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Food Safety and Inspection Service
FY2023 Public Health Regulations**

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Table of Contents

Summary	5
1.0 Introduction	8
2.0 Selection of PHRs	9
2.1 Criteria for Selection of Candidate Regulations	9
2.2 Relationship with Pathogen Positives and Enforcement Actions	10
3.0 Candidate Regulations	11
4.0 Relationship Between Candidate Regulations and Pathogen Positives and Enforcement Actions	11
4.1 <i>Salmonella</i>	11
4.1.1 <i>Salmonella</i> in Intact Chicken	14
4.1.2 <i>Salmonella</i> in Intact Turkey	15
4.1.3 <i>Salmonella</i> in Ground Beef	15
4.1.4 <i>Salmonella</i> in Intact Beef	17
4.1.5 <i>Salmonella</i> in Ground Chicken	20
4.1.6 <i>Salmonella</i> in Ground Turkey	21
4.1.7 <i>Salmonella</i> in Intact Pork	22
4.1.8 <i>Salmonella</i> in Ground Pork	23
4.1.9 <i>Salmonella</i> in Chicken Parts	24
4.1.10 <i>Salmonella</i> in Siluriformes	25
4.1.11 <i>Salmonella</i> in Ready-to-Eat (RTE)	26
4.2 <i>E. coli</i>	26
4.2.1 <i>E. coli</i> O157:H7	26
4.2.2 Non-O157 STEC	27
4.3 <i>Listeria monocytogenes</i>	28
4.4 <i>Campylobacter</i>	29
4.4.1 <i>Campylobacter</i> in Intact Chicken	31
4.4.2 <i>Campylobacter</i> in Intact Turkey	32
4.4.3 <i>Campylobacter</i> in Ground Chicken	33
4.4.4 <i>Campylobacter</i> in Ground Turkey	33
4.4.5 <i>Campylobacter</i> in Chicken Parts	34
4.5 Enforcement Actions	35
5.0 List of FY2023 PHRs	40
6.0 Cut Points for FY2023 PHRs	44
7.0 Conclusion	47
8.0 References	48
Appendix A: FY2023 PHR Regulations	49
Appendix B: FY2023 Candidate Regulations	52
Appendix C: Comparison of FY2022 PHR List with FY2023 PHR List	67
Appendix D: Methodology and Calculation of PHR Cut Points	68

List of Figures and Tables

Table S-1 PHR Upper Cut Points	6
Table S-2 PHR Lower Cut Points	6
Table S-3 Number of Establishments in Levels Based Solely on the PHR Criterion	7
Table 4-1 Comparison of Noncompliance Rates 90 Days before a <i>Salmonella</i> Positive with Those for Establishments with No <i>Salmonella</i> Positive	12
Table 4-2 Comparison of Noncompliance Rates 90 Days before an Intact Chicken <i>Salmonella</i> Positive with Those for Establishments with No Intact Chicken <i>Salmonella</i> Positive.....	14
Table 4-3 Comparison of Noncompliance Rates 90 Days before an Intact Turkey <i>Salmonella</i> Positive with Those for Establishments with No Intact Turkey <i>Salmonella</i> Positive	15
Table 4-4 Comparison of Noncompliance Rates 90 Days before a Ground Beef <i>Salmonella</i> Positive with Those for Establishments with No Ground Beef <i>Salmonella</i> Positive	16
Table 4-5 Comparison of Noncompliance Rates 90 Days before an Intact Beef <i>Salmonella</i> Positive with Those for Establishments with No Intact Beef <i>Salmonella</i> Positive	17
Table 4-6 Comparison of Noncompliance Rates 90 Days before a Ground Chicken <i>Salmonella</i> Positive with Those for Establishments with No Ground Chicken <i>Salmonella</i> Positive	20
Table 4-7 Comparison of Noncompliance Rates 90 Days before a Ground Turkey <i>Salmonella</i> Positive with Those for Establishments with No Ground Turkey <i>Salmonella</i> Positive	21
Table 4-8 Comparison of Noncompliance Rates 90 Days before an Intact Pork <i>Salmonella</i> Positive with Those for Establishments with No Intact Pork <i>Salmonella</i> Positive	22
Table 4-9 Comparison of Noncompliance Rates 90 Days before a Ground Pork <i>Salmonella</i> Positive with those for Establishments with No Ground Pork <i>Salmonella</i> Positive.....	23
Table 4-10 Comparison of Noncompliance Rates 90 Days before a Chicken Parts <i>Salmonella</i> Positive with Those for Establishments with No Chicken Parts <i>Salmonella</i> Positive.....	24
Table 4-11 Comparison of Noncompliance Rates 90 Days before a Siluriformes <i>Salmonella</i> Positive with Those for Establishments with No Siluriformes <i>Salmonella</i>	25
Table 4-12 Comparison of Noncompliance Rates 90 Days before a RTE <i>Salmonella</i> Positive with Those for Establishments with No RTE <i>Salmonella</i>	26
Table 4-13 Comparison of Noncompliance Rates 90 Days before an <i>E. coli</i> O157:H7 Positive with Those for Establishments with no <i>E. coli</i> O157:H7 Positive	27
Table 4-14 Comparison of Noncompliance Rates 90 Days before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive	28
Table 4-15 Comparison of Noncompliance Rates 90 Days before a <i>Lm</i> Positive with Those for Establishments with No <i>Lm</i> Positive.....	28
Table 4-16 Comparison of Noncompliance Rates 90 Days before a <i>Campylobacter</i> Positive with Those for Establishments with No <i>Campylobacter</i> Positive	30
Table 4-17 Comparison of Noncompliance Rates 90 Days before a <i>Campylobacter</i> Intact Chicken Positive with Those for Establishments with No <i>Campylobacter</i> Intact Chicken Positive	31
Table 4-18 Comparison of Noncompliance Rates 90 Days before a <i>Campylobacter</i> Intact Turkey Positive with Those for Establishments with No <i>Campylobacter</i> Intact Turkey Positive	32
Table 4-19 Comparison of Noncompliance Rates 90 Days before a Ground Chicken <i>Campylobacter</i> Positive with Those for Establishments with No Ground Chicken <i>Campylobacter</i> Positive	33

Table 4-20 Comparison of Noncompliance Rates 90 Days before a Ground Turkey <i>Campylobacter</i> Positive with those for Establishments with No Ground Turkey <i>Campylobacter</i> Positive.....	34
Table 4-21 Comparison of Noncompliance Rates 90 Days before a Chicken Parts <i>Campylobacter</i> Positive with Those for Establishments with No Chicken Parts <i>Campylobacter</i> Positive.....	34
Table 4-22 Comparison of Noncompliance Rates 90 Days before an Enforcement Action with Those for Establishments with No Enforcement Action	36
Table 5-1 List of FY2023 PHRs	40
Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2023 PHR List	43
Table 5-3 Regulations Triggered for Inclusion in the FY2023 PHR List by Only a Single Event.....	44
Table 6-1 Mean and Standard Deviation of Quarterly FY2023 PHR Rate	45
Table 6-2 FY2023 PHR Upper-Level Cut Points.....	46
Table 6-3 FY2023 PHR Lower-Level Cut Points.....	46
Table 6-4 Classification of Establishments Based Solely on the PHR Criterion	46
Table 7-1 FY2023 PHR Cut Points	47
Table A-1 List of FY2023 PHRs	49
Table B-1 FY2023 List of Candidate Regulations	52
Table C-1 Regulations on the FY2022 PHR List No Longer on the FY2023 PHR List.....	67
Table C-2 Regulations on the FY2023 PHR List That Were Not on the FY2022 PHR List	67
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.....	68
Figure D-2 Goodness of Fit for Normal Distribution of the Log Transformation.....	69
Table D-1 Quarterly PHR Mean, Standard Deviation and Level Distribution.....	69
Table D-2 Average Mean and Standard Deviation of Log Transformed Non-Zero PHR Rates by Establishment Type.....	70
Table D-3 FY2023 PHR Upper and Lower Cut Points	70
Table D-4 March 2022 Level Distribution Based on the Previous Year's (FY2022) PHR Cut Points.....	70

SUMMARY

Public Health Regulations (PHRs) are regulations¹ that have significantly higher individual noncompliance rates at establishments within a 90 day period prior to identification of a pathogen-positive laboratory sample or a public health-related enforcement action. The comparison is to establishments with no positives or enforcement actions². This correlation does not inherently imply that a particular regulation constitutes a more serious food safety concern, but gives a guide to better assign agency resources.

This report describes the data-driven approach used to select the PHRs that will be used for the period October 1, 2022, to September 30, 2023, (FY2023) to prioritize certain FY2023 FSIS inspection activities.

FSIS uses decision criteria to prioritize establishments for Public Health Risk Evaluations³ (PHREs), which are reviews of FSIS information for an establishment and are used to determine the need for a Food Safety Assessment (FSA) or enforcement action. The decision criteria include exceeding an upper threshold for PHR noncompliance rate and other factors such as pathogen testing results, recalls, outbreaks, regulatory findings, and inspection results. Updates to the list of PHRs, as well as the upper and lower thresholds used to prioritize establishments for PHREs and to alert inspection personnel of elevated PHR noncompliance rate, are announced around July 1 each year with a targeted implementation month of October.

The updated list of FY2023 PHRs is based on January 1, 2021, to December 31, 2021, (CY2021) verification inspection results and will be implemented in FY2023. For inclusion in the FY2023 PHR list, a curated list of candidate regulations from 9 CFR was evaluated to determine whether noncompliance with each regulation occurred at a more frequent rate in establishments in the 90 days before *Salmonella*, *E. coli* O157:H7, Non-O157 Shiga toxin-producing *Escherichia coli* (STEC), *Listeria monocytogenes* (*Lm*), *Campylobacter* positives or enforcement actions than in establishments without positives or enforcement actions.

The final list of FY2023 PHRs consists of 71 regulations that have higher rate of noncompliance in the 90 days before a pathogen positive or enforcement action. This compares with 62 regulations that were identified in the prior fiscal year PHR list. The full list of FY2023 PHRs is given in Appendix A. Fifty-two regulations from the FY2022 PHR list remain on the FY2023 PHR list.

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 PHR list allows FSIS to focus on specific health-related provisions of regulations that may be most informative for prioritizing 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.

The average noncompliance rate of FY2023 PHR regulations in the 90 days before a pathogen positive or enforcement action is 7.37 times higher than the average FY2023 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action. Noncompliance with a single FY2023 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 FY2023 PHR noncompliance rate by establishments is evaluated and compared to thresholds (also referred to as cut points), that have been set for two broad categories of establishment operations: Processing Only and both Slaughter and Processing, labeled respectively as Processing and Combination in the main body of the report.

The FY2023 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2023 PHR rates for each of the four quarters in CY2021 (the log transform of the non-zero FY2023 PHR rates is taken to obtain an approximately normal distribution). The mean and standard deviation are averaged over the four quarters and the upper cut point is defined as the mean plus two times the standard deviation of the log transformed non-zero PHR rates. The antilog is then taken to obtain the upper cut point of the non-transformed PHR noncompliance data. Establishments that have PHR noncompliance rates higher than the upper cut point for similar establishments are classified as Upper and are considered for a “for cause” PHRE if they have not had a PHRE in the last 180 days. The lower cut point is defined as the mean plus one and a half times the standard deviation of the log transformed non-zero PHR rates. Establishments that have PHR noncompliance rates below the lower cut point for similar establishments are classified as Lower. Establishments with a PHR noncompliance rate between the Upper and Lower cut points will be notified by FSIS inspection personnel that the establishment is at an elevated level of noncompliance. Tables S-1 and S-2 present the Upper and Lower FY2023 PHR cut points for the non-transformed PHR noncompliance data for each of the two establishment operation types. The FY2022 and FY2021 PHR cut points are included for comparison. (See Section 6 and Appendix D for more details.)

Table S-1 PHR Upper Cut Points

Operation Type	FY2023	FY2022	FY2021
Processing	3.65%	3.63%	3.73%
Combination	7.48%	7.33%	9.84%

Table S-2 PHR Lower Cut Points

Operation Type	FY2023	FY2022	FY2021
Processing	2.45%	2.44%	2.50%
Combination	4.59%	4.60%	5.85%

Table S-3 presents the number of establishments in each level from January 1, 2022, to March 31, 2022, based on the PHR criterion. The period used for calculating the noncompliance rate of the PHRs was January 1, 2022, to March 31, 2022. The number of “for cause” PHREs for Upper cut point establishments is approximately the same as in previous years.

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

Level	Processing	Combination	Total
Upper	65	14	79
Mid	69	22	91
Lower	4,143	1,087	5,230
Total	4,277	1,123	5,400

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 factors such as pathogen testing results, recalls, outbreaks, regulatory findings, and a record of noncompliance with certain 9 CFR regulations. These criteria are described in detail in FSIS' Public Health Decision Criteria Report (FSIS 2010). 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 District Office first performs the evaluation as described in [FSIS Directive 5100.4](#) to review the operational and compliance history of the establishment to decide if a Food Safety Assessment (FSA) or enforcement action is appropriate.

The subset of 9 CFR regulations used to schedule PHREs was initially called W3NR regulations to indicate they are the most serious noncompliance. In January 2012, FSIS developed a more transparent and data-driven approach to refine the list of W3NR regulations (FSIS 2012). The updated list of regulations was called Public Health Regulations (PHRs). In January 2013, FSIS submitted plans to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to implement the PHRs. NACMPI endorsed the use of PHRs and suggested that the PHR list be updated annually (NACMPI 2013). The purpose of this report is to update the list of PHRs using current verification inspection results from the Public Health Information System (PHIS). The updated list is called the FY2023 PHRs (PHRs that will be used for the time period October 1, 2022, to September 30, 2023).

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. These provisions define in greater detail the specific requirements of a regulation. The inclusion of provisions in the PHR list allows FSIS to focus on specific public health-related provisions that may be most informative for prioritizing PHREs.

The methodology used in developing the FY2023 PHR list is the same as that used for the FY2022 PHR list. For inclusion in the FY2023 PHR 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*, *E. coli* O157: H7, Non-O157 STEC, *Listeria monocytogenes* (Lm), *Campylobacter* positives or enforcement actions than in establishments without positives or enforcement actions⁴. The analysis was based on 1 year of FSIS verification inspection results recorded in PHIS from January 1 to December 31, 2021 (CY2021). Candidate regulations related to egg products are not included in this report as one calendar year of data is required for inclusion in this analysis. HACCP in egg establishments is not required to be implemented until October 2022.

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.

Sections Two and Three detail how candidate regulations were determined and the results of the analysis to select the PHRs from the candidate 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 FY2023 PHR list is presented in Appendix A. Appendix B lists the candidate regulations evaluated to determine PHRs. Appendix C describes the differences between the FY2023 PHR list and FY2022 PHR list. Appendix D explains the methodology and calculations used to determine the PHR cut points.

2.0 SELECTION OF PHRS

The PHR 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*, *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 HACCP 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*, *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 provide control of operating conditions that are necessary to produce safe, wholesome food.

FSIS requires that establishments develop HACCP plans for controlling food safety hazards that can affect their products. These plans delineate a system of process control for each establishment's operation. 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 of the 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 be indicative of 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*, *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*, *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 as being indicators of 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 are 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*, *Campylobacter* positives during FSIS verification testing or enforcement actions. The noncompliance rate of each of the FY2023 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 CY2021. Those with more than 30 verifications in a year, an odds 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 before a pathogen positive or enforcement action is statistically higher than the noncompliance rate for establishments with no positives are selected 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.

An odds 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. An odds ratio is calculated by dividing the odds of a test group (in our 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 our 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 odds ratio size. In this report, an odds ratio size of 3.0 is taken as the threshold for a meaningful odds 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 PHR noncompliance rates for the 2,161 establishments with *Salmonella* testing data. There were 791 establishments that had 4,189 *Salmonella* positives. There were 1,370 establishments that did not have any *Salmonella* positives. There were 56,002 total *Salmonella* tests performed.

Table 4-1 presents the 32 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
301.2 Adulterated	Adulterated	Yes	51.58%	2.47%	42.09	1.34E-136
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	0.88%	0.23%	3.94	1.07E-04
310.18(c)(2)(i)	Sampling frequency	No	2.26%	0.10%	22.36	1.72E-04
310.22(c)	Disposal of SRM	Yes	5.93%	0.45%	13.95	9.91E-119
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	7.51%	2.46%	3.22	1.83E-12
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	18.44%	1.22%	18.25	3.77E-73
310.26(b)	Carcass sorting and disposition	No	2.08%	0.12%	17.86	7.05E-06
311.14	Abrasions, bruises, abscesses, pus, etc.	No	0.12%	0.01%	12.73	3.91E-03
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	0.07%	0.02%	3.45	3.09E-02
381.1 Adulterated	Adulterated	No	4.01%	0.87%	4.79	8.59E-03
416.12(c)	Plan identifies procedures for pre-op	No	0.37%	0.11%	3.39	3.87E-04
416.13(a)	Conduct pre-op procedures	Yes	7.98%	1.44%	5.92	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.69%	0.19%	3.64	6.40E-271
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.67%	0.96%	5.07	0.00E+00

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact <i>p</i> Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.70%	0.13%	5.41	0.00E+00
416.15(b)	Corrective action, procedures for	Yes	9.87%	3.05%	3.48	8.04E-61
416.2(a)	Grounds and pest control	No	12.23%	3.33%	4.04	0.00E+00
416.2(b)(1)	Sound construction, good repair & sufficient size	No	11.70%	3.43%	3.72	0.00E+00
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	11.44%	3.89%	3.20	0.00E+00
416.2(b)(4)	Inedible from edible separated by time or space	No	1.59%	0.32%	5.04	6.41E-50
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	4.65%	0.88%	5.52	6.04E-96
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	12.99%	3.60%	4.00	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	16.67%	4.45%	4.30	0.00E+00
417.2(c)(4)	List of procedures & frequency	Yes	0.66%	0.21%	3.19	4.34E-198
417.3(a)(1)	Identify and eliminate the cause	Yes	15.26%	2.46%	7.13	1.85E-79
417.3(a)(2)	CCP is under control	Yes	1.57%	0.30%	5.25	5.66E-77
417.3(a)(3)	Establish measures to prevent recurrence	Yes	20.54%	7.34%	3.27	7.66E-34
417.3(b)(1)	Segregate and hold the affected product	Yes	5.54%	1.54%	3.75	4.57E-06
417.6	Inadequate HACCP systems	No	32.61%	10.87%	3.97	3.47E-04

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact <i>p</i> Value
430.4(b)(2)	Alternative 2	Yes	2.06%	0.32%	6.62	1.09E-03
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	No	2.20%	0.09%	24.81	1.73E-03
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	Yes	7.27%	0.72%	10.86	2.06E-03

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 PHR noncompliance rates for the 210 establishments with Intact Chicken *Salmonella* testing data, of which 155 had 403 *Salmonella* positives and 55 did not have *Salmonella* positives. There were 9,626 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 3 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact <i>p</i> Value
381.71(a)	Condemnation on ante mortem inspection	No	5.58%	0.90%	6.50	4.25E-02
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	1.94%	0.63%	3.14	1.73E-03
417.5(a)(2)	Written HACCP plan	Yes	0.08%	0.03%	3.01	4.98E-03

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 PHR noncompliance rates for the 43 establishments with Intact Turkey *Salmonella* testing data, of which 4 establishments had 8 *Salmonella* positives and 39 establishments did not have *Salmonella* positives. There were 1,691 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the 6 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.65(f)	Procedures for controlling visible fecal contamination	Yes	7.27%	1.14%	6.81	3.12E-27
416.2(a)	Grounds and pest control	No	50.00%	9.30%	9.75	1.89E-07
416.2(b)(4)	Inedible from edible separated by time or space	No	17.07%	0.85%	24.01	2.95E-07
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	40.00%	1.49%	44.10	1.85E-05
417.2(c)(4)	List of procedures & frequency	Yes	5.00%	0.41%	12.90	3.41E-37
417.5(a)(1)	Written hazard analysis	Yes	1.95%	0.27%	7.32	2.28E-08

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 PHR noncompliance rates for the 1,252 establishments with Ground Beef *Salmonella* testing data, of which 121 establishments had 180 *Salmonella* positives and 1,131 establishments did not have *Salmonella* positives. There were 11,311 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 11 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
301.2 Adulterated	Adulterated	Yes	35.06%	3.46%	15.05	2.10E-18
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.76%	1.11%	5.44	5.75E-149
310.22(c)	Disposal of SRM	Yes	4.40%	0.34%	13.54	8.75E-30
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	8.92%	2.36%	4.05	3.95E-05
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	8.28%	0.96%	9.28	1.21E-08
416.13(b)	Conduct other procedures listed in the plan	Yes	0.63%	0.20%	3.24	1.07E-22
416.2(b)(4)	Inedible from edible separated by time or space	No	0.80%	0.21%	3.78	2.45E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	2.84%	0.49%	5.93	8.59E-06
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	30.77%	2.95%	14.64	6.76E-04
417.2(c)(4)	List of procedures & frequency	Yes	1.28%	0.25%	5.13	2.76E-58
417.3(a)(2)	CCP is under control	Yes	2.48%	0.29%	8.62	2.31E-08

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, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p 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

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
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 SSOP's & maintain plan	Yes	0.82%	0.16%	5.04	5.18E-38
416.15(b)	Corrective action, procedures for	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

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
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
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 PHR noncompliance rates for the 148 establishments with Ground Chicken *Salmonella* testing data, of which 90 establishments had 661 *Salmonella* positives and 58 establishments did not have *Salmonella* positives. There were 2,197 total Ground Chicken *Salmonella* tests performed.

Table 4-6 presents the 7 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
310.22(c)	Disposal of SRM	Yes	7.27%	1.15%	6.75	3.08E-02
381.1_Adulterated	Adulterated	No	13.90%	0.87%	18.48	6.65E-11
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	1.41%	0.21%	6.83	1.18E-42
381.71(a)	Condemnation on ante mortem inspection	No	18.75%	0.72%	31.73	1.89E-05
381.76(a)	Post-mortem inspection, when required, extent	No	21.36%	0.61%	44.61	3.08E-20
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	17.66%	0.32%	66.76	7.30E-84
417.3(a)(1)	Identify and eliminate the cause	Yes	1.53%	0.33%	4.63	2.30E-02

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 PHR noncompliance rates for the 52 establishments with Ground Turkey *Salmonella* testing data, of which 38 establishments had 236 *Salmonella* positives and 14 establishments did not have *Salmonella* positives. There were 1,463 total Ground Turkey *Salmonella* tests performed.

Table 4-7 presents the 10 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.13(a)	Conduct pre-op procedures	Yes	15.65%	4.03%	4.42	5.29E-51
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.90%	1.24%	4.98	4.83E-89
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.96%	0.02%	41.83	1.41E-15
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.33%	0.07%	5.03	1.05E-06
416.2(a)	Grounds and pest control	No	8.44%	2.71%	3.31	1.23E-06
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	12.40%	3.15%	4.35	4.72E-15
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	18.39%	3.85%	5.63	2.84E-32
417.3(a)(1)	Identify and eliminate the cause	Yes	29.18%	2.33%	17.31	1.06E-05
417.3(a)(2)	CCP is under control	Yes	12.80%	0.20%	73.26	3.34E-27
417.5(a)(1)	Written hazard analysis	Yes	0.39%	0.09%	4.18	8.94E-04

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 PHR noncompliance rates for the 90 establishments with Intact Pork *Salmonella* testing data, of which 38 establishments had 191 *Salmonella* positives and 52 establishments did not have *Salmonella* positives. There were 2,272 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the 12 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	1.43%	0.15%	9.77	2.79E-02
310.3	Carcasses and parts in certain instances to be retained.	Yes	34.78%	10.19%	4.70	8.08E-04
318.2(a)	All products subject to reinspection by program employees	Yes	0.88%	0.07%	12.74	3.97E-03
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.93%	0.38%	5.10	9.56E-45
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.46%	0.12%	3.80	1.90E-16
416.2(a)	Grounds and pest control	No	19.55%	3.84%	6.09	9.17E-53
416.2(b)(1)	Sound construction, good repair & sufficient size	No	16.80%	3.62%	5.38	2.54E-46
416.2(b)(4)	Inedible from edible separated by time or space	No	4.48%	0.48%	9.72	1.70E-14
417.3(a)(2)	CCP is under control	Yes	3.05%	0.48%	6.54	1.44E-03
417.3(a)(3)	Establish measures to prevent recurrence	Yes	71.43%	5.80%	40.63	1.30E-04
417.3(b)(4)	Reassessment	Yes	5.37%	0.34%	16.44	3.89E-04
417.3(c)	Document corrective actions	Yes	16.67%	4.73%	4.03	3.26E-02

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 PHR noncompliance rates for the 308 establishments with Ground Pork *Salmonella* testing data, of which 147 establishments had 1,275 *Salmonella* positives and 161 establishments did not have *Salmonella* positives. There were 6,314 total Ground Pork *Salmonella* tests performed.

Table 4-9 presents the 10 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
301.2_Adulterated	Adulterated	Yes	92.68%	33.33%	25.33	1.20E-03
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	1.94%	0.55%	3.60	1.85E-41
310.22(c)	Disposal of SRM	Yes	11.46%	0.13%	96.96	7.86E-44
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	47.83%	0.40%	228.25	1.38E-31
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.12%	0.33%	6.55	1.26E-63
416.13(a)	Conduct pre-op procedures	Yes	4.16%	1.07%	4.01	5.92E-110
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	2.50%	0.55%	4.66	1.01E-283

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.59%	0.05%	11.85	2.48E-66
416.2(b)(4)	Inedible from edible separated by time or space	No	0.51%	0.17%	3.12	7.29E-03
417.3(b)(3)	No adulterated product enters commerce	Yes	3.62%	0.37%	10.03	5.43E-03

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 PHR noncompliance rates for the 484 establishments with Chicken Parts *Salmonella* testing data, of which 342 establishments had 1,078 *Salmonella* positives and 142 establishments did not have *Salmonella* positives. There were 14,186 total Chicken Parts *Salmonella* tests performed.

Table 4-10 presents the 6 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in New Poultry Inspection System (NPIS)	Yes	15.61%	2.16%	8.37	2.95E-27
416.15(b)	Corrective action, procedures for	Yes	13.40%	3.59%	4.15	7.28E-20
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	8.14%	1.79%	4.86	1.32E-22

417.3(a)(1)	Identify and eliminate the cause	Yes	1.60%	0.54%	3.00	4.70E-02
417.3(b)(1)	Segregate and hold the affected product	Yes	17.70%	3.70%	5.59	2.90E-03
417.3(b)(4)	Reassessment	Yes	2.28%	0.53%	4.38	8.35E-04

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 PHR noncompliance rates for the 74 establishments with Siluriformes *Salmonella* testing data, of which 11 establishments had 19 *Salmonella* positives and 63 establishments did not have *Salmonella* positives. There were 594 total Siluriformes *Salmonella* tests performed.

Table 4-11 presents the 3 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.2(b)(1)	Sound construction, good repair & sufficient size	No	20.00%	2.30%	10.64	2.34E-02
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	30.00%	2.47%	16.95	1.21E-05
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	50.00%	0.30%	335.00	8.89E-03

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

4.1.11 *Salmonella* in Ready-to-Eat (RTE)

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,257 establishments with RTE *Salmonella* testing data, of which 4 establishments had 4 *Salmonella* positives and 2,253 establishments did not have *Salmonella* positives. There were 14,835 total RTE *Salmonella* tests performed.

There was 1 regulation that had more than 30 verifications in a year in total, an odds 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 CY2021.

Table 4-12 Comparison of Noncompliance Rates 90 Days before a RTE *Salmonella* Positive with Those for Establishments with No RTE *Salmonella*

Regulation Verified	Description	On FY 2022 PHR List	Noncompliance Rate 90 Days before a RTE <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no RTE <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	66.67%	3.24%	59.67	3.09E-03

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 PHR noncompliance rates for the 1,425 establishments with *E. coli* O157:H7 testing data, of which 16 establishments had 16 *E. coli* O157:H7 positives and 1,409 establishments did not have *E. coli* O157:H7 positives. There were 17,659 total *E. coli* O157:H7 tests performed.

Table 4-13 presents the 8 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

Table 4-13 Comparison of Noncompliance Rates 90 Days before an *E. coli* O157:H7 Positive with Those for Establishments with no *E. coli* O157:H7 Positive

Regulation Verified	Description ¹	On FY 2022 PHR 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 Positive	Odds Ratio	Two-Sided Fisher Exact p Value
310.22(c)	Disposal of SRM	Yes	2.75%	0.70%	4.00	4.29E-02
416.13(a)	Conduct pre-op procedures	Yes	4.42%	1.46%	3.12	1.76E-05
416.2(a)	Grounds and pest control	No	18.87%	3.04%	7.43	4.05E-06
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	17.31%	3.60%	5.60	9.36E-05
416.2(b)(4)	Inedible from edible separated by time or space	No	9.09%	0.25%	39.94	2.75E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	50.00%	0.79%	126.35	9.96E-06
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	18.58%	3.40%	6.49	2.64E-10
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	31.88%	5.17%	8.59	2.88E-12

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 Shiga toxin-producing *E. coli* (STEC) positives in MT60 (beef or veal trim). FSIS has declared there are 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 PHR noncompliance rates for the 534 establishments with Non-O157 STEC testing data, of which 20 establishments had 23 Non-O157 STEC positives and 514 establishments did not have Non-O157 STEC positives. There were 3,861 total Non-O157 STEC tests performed.

Table 4-14 presents the 5 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

Table 4-14 Comparison of Noncompliance Rates 90 Days before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a Non-O157 STEC Positive	Noncompliance Rate for Establishments with no Non-O157 STEC Positive	Odds Ratio	Two-Sided Fisher Exact p Value
310.22(c)	Disposal of SRM	Yes	4.09%	0.76%	5.53	1.19E-05
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	19.18%	3.53%	6.48	3.63E-07
310.22(e)(2)	Appropriate corrective actions	Yes	30.00%	5.85%	6.90	2.04E-02
417.2(c)(4)	List of procedures & frequency	Yes	1.88%	0.57%	3.33	2.59E-08
417.3(a)(3)	Establish measures to prevent recurrence	Yes	80.00%	16.65%	20.02	3.49E-03

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 PHR noncompliance rates for the 2,257 establishments with *Lm* testing data, of which 37 establishments had 40 *Lm* positives and 2,220 establishments did not have *Lm* positives. There were 15,134 total *Lm* tests performed.

Table 4-15 presents the 11 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Lm</i> Positive	Noncompliance Rate for Establishments with no <i>Lm</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	33.33%	1.54%	32.00	4.85E-02
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	11.20%	3.66%	3.32	1.35E-07

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Lm</i> Positive	Noncompliance Rate for Establishments with no <i>Lm</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.17%	0.52%	6.28	4.34E-02
417.2(c)	Contents of HACCP plan	Yes	10.00%	0.32%	34.69	3.22E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	75.00%	3.71%	77.89	2.19E-04
417.5(a)(2)	Written HACCP plan	Yes	0.39%	0.09%	4.48	1.23E-03
417.5(a)(3)	Records documentation and monitoring of CCP's and critical limits	Yes	0.80%	0.21%	3.91	7.30E-06
430.4(a)	Lm, post-lethality exposed RTE	Yes	0.45%	0.02%	18.53	8.87E-05
430.4(b)(3)	Alternative 3	No	4.23%	1.00%	4.35	3.58E-02
430.4(c)(5)	Lm, evaluate control measures in Sanitation SOP	No	8.33%	0.11%	80.85	1.60E-02
430.4(c)(6)	Lm, prerequisite program requirements	Yes	50.00%	0.67%	148.68	1.37E-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 PHR noncompliance rates for the 613 establishments with *Campylobacter* testing data, of which 465 establishments had 4,278 *Campylobacter* positives and 148 establishments did not have *Campylobacter* positives. There were 29,124 total *Campylobacter* tests performed.

Table 4-16 presents the 19 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	9.26%	0.75%	13.47	7.33E-04
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	1.79%	0.33%	5.53	4.46E-08
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	0.68%	0.17%	4.11	6.08E-04
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	12.27%	3.62%	3.72	9.05E-04
416.13(b)	Conduct other procedures listed in the plan	Yes	1.17%	0.29%	4.04	1.63E-103
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.82%	0.18%	4.70	2.47E-68
416.15(b)	Corrective action, procedures for	Yes	14.24%	2.22%	7.31	1.35E-36
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.38%	0.07%	5.19	4.38E-63
416.2(a)	Grounds and pest control	No	23.67%	4.01%	7.43	1.65E-232
416.2(b)(1)	Sound construction, good repair & sufficient size	No	27.12%	5.19%	6.80	5.12E-213
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	24.59%	4.43%	7.03	1.35E-274
416.2(b)(4)	Inedible from edible separated by time or space	No	4.32%	0.81%	5.53	2.76E-26
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.75%	0.45%	10.96	6.91E-27
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	10.98%	1.55%	7.85	3.31E-54

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	23.49%	2.21%	13.61	1.82E-10
417.2(c)(4)	List of procedures & frequency	Yes	1.13%	0.18%	6.30	1.41E-107
417.3(a)(3)	Establish measures to prevent recurrence	Yes	3.82%	1.08%	3.64	4.93E-02
417.6	Inadequate HACCP systems	No	84.00%	18.75%	22.75	9.51E-07
430.4(b)(3)	Alternative 3	No	4.28%	1.30%	3.39	2.76E-02

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 PHR noncompliance rates for the 210 establishments with Intact Chicken *Campylobacter* testing data, of which 202 establishments had 1,819 *Campylobacter* positives and 8 establishments did not have *Campylobacter* positives. There were 9,618 total Intact Chicken *Campylobacter* tests performed.

Table 4-17 presents the 6 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	0.61%	0.14%	4.34	3.11E-04
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	7.79%	2.49%	3.30	5.78E-48

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.2(a)	Grounds and pest control	No	27.83%	8.13%	4.36	3.28E-14
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	25.87%	9.44%	3.35	1.05E-14
417.2(c)(4)	List of procedures & frequency	Yes	1.37%	0.38%	3.68	7.99E-06
417.5(a)(1)	Written hazard analysis	Yes	0.42%	0.09%	4.83	8.05E-03

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 PHR noncompliance rates for the 43 establishments with Intact Turkey *Campylobacter* testing data, of which 10 establishments had 17 *Campylobacter* positives and 33 establishments did not have *Campylobacter* positives. There were 1,693 total Intact Turkey *Campylobacter* tests performed.

Table 4-18 presents the 2 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
417.2(c)(4)	List of procedures & frequency	Yes	3.28%	0.50%	6.72	2.81E-22
417.3(c)	Document corrective actions	Yes	27.27%	2.91%	12.53	5.37E-03

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 PHR noncompliance rates for the 95 establishments with Ground Chicken *Campylobacter* testing data, of which 50 establishments had 204 *Campylobacter* positives and 45 establishments did not have *Campylobacter* positives. There were 2,097 total Ground Chicken *Campylobacter* tests performed.

Table 4-19 presents the 2 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

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

Regulation Verified	Description ¹	On FY2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	0.61%	0.06%	10.61	7.71E-06
417.3(b)(4)	Reassessment	Yes	8.93%	1.49%	6.47	1.12E-03

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 PHR noncompliance rates for the 52 establishments with Ground Turkey *Campylobacter* testing data, of which 18 establishments had 52 *Campylobacter* positives and 34 establishments did not have *Campylobacter* positives. There were 1,457 total Ground Turkey *Campylobacter* tests performed.

Table 4-20 presents the 4 regulations that had more than 30 verifications in a year in total, an odds 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 CY2021.

Table 4-20 Comparison of Noncompliance Rates 90 Days before a Ground Turkey *Campylobacter* Positive with those for Establishments with No Ground Turkey *Campylobacter* Positive

Regulation Verified	Description ¹	On FY2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.13(a)	Conduct pre-op procedures	Yes	13.97%	5.05%	3.05	1.14E-33
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.17%	0.19%	6.22	4.75E-15
417.3(a)(2)	CCP is under control	Yes	4.61%	1.10%	4.34	6.93E-07
417.3(a)(3)	Establish measures to prevent recurrence	Yes	37.72%	11.43%	4.69	1.41E-05

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 PHR noncompliance rates for the 490 establishments with Chicken Parts *Campylobacter* testing data, of which 390 establishments had 2,186 *Campylobacter* positives and 100 establishments did not have *Campylobacter* positives. There were 14,259 total Chicken Parts *Campylobacter* tests performed.

Table 4-21 presents the 15 regulations which had more than 30 verifications in a year, an odds 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 CY2021.

Table 4-21 Comparison of Noncompliance Rates 90 Days before a Chicken Parts *Campylobacter* Positive with Those for Establishments with No Chicken Parts *Campylobacter* Positive

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	1.66%	0.54%	3.09	1.79E-20
416.13(b)	Conduct other procedures listed in the plan	Yes	1.11%	0.09%	12.83	2.56E-116
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.79%	0.26%	3.10	1.76E-30

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.15(b)	Corrective action, procedures for	Yes	14.24%	3.87%	4.13	2.86E-13
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.36%	0.09%	4.04	1.88E-32
416.2(a)	Grounds and pest control	No	21.43%	4.55%	5.72	9.94E-105
416.2(b)(1)	Sound construction, good repair & sufficient size	No	23.91%	6.18%	4.77	9.42E-82
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	22.96%	6.08%	4.60	1.21E-104
416.2(b)(4)	Inedible from edible separated by time or space	No	3.75%	0.56%	6.93	1.86E-14
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.00%	0.73%	5.65	7.57E-11
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	9.38%	1.31%	7.77	4.99E-28
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	21.11%	7.18%	3.46	5.50E-119
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	22.60%	8.14%	3.30	2.11E-98
417.2(c)(4)	List of procedures & frequency	Yes	0.95%	0.27%	3.51	2.24E-38
417.3(b)(4)	Reassessment	Yes	2.69%	0.78%	3.52	2.61E-03

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 (SPS) violation.

The enforcement action list of regulations is selected from the same list of candidate regulations used to select all other FY2023 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 CY2021. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,681 active meat and poultry establishments, of which 70 establishments had 80 enforcement actions and 5,611 establishments did not have any enforcement actions.

Table 4-22 presents the 48 regulations that had more than 30 verifications in a year, an odds 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 CY2021.

Table 4-22 Comparison of Noncompliance Rates 90 Days before an Enforcement Action with Those for Establishments with No Enforcement Action

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
301.2_Adulterated	Adulterated	Yes	36.36%	3.77%	14.59	5.66E-04
309.19(d)	Records of animals disposed of per day	No	14.29%	0.03%	590.50	3.94E-03
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	2.38%	0.07%	32.67	2.14E-03
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	33.33%	0.75%	66.53	2.34E-02
310.22(c)	Disposal of SRM	Yes	2.15%	0.70%	3.13	4.32E-02
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	23.53%	2.83%	10.55	4.42E-06

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two- Sided Fisher Exact p Value
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	20.00%	0.70%	35.56	4.27E-02
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	20.00%	0.50%	49.28	2.74E-02
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	0.34%	0.01%	24.04	4.39E-02
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	33.33%	0.53%	93.45	1.64E-02
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	5.28%	0.53%	10.41	9.37E-28
381.65(h)	Recordkeeping requirements	No	2.98%	0.08%	36.16	7.66E-07
381.76(a)	Post-mortem inspection, when required, extent	No	6.67%	2.18%	3.21	4.32E-02
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	0.35%	0.06%	5.79	1.75E-02
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	56.82%	3.45%	36.83	1.48E-24
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	9.50%	1.38%	7.49	2.00E-10

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.26%	0.75%	3.05	3.59E-08
416.12(c)	Plan identifies procedures for pre-op	No	3.80%	0.12%	33.58	1.38E-04
416.13(a)	Conduct pre-op procedures	Yes	9.43%	2.07%	4.93	1.15E-65
416.13(b)	Conduct other procedures listed in the plan	Yes	0.89%	0.25%	3.58	1.43E-12
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.13%	1.35%	3.94	7.23E-104
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.61%	0.20%	3.04	8.27E-07
416.15(a)	Appropriate corrective actions	Yes	16.67%	1.75%	11.23	1.64E-16
416.15(b)	Corrective action, procedures for	Yes	19.51%	3.07%	7.65	6.94E-13
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.77%	0.13%	5.91	2.34E-26
416.2(a)	Grounds and pest control	No	19.93%	3.98%	6.00	7.83E-47
416.2(b)(1)	Sound construction, good repair & sufficient size	No	20.71%	4.77%	5.22	9.17E-31
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	21.06%	4.65%	5.47	2.93E-43
416.2(b)(4)	Inedible from edible separated by time or space	No	3.33%	0.47%	7.25	2.47E-05
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	9.52%	0.66%	15.91	7.44E-11

Regulation Verified	Description¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.26%	1.43%	3.84	1.69E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	13.24%	4.59%	3.17	2.55E-26
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	17.76%	6.21%	3.26	1.38E-32
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	50.00%	4.25%	22.52	1.05E-02
417.2(a)(1)	Hazard analysis	Yes	4.72%	1.04%	4.70	1.98E-05
417.2(c)(4)	List of procedures & frequency	Yes	1.14%	0.36%	3.21	2.95E-12
417.3(a)(2)	CCP is under control	Yes	3.06%	0.54%	5.82	6.11E-06
417.3(a)(4)	No adulterated product enters commerce.	Yes	15.22%	0.62%	28.64	1.91E-08
417.3(b)(4)	Reassessment	Yes	2.42%	0.57%	4.35	3.51E-02
417.3(c)	Document corrective actions	Yes	25.00%	4.80%	6.61	2.27E-03
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	62.50%	3.30%	48.82	2.18E-06
417.5(a)(1)	Written hazard analysis	Yes	1.63%	0.24%	6.87	6.86E-37
417.5(a)(2)	Written HACCP plan	Yes	0.40%	0.09%	4.65	8.32E-07

Regulation Verified	Description ¹	On FY 2022 PHR List	Noncompliance Rate 90 Days before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	1.17%	0.22%	5.45	2.19E-20
418.3	Recall plans	Yes	3.13%	0.21%	15.06	9.01E-03
430.4(a)	Lm, post-lethality exposed RTE	Yes	0.22%	0.03%	8.04	2.72E-02
430.4(b)(2)	Alternative 2	Yes	10.81%	0.41%	29.22	2.03E-05
430.4(b)(3)	Alternative 3	No	11.54%	0.99%	13.08	2.18E-03

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

5.0 LIST OF FY2023 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2023 PHR list. Table 5-1 presents the complete list of the 71 FY2023 PHRs. These 71 PHRs were selected since they were verified more than 30 times in a year, had an odds 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 FY2023 PHRs

Regulation Verified	Description ¹	On FY 2022 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
301.2_Adulterated	Adulterated	Yes	24.01	3.53E-04
309.19(d)	Records of animals disposed of per day	No	590.50	3.94E-03
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.62	6.15E-42
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	6.85	1.40E-02
310.18(c)(2)(i)	Sampling frequency	No	22.36	1.72E-04
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	32.67	2.14E-03
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	66.53	2.34E-02
310.22(c)	Disposal of SRM	Yes	19.86	1.46E-02
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	5.77	8.85E-06
310.22(e)(2)	Appropriate corrective actions	Yes	5.10	1.04E-02

Regulation Verified	Description¹	On FY 2022 PHR List	Average Odds 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	67.40	3.02E-09
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	35.56	4.27E-02
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	49.28	2.74E-02
310.26(b)	Carcass sorting and disposition	No	17.86	7.05E-06
310.3	Carcasses and parts in certain instances to be retained.	Yes	4.44	4.04E-04
311.14	Abrasions, bruises, abscesses, pus, etc.	No	21.05	3.44E-03
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	13.75	3.74E-02
318.2(a)	All products subject to reinspection by program employees	Yes	12.74	3.97E-03
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	53.46	8.54E-03
381.1_Adulterated	Adulterated	No	11.63	4.29E-03
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	5.53	4.46E-08
381.65(f)	Procedures for controlling visible fecal contamination	Yes	6.13	1.07E-03
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	7.19	1.04E-04
381.65(h)	Recordkeeping requirements	No	36.16	7.66E-07
381.71(a)	Condemnation on ante mortem inspection	No	19.12	2.13E-02
381.76(a)	Post-mortem inspection, when required, extent	No	23.91	2.16E-02
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	15.57	1.64E-02
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	5.79	1.75E-02
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	16.31	3.02E-04
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	25.79	5.77E-04
416.1	Operate in a manner to prevent insanitary conditions	Yes	4.23	1.20E-08
416.12(c)	Plan identifies procedures for pre-op	No	18.49	2.62E-04
416.13(a)	Conduct pre-op procedures	Yes	4.24	2.93E-06
416.13(b)	Conduct other procedures listed in the plan	Yes	5.47	2.86E-13
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.53	9.64E-49

Regulation Verified	Description¹	On FY 2022 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	9.59	9.19E-08
416.15(a)	Appropriate corrective actions	Yes	11.23	1.64E-16
416.15(b)	Corrective action, procedures for	Yes	5.06	1.29E-05
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	4.79	2.09E-07
416.2(a)	Grounds and pest control	No	5.87	5.48E-07
416.2(b)(1)	Sound construction, good repair & sufficient size	No	6.09	3.89E-03
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized	No	6.31	1.32E-05
416.2(b)(4)	Inedible from edible separated by time or space	No	11.48	3.73E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	54.00	6.53E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	22.81	1.80E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	12.25	4.41E-04
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	4.81	5.76E-13
416.6	Only FSIS program employee may remove ""U.S. Rejected"" tag	Yes	16.47	2.84E-03
417.2(a)(1)	Hazard analysis	Yes	4.70	1.98E-05
417.2(c)	Contents of HACCP Plan	Yes	34.69	3.22E-02
417.2(c)(4)	List of procedures & frequency	Yes	5.67	8.01E-07
417.3(a)(1)	Identify and eliminate the cause	Yes	7.72	1.40E-02
417.3(a)(2)	CCP is under control	Yes	15.53	2.08E-04
417.3(a)(3)	Establish measures to prevent recurrence	Yes	12.92	8.82E-03
417.3(a)(4)	No adulterated product enters commerce.	Yes	17.07	1.09E-02
417.3(b)(1)	Segregate and hold the affected product	Yes	4.71	5.98E-03
417.3(b)(3)	No adulterated product enters commerce	Yes	10.03	5.43E-03
417.3(b)(4)	Reassessment	Yes	7.03	8.01E-03
417.3(c)	Document corrective actions	Yes	7.72	1.34E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	73.78	7.37E-05
417.5(a)(1)	Written hazard analysis	Yes	5.80	2.23E-03
417.5(a)(2)	Written HACCP plan	Yes	4.05	2.07E-03
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	4.68	3.65E-06
417.6	Inadequate HACCP systems	No	13.36	1.74E-04
418.2	Notification of adulterated or misbranded product in commerce	Yes	59.72	6.02E-10
418.3	Recall Plans	Yes	15.06	9.01E-03
430.4(a)	Lm, post-lethality exposed RTE	Yes	13.28	1.37E-02

Regulation Verified	Description ¹	On FY 2022 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
430.4(b)(2)	Alternative 2	Yes	17.92	5.55E-04
430.4(b)(3)	Alternative 3	No	6.94	2.19E-02
430.4(c)(5)	Lm, evaluate control measures in Sanitation SOP	No	52.83	8.88E-03
430.4(c)(6)	Lm, prerequisite program requirements	Yes	79.77	7.90E-03

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

In FY2022 there were 62 PHRs, 52 of which are FY2023 PHRs. There are 10 regulations on the FY2022 PHR list that are not on the FY2023 PHR list (See Appendix C). There are 19 regulations that are on the FY2023 PHR list that were not on the FY2022 PHR list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2023 PHR list. Most regulations were triggered by multiple events. Similar to the FY2022 PHR list, *Salmonella* pathogen positives and enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2023 PHR List

Product	Number of Regulations
<i>Campylobacter</i>	19
<i>Campylobacter</i> Chicken Parts	15
<i>Campylobacter</i> Ground Chicken	2
<i>Campylobacter</i> Ground Turkey	4
<i>Campylobacter</i> Intact Chicken	6
<i>Campylobacter</i> Intact Turkey	2
Enforcements	48
<i>Lm</i>	11
NonO157 <i>E. coli</i>	5
O157 <i>E. coli</i>	8
<i>Salmonella</i>	32
<i>Salmonella</i> Chicken Parts	6
<i>Salmonella</i> Ground Beef	11
<i>Salmonella</i> Ground Chicken	7
<i>Salmonella</i> Ground Pork	10
<i>Salmonella</i> Ground Turkey	10
<i>Salmonella</i> Intact Beef	26
<i>Salmonella</i> Intact Chicken	3
<i>Salmonella</i> Intact Pork	12
<i>Salmonella</i> Intact Turkey	6
<i>Salmonella</i> RTE	1
<i>Salmonella</i> Siluriformes	3

There were 18 regulations triggered by a single type of event: 11 were from Enforcement Actions, 2 were from *Salmonella*, 1 was from *Salmonella* in Intact Beef, 1 was from *Salmonella* Ground Pork, 1 was from *Salmonella* in Intact Pork, 1 was from *Campylobacter*, and 1 was from *Lm*. Table 5-3 presents the regulations triggered for inclusion in the FY2023 PHR list by only single pathogen product or enforcement action type (event).

Table 5-3 Regulations Triggered for Inclusion in the FY2023 PHR List by Only a Single Event

Regulation Verified	Description ¹	Event
309.19(d)	Records of animals disposed of per day	Enforcements
310.18(c)(2)(i)	Sampling frequency	<i>Salmonella</i>
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Enforcements
310.22(b)	Inedible and prohibited SRM for use as human food	Enforcements
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	Enforcements
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	Enforcements
310.26(b)	Carcass sorting and disposition	<i>Salmonella</i>
318.2(a)	All products subject to reinspection by program employees	<i>Salmonella</i> Intact Pork
381.65(a)	Clean and sanitary practices; products not adulterated	<i>Campylobacter</i>
381.65(h)	Recordkeeping requirements	Enforcements
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Enforcements
416.15(a)	Appropriate corrective actions	Enforcements
417.2(a)(1)	Hazard analysis	Enforcements
417.2(c)	Contents of HACCP Plan	<i>Lm</i>
417.3(b)(3)	No adulterated product enters commerce	<i>Salmonella</i> Ground Pork
418.2	Notification of adulterated or misbranded product in commerce	<i>Salmonella</i> Intact Beef
418.3	Recall plans	Enforcements

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

6.0 CUT POINTS FOR FY2023 PHRS

The FY2023 PHRs are one of seven public health-based decision criteria that are used in prioritizing Public Health Risk Evaluations (PHREs). These seven decision criteria are described in detail in FSIS' Public Health Decision Criteria Report (FSIS 2010). 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 FY2023 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 rate is calculated as the number of times PHR regulations are cited as non-compliant divided by the number of times the PHR regulations are verified. This combines the verifications for all the PHR regulations in a

90-day period together into a single aggregate ratio. The aggregate FY2023 PHR noncompliance rate by establishments is compared to cut points that have been set for two broad categories of establishment operations: Processing and Combination (Slaughter plus Processing). Only establishments with greater than or equal to 20 verifications and at least 2 noncompliances were considered when developing cut points.

The aggregate non-zero PHR 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 FY2023 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 PHR noncompliance rates).

Table 6-1 Mean and Standard Deviation of Quarterly FY2023 PHR Rate

CY2021	Mean of Natural Log PHR Rate		Standard Deviation PHR Rate	
	Processing	Combination	Processing	Combination
Jan-Mar	-4.92	-4.58	0.79	0.96
Apr-Jun	-4.93	-4.54	0.78	1.01
Jul-Sept	-4.87	-4.49	0.82	0.97
Oct-Dec	-4.91	-4.57	0.80	0.97
Average	-4.91	-4.55	0.80	0.98

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 that have PHR 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 $-4.54511 + 2 \times 0.97638 = -4.54511 + 1.95276 = -2.59235$. The cut point of the original, non-transformed PHR noncompliance data is the antilog of -2.59235 or $\text{Exp}(-2.59235) = 7.48\%$. Establishments that are below the Upper-level threshold but meet or exceed the Lower-level threshold will be notified by inspection personnel of an elevated level of noncompliance.

The PHR cut points are defined as follows for each of the two establishment types: (1) Processing and (2) Slaughter/Processing Combination:

- Any establishment with a PHR rate that is less than the lower cut point for all establishments with the same establishment type would continue to receive routine inspection procedures. These establishments are performing better on average than their peers with respect to compliance with the PHR regulations.
- Establishments with a PHR rate that is 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 inspection personnel of elevated PHR noncompliance levels.

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

Tables 6-2 and 6-3 present the FY2023 PHR upper and lower cut points for each of the two establishment operation types. The FY2022 and FY2021 PHR cut points are included for comparison. (See Appendix D for more details). The cut points are determined once a year. The next update to the cut points is planned for October 2023.

Table 6-2 FY2023 PHR Upper-Level Cut Points

Operation Type	FY2023 PHR Cut Points	FY2022 PHR Cut Points	FY2021 PHR Cut Points
Processing	3.65%	3.63%	3.73%
Combination	7.48%	7.33%	9.84%

Table 6-3 FY2023 PHR Lower-Level Cut Points

Operation Type	FY2023 PHR Cut Points	FY2022 PHR Cut Points	FY2021 PHR Cut Points
Processing	2.45%	2.44%	2.50%
Combination	4.59%	4.60%	5.85%

Table 6-4 presents the number of establishments in each level based solely on the FY2023 PHR criterion and the cut points in Table 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. Seventy-nine establishments are in the Upper level and candidates to receive a recommendation for a for cause PHRE. Table 6-4 is based on regulatory noncompliances for the period January 1-March 31, 2022.

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

Classification	Processing	Combination	Total
Upper	65	14	79
Mid	69	22	91
Lower	4,143	1,087	5,230
Total	4,277	1,123	5,400

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2023 PHR regulations used to prioritize certain FY2023 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 and (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 COVID pandemic occurred during this period but no significant impacts were observed.

The list of FY2023 PHRs has 71 regulations whose individual noncompliance rates are higher in establishments 90 days before *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positives or enforcement action than in establishments without positives or enforcement actions. Fifty-two regulations on the FY2022 PHR list are also on the FY2023 PHR list.

Establishments that have PHR noncompliance rates higher than the antilog of the mean plus two standard deviations of the log transformed distribution of the non-zero PHR rates for similar establishments are recommended to receive a PHRE. Upon completion of a PHRE, the 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](#).

Table 7-1 presents the FY2023 PHR upper and lower cut points.

Table 7-1 FY2023 PHR Cut Points

Operation Type	Upper	Lower
Processing	3.65%	2.45%
Combination	7.48%	4.59%

8.0 REFERENCES

1. Food Safety and Inspection Service (FSIS) 2010, “Data-Driven Inspection for Processing and Slaughter Establishments, Public Health Decision Criteria.”
2. Food Safety and Inspection Service (FSIS) 2013, “FSIS Data Analysis and Reporting: Public Health Regulations.”
3. Food Safety and Inspection Service (FSIS) 2021, “[FY2022 Public Health Regulations.](#)”
4. National Advisory Committee on Meat and Poultry Inspection (NACMPI) 2013, “Subcommittee Two, Issue Two: Data Analysis.”

APPENDIX A: FY2023 PHR REGULATIONS

Table A-1 presents the list of 71 FY2023 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates 90 days prior to a pathogen positive or enforcement action that is 7.37 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2023 PHRs

Regulation	Description ¹
301.2_Adulterated	Adulterated
309.19(d)	Records of animals disposed of per day
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)(i)	Sampling frequency
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(c)	Disposal of SRM
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
310.22(e)(2)	Appropriate corrective actions
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
310.22(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
310.26(b)	Carcass sorting and disposition
310.3	Carcasses and parts in certain instances to be retained.
311.14	Abrasions, bruises, abscesses, pus, etc.
318.1(b)	Only inspected and passed poultry product to enter official establishment
318.2(a)	All products subject to reinspection by program employees
318.2(d)	Removal of U.S. retained by authorized Program employees only
381.1_Adulterated	Adulterated
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

Regulation	Description¹
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)	Corrective action, procedures for
416.16(a)	Daily records required, responsible individual, initialed and dated
416.2(a)	Grounds and pest control
416.2(b)(1)	Sound construction, good repair & sufficient size
416.2(b)(2)	Walls/floors/ceilings durable, impervious, cleaned & sanitized
416.2(b)(4)	Inedible from edible separated by time or space
416.3(b)	Constructed, located & operated in a manner that does not deter inspection
416.3(c)	Receptacles for storing inedible material must identify permitted use
416.4(a)	Food contact surface, cleaning & sanitizing as frequency
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
416.6	Only FSIS program employee may remove ""U.S. Rejected"" tag
417.2(a)(1)	Hazard analysis
417.2(c)	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)(1)	Segregate and hold the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions
417.4(a)	Adequacy of HACCP in controlling food safety hazards
417.5(a)(1)	Written hazard analysis
417.5(a)(2)	Written HACCP plan
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
417.6	Inadequate HACCP systems
418.2	Notification of adulterated or misbranded product in commerce
418.3	Recall Plans

Regulation	Description¹
430.4(a)	<i>Lm</i> , post-lethality exposed RTE
430.4(b)(2)	Alternative 2
430.4(b)(3)	Alternative 3
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements

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

APPENDIX B: FY2023 CANDIDATE REGULATIONS

Table B-1 presents the list of candidate regulations. Of the 159 candidate regulations, 2 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 PHIS data for January 1, 2021, through December 31, 2021.

Table B-1 FY2023 List of Candidate Regulations

Regulation ¹	Description ²	FY 2022 PHR	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
301.2_Adulterated	Adulterated	Yes	No	4,746	185	3.90%
304.3(a)	Develop written SSOP	No	No	416	0	0.00%
304.3(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	188	2	1.06%
309.19(a)	Market hog sorting activities	No	No	1,605	2	0.12%
309.19(c)	Sorted and removed hogs identified; written procedures	No	No	1,268	1	0.08%
309.19(d)	Records of animals disposed of per day	No	No	4,090	2	0.05%
309.19(e)	Notifiable animal disease	No	No	104	0	0.00%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	222	5	2.25%
309.3	(Modernized ONLY) Dead, dying, disabled or diseased and similar livestock.	No	No	225	0	0.00%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
309.3(e)	Establishment notify IPP of non-ambulatory livestock; Prompt condemnation and disposal	No	No	88	1	1.14%
309.4	(Modernized ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases	No	No	153	1	0.65%
309.5	(Modernized ONLY) Swine; disposal because of hog cholera	No	No	137	0	0.00%
309.9	(Modernized ONLY) Swine erysipelas	No	No	140	0	0.00%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	357,444	4,681	1.31%
310.18(b)	Brains, cheek meat, head trimmings from animals slaughtered by gunshot	No	No	20,998	5	0.02%
310.18(c)	Written procedures to prevent contamination; all swine slaughter	Yes	No	10,059	26	0.26%
310.18(c)(1)	Sampling locations	No	No	1,506	0	0.00%
310.18(c)(1)(i)	Very low volume establishments	No	No	2,930	1	0.03%
310.18(c)(2)(i)	Sampling frequency	No	No	2,506	3	0.12%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
310.18(c)(2)(ii)	Sampling frequency for very low volume establishments	No	No	1,626	2	0.12%
310.18(c)(2)(iii)	Records of test results for sampling program	No	No	19,592	7	0.04%
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	Yes	No	33,998	35	0.10%
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	No	2,850	20	0.70%
310.22(c)	Disposal of SRM	Yes	Yes	52,618	269	0.51%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar US products	No	No	56	0	0.00%
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	11,834	258	2.18%
310.22(e)(2)	Appropriate corrective actions	Yes	No	1,683	69	4.10%
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	8,044	120	1.49%

Regulation ¹	Description ²	FY 2022 PHR	Mandatory Regulation ³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
310.22(e)(4)(i)	Maintain daily records	No	No	70,002	138	0.20%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	No	14,552	29	0.20%
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federally inspected establishment	No	No	809	7	0.87%
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	No	3,224	18	0.56%
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	Yes	No	28,164	289	1.03%
310.25(b)	Pathogen reduction performance standards; <i>Salmonella</i>	No	No	175	0	0.00%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	37	0	0.00%
310.26(b)	Carcass sorting and disposition	No	Yes	3,909	42	1.07%
310.26(d)(2)	Document number of carcasses disposed of per day	No	No	2,499	2	0.08%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
310.3	Carcasses and parts in certain instances to be retained.	Yes	No	2,086	256	12.27%
311.14	Abrasions, bruises, abscesses, pus, etc.	No	No	26,568	11	0.04%
311.16	(Modernized ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.	No	No	355	22	6.20%
311.17	(Modernized ONLY) Necrobacillosis, pyemia, septicemia.	No	No	369	1	0.27%
311.24	(Modernized ONLY) Hogs affected with tapeworm cysts.	No	No	133	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	21	0	0.00%
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	Yes	No	12,442	46	0.37%
317.24(a)	Packaging materials composed of poisonous or deleterious substances	No	No	2,237	10	0.45%
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	No	105,500	16	0.02%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	282	2	0.71%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	646	0	0.00%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision	No	No	156	0	0.00%
318.16(b)	Pesticides, chemicals & other residues in products not to exceed FD&C Act levels - Meat ingredients	No	No	258	0	0.00%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	2,691	3	0.11%
318.17(b)	Lethality and Stabilization processes other than HACCP for cooked beef	No	No	558	1	0.18%
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	128	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	46,004	74	0.16%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	7,626	38	0.50%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully cooked meat patties	No	No	389	2	0.51%
318.23(b)(3)	Heat deviations for meat patties	No	No	82	2	2.44%
318.23(c)(1)	Stabilization requirements for meat patties	No	No	322	0	0.00%
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	9	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	286	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	96	0	0.00%
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2,350	17	0.72%
318.6(b)(1)	Requirements for use of casings, used as containers	No	No	1,916	1	0.05%
318.6(b)(4)	Detached spinal cords	No	No	9,482	0	0.00%
318.6(b)(6)	Tonsils	No	No	10,064	0	0.00%
318.6(b)(8)	Intestines as ingredients	No	No	224	0	0.00%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
319.5(b)	Mechanically separated (beef) - prohibited for use in human food	No	No	198	0	0.00%
354.242(b)	All equipment and utensils clean and sanitary	No	No	33	0	0.00%
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	9	0	0.00%
354.243(a)	No handling or storage of objectionable materials	No	No	1	0	0.00%
381.1_Adulterated	Adulterated	No	No	3,828	66	1.72%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	1,866	0	0.00%
381.150(a)	Lethality and stabilization requirements for cooked poultry	No	No	1,283	4	0.31%
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry	No	No	137	0	0.00%
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	78	1	1.28%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	203	0	0.00%
381.193(a)	Poultry not intended for human food in commerce	Yes	No	200	7	3.50%
381.22(a)	Develop written SSOP	No	No	196	2	1.02%
381.22(b)	Conduct hazard analysis & develop and validate HACCP plan	No	No	846	0	0.00%
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	206	0	0.00%
381.37(a)	Product not produced under supervision of program employee	No	No	1,436	8	0.56%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	30,105	205	0.68%
381.65(f)	Procedures for controlling visible fecal contamination	Yes	No	1,612,666	10,891	0.68%
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	No	111,278	620	0.56%
381.65(h)	Recordkeeping requirements	No	No	27,588	39	0.14%
381.71(a)	Condemnation on ante mortem inspection	No	No	1,210	14	1.16%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
381.72(a)	Poultry	No	No	414	1	0.24%
381.72(b)	Ratites	No	No	16	0	0.00%
381.76(a)	Post-mortem inspection, when required, extent	No	No	8,374	184	2.20%
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	No	55,592	350	0.63%
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	No	79,181	48	0.06%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	No	1,427,956	90	0.01%
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	No	4,423	336	7.60%
381.83	Septicemia or toxemia	No	No	1,308,067	78	0.01%
381.85	Special diseases (organisms or toxins dangerous to the consumer)	No	No	35	0	0.00%
381.91(a)	Certain contaminated carcasses to be condemned	No	No	4,593	4	0.09%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	No	11,000	164	1.49%
381.94(a)	Verification criteria for <i>E. coli</i> testing ratites	No	No	927	0	0.00%
416.1	Operate in a manner to prevent insanitary conditions	Yes	Yes	611,964	4,744	0.78%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
416.12(c)	Plan identifies procedures for pre-op	No	No	42,430	54	0.13%
416.12(d)	Plan list frequency for each procedure & responsible individual	Yes	No	59,149	64	0.11%
416.13(a)	Conduct pre-op procedures	Yes	Yes	762,803	14,414	1.89%
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	1,934,051	4,610	0.24%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2,746,830	34,868	1.27%
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	Yes	1,689,597	3,332	0.20%
416.15(a)	Appropriate corrective actions	Yes	Yes	64,383	854	1.33%
416.15(b)	Corrective action, procedures for	Yes	Yes	41,222	1,075	2.61%
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	Yes	2,957,432	4,277	0.14%
416.2(a)	Grounds and pest control	No	No	177,134	6,911	3.90%
416.2(b)(1)	Sound construction, good repair & sufficient size	No	No	141,974	6,728	4.74%
416.2(b)(2)	Walls/floors/ceiling durable, impervious, cleaned & sanitized	No	No	191,398	9,233	4.82%
416.2(b)(4)	Inedible from edible separated by time or space	No	No	107,602	478	0.44%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	No	79,641	490	0.62%
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	67,212	919	1.37%
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	No	274,603	12,063	4.39%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	259,797	14,949	5.75%
416.5(c)	Employees who appear to have any abnormal source of microbial contamination	Yes	No	35,536	10	0.03%
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2,938	118	4.02%
417.2(a)(1)	Hazard analysis	Yes	Yes	126,952	1,467	1.16%
417.2(c)	Contents of HACCP Plan	Yes	No	29,249	69	0.24%
417.2(c)(4)	List of procedures & frequency	Yes	Yes	1,322,781	4,431	0.33%
417.3(a)(1)	Identify and eliminate the cause	Yes	No	8,352	554	6.63%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
417.3(a)(2)	CCP is under control	Yes	No	123,379	636	0.52%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	No	6,137	672	10.95%
417.3(a)(4)	No adulterated product enters commerce.	Yes	No	24,914	160	0.64%
417.3(b)(1)	Segregate and hold the affected product	Yes	No	2,762	76	2.75%
417.3(b)(2)	Determine the acceptability of the affected product	Yes	No	2,308	58	2.51%
417.3(b)(3)	No adulterated product enters commerce	Yes	No	16,239	72	0.44%
417.3(b)(4)	Reassessment	Yes	Yes	27,836	204	0.73%
417.3(c)	Document corrective actions	Yes	No	4,394	227	5.17%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	6,909	233	3.37%
417.4(a)(1)	Initial validation	Yes	No	5,873	280	4.77%
417.4(b)	Reassessment of hazard analysis	No	Yes	30,129	63	0.21%
417.5(a)(1)	Written hazard analysis	Yes	Yes	1,414,192	3,521	0.25%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1,242,762	1,152	0.09%
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1,399,595	3,423	0.24%
417.5(f)	Official review	Yes	No	89,037	80	0.09%
417.6	Inadequate HACCP systems	No	No	529	162	30.62%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
418.2	Notification of adulterated or misbranded product in commerce	Yes	No	1,991	97	4.87%
418.3	Recall plans	Yes	No	23,419	57	0.24%
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	Yes	305,924	114	0.04%
430.4(b)(1)	Alternative 1	No	No	643	1	0.16%
430.4(b)(2)	Alternative 2	Yes	No	14,356	72	0.50%
430.4(b)(3)	Alternative 3	No	No	19,535	235	1.20%
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	No	Yes	298,380	161	0.05%
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	Yes	299,454	152	0.05%
430.4(c)(4)	<i>Lm</i> , validate and verify control measures in HACCP plan	No	No	3,541	9	0.25%
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	No	No	5,072	10	0.20%
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	Yes	No	4,800	44	0.92%
431.11	Personnel and training	No	No	41	1	2.44%
431.12	Recall procedure	No	No	61	0	0.00%
431.4	Critical factors and the application of the process schedule	No	Yes	10,178	8	0.08%
431.9(b)	Procedures for handling of process deviations	No	Yes	9,186	2	0.02%

Regulation¹	Description²	FY 2022 PHR	Mandatory Regulation³	Total Regulations Verified	Total Noncompliant Regulations Verified	PHR Noncompliance Rate
431.9(c)(1)	Process deviations identified in-process	No	No	107	1	0.93%
431.9(c)(2)	Process deviations identified through record review	No	No	60	1	1.67%
431.9(d)	Process deviation file	No	No	127	0	0.00%
537.1	Basic requirements	No	No	30,967	78	0.25%

¹Regulations 417.3(a) and 417.4(a)(3) are not included in this table as they had zero regulations verified in CY2021.

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 FY2022 PHR LIST WITH FY2023 PHR LIST

There are 11 regulations from the FY2022 PHR list that no longer appear in the FY2023 PHR list. These are shown in Table C-1.

Table C-1 Regulations on the FY2022 PHR List No Longer on the FY2023 PHR List

FY2022 PHRs	Description ¹
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
310.25(a)	Verification criteria for <i>E. coli</i> testing meat
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations
416.12(d)	Plan list frequency for each procedure & responsible individual
416.5(c)	Employees who appear to have any abnormal source of microbial contamination
417.3(b)(2)	Determine the acceptability of the affected product
417.4(a)(1)	Initial validation
417.5(f)	Official review
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment
381.193(a)	Poultry not intended for human food in commerce
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis

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

There are 19 regulations on the FY2023 PHR list that were not on the FY2022 PHR list.

Table C-2 Regulations on the FY2023 PHR List That Were Not on the FY2022 PHR List

FY2023 PHRs	Description ¹
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
381.1 Adulterated	Adulterated
381.71(a)	Condemnation on ante mortem inspection
416.12(c)	Plan identifies procedures for pre-op
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
417.6	Inadequate HACCP systems
430.4(b)(3)	Alternative 3
430.4(c)(5) *	<i>Lm</i> , evaluate control measures in Sanitation SOP
381.65(h) *	Recordkeeping requirements
381.76(a) *	Post-mortem inspection, when required, extent
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage
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.

*Indicates first time regulation qualified for PHR list.

APPENDIX D: METHODOLOGY AND CALCULATION OF PHR CUT POINTS

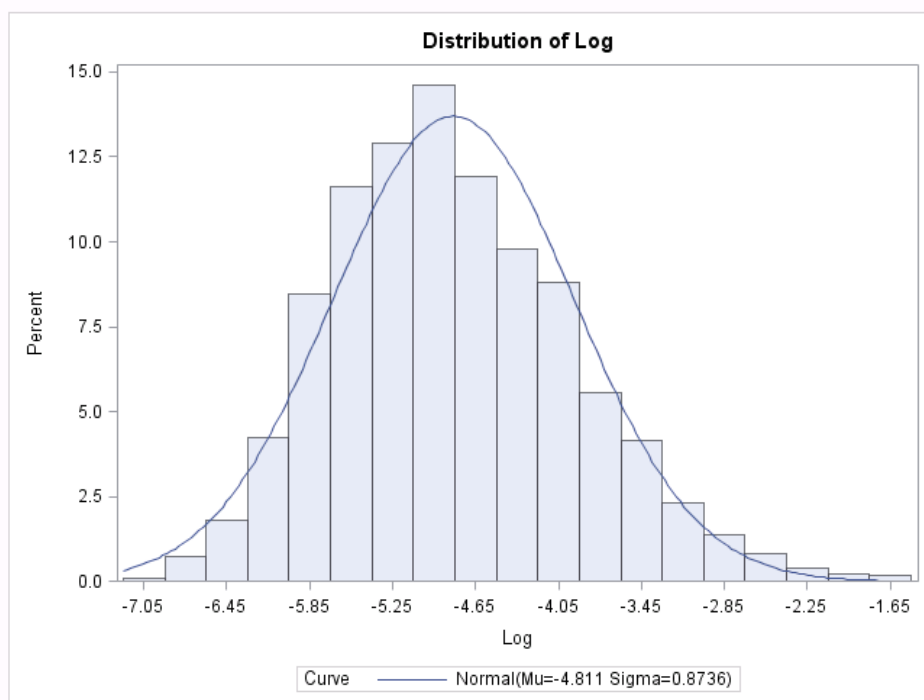
The purpose of this Appendix is to explain the methodology and calculations used to develop the PHR cut points. The PHR noncompliance rate is calculated by the following formula using the most recent 90 days of establishment verification inspection data:

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

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 PHR noncompliance rates are approximately log normally distributed. That means that the natural logarithm of the non-zero PHR noncompliance rates is approximately normally distributed. Figure D-1 presents a histogram for the log transformed non-zero PHR 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		<i>p</i> Value	
Kolmogorov-Smirnov	D	0.04305090	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.14108074	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	6.89254177	Pr > A-Sq	<0.005

The final list of log-transformed cut points is derived from the average of the mean and standard deviation of the log transformed non-zero PHR rate from four quarters of PHR data. (The antilog of these cut points is taken to obtain the cut points of the non-transformed PHR 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 PHR noncompliances) using the quarterly cut points.

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

Quarter/ Establishment Type	Number of Establishments	Mean	Standard Deviation	Level	Tier Distribution (Number of Establishments)
Q1CY2021					
				Upper	68
Combination	1,081	-4.57746	0.95572	Mid	112
Processing	4,240	-4.91922	0.78735	Lower	5,141
Q2CY2021					
				Upper	82
Combination	1,107	-4.53670	1.00994	Mid	98
Processing	4,273	-4.93214	0.78459	Lower	5,200
Q3CY2021					
				Upper	78
Combination	1,125	-4.49354	0.96693	Mid	106
Processing	4,279	-4.86778	0.82093	Lower	5,220
Q4CY2021					
				Upper	71
Combination	1,128	-4.57272	0.97291	Mid	112
Processing	4,334	-4.90955	0.79859	Lower	5,279

Table D-2 shows the average mean and standard deviation of the log transformed non-zero PHR rate over four quarters for each establishment type based on the quarterly data in Table D-1. Table D-3 shows the upper and lower cut points for FY2023 PHRs. Table D-4 show the distribution of establishments using data from January to March 2022 utilizing the proposed FY2023 PHRs.

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

Statistic	Combination	Processing
Mean	-4.54511	-4.90717
Standard Deviation	0.97638	0.79787

Table D-3 FY2023 PHR Upper and Lower Cut Points

Operation Type	Upper Cut Points	Lower Cut Points
Processing	3.65%	2.45%
Combination	7.48%	4.59%

Table D-4 March 2022 Level Distribution Based on the Previous Year's (FY2022) PHR 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	81
Mid	91
Lower	5,228
Total	5,400