobacter* testing data, of which 408 establishments had 2,470 *Campylobacter* positives and 89 establishments did not have *Campylobacter* positives. There were 14,583 total chicken parts *Campylobacter* tests performed.

Table 4-20 presents the 10 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 CY2022.

Table 4-20 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 2023 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 p Value
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	0.02	0.00	5.14	4.25E-05
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.00	4.83	1.19E-126
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.00	0.00	4.34	5.49E-26
416.15(b)	Corrective action, procedures for	Yes	0.11	0.02	7.26	7.33E-08
416.2(a)	Grounds and pest control	Yes	0.18	0.04	5.50	1.22E-104
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	0.20	0.07	3.07	4.06E-50
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	0.19	0.05	4.34	3.31E-105
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.04	0.01	4.27	1.69E-09
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.16	0.06	3.04	4.80E-75
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	0.05	0.02	3.30	2.55E-02

¹ Refer to the [2021 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 FY2024 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 CY2022. The dataset used in the analysis consists of candidate PHRs noncompliance rates for the 5,770 active meat and poultry establishments, of which 96 establishments had 110 enforcement actions and 5,674 establishments did not have any enforcement actions.

Table 4-21 presents the 38 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 CY2022.

Table 4-21 Comparison of Noncompliance Rates 90 Days before an Enforcement Action with Those for Establishments with No Enforcement Actions

Regulation Verified	Description ¹	On FY 2023 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
310.3	Carcasses and parts in certain instances to be retained.	Yes	0.60	0.12	10.67	1.58E-02
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.50	0.01	97.17	6.52E-04
416.1	Operate in a manner to prevent insanitary conditions	Yes	0.02	0.01	3.78	5.55E-14
416.13(b)	Conduct other procedures listed in the plan	Yes	0.02	0.00	4.68	4.89E-37
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.01	0.00	3.32	4.66E-09
416.15(a)	Appropriate corrective actions	Yes	0.17	0.02	11.81	8.65E-26
416.15(b)	Procedures for corrective action	Yes	0.38	0.03	18.59	4.29E-28

Regulation Verified	Description¹	On FY 2023 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
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.01	0.00	4.82	9.52E-24
416.2(a)	Grounds and pest control	Yes	0.12	0.04	3.40	1.56E-22
416.2(b)(4)	Inedible from edible separated by time or space	Yes	0.03	0.00	7.47	1.92E-07
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	0.04	0.01	7.84	1.35E-06
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.13	0.04	3.19	3.46E-23
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.16	0.06	3.26	1.37E-28
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	0.60	0.04	31.90	8.89E-04
417.2(a)(1)	Hazard analysis	Yes	0.05	0.01	5.64	1.60E-10
417.2(c)(4)	List of procedures & frequency	Yes	0.02	0.00	4.83	2.00E-29
417.3(a)(1)	Identify and eliminate the cause	Yes	0.32	0.02	23.98	2.65E-10
417.3(a)(2)	CCP is under control	Yes	0.04	0.00	8.89	1.55E-06
417.3(a)(3)	Establish measures to prevent recurrence	Yes	0.40	0.03	24.06	9.11E-12
417.3(a)(4)	No adulterated product enters commerce.	Yes	0.05	0.00	19.06	1.45E-06

Regulation Verified	Description¹	On FY 2023 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(b)(4)	Reassessment	Yes	0.10	0.00	33.56	5.27E-09
417.3(c)	Document corrective actions	Yes	0.29	0.01	55.56	7.56E-09
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	0.73	0.03	95.25	1.63E-14
417.4(a)(1)	Initial validation	No	0.82	0.06	70.96	5.81E-10
417.5(a)(1)	Written hazard analysis	Yes	0.02	0.00	8.52	2.26E-56
417.5(a)(2)	Written HACCP plan	Yes	0.00	0.00	4.33	4.16E-06
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.01	0.00	6.16	1.65E-30
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	0.00	0.00	7.37	8.88E-03
430.4(b)(3)	Alternative 3	Yes	0.17	0.01	15.80	5.12E-09
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	No	0.00	0.00	10.70	6.86E-04
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	No	0.00	0.00	10.55	7.16E-04
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Yes	0.07	0.00	66.20	8.28E-04
418.2	Notification of adulterated or misbranded product in commerce	Yes	0.33	0.04	11.76	2.31E-02
381.65(f)	Procedures for controlling visible fecal contamination	Yes	0.16	0.01	26.66	3.79E-22
381.65(g)	Procedures for controlling contamination throughout the slaughter and	Yes	0.10	0.01	19.19	1.90E-07

Regulation Verified	Description ¹	On FY 2023 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
	dressing operation					
381.65(h)	Recordkeeping requirements	Yes	0.50	0.00	2767.00	6.66E-28
310.18(c)(2)(iii)	Records of test results for sampling program	No	0.01	0.00	44.84	1.51E-03
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	0.01	0.00	9.37	2.23E-02

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

5.0 LIST OF FY2024 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2024 PHRs list. Table 5-1 presents the complete list of the 63 FY2024 PHRs. These 63 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* O157:H7, non-O157 STEC, *Lm*, *Campylobacter* positives or enforcement actions than in establishments with no positives or enforcement actions.

Table 5-1 List of FY2024 PHRs

Regulation Verified	Description ¹	On FY 2023 PHRs List	Average Rates ratio	Average of Two-Sided Fisher Exact p Value
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.50	2.15E-70
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	6.91	8.20E-06
310.18(c)(2)(iii)	Records of test results for sampling program	No	44.84	1.51E-03
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	9.37	2.23E-02
310.22(c)	Disposal of SRM	Yes	15.50	6.06E-04
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	5.83	1.65E-09
310.22(e)(2)	Appropriate corrective actions	Yes	3.84	5.50E-04

Regulation Verified	Description¹	On FY 2023 PHRs List	Average Rates ratio	Average of Two-Sided Fisher Exact p Value
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	25.15	4.07E-05
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	No	5.01	4.99E-04
310.3	Carcasses and parts in certain instances to be retained.	Yes	7.59	7.89E-03
318.2(a)	All products subject to reinspection by program employees	Yes	7.51	1.27E-02
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	28.83	8.08E-03
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	3.51	5.19E-08
381.65(f)	Procedures for controlling visible fecal contamination	Yes	26.66	3.79E-22
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	19.19	1.90E-07
381.65(h)	Recordkeeping requirements	Yes	2767.00	6.66E-28
381.71(a)	Condemnation on ante mortem inspection	Yes	8.17	8.31E-03
381.76(a)	Post-mortem inspection, when required, extent	Yes	10.77	7.74E-03
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	7.94	1.08E-08
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Yes	9.76	7.05E-11
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	3.30	2.55E-02
381.91(a)	Certain contaminated carcasses to be condemned	No	15.09	1.91E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	26.32	8.53E-06
416.1	Operate in a manner to prevent insanitary conditions	Yes	3.78	5.55E-14
416.12(c)	Plan identifies procedures for pre-op	Yes	10.63	2.00E-02
416.13(a)	Conduct pre-op procedures	Yes	3.86	3.19E-08
416.13(b)	Conduct other procedures listed in the plan	Yes	4.46	8.21E-05
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	3.96	3.36E-21
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	4.62	7.33E-05
416.15(a)	Appropriate corrective actions	Yes	10.15	3.60E-03
416.15(b)	Procedures for corrective action	Yes	15.90	9.15E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	3.98	4.70E-07
416.2(a)	Grounds and pest control	Yes	4.80	1.65E-06

Regulation Verified	Description ¹	On FY 2023 PHRs List	Average Rates ratio	Average of Two-Sided Fisher Exact p Value
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	4.27	4.28E-12
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	5.48	2.27E-14
416.2(b)(4)	Inedible from edible separated by time or space	Yes	9.01	4.76E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.81	1.25E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	4.81	1.85E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	6.12	1.08E-06
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	3.77	2.53E-15
416.6	Only FSIS program employee may remove ""U.S. Rejected"" tag	Yes	18.72	7.90E-03
417.2(a)(1)	Hazard analysis	Yes	5.64	1.60E-10
417.2(c)	Contents of HACCP Plan	Yes	12.33	3.96E-04
417.2(c)(4)	List of procedures & frequency	Yes	6.25	1.80E-18
417.3(a)(1)	Identify and eliminate the cause	Yes	20.99	9.22E-05
417.3(a)(2)	CCP is under control	Yes	37.82	9.09E-04
417.3(a)(3)	Establish measures to prevent recurrence	Yes	11.38	6.42E-07
417.3(a)(4)	No adulterated product enters commerce.	Yes	14.85	1.00E-03
417.3(b)(3)	No adulterated product enters commerce	Yes	44.62	4.99E-12
417.3(b)(4)	Reassessment	Yes	33.56	5.27E-09
417.3(c)	Document corrective actions	Yes	44.54	8.87E-05
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	107.08	7.54E-04
417.4(a)(1)	Initial validation	No	51.12	5.85E-03
417.4(b)	Reassessment of hazard analysis	No	6.50	1.74E-02
417.5(a)(1)	Written hazard analysis	Yes	8.52	2.26E-56
417.5(a)(2)	Written HACCP plan	Yes	4.42	1.50E-06
417.5(a)(3)	Records documentation and monitoring of CCP's and critical limits	Yes	6.16	1.65E-30
418.2	Notification of adulterated or misbranded product in commerce	Yes	11.76	2.31E-02
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	6.59	2.89E-02
430.4(b)(3)	Alternative 3	Yes	12.07	7.75E-05
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	No	8.58	2.07E-02
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	No	8.18	2.49E-02

Regulation Verified	Description ¹	On FY 2023 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	66.20	8.28E-04

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

In FY2023 there were 71 PHRs, 56 of which are FY2024 PHRs. There are 15 regulations on the FY2023 PHRs list that are not on the FY2024 PHRs list (see Appendix C). There are seven regulations that are on the FY2024 PHRs list that were not on the FY2023 PHRs list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2024 PHRs list. Most regulations were triggered by multiple events. Similar to the FY2023 PHRs list, *Salmonella* pathogen positives and enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2024 PHRs List

Product	Number of Regulations
<i>Campylobacter</i>	15
<i>Campylobacter</i> Chicken Parts	10
<i>Campylobacter</i> Ground Chicken	3
<i>Campylobacter</i> Ground Turkey	11
<i>Campylobacter</i> Intact Chicken	5
<i>Campylobacter</i> Intact Turkey	4
Enforcements	38
<i>Lm</i>	7
NonO157 <i>E. coli</i>	3
O157 <i>E. coli</i>	10
<i>Salmonella</i>	24
<i>Salmonella</i> Chicken Parts	5
<i>Salmonella</i> Ground Beef	11
<i>Salmonella</i> Ground Chicken	9
<i>Salmonella</i> Ground Pork	11
<i>Salmonella</i> Ground Turkey	7
<i>Salmonella</i> Intact Beef	17
<i>Salmonella</i> Intact Chicken	2
<i>Salmonella</i> Intact Pork	9
<i>Salmonella</i> Intact Turkey	1
<i>Salmonella</i> RTE	0
<i>Salmonella</i> Siluriformes	1

There were 22 regulations triggered by a single type of event: 12 were from Enforcement Actions, 2 were from *Salmonella*, two were from *Salmonella* in ground beef, two were from

Salmonella ground pork, one was from *Salmonella* in intact beef, one was from *Salmonella* in ground chicken, one was from *Salmonella* in intact chicken, and one was from *Campylobacter* in chicken parts. Table 5-3 presents the regulations triggered for inclusion in the FY2024 PHRs list by only a single pathogen product or enforcement action type (event).

Table 5-3 Regulations Triggered for Inclusion in the FY2024 PHRs List by Only a Single Event

Regulation Verified	Description¹	Event
310.18(c)	Written procedures to prevent contamination; all swine slaughter	<i>Salmonella</i>
310.18(c)(2)(iii)	Records of test results for sampling program	Enforcements
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Enforcements
310.22(e)(2)	Appropriate corrective actions	<i>Salmonella</i> Intact Beef
381.65(f)	Procedures for controlling visible fecal contamination	Enforcements
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Enforcements
381.65(h)	Recordkeeping requirements	Enforcements
381.71(a)	Condemnation on ante mortem inspection	<i>Salmonella</i>
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	<i>Salmonella</i> Ground Chicken
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	<i>Campylobacter</i> Chicken Parts
381.91(a)	Certain contaminated carcasses to be condemned	<i>Salmonella</i> Intact Chicken
416.1	Operate in a manner to prevent insanitary conditions	Enforcements
416.12(c)	Plan identifies procedures for pre-op	<i>Salmonella</i> Ground Beef
417.2(a)(1)	Hazard analysis	Enforcements
417.2(c)	Contents of HACCP plan	<i>Salmonella</i> Ground Pork
417.3(b)(3)	No adulterated product enters commerce	<i>Salmonella</i> Ground Pork
417.3(b)(4)	Reassessment	Enforcements
417.4(b)	Reassessment of hazard analysis	<i>Salmonella</i> Ground Beef
417.5(a)(1)	Written hazard analysis	Enforcements
417.5(a)(3)	Records documentation and monitoring of CCP's and critical limits	Enforcements
418.2	Notification of adulterated or misbranded product in commerce	Enforcements
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Enforcements

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

6.0 CUT POINTS FOR FY2024 PHRS

The FY2024 PHRs are one of seven public health-based decision criteria that are used in prioritizing PHREs. Other decision criteria for PHREs 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 FY2024 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 FY2024 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 FY2024 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 FY2024 PHRs Rate

CY2022	Mean of Natural Log PHRs Rate		Standard Deviation PHRs Rate	
	Processing	Combination	Processing	Combination
Jan-Mar	-4.94	-4.58	0.84	0.93
Apr-Jun	-4.92	-4.54	0.82	0.96
Jul-Sept	-4.87	-4.52	0.82	0.96
Oct-Dec	-4.96	-4.56	0.82	0.95
Average	-4.93	-4.55	0.82	0.96

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 $-4.54884 + 2 \times 0.95651 = -4.54884 + 1.91302 = -2.63582$. The cut point of the original, non-transformed PHRs noncompliance data is the antilog of -2.63582 or $\text{Exp}(-2.63582) = 7.17\%$. 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 PHRs 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 regulations.

- Establishments with a PHRs 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 PHRs 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 FY2024 PHRs upper and lower cut points for each of the two establishment operation types. The FY2023 and FY2022 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 2024.

Table 6-2 FY2024 PHRs Upper-Level Cut Points

Operation Type	FY2024 PHRs Cut Points	FY2023 PHRs Cut Points	FY2022 PHRs Cut Points
Processing	3.76%	3.65%	3.63%
Combination	7.17%	7.48%	7.33%

Table 6-3 FY2024 PHRs Lower-Level Cut Points

Operation Type	FY2024 PHRs Cut Points	FY2023 PHRs Cut Points	FY2022 PHRs Cut Points
Processing	2.49%	2.45%	2.44%
Combination	4.44%	4.59%	4.60%

Table 6-4 presents the number of establishments in each level based solely on the FY2024 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. Fifty-seven 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, 2023.

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

Classification	Processing	Combination	Total
Upper	43	14	57
Mid	64	25	89
Lower	4,213	1,117	5,330
Total	4320	1,156	5476

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2024 PHRs regulations used to prioritize certain FY2024 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 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 FY2024 PHRs has 63 regulations whose individual noncompliance rates are higher in establishments 90 days before *Salmonella*, *E. coli* O157:H7, non-O157 STEC, *Lm*, or *Campylobacter* positives or enforcement action than in establishments without positives or enforcement actions. Fifty-six regulations on the FY2023 PHRs list are also on the FY2024 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 PHRs 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: FY2024 PHRS REGULATIONS

Table A-1 presents the list of 63 FY2024 Public Health Regulations (PHRs). On average, these PHRs have noncompliance rates 90 days prior to a pathogen positive or enforcement action that is 5.64 times higher than the PHRs noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2024 PHRs

Regulation	Description ¹
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
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
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(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
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
381.65(a)	Clean and sanitary practices; products not adulterated
381.65(f)	Procedures for controlling visible fecal contamination
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation
381.65(h)	Recordkeeping requirements
381.71(a)	Condemnation on ante mortem inspection
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)(B)	NPIS reprocessing and salvage
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
381.91(a)	Certain contaminated carcasses to be condemned
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

416.13(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)	Procedures for corrective action
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)	Contents of HACCP Plan
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(a)(4)	No adulterated product enters commerce.
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
417.4(b)	Reassessment of hazard analysis
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
418.2	Notification of adulterated or misbranded product in commerce

430.4(a)	<i>Lm</i> , post-lethality exposed RTE
430.4(b)(3)	Alternative 3
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis
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

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

APPENDIX B: FY2024 CANDIDATE REGULATIONS

Table B-1 presents the list of candidate regulations. Of the 159 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, 2022.

Table B-1 FY2024 List of Candidate Regulations

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
301.2_Adulterated	Adulterated	Yes	No	3198	146	4.57%
304.3(a)	Develop written SSOP	No	No	369	0	0.00%
304.3(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	157	4	2.55%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	150	0	0.00%
309.3	(Modernized ONLY) Dead, dying, disabled or diseased and similar livestock.	No	No	278	3	1.08%
309.4	(Modernized ONLY) Livestock showing symptoms of metabolic,	No	No	172	2	1.16%

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	toxic, nervous, or diseases					
309.5	(Modernized ONLY) Swine; disposal because of hog cholera	No	No	96	0	0.00%
309.9	(Modernized ONLY) Swine erysipelas	No	No	95	0	0.00%
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	No	2441	10	0.41%
310.22(c)	Disposal of SRM	Yes	Yes	53625	254	0.47%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar U.S. products	No	No	17	0	0.00%
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	10682	240	2.25%
310.22(e)(2)	Appropriate corrective actions	Yes	No	1744	53	3.04%
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	7601	124	1.63%
310.22(e)(4)(i)	Maintain daily records	No	No	67847	125	0.18%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used	No	No	14009	35	0.25%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	to cut through SRMs					
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	Yes	No	935	4	0.43%
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	Yes	No	3382	17	0.50%
310.25(a)	Verification criteria for E. coli testing meat	No	No	27810	330	1.19%
310.25(b)	Pathogen reduction performance standards; Salmonella	No	No	180	0	0.00%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	11	1	9.09%
310.3	Carcasses and parts in certain instances to be retained.	Yes	No	2065	230	11.14%
311.16	(Modernized ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.	No	No	394	22	5.58%
311.17	(Modernized ONLY) Necrobacillosis,	No	No	376	3	0.80%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	pyemia, septicemia.					
311.24	(Modernized ONLY) Hogs affected with tapeworm cysts.	No	No	123	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	13	0	0.00%
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	No	12802	60	0.47%
317.24(a)	Packaging materials composed of poisonous or deleterious substances	No	No	1664	11	0.66%
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	No	102044	11	0.01%
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	153	0	0.00%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	513	0	0.00%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled	No	No	62	0	0.00%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	under FSIS supervision					
318.16(b)	Pesticides chemicals & other residues in products not to exceed FD&C Act levels - Meat ingredients	No	No	135	0	0.00%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	2172	3	0.14%
318.17(b)	Lethality and Stabilization processes other than HACCP for cooked beef	No	No	446	0	0.00%
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	28	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	41323	69	0.17%
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	5953	52	0.87%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully-cooked meat patties	No	No	358	1	0.28%
318.23(b)(3)	Heat deviations for meat patties	No	No	44	3	6.82%
318.23(c)(1)	Stabilization requirements for meat patties	No	No	179	0	0.00%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	61	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	193	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	46	0	0.00%
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2604	19	0.73%
318.6(b)(1)	Requirements for use of casings, used as containers	No	No	1609	0	0.00%
318.6(b)(4)	Detached spinal cords	No	No	8977	1	0.01%
318.6(b)(6)	Tonsils	No	No	9955	1	0.01%
318.6(b)(8)	Intestines as ingredients	No	No	203	0	0.00%
319.5(b)	Mechanically separated (beef) - prohibited for use in human food	No	No	243	0	0.00%
381.1_Adulterated	Adulterated	Yes	No	2481	73	2.94%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	1805	0	0.00%
381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	No	944	3	0.32%
381.150(c)	Lethality and Stabilization processes	No	No	50	0	0.00%

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	other than HACCP for cooked poultry					
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	14	0	0.00%
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	432	0	0.00%
381.22(a)	Develop written SSOP	No	No	176	1	0.57%
381.22(b)	Conduct hazard analysis & develop and validate HACCP plan	No	No	1007	2	0.20%
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	221	1	0.45%
381.37(a)	Product not produced under supervision of program employee	No	No	1280	13	1.02%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	26841	165	0.61%
381.71(a)	Condemnation on ante mortem inspection	Yes	No	933	15	1.61%
381.72(a)	Poultry	No	No	211	0	0.00%
381.72(b)	Ratites	No	No	57	0	0.00%
381.83	Septicemia or toxemia	No	No	1339159	65	0.00%
381.85	Special Diseases (organisms or toxins)	No	No	114	0	0.00%

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	dangerous to the consumer)					
381.91(a)	Certain contaminated carcasses to be condemned	No	No	4669	11	0.24%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	No	8862	228	2.57%
416.1	Operate in a manner to prevent insanitary conditions	Yes	Yes	623867	4270	0.68%
416.12(c)	pPlan identifies procedures for pre-op	Yes	No	39691	67	0.17%
416.12(d)	Plan list frequency for each procedure & responsible individual	No	No	57581	73	0.13%
416.13(a)	Conduct pre-op procedures	Yes	Yes	782372	15510	1.98%
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	1976382	6512	0.33%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2802361	30565	1.09%
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	Yes	1724591	2863	0.17%
416.15(a)	Appropriate corrective actions	Yes	Yes	62388	739	1.18%
416.15(b)	Procedures for corrective actionI	Yes	Yes	39372	953	2.42%
416.16(a)	Daily records required,	Yes	Yes	2982522	4297	0.14%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	responsible individual, initialed and dated					
416.2(a)	Grounds and pest control	Yes	No	185698	6753	3.64%
416.2(b)(1)	Sound construction, good repair & sufficient size	Yes	No	145806	6572	4.51%
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	Yes	No	197480	8778	4.45%
416.2(b)(4)	Inedible from edible separated by time or space	Yes	No	110626	478	0.43%
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	No	78650	429	0.55%
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	66282	781	1.18%
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	No	262460	10679	4.07%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	241439	12676	5.25%
416.5(c)	Employees who appears to have any abnormal source of	No	No	33075	10	0.03%

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	microbial contamination					
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2635	119	4.52%
417.2(a)(1)	Hazard analysis	Yes	Yes	125136	1485	1.19%
417.2(c)	Contents of HACCP Plan	Yes	No	27178	54	0.20%
417.2(c)(4)	List of procedures & frequency	Yes	Yes	1349538	4371	0.32%
417.3(a)(1)	Identify and eliminate the cause	Yes	No	24884	529	2.13%
417.3(a)(2)	CCP is under control	Yes	No	140997	639	0.45%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	No	22630	641	2.83%
417.3(a)(4)	No adulterated product enters commerce.	Yes	No	42034	136	0.32%
417.3(b)(1)	Segregate and hold the affected product	Yes	No	18715	66	0.35%
417.3(b)(2)	Determine the acceptability of the affected product	No	No	18435	62	0.34%
417.3(b)(3)	No adulterated product enters commerce	Yes	No	29894	58	0.19%
417.3(b)(4)	Reassessment	Yes	Yes	42851	183	0.43%
417.3(c)	Document corrective actions	Yes	No	20740	174	0.84%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	6208	197	3.17%
417.4(a)(1)	Initial validation	No	No	5454	294	5.39%
417.4(b)	Reassessment of hazard analysis	No	Yes	28408	81	0.29%

Regulation ¹	Description ²	FY 2023 PHRs	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
417.5(a)(1)	Written hazard analysis	Yes	Yes	1429037	3508	0.25%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1268134	1113	0.09%
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1401482	3449	0.25%
417.5(f)	Official Review	No	No	89274	61	0.07%
417.6	Inadequate HACCP systems	Yes	No	428	103	24.07%
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	Yes	300653	121	0.04%
430.4(b)(1)	Alternative 1	No	No	700	5	0.71%
430.4(b)(2)	Alternative 2	Yes	No	13063	55	0.42%
430.4(b)(3)	Alternative 3	Yes	No	17012	276	1.62%
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	No	Yes	293279	116	0.04%
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	No	Yes	293022	104	0.04%
430.4(c)(4)	<i>Lm</i> , validate and verify control measures in HACCP plan	No	No	3250	6	0.18%
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	Yes	No	4558	8	0.18%
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	Yes	No	4076	50	1.23%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	372189	4727	1.27%
310.18(b)	Brains, cheek meat, head trimmings from animals	No	No	21415	7	0.03%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	slaughtered by gunshot					
418.2	Notification of adulterated or misbranded product in commerce	Yes	No	2054	85	4.14%
418.3	Recall Plans	Yes	No	22713	45	0.20%
354.242(b)	All equipment and utensils clean and sanitary	No	No	51	0	0.00%
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	21	1	4.76%
354.243(a)	No handling or storage of objectionable materials	No	No	6	0	0.00%
381.193(a)	Poultry not intended for human food in commerce	No	No	233	10	4.29%
381.65(f)	Procedures for controlling visible fecal contamination	Yes	No	1627861	11364	0.70%
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	No	115573	666	0.58%
381.65(h)	Recordkeeping requirements	Yes	No	26944	24	0.09%
381.76(a)	Post-mortem inspection, when required, extent	Yes	No	7378	81	1.10%
381.94(a)	Verification criteria for E. coli testing ratites	No	No	1000	5	0.50%
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	No	64270	394	0.61%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	No	4407	225	5.11%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	No	1459226	67	0.00%
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Yes	No	71949	68	0.09%
537.1	Basic Requirements	No	No	25662	98	0.38%
311.14	Abrasions, bruises, abscesses, pus, etc.	Yes	No	27713	16	0.06%
309.3(e)	Establishment notify Inspection Program Personnel (IPP) of non-ambulatory livestock; Prompt condemnation and disposal	No	No	33	4	12.12%
431.4	Critical factors and the application of the process schedule	No	Yes	10053	17	0.17%
431.9(b)	Procedures for handling of process deviations	No	Yes	8800	0	0.00%
431.9(c)(1)	Process deviations identified in-process	No	No	77	1	1.30%
431.9(c)(2)	Process deviations identified through record review	No	No	19	1	5.26%
431.9(d)	Process deviation file	No	No	101	0	0.00%
431.11	Personnel and training	No	No	33	1	3.03%
431.12	Recall procedure	No	No	65	0	0.00%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
309.19(a)	Market hog sorting activities	No	No	1395	2	0.14%
309.19(c)	Sorted and removed hogs identified; written procedures	No	No	935	0	0.00%
309.19(d)	Records of animals disposed of per day	Yes	No	4445	1	0.02%
309.19(e)	Notifiable animal disease	No	No	134	0	0.00%
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	No	9752	38	0.39%
310.18(c)(1)	Sampling locations	No	No	1787	3	0.17%
310.18(c)(1)(i)	Very low volume establishments	No	No	3133	0	0.00%
310.18(c)(2)(i)	Sampling frequency	Yes	No	2945	4	0.14%
310.18(c)(2)(ii)	Sampling frequency for very low volume establishments	No	No	1958	2	0.10%
310.18(c)(2)(iii)	Records of test results for sampling program	No	No	23314	14	0.06%
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	No	37928	32	0.08%
310.26(b)	Carcass sorting and disposition	Yes	Yes	3389	38	1.12%
310.26(d)(2)	Document number of carcasses	No	No	2565	2	0.08%

Regulation¹	Description²	FY 2023 PHRs	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHRs Noncompliance Rate
	disposed of per day					

¹Regulations 417.3(a) and 417.4(a)(3) are not included in this table as they had zero regulations verified in CY2022.

²Refer to the [2021 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 FY2023 PHRS LIST WITH FY2024 PHRS LIST

There are 15 regulations from the FY2023 PHRs list that no longer appear in the FY2024 PHRs list. These are shown in Table C-1.

Table C-1 Regulations on the FY2023 PHRs List No Longer on the FY2024 PHRs List

FY2023 PHRs	Description ¹
301.2 Adulterated	Adulterated
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns
318.1(b)	Only inspected and passed poultry product to enter official establishment
381.1 Adulterated	Adulterated
417.3(b)(1)	Segregate and hold the affected product
417.6	Inadequate HACCP systems
430.4(b)(2)	Alternative 2
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements
418.3	Recall Plans
311.14	Abrasions, bruises, abscesses, pus, etc.
309.19(d)	Records of animals disposed of per day
310.18(c)(2)(i)	Sampling frequency
310.26(b)	Carcass sorting and disposition

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

There are seven regulations on the FY2024 PHRs list that were not on the FY2023 PHRs list.

Table C-2 Regulations on the FY2024 PHRs List That Were Not on the FY2023 PHRs List

FY2024 PHRs	Description ¹
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
381.91(a)	Certain contaminated carcasses to be condemned
417.4(a)(1)	Initial validation
417.4(b)	Reassessment of hazard analysis
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment
310.18(c)(2)(iii)*	Records of test results for sampling program

¹ Refer to the [2021 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

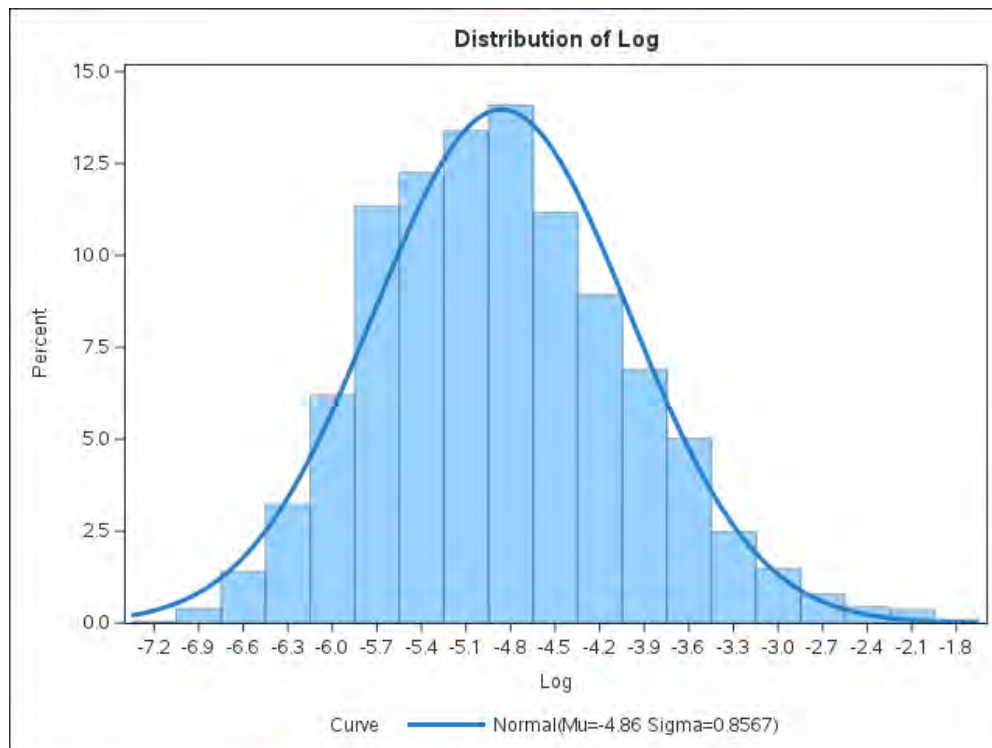
The purpose of this appendix is to explain the methodology and calculations used to develop the PHRs cut points. The PHRs noncompliance rate is calculated by the following formula using the most recent 90 days of establishment verification inspection data:

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

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 from 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 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	0.03067772	Pr > D	<0.010
Cramer-von Mises	W-Sq	0.63813471	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	4.12389603	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 PHRs 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 Establishments	Mean	Standard Deviation	Level	Tier Distribution (Number of Establishments)
Q1CY2022					
				Upper	80
Combination	1,128	-4.57674	0.93148	Mid	92
Processing	4,325	-4.94081	0.83789	Lower	5,281
Q2CY2022					
				Upper	69
Combination	1,157	-4.53727	0.95592	Mid	106
Processing	4,338	-4.92279	0.81704	Lower	5,320
Q3CY2022					
				Upper	70
Combination	1,161	-4.52175	0.98877	Mid	111
Processing	4,336	-4.87322	0.81869	Lower	5,316
Q4CY2022					
				Upper	68
Combination	1,165	-4.55961	0.94987	Mid	85
Processing	4,337	-4.96510	0.81607	Lower	5,349

Table D-2 shows the average mean and standard deviation of the log transformed non-zero PHRs 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 FY2024 PHRs. Table D-4 show the distribution of establishments using data from January to March 2023 utilizing the proposed FY2024 PHRs.

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

Statistic	Combination	Processing
Mean	-4.54884	-4.92548
Standard Deviation	0.95651	0.822422

Table D-3 FY2024 PHRs Upper and Lower Cut Points

Operation Type	Upper Cut Points	Lower Cut Points
Processing	3.76%	2.49%
Combination	7.17%	4.44%

Table D-4 March 2023 Level Distribution Based on the Previous Year's (FY2023) 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	57
Mid	90
Lower	5,330
Total	5,477