

**U.S. Department of Agriculture/
Food Safety and Inspection Service
FY2022 Public Health Regulations**

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SUMMARY

Public Health Regulations (PHRs) are verified regulations¹ with statistically higher individual noncompliance rates in establishments in the 3 months prior to a microbiological positive or a public health-related enforcement action than in establishments with no positives or enforcement actions². This statistical association does not inherently imply that a particular regulation constitutes a more serious food safety concern but gives a statistical association to better align scheduling criteria and agency resources. PHRs are not the only important food safety and public health-related regulations; noncompliance with many other regulations are critical indicators of public health concern but may not be statistically associated with the outlined criteria. This report describes the data-driven approach used to select the PHRs that will be used for the period October 1, 2021, to September 30, 2022, (FY2022) to prioritize certain FY2022 FSIS inspection activities.

FSIS uses decision criteria to prioritize establishments for Public Health Risk Evaluations (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 PHR noncompliance rate threshold 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 levels are announced around July 1 each year with a targeted implementation month of October.

The updated list of FY2022 PHRs is based on January 1, 2020, to December 31, 2020, (CY2020) verification inspection results and will be implemented in FY2022. If an establishment is prioritized 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. For inclusion in the FY2022 PHR list, 9 CFR regulations from a curated list of candidate regulations were evaluated individually to determine whether noncompliance with each regulation occurred at a more frequent rate in establishments in the 3-month period 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 FY2022 PHRs consists of 62 regulations that have higher rates of noncompliance 3 months before a pathogen positive or enforcement action. This compares with 56 regulations that were identified in the October 1, 2020, to September 30, 2021, (FY2021) PHR list. The full list of FY2022 PHRs is listed in Appendix A. Forty-nine regulations from the FY2021 PHR list remain on the FY2022 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.

The 62 FY2022 PHRs comprise 9 regulations and 54 provisions of regulations. The 62 FY2022 PHRs represent 29 regulations, with the majority of FY2022 PHRs being provisions of regulations that provide greater specificity as to the nature of the noncompliance associated with a regulation violation. The provisions of regulations may be independent of the full regulations, that a single provision of a regulation can vary from year-to-year and if a regulation has provisions all provisions are not necessarily included.

The average noncompliance rate of FY2022 PHR regulations 3 months before a pathogen positive or enforcement action is 18.3 times higher than the average FY2022 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action. Noncompliance with a single FY2022 PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the 3-month rolling average noncompliance rate for all similar establishments. The aggregate FY2022 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 FY2022 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2022 PHR rates for each of the four quarters in CY2020 (the log transform of the non-zero FY2022 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 6 months. 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 non-compliance. Tables S-1 and S-2 present the Upper and Lower FY2022 PHR cut points for the non-transformed PHR noncompliance data for each of the two establishment operation types. The FY2021 PHR cut points are included for comparison. (See Section 6 and Appendix D for more details.)

Table S-1 FY2022 PHR Upper Cut Points

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

Table S-2 FY2022 PHR Lower Cut Points

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

Table S-3 presents the number of establishments in each level from January 1, 2021, to March 31, 2021, based on the PHR criterion. The period used for calculating the noncompliance rate of the PHRs was January 1, 2021, to March 31, 2021. The number of “for cause” PHREs for Upper 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	35	13	48
Mid	58	32	60
Lower	4,143	1,036	5,179
Total	4,236	1,081	5,137

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 prioritized 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 FY2022 PHRs (PHRs that will be used for the time period October 1, 2021, to September 30, 2022).

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 FY2022 PHR list is the same as that used for the FY2021 PHR list. For inclusion in the FY2022 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 3-month period before *Salmonella*, *E. coli* O157: H7, Non-O157 STEC, *Listeria monocytogenes* (*Lm*), *Campylobacter* positives or enforcement actions than in establishments without positives or enforcement actions³. The analysis was based on 1 year of FSIS verification inspection results recorded in PHIS from January 1 to December 31, 2020 (CY2020). Candidate regulations related to egg products are not included in this report.

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

³ 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.

establishments that need to be scheduled for an FSA or a PHRE. The final FY2022 PHR list is presented in Appendix A. Appendix B lists the candidate regulations evaluated to determine PHRs. Appendix C describes the differences between the FY2022 PHR list and FY2021 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 than in establishments in the 3-month period 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 3 months 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 3-month 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**

- Failure to maintain adequate HACCP Plan.
- Adequacy of 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.
- **Corrective Actions**
 - Procedures for and selection of appropriate corrective actions.
 - Document corrective actions.
 - Identify and eliminate the cause.
 - Establish measures to prevent recurrence.
 - Reassess hazard analysis.

In addition to these criteria, regulations relating to operation of establishments in a way that does not deter FSIS' ability to conduct verification inspections are also included. Inclusion of 9 CFR regulations in the list of candidate regulations errs on the side of inclusiveness.

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 3 months before the occurrence of a pathogen positive during FSIS sampling or enforcement action. The 3-month time period 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 3 months before a *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positive or enforcement actions than the average noncompliance rate in establishments that do not have a *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positive or 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 155 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 155 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, *Listeria monocytogenes*, *Campylobacter* positives during FSIS verification testing or enforcement actions. The noncompliance rate of each of the FY2022 155 candidate regulations in establishments 3 months 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 CY2020. 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 3 months 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 3 months 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 than 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 2,088 establishments with *Salmonella* testing data, of which 800 had 5,871 *Salmonella* positives and 1,288 did not have *Salmonella* positives. There were 63,304 total *Salmonella* tests performed.

Table 4-1 presents the 34 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 3 months prior to a *Salmonella* positive is higher than the average noncompliance rate for establishments with no *Salmonella* positive for CY2020.

Table 4-1 Comparison of Noncompliance Rates 3 Months before a *Salmonella* Positive with Those for Establishments with No *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	39.36%	2.38%	26.58	3.00E-150
310.18(c)	Written procedures to prevent contamination; all swine slaughter	No	1.51%	0.26%	5.87	4.00E-07
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	No	0.96%	0.05%	19.23	1.70E-15
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	2.49%	0.14%	17.93	7.00E-05
310.22(c)	Disposal of SRM	Yes	5.09%	0.29%	18.56	5.00E-129
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	6.61%	1.52%	4.59	7.40E-22
310.22(e)(2)	Appropriate corrective actions	Yes	1.23%	0.37%	3.30	4.65E-02
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	21.19%	1.07%	24.89	2.00E-122
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	1.00%	0.10%	10.03	1.50E-08

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	0.72%	0.16%	4.62	3.60E-04
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	0.93%	0.18%	5.28	6.60E-11
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	8.17%	1.71%	5.12	5.10E-05
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	1.52%	0.36%	4.25	1.87E-02
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.34%	0.66%	3.60	8.00E-301
416.13(a)	Conduct pre-op procedures	Yes	6.85%	1.20%	6.03	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.60%	0.14%	4.41	5.00E-302
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.56%	0.90%	5.28	0.00E+00
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.52%	0.16%	3.26	4.00E-168
416.15(a)	Appropriate corrective actions	Yes	4.42%	1.18%	3.89	4.80E-47
416.15(b)	Corrective action, procedures for	Yes	9.93%	3.47%	3.06	9.80E-49
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.18%	0.38%	3.15	5.10E-19
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	3.53%	0.89%	4.08	9.30E-66

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	16.12%	3.34%	5.56	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	17.42%	4.00%	5.06	0.00E+00
416.5(c)	Employees who appear to have any abnormal source of microbial contamination	No	0.10%	0.02%	6.82	4.44E-02
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	9.62%	2.89%	3.57	2.00E-07
417.2(c)(4)	List of procedures & frequency	Yes	0.90%	0.23%	3.87	0.00E+00
417.3(a)(1)	Identify and eliminate the cause	Yes	13.41%	2.61%	5.77	1.30E-56
417.3(a)(2)	CCP is under control	Yes	1.44%	0.33%	4.35	9.10E-60
417.3(a)(3)	Establish measures to prevent recurrence	Yes	20.91%	5.04%	4.98	1.20E-58
417.3(a)(4)	No adulterated product enters commerce.	No	1.09%	0.26%	4.23	2.20E-11
417.3(b)(3)	No adulterated product enters commerce	Yes	0.96%	0.30%	3.27	4.20E-05
417.5(a)(2)	Written HACCP plan	Yes	0.24%	0.07%	3.37	4.80E-77
418.2	Notification of adulterated or misbranded product in commerce	Yes	22.18%	3.27%	8.42	3.50E-16

4.1.1 *Salmonella* in Intact Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 206 establishments with Intact Chicken *Salmonella* testing data, of which 169 had 453 *Salmonella* positives and 37 did not have *Salmonella* positives. There were 9,723 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 16 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 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 3 months prior to an Intact Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Chicken *Salmonella* positive for CY2020.

Table 4-2 Comparison of Noncompliance Rates 3 Months before an Intact Chicken *Salmonella* Positive with Those for Establishments with No Intact Chicken *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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
318.2(a)	All products subject to reinspection by program employees	Yes	9.21%	0.71%	14.20	3.06E-03
381.193(a)	Poultry not intended for human food in commerce	No	24.14%	2.56%	12.09	1.40E-03
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	5.96%	1.56%	3.98	1.60E-06
416.15(b)	Corrective action, procedures for	Yes	19.06%	6.70%	3.28	1.39E-10
417.2(a)(1)	Hazard analysis	Yes	2.34%	0.36%	6.63	7.39E-08
417.2(c)(4)	List of procedures & frequency	Yes	1.74%	0.58%	3.06	1.37E-58
417.3(a)(1)	Identify and eliminate the cause	Yes	2.86%	0.83%	3.52	8.56E-03
417.3(a)(2)	CCP is under control	Yes	0.37%	0.11%	3.32	1.60E-04
417.3(a)(3)	Establish measures to prevent recurrence	Yes	4.50%	1.46%	3.18	4.32E-03
417.3(a)(4)	No adulterated product enters commerce.	No	1.86%	0.12%	16.22	4.28E-11
417.3(b)(3)	No adulterated product enters commerce	Yes	1.91%	0.08%	23.97	2.37E-06
417.3(b)(4)	Reassessment	Yes	3.09%	0.38%	8.48	2.79E-04
417.3(c)	Document corrective actions	Yes	4.27%	0.49%	8.98	1.41E-04

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	3.03%	0.32%	9.88	1.29E-03
417.5(a)(1)	Written hazard analysis	Yes	0.56%	0.14%	4.11	1.31E-18
417.5(a)(2)	Written HACCP plan	Yes	0.12%	0.03%	3.59	4.07E-04

4.1.2 *Salmonella* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 42 establishments with Intact Turkey *Salmonella* testing data, of which 12 establishments had 18 *Salmonella* positives and 30 establishments did not have *Salmonella* positives. There were 1,731 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the two 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 3 months prior to an Intact Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Turkey *Salmonella* positive for CY2020.

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

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	3.27%	0.35%	9.53	6.50E-07
417.3(c)	Document corrective actions	Yes	37.50%	0.84%	71.16	8.24E-05

4.1.3 *Salmonella* in Ground Beef

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,215 establishments with Ground Beef *Salmonella* testing data, of which 108 establishments had 166 *Salmonella* positives and 1,107 establishments did not have *Salmonella* positives. There were 10,718 total Ground Beef *Salmonella* tests performed.

Table 4-4 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 Test *p* value of less than 0.05) that the noncompliance rate of the regulation in establishments 3 months prior to a Ground Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ground Beef *Salmonella* positive for CY2020.

Table 4-4 Comparison of Noncompliance Rates 3 Months before a Ground Beef *Salmonella* Positive with Those for Establishments with No Ground Beef *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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
301.2_Adulterated	Adulterated	Yes	8.70%	2.90%	3.18	4.86E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.02%	1.04%	3.97	1.11E-78
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	7.56%	2.44%	3.27	4.88E-05
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	2.85%	0.19%	15.50	2.55E-10
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	6.00%	0.66%	9.67	7.49E-06
318.1(b)	Only inspected and passed poultry product to enter official establishment	No	0.22%	0.01%	38.92	4.96E-02

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	6.67%	1.14%	6.20	8.51E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	10.68%	3.14%	3.68	1.48E-64
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	22.22%	2.94%	9.43	3.18E-02
417.2(c)(4)	List of procedures & frequency	Yes	1.72%	0.24%	7.40	2.85E-102
417.3(b)(1)	Segregate and hold the affected product	Yes	10.00%	1.38%	7.97	3.60E-02
418.2	Notification of adulterated or misbranded product in commerce	Yes	33.33%	4.06%	11.82	2.63E-02

4.1.4 *Salmonella* in Intact Beef

FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 907 establishments with Intact Beef *Salmonella* testing data, of which 90 establishments had 177 *Salmonella* positives and 817 establishments did not have *Salmonella* positives. There were 6,417 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 31 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 3 months prior to an Intact Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Beef *Salmonella* positive for CY2020.

Table 4-5 Comparison of Noncompliance Rates 3 Months before an Intact Beef *Salmonella* Positive with Those for Establishments with No Intact Beef *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	25.13%	2.82%	11.59	6.91E-39
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	3.99%	1.02%	4.02	1.44E-158
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	7.06%	0.24%	31.85	1.14E-06
310.22(c)	Disposal of SRM	Yes	3.04%	0.30%	10.53	1.59E-35
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	10.25%	1.67%	6.73	7.42E-27
310.22(e)(2)	Appropriate corrective actions	Yes	15.31%	0.53%	33.80	4.46E-13
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	10.11%	1.11%	9.99	1.49E-22
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.58%	0.16%	3.75	2.34E-02
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	4.48%	0.56%	8.29	4.73E-04
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	4.71%	0.06%	79.38	5.90E-06

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	No	4.22%	0.83%	5.27	1.16E-04
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.69%	0.73%	3.79	9.94E-38
416.12(d)	Plan list frequency for each procedure & responsible individual	No	1.82%	0.05%	40.81	2.21E-05
416.13(a)	Conduct pre-op procedures	Yes	3.93%	1.25%	3.23	6.30E-48
416.13(b)	Conduct other procedures listed in the plan	Yes	0.74%	0.12%	6.21	7.56E-51
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.89%	0.87%	5.86	0.00E+00
416.15(a)	Appropriate corrective actions	Yes	5.72%	1.35%	4.43	3.63E-09
416.15(b)	Corrective action, procedures for	Yes	18.75%	2.06%	10.95	6.32E-27
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.64%	0.31%	5.35	3.46E-05
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	9.77%	3.07%	3.42	1.94E-70
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	19.97%	3.71%	6.47	1.46E-261
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	20.51%	3.07%	8.15	1.26E-04
417.2(a)(1)	Hazard analysis	Yes	3.65%	1.24%	3.03	2.49E-05

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
417.2(c)(4)	List of procedures & frequency	Yes	1.43%	0.27%	5.33	9.45E-78
417.3(a)(2)	CCP is under control	Yes	1.89%	0.35%	5.44	2.09E-10
417.3(a)(3)	Establish measures to prevent recurrence	Yes	21.33%	4.70%	5.49	1.16E-06
417.3(a)(4)	No adulterated product enters commerce.	No	3.48%	0.20%	18.01	2.26E-07
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	88.89%	2.71%	287.13	1.59E-22
417.4(a)(1)	Initial validation	No	22.22%	5.57%	4.84	1.84E-02
417.5(a)(1)	Written hazard analysis	Yes	0.65%	0.21%	3.14	1.60E-19
418.2	Notification of adulterated or misbranded product in commerce	Yes	90.00%	3.36%	258.75	2.79E-11

4.1.5 *Salmonella* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 91 establishments with Comminuted Chicken *Salmonella* testing data, of which 79 establishments had 536 *Salmonella* positives and 12 establishments did not have *Salmonella* positives. There were 2,111 total Comminuted 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 3 months before a Comminuted Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Salmonella* positive for CY2020.

Table 4-6 Comparison of Noncompliance Rates 3 Months before a Comminuted Chicken *Salmonella* Positive with Those for Establishments with No Comminuted Chicken *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	2.08%	0.63%	3.36	2.37E-02
416.13(a)	Conduct pre-op procedures	Yes	9.33%	2.25%	4.47	4.47E-33
416.13(b)	Conduct other procedures listed in the plan	Yes	0.66%	0.17%	3.90	1.04E-06
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	29.58%	6.79%	5.77	1.90E-33
417.2(c)(4)	List of procedures & frequency	Yes	1.55%	0.08%	20.68	1.59E-21
417.3(a)(3)	Establish measures to prevent recurrence	Yes	11.76%	0.72%	18.40	2.45E-05
417.5(a)(2)	Written HACCP plan	Yes	0.74%	0.15%	5.01	6.32E-07

4.1.6 *Salmonella* in Comminuted Turkey

There are 49 establishments with Comminuted Turkey *Salmonella* testing data, of which 40 establishments had 280 *Salmonella* positives and 9 establishments did not have *Salmonella* positives. There were 1,525 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the 9 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 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 3 months before a Comminuted Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Salmonella* positive for CY2020.

Table 4-7 Comparison of Noncompliance Rates 3 Months before a Comminuted Turkey *Salmonella* Positive with Those for Establishments with No Comminuted Turkey *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	14.68%	1.75%	9.67	2.09E-53
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.89%	1.02%	6.07	7.06E-73
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.35%	0.03%	10.79	6.58E-07
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.23%	0.65%	5.15	1.03E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	8.86%	1.30%	7.37	4.46E-07
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	23.82%	2.08%	14.70	4.89E-56
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	17.82%	3.42%	6.12	1.06E-32
417.2(c)(4)	List of procedures & frequency	Yes	0.75%	0.08%	9.86	1.68E-06
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.73%	0.10%	7.56	1.13E-06

4.1.7 *Salmonella* in Intact Pork

There are 87 establishments with Intact Pork *Salmonella* testing data, of which 32 establishments had 215 *Salmonella* positives and 55 establishments did not have *Salmonella* positives. There were 2,070 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the 9 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 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 3

months before an Intact Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Pork *Salmonella* positive for CY2020.

Table 4-8 Comparison of Noncompliance Rates 3 Months before an Intact Pork *Salmonella* Positive with Those for Establishments with No Intact Pork *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.54%	0.70%	3.71	8.06E-20
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.18%	0.26%	4.56	1.25E-28
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.36%	0.10%	3.52	1.94E-13
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.12%	0.10%	11.05	3.57E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	2.84%	0.95%	3.05	7.95E-05
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	13.08%	4.12%	3.50	1.43E-45
417.3(b)(4)	Reassessment	Yes	5.28%	1.19%	4.65	1.17E-02
417.3(c)	Document corrective actions	Yes	17.39%	1.30%	16.00	9.50E-03
418.2	Notification of adulterated or misbranded product in commerce	Yes	50.00%	7.69%	12.00	3.29E-02

4.1.8 *Salmonella* in Comminuted Pork

There are 299 establishments with Comminuted Pork *Salmonella* testing data, of which 146 establishments had 1,340 *Salmonella* positives and 153 establishments did not have *Salmonella* positives. There were 6,196 total Comminuted Pork *Salmonella* tests performed.

Table 4-9 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 an 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 3 months before a Comminuted Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Pork *Salmonella* positive for CY2020.

Table 4-9 Comparison of Noncompliance Rates 3 Months before a Comminuted Pork *Salmonella* Positive with those for Establishments with No Comminuted Pork *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	66.85%	35.71%	3.63	3.79E-02
310.18(c)	Written procedures to prevent contamination; all swine slaughter	No	1.74%	0.17%	10.49	1.73E-03
310.22(c)	Disposal of SRM	Yes	12.41%	0.11%	125.87	4.96E-52
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	39.89%	0.49%	136.05	4.34E-27
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.37%	0.59%	4.11	1.44E-56

4.1.9 *Salmonella* in Chicken Parts

There are 473 establishments with Chicken Parts *Salmonella* testing data, of which 361 establishments had 1,103 *Salmonella* positives and 112 establishments did not have *Salmonella* positives. There were 13,856 total Chicken Parts *Salmonella* tests performed.

Table 4-10 presents the 8 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 3 months before a Chicken Parts *Salmonella* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Salmonella* positive for CY2020.

Table 4-10 Comparison of Noncompliance Rates 3 Months before a Chicken Parts *Salmonella* Positive with Those for Establishments with No Chicken Parts *Salmonella* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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 NPIS	Yes	4.00%	0.27%	15.28	2.86E-05
416.13(a)	Conduct pre-op procedures	Yes	10.28%	3.25%	3.41	1.14E-178
416.13(b)	Conduct other procedures listed in the plan	Yes	0.83%	0.20%	4.30	4.92E-56
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.83%	0.25%	3.28	4.34E-35
417.3(a)(3)	Establish measures to prevent recurrence	Yes	7.27%	1.19%	6.51	3.08E-06
417.3(b)(3)	No adulterated product enters commerce	Yes	1.03%	0.24%	4.30	2.75E-02
417.3(b)(4)	Reassessment	Yes	2.90%	0.21%	13.92	2.23E-07
417.5(a)(2)	Written HACCP plan	Yes	0.56%	0.05%	11.82	1.75E-44

4.1.10 *Salmonella* in Siluriformes

There are 74 establishments with Siluriformes *Salmonella* testing data, of which 21 establishments had 23 *Salmonella* positives and 53 establishments did not have *Salmonella* positives. There were 590 total Siluriformes *Salmonella* tests performed.

There were no regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 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 3 months before a Siluriformes *Salmonella* positive is higher than the average noncompliance rate for establishments with no Siluriformes *Salmonella* positive for CY2020.

4.1.11 *Salmonella* in RTE

There are 2,199 establishments with RTE *Salmonella* testing data, of which 3 establishments had 3 *Salmonella* positives and 2,196 establishments did not have *Salmonella* positives. There were 14,018 total RTE *Salmonella* tests performed.

There were no 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 an 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 3 months before an RTE *Salmonella* positive is higher than the average noncompliance rate for establishments with no RTE *Salmonella* positives for CY2020.

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), MT54 (components and other trim), MT55 (bench trim) and MT60 (beef or veal trim). The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,372 establishments with *E. coli* O157:H7 testing data, of which 22 establishments had 22 *E. coli* O157:H7 positives and 1,350 establishments did not have *E. coli* O157:H7 positives. There were 17,134 total *E. coli* O157:H7 tests performed.

Table 4-11 presents the 12 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and there is an 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 3 months before an *E. coli* O157:H7 positive is higher than the average noncompliance rate for establishments with no *E. coli* O157:H7 positive for CY2020.

Table 4-11 Comparison of Noncompliance Rates 3 Months before an *E. coli* O157:H7 Positive with Those for Establishments with *E. coli* O157:H7 Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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
301.2_Adulterated	Adulterated	Yes	66.67%	5.37%	35.21	8.56E-03
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	19.35%	3.06%	7.59	3.37E-04
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	10.34%	2.29%	4.93	2.90E-02
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	3.45%	1.08%	3.26	2.19E-20
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.67%	0.17%	3.88	3.78E-04
416.15(a)	Appropriate corrective actions	Yes	10.00%	2.07%	5.26	3.92E-03
416.15(b)	Corrective action, procedures for	Yes	30.77%	5.00%	8.44	3.19E-03
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	25.23%	5.22%	6.12	1.06E-32
417.2(c)	Contents of HACCP Plan	Yes	6.25%	0.26%	25.76	4.21E-02
417.2(c)(4)	List of procedures & frequency	Yes	1.16%	0.31%	3.71	1.28E-06
417.3(a)(2)	CCP is under control	Yes	3.28%	0.38%	8.79	2.38E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	40.00%	3.48%	18.47	1.17E-02

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 MT55 (bench trim) and 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 483 establishments with Non-O157 STEC testing data, of which 17 establishments had 18 Non- O157 STEC positives and 466

establishments did not have Non-O157 STEC positives. There were 3,919 total Non-O157 STEC tests performed.

Table 4-12 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 3 months before a Non-O157 STEC positive is higher than the average noncompliance rate for establishments with no Non-O157 STEC positive for CY2020.

Table 4-12 Comparison of Noncompliance Rates 3 Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	2.38%	0.71%	3.41	1.87E-02
310.3	Carcasses and parts in certain instances to be retained.	Yes	38.89%	14.72%	3.69	1.18E-02
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	75.00%	6.09%	46.24	1.16E-03

4.3 *Listeria monocytogenes*

The purpose of this section is to provide the results of the analysis between the candidate regulations and *Listeria monocytogenes*. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,199 establishments with *Listeria monocytogenes* testing data, of which 24 establishments had 25 *Listeria monocytogenes* positives and 2,175 establishments did not have *Listeria monocytogenes* positives. There were 14,019 total *Listeria monocytogenes* tests performed.

Table 4-13 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 regulation in the 3 months before a *Listeria monocytogenes* positive is higher than the noncompliance rate for establishments with no *Listeria monocytogenes* positive for CY2020.

Table 4-13 Comparison of Noncompliance Rates 3 Months before a *Listeria monocytogenes* Positive with Those for Establishments with No *Listeria monocytogenes* Positive

Regulation Verified	Description	On FY2021 PHR List	Noncompliance Rate in 3 Months before a <i>Listeria monocytogenes</i> Positive	Noncompliance Rate for Establishments with no <i>Listeria monocytogenes</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.65(f)	Procedures for controlling visible fecal contamination	No	2.54%	0.81%	3.21	4.52E-07
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.96%	0.14%	6.84	1.52E-08

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 593 establishments with *Campylobacter* testing data, of which 455 establishments had 4,388 *Campylobacter* positives and 138 establishments did not have *Campylobacter* positives. There were 28,934 total *Campylobacter* tests performed.

Table 4-14 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 the 3 months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2020.

Table 4-14 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Positive with Those for Establishments with No *Campylobacter* Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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(a)	All products subject to reinspection by program employees	Yes	5.36%	0.09%	63.96	2.63E-17
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	1.74%	0.48%	3.68	1.94E-07
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	1.16%	0.29%	4.02	9.26E-07

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	0.55%	0.04%	12.65	8.49E-05
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.99%	0.89%	3.42	1.85E-63
416.13(b)	Conduct other procedures listed in the plan	Yes	0.70%	0.09%	7.50	2.33E-89
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.06%	0.18%	5.85	1.86E-96
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.45%	0.11%	4.21	4.13E-61
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.89%	0.56%	11.11	1.21E-32
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	8.07%	2.20%	3.90	4.96E-20
417.2(c)(4)	List of procedures & frequency	Yes	1.40%	0.18%	7.77	3.92E-139

4.4.1 *Campylobacter* in Intact Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 206 establishments with Intact Chicken *Campylobacter* testing data, of which 202 establishments had 1,931 *Campylobacter* positives and 4 establishments did not have *Campylobacter* positives. There were 9,687 total Intact Chicken *Campylobacter* tests performed.

Table 4-15 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 regulation in the 3 months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2020.

Table 4-15 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Intact Chicken Positive with Those for Establishments with No *Campylobacter* Intact Chicken Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.15%	0.23%	4.99	4.91E-05
417.2(c)(4)	List of procedures & frequency	Yes	1.51%	0.13%	11.77	1.17E-11

4.4.2 *Campylobacter* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 42 establishments with Intact Turkey *Campylobacter* testing data, of which 19 establishments had 32 *Campylobacter* positives and 23 establishments did not have *Campylobacter* positives. There were 1,727 total Intact Turkey *Campylobacter* tests performed.

Table 4-16 presents the 8 regulation 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 the 3 months before an Intact Turkey *Campylobacter* positive is higher than the noncompliance rate for establishments with no Intact Turkey *Campylobacter* positive for CY2020.

Table 4-16 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Intact Turkey Positive with Those for Establishments with No *Campylobacter* Intact Turkey Positive

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	0.72%	0.08%	8.62	9.06E-04
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	13.54%	4.70%	3.18	1.71E-02
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	5.23%	1.14%	4.78	3.26E-04

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	6.74%	1.60%	4.46	9.75E-03
417.3(a)(1)	Identify and eliminate the cause	Yes	44.44%	2.20%	35.63	9.20E-20
417.3(a)(2)	CCP is under control	Yes	5.37%	0.42%	13.61	5.44E-15
417.3(a)(3)	Establish measures to prevent recurrence	Yes	51.72%	5.59%	18.09	2.86E-16
417.3(c)	Document corrective actions	Yes	15.00%	1.03%	16.91	2.34E-03

4.4.3 *Campylobacter* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 91 establishments with Comminuted Chicken *Campylobacter* testing data, of which 44 establishments had 163 *Campylobacter* positives and 47 establishments did not have *Campylobacter* positives. There were 2,097 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-17 presents the 8 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 3 months before a Comminuted Chicken *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Campylobacter* positive for CY2020.

Table 4-17 Comparison of Noncompliance Rates 3 Months before a Comminuted Chicken *Campylobacter* Positive with Those for Establishments with No Comminuted Chicken *Campylobacter* Positive

Regulation Verified	Description	On FY2021 PHR List	Noncompliance Rate in 3 Months 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(a)	Clean and sanitary practices; products not adulterated	Yes	2.27%	0.40%	5.81	4.25E-03

Regulation Verified	Description	On FY2021 PHR List	Noncompliance Rate in 3 Months 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	2.90%	0.31%	9.46	2.11E-14
416.13(b)	Conduct other procedures listed in the plan	Yes	1.26%	0.28%	4.49	7.01E-28
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.84%	0.46%	4.02	2.69E-29
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	12.87%	0.52%	27.98	3.49E-10
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	48.54%	16.73%	4.69	3.03E-114
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	40.77%	17.87%	3.16	2.67E-71
417.5(a)(2)	Written HACCP plan	Yes	0.73%	0.07%	11.01	1.08E-21

4.4.4 *Campylobacter* in Comminuted Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 49 establishments with Comminuted Turkey *Campylobacter* testing data, of which 15 establishments had 42 *Campylobacter* positives and 34 establishments did not have *Campylobacter* positives. There were 1,517 total Comminuted Turkey *Campylobacter* tests performed.

Table 4-18 presents the 7 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 an 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 3 months before a Comminuted Turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Campylobacter* positive for CY2020.

Table 4-18 Comparison of Noncompliance Rates 3 Months before a Comminuted Turkey *Campylobacter* Positive with those for Establishments with No Comminuted Turkey *Campylobacter* Positive

Regulation Verified	Description	On FY2021 PHR List	Noncompliance Rate in 3 Months 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	12.65%	4.00%	3.47	4.25E-35
416.13(b)	Conduct other procedures listed in the plan	Yes	0.72%	0.18%	4.10	6.13E-09
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.40%	1.78%	3.15	6.32E-57
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.79%	0.99%	5.03	4.47E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	10.58%	3.41%	3.35	4.52E-04
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.78%	0.24%	3.31	1.34E-08
417.5(f)	Official Review	Yes	1.53%	0.11%	13.52	1.74E-03

4.4.5 *Campylobacter* in Chicken Parts

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 473 establishments with Chicken Parts *Campylobacter* testing data, of which 379 establishments had 2,193 *Campylobacter* positives and 94 establishments did not have *Campylobacter* positives. There were 13,805 total Chicken Parts *Campylobacter* tests performed.

Table 4-19 presents the 13 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 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 3 months before an Chicken Parts *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Campylobacter* positive for CY2020.

**Table 4-19 Comparison of Noncompliance Rates 3 Months before a Chicken Parts
Campylobacter Positive with Those for Establishments with No Chicken Parts
Campylobacter Positive**

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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(a)	Clean and sanitary practices; products not adulterated	Yes	1.78%	0.58%	3.10	7.23E-04
416.13(a)	Conduct pre-op procedures	Yes	9.43%	1.59%	6.46	2.09E-239
416.13(b)	Conduct other procedures listed in the plan	Yes	0.68%	0.07%	9.23	1.05E-63
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.93%	0.15%	6.23	2.55E-59
416.15(b)	Corrective action, procedures for	Yes	10.03%	3.25%	3.32	1.11E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.42%	0.11%	3.73	2.40E-34
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.91%	0.86%	5.94	9.69E-12
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	6.85%	2.25%	3.19	3.00E-08
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	23.95%	6.93%	4.23	3.03E-160
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	28.18%	7.98%	4.53	1.27E-204
417.2(c)(4)	List of procedures & frequency	Yes	1.31%	0.09%	15.17	2.58E-105
417.3(b)(4)	Reassessment	Yes	1.16%	0.25%	4.61	2.00E-02
417.5(a)(2)	Written HACCP plan	Yes	0.33%	0.09%	3.54	5.11E-13

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. Plant 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 a plant indicating that FSIS is considering withholding the marks of inspection or suspending the assignment of inspectors if not corrected. The plant 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 FY2022 PHRs. The enforcement action list consists of candidate 9 CFR regulations in which noncompliances occurs at a more frequent rate in establishments in the 3-month period prior to an NOIE or suspension than in establishments without an NOIE or suspension for CY2020. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,588 active meat and poultry establishments, of which 99 establishments had 113 enforcement actions and 5,489 establishments did not have any enforcement actions.

Table 4-20 presents the 41 regulations which 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 the 3 months before an enforcement action is higher than the noncompliance rate for establishments with no enforcement action for CY2020.

Table 4-20 Comparison of Noncompliance Rates 3 Months before an Enforcement Action with Those for Establishments with No Enforcement Action

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months 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	94.12%	3.20%	484.13	4.49E-23
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.89%	1.54%	3.29	3.92E-41
310.22(c)	Disposal of SRM	Yes	2.72%	0.54%	5.20	1.97E-05
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	12.82%	2.47%	5.80	2.74E-05
310.22(e)(3)	Evaluate effectiveness of procedures for removal,	Yes	8.70%	2.17%	4.30	1.83E-02

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
	segregation, and disposition of SRMs					
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	1.53%	0.25%	6.31	4.56E-02
310.25(a)	Verification criteria for E. coli testing meat	Yes	8.39%	0.92%	9.91	6.32E-16
310.3	Carcasses and parts in certain instances to be retained.	Yes	38.10%	9.02%	6.21	3.38E-04
318.2(a)	All products subject to reinspection by program employees	Yes	3.37%	0.13%	26.98	2.52E-04
416.1	Operate in a manner to prevent insanitary conditions	Yes	10.28%	0.90%	12.60	3.08E-145
416.13(a)	Conduct pre-op procedures	Yes	6.41%	1.98%	3.39	1.71E-42
416.13(b)	Conduct other procedures listed in the plan	Yes	1.29%	0.19%	6.93	4.30E-44
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.37%	1.53%	3.66	7.05E-136
416.15(a)	Appropriate corrective actions	Yes	19.88%	1.92%	12.69	9.82E-23
416.15(b)	Corrective action, procedures for	Yes	43.59%	3.12%	24.00	4.13E-30
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.61%	0.13%	4.67	4.85E-23
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	6.13%	0.66%	9.80	1.98E-07
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	12.23%	1.38%	9.96	1.55E-11

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	21.63%	5.11%	5.13	6.97E-76
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	35.06%	7.10%	7.06	8.39E-144
416.5(c)	Employees who appear to have any abnormal source of microbial contamination	No	4.00%	0.05%	86.41	1.28E-02
417.2(a)(1)	Hazard analysis	Yes	16.13%	0.96%	19.93	2.18E-52
417.2(c)	Contents of HACCP Plan	Yes	20.45%	0.21%	123.52	1.04E-15
417.2(c)(4)	List of procedures & frequency	Yes	2.36%	0.43%	5.57	7.68E-47
417.3(a)(1)	Identify and eliminate the cause	Yes	66.67%	5.47%	34.57	2.12E-13
417.3(a)(2)	CCP is under control	Yes	2.84%	0.48%	6.11	7.62E-08
417.3(a)(3)	Establish measures to prevent recurrence	Yes	79.31%	9.62%	36.01	1.63E-18
417.3(b)(2)	Determine the acceptability of the affected product	Yes	50.00%	2.46%	39.57	3.10E-04
417.3(b)(4)	Reassessment	Yes	6.10%	0.53%	12.27	8.73E-05
417.3(c)	Document corrective actions	Yes	42.86%	5.09%	13.98	3.99E-05
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	90.91%	2.30%	424.59	1.65E-30
417.4(a)(1)	Initial validation	No	80.00%	5.82%	64.79	8.35E-13
417.5(a)(1)	Written hazard analysis	Yes	1.92%	0.25%	7.94	3.50E-53
417.5(a)(2)	Written HACCP plan	Yes	0.86%	0.10%	8.80	6.48E-24
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	1.19%	0.22%	5.58	8.27E-26

Regulation Verified	Description	On FY 2021 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher Exact p Value
418.2	Notification of adulterated or misbranded product in commerce	Yes	23.53%	5.49%	5.30	1.31E-02
418.3	Recall Plans	No	2.94%	0.18%	16.85	7.33E-03
430.4(a)	Lm, post-lethality exposed RTE	Yes	0.31%	0.02%	12.80	1.15E-02
430.4(b)(2)	Alternative 2: The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product or the establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.	No	12.50%	0.35%	40.36	2.84E-02
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Yes	0.32%	0.05%	6.17	4.34E-02
430.4(c)(6)	Lm, prerequisite program requirements	No	50.00%	0.77%	129.24	1.57E-02

5.0 LIST OF FY2022 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2022 PHR list. Table 5-1 presents the complete list of the 62 FY2022 PHRs. These 62 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 3 months before *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positives or enforcement actions than in establishments with no positives or enforcement actions.

The 62 FY2022 PHRs are composed of 9 regulations and 54 provisions of regulations. The 62 FY2022 PHRs represent 29 regulations, with the majority of FY2022 PHRs being provisions of regulations that provide greater specificity as to the nature of the noncompliance associated with a regulation violation.

Table 5-1 List of FY2022 PHRs

Regulation Verified	Description	On FY 2021 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
301.2_Adulterated	Adulterated	Yes	94.05	1.59E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	3.66	5.93E-03
310.18(c)	Written procedures to prevent contamination; all swine slaughter	No	8.18	8.65E-04
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	No	19.23	1.73E-15
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	24.89	3.58E-05
310.22(c)	Disposal of SRM	Yes	32.71	3.75E-03
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	5.6	8.26E-05
310.22(e)(2)	Appropriate corrective actions	Yes	18.55	2.32E-02
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	36.03	9.47E-03
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	8.9	1.72E-02
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	Yes	9.91	6.32E-16
310.3	Carcasses and parts in certain instances to be retained.	Yes	4.95	6.05E-03
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	8.98	2.40E-04

Regulation Verified	Description	On FY 2021 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
318.1(b)	Only inspected and passed poultry product to enter official establishment	No	38.92	4.96E-02
318.2(a)	All products subject to reinspection by program employees	Yes	35.05	1.10E-03
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	42	1.82E-04
381.193(a)	Poultry not intended for human food in commerce	No	12.09	1.40E-03
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	4.47	1.24E-03
381.65(f)	Procedures for controlling visible fecal contamination	No	4.24	5.80E-05
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	6.56	2.84E-03
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	10.63	4.95E-04
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	6.89	4.29E-03
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	6.18	6.34E-03
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.2	1.34E-20
416.12(d)	Plan list frequency for each procedure & responsible individual	No	40.81	2.21E-05
416.13(a)	Conduct pre-op procedures	Yes	5.02	5.64E-34
416.13(b)	Conduct other procedures listed in the plan	Yes	5.67	1.17E-07
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.55	3.65E-21
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	4.77	4.75E-05
416.15(a)	Appropriate corrective actions	Yes	6.57	9.79E-04
416.15(b)	Corrective action, procedures for	Yes	8.84	5.51E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	5.39	1.32E-07
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	8.9	2.82E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	4.99	7.60E-05
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	5.63	2.11E-34

Regulation Verified	Description	On FY 2021 PHR List	Average Odds Ratio	Average of Two-Sided Fisher Exact p Value
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	5.51	3.02E-33
416.5(c)	Employees who appear to have any abnormal source of microbial contamination	No	46.62	2.86E-02
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	16.85	8.27E-03
417.2(a)(1)	Hazard analysis	Yes	9.86	8.32E-06
417.2(c)	Contents of HACCP Plan	Yes	74.64	2.11E-02
417.2(c)(4)	List of procedures & frequency	Yes	8.56	2.69E-07
417.3(a)(1)	Identify and eliminate the cause	Yes	19.87	2.14E-03
417.3(a)(2)	CCP is under control	Yes	6.94	3.99E-03
417.3(a)(3)	Establish measures to prevent recurrence	Yes	13.24	6.22E-04
417.3(a)(4)	No adulterated product enters commerce.	No	12.82	7.52E-08
417.3(b)(1)	Segregate and hold the affected product	Yes	7.97	3.60E-02
417.3(b)(2)	Determine the acceptability of the affected product	Yes	39.57	3.10E-04
417.3(b)(3)	No adulterated product enters commerce	Yes	10.51	9.19E-03
417.3(b)(4)	Reassessment	Yes	8.78	6.43E-03
417.3(c)	Document corrective actions	Yes	25.41	2.42E-03
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	185.02	3.25E-03
417.4(a)(1)	Initial validation	No	34.82	9.19E-03
417.5(a)(1)	Written hazard analysis	Yes	5.06	4.91E-19
417.5(a)(2)	Written HACCP plan	Yes	6.73	5.82E-05
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	5.48	3.82E-07
417.5(f)	Official Review	Yes	13.52	1.74E-03
418.2	Notification of adulterated or misbranded product in commerce	Yes	59.26	1.44E-02
418.3	Recall Plans	No	16.85	7.33E-03
430.4(a)	Lm, post-lethality exposed RTE	Yes	12.8	1.15E-02
430.4(b)(2)	Alternative 2: The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product or the establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.	No	40.36	2.84E-02
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Yes	6.17	4.34E-02
430.4(c)(6)	Lm, prerequisite program requirements	No	129.24	1.57E-02

Forty-nine of the previous 56 FY2021 PHRs are included in the FY2022 PHRs. There are seven regulations on the FY2021 PHR list that are not in the FY2022 PHR list (See Appendix C). There are 13 regulations that are on the FY2022 PHR list that were not on the FY2021 PHR list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2022 PHR list. Most regulations were triggered by multiple events. Similar to the FY2021 PHR list, *Salmonella* pathogen positives and enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2022 PHR List

Product	Number of Regulations
<i>Campylobacter</i>	11
<i>Campylobacter</i> Chicken Parts	13
<i>Campylobacter</i> Ground Chicken	8
<i>Campylobacter</i> Ground Turkey	7
<i>Campylobacter</i> Intact Chicken	2
<i>Campylobacter</i> Intact Turkey	8
Enforcements	41
<i>Listeria</i>	2
Non-O157 <i>E. coli</i>	3
O157 <i>E. coli</i>	12
<i>Salmonella</i>	34
<i>Salmonella</i> Chicken Parts	8
<i>Salmonella</i> Ground Beef	12
<i>Salmonella</i> Ground Chicken	7
<i>Salmonella</i> Ground Pork	5
<i>Salmonella</i> Ground Turkey	9
<i>Salmonella</i> Intact Beef	31
<i>Salmonella</i> Intact Chicken	16
<i>Salmonella</i> Intact Pork	9
<i>Salmonella</i> Intact Turkey	2
<i>Salmonella</i> Siluriformes	0
RTE <i>Salmonella</i>	0

There were 13 regulations triggered by a single type of event: Seven were from Enforcement Actions, two were from *Salmonella* in Ground Beef, one was from *Salmonella* in Intact Beef, one was from *Salmonella* in Intact Chicken, one was *Salmonella*, and one was from *Campylobacter* in Ground Turkey. Table 5-3 presents the regulations triggered for inclusion in the FY2022 PHR list by only single pathogen product or enforcement action type (event).

Table 5-3 Regulations Triggered for Inclusion in the FY2022 PHR List by Only a Single Event

Regulation Verified	Description	Event
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	<i>Salmonella</i>
310.25(a)	Verification criteria for E. coli testing meat	Enforcements
318.1(b)	Only inspected and passed poultry product to enter official establishment	<i>Salmonella</i> Ground Beef
381.193(a)	Poultry not intended for human food in commerce	<i>Salmonella</i> Intact Chicken
416.12(d)	Plan list frequency for each procedure & responsible individual	<i>Salmonella</i> Intact Beef
417.3(b)(1)	Segregate and hold the affected product	<i>Salmonella</i> Ground Beef
417.3(b)(2)	Determine the acceptability of the affected product	Enforcements
417.5(f)	Official Review	<i>Campylobacter</i> Ground Turkey
418.3	Recall Plans	Enforcements
430.4(a)	Lm, post-lethality exposed RTE	Enforcements
430.4(b)(2)	Alternative 2: The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product or the establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.	Enforcements
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Enforcements
430.4(c)(6)	Lm, prerequisite program requirements	Enforcements

6.0 CUT POINTS FOR FY2022 PHRS

The FY2022 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 FY2022 PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the 3-month 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 FY2022 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 two non-compliances 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 FY2022 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 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 number between zero and one (the non-zero PHR noncompliance rates).

Table 6-1 Mean and Standard Deviation of Quarterly FY2022 PHR Rate

Timeframe	Mean of Natural Log FY2022PHR Rate		Standard Deviation FY2022 PHR Rate	
	Processing	Combination	Processing	Combination
Jan-Mar 2020	-4.89	-4.51	0.82	0.96
Apr-Jun 2020	-4.72	-4.46	0.74	0.90
July-Sept 2020	-4.99	-4.52	0.80	0.98
Oct-Dec 2020	-5.01	-4.57	0.81	0.95
Average	-4.90	-4.51	0.79	0.95

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 example⁴, the upper cut point for the log transformed data for Combination establishments is $-4.51 + 2 \times 0.95 = -4.51 + 1.9 = -2.61$. The cut point of the original, non-transformed PHR noncompliance data is the antilog of -2.61 or $\text{Exp}(-2.61) = 7.33\%$. 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 non-compliance.

The PHR cut points are defined as follows for each of the two plant 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

⁴ This is an illustrative example. Exact numbers may vary due to rounding.

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 6 months are recommended for a PHRE to determine if an FSA is appropriate.

Tables 6-2 and 6-3 present the FY2022 PHR upper and lower cut points for each of the two establishment operation types. The FY2020 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 2021.

Table 6-2 FY2022 PHR Upper Level Cut Points

Operation Type	FY2022 PHR Cut Points	FY2021 PHR Cut Points	FY2020 PHR Cut Points
Processing	3.63%	3.73%	3.86%
Combination	7.33%	9.84%	8.83%

Table 6-3 FY2022 PHR Lower Level Cut Points

Operation Type	FY2022 PHR Cut Points	FY2021 PHR Cut Points	FY2020 PHR Cut Points
Processing	2.44%	2.50%	2.58%
Combination	4.60%	5.85%	5.42%

Table 6-4 presents the number of establishments in each level based solely on the FY2022 PHR criterion and the cut points in Table 6-2. When applying the cut points to establishments with less than 20 verifications, establishments that qualify for the Upper level but only have one noncompliance are moved to the Mid level. Forty-eight establishments are in the Upper level and candidates to receive recommended for a for cause PHREs. Table 6-4 is based on regulatory noncompliances for the period January 1-March 31, 2021.

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

Classification	Number of Establishments
Upper	48
Mid	90
Lower	5,179
Total	5,317

Table 6-5 shows the number of establishments by operation type.

Table 6-5 Classification of Establishments Based on Operation Type and Only the PHR Criterion

Classification	Processing	Combination
Upper	35	13
Mid	58	32
Lower	4,143	1,036
Total	4,236	1,081

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2022 PHR regulations used to prioritize certain FY2022 FSIS inspection activities. This process involves (1) selecting a list of candidate regulations related to food safety process control, selecting a subset of these regulations whose noncompliance rates are higher in establishments 3 months prior to a pathogen positive or enforcement action and (2) 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 FY2022 PHRs has 62 regulations whose individual noncompliance rates are higher in establishments 3 months before *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Listeria monocytogenes*, *Campylobacter* positives or enforcement action than in establishments without positives or enforcement actions. Forty-nine regulations on the FY2021 PHR list are also on the FY2022 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 scheduled to receive a PHRE and become candidates to receive a for-cause FSA. FSAs are performed when the District Office determines that one is appropriate based on its analysis of the PHRE as described in [FSIS Directive 5100.4](#).

Tables 7-1 and 7-2 present the FY2022 PHR upper and lower cut points. The FY2021 PHR upper cut points are included for comparison although they are not directly comparable since they are based on different sets of PHRs.

Table 7-1 FY2022 PHR Upper-Level Cut Points

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

Table 7-2 FY2022 PHR Lower-Level Cut Points

Operation Type	FY2022 PHR Cut Points	FY2021PHR Cut Points
Processing	2.44%	2.50%
Combination	4.60%	5.85%

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) 2020, FY2021 Public Health Regulations.
4. National Advisory Committee on Meat and Poultry Inspection (NACMPI) 2013, Subcommittee Two, Issue Two: Data Analysis.

APPENDIX A: FY2022 PHR REGULATIONS

Table A-1 presents the list of 62 FY2022 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates 3 months prior to a pathogen positive or enforcement action that is 18.3 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2022 PHRs

Regulation	Description
301.2_Adulterated	Adulterated
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(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(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
310.25(a)	Verification criteria for E. coli testing meat
310.3	Carcasses and parts in certain instances to be retained.
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations
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
381.193(a)	Poultry not intended for human food in commerce
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
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
416.1	Operate in a manner to prevent insanitary conditions
416.12(d)	Plan list frequency for each procedure & responsible individual
416.13(a)	Conduct pre-op procedures
416.13(b)	Conduct other procedures listed in the plan
416.13(c)	Plant monitors implementation of SSOP procedures
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.15(a)	Appropriate corrective actions

Regulation	Description
416.15(b)	Corrective action, procedures for
416.16(a)	Daily records required, responsible individual, initialed and dated
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
416.5(c)	Employees who appear to have any abnormal source of microbial contamination
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)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions
417.4(a)	Adequacy of HACCP in controlling food safety hazards
417.4(a)(1)	Initial validation
417.5(a)(1)	Written hazard analysis
417.5(a)(2)	Written HACCP plan
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
417.5(f)	Official Review
418.2	Notification of adulterated or misbranded product in commerce
418.3	Recall Plans
430.4(a)	Lm, post-lethality exposed RTE
430.4(b)(2)	Alternative 2: The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product or the establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment
430.4(c)(6)	Lm, prerequisite program requirements

APPENDIX B: FY2022 CANDIDATE REGULATIONS

Table B-1 presents the list of candidate regulations. Of the 155 candidate regulations, four 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, 2020, through December 31, 2020.

Table B-1 FY2022 List of Candidate Regulations

Regulation	Description	FY2021 PHR	Mandatory Regulation ¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
301.2_Adulterated	Adulterated	Yes	No	6,350	204	3.21%
304.3(a)	Develop written SSOP	No	No	531	1	0.19%
304.3(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	1,188	5	0.42%
309.19(a)	Market hog sorting activities	No	No	1,637	0	0.00%
309.19(c)	Sorted and removed hogs identified; written procedures	No	No	1,278	1	0.08%
309.19(d)	Records of animals disposed of per day	No	No	2,691	2	0.07%
309.19(e)	Notifiable animal disease	No	No	69	0	0.00%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	342	4	1.17%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
309.3	(Modernized ONLY) Dead, dying, disabled or diseased and similar livestock	No	No	248	4	1.61%
309.3(e)	Establishment notify IPP of non-ambulatory livestock; Prompt condemnation and disposal	No	No	227	3	1.32%
309.4	(Modernized ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases	No	No	203	1	0.49%
309.5	(Modernized ONLY) Swine; disposal because of hog cholera	No	No	171	0	0.00%
309.9	(Modernized ONLY) Swine erysipelas	No	No	174	0	0.00%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	345,676	4,456	1.29%
310.18(b)	Brains, cheek meat, head trimmings from animals slaughtered by gunshot	No	No	21,556	4	0.02%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
310.18(c)	Written procedures to prevent contamination; all swine slaughter	No	No	7,086	16	0.23%
310.18(c)(1)	Sampling locations	No	No	1,030	1	0.10%
310.18(c)(1)(i)	Very low volume establishments	No	No	2,068	0	0.00%
310.18(c)(2)(i)	Sampling frequency	No	No	1,556	2	0.13%
310.18(c)(2)(ii)	Sampling frequency for very low volume establishments	No	No	925	1	0.11%
310.18(c)(2)(iii)	Records of test results for sampling program	No	No	9,694	3	0.03%
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures	No	No	18,341	26	0.14%
310.22(b)	Inedible and prohibited SRM for use as human food	Yes	No	3,431	13	0.38%
310.22(c)	Disposal of SRM	Yes	Yes	53,355	220	0.41%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar US products	No	No	101	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	14,295	273	1.91%
310.22(e)(2)	Appropriate corrective actions	Yes	No	3,618	54	1.49%
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	8,910	155	1.74%
310.22(e)(4)(i)	Maintain daily records	Yes	No	78,045	175	0.22%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	No	15,046	33	0.22%
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	No	1,144	6	0.52%
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	No	3,736	11	0.29%
310.25(a)	Verification criteria for E. coli testing meat	Yes	No	28,548	320	1.12%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
310.25(b)	Pathogen reduction performance standards; Salmonella	No	No	233	1	0.43%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	84	0	0.00%
310.26(b)	Carcass sorting and disposition	No	Yes	2,451	56	2.28%
310.26(d)(2)	Document number of carcasses disposed of per day	No	No	1,705	1	0.06%
310.3	Carcasses and parts in certain instances to be retained.	Yes	No	2,655	238	8.96%
311.14	Abrasions, bruises, abscesses, pus, etc.	Yes	No	26,364	9	0.03%
311.16	(Modernized ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.	No	No	268	29	10.82%
311.17	(Modernized ONLY) Necrobacillosis, pyemia, septicemia.	No	No	357	0	0.00%
311.24	(Modernized ONLY) Hogs affected with tapeworm cysts.	No	No	153	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	68	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	No	12,736	50	0.39%
317.24(a)	Packaging materials composed of poisonous or deleterious substances	No	No	2,398	12	0.50%
318.1(b)	Only inspected and passed poultry product to enter official establishment	No	No	105,049	14	0.01%
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	700	1	0.14%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	1,073	0	0.00%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision	No	No	368	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
318.16(b)	Pesticides, chemicals & other residues in products not to exceed FD&C Act levels - Meat ingredients	No	No	543	0	0.00%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	2,659	1	0.04%
318.17(b)	Lethality and Stabilization processes other than HACCP for cooked beef	No	No	732	0	0.00%
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	110	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	47,103	62	0.13%
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	9,407	44	0.47%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully-cooked meat patties	No	No	574	2	0.35%
318.23(b)(3)	Heat deviations for meat patties	No	No	45	1	2.22%
318.23(c)(1)	Stabilization requirements for meat patties	No	No	411	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	12	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	412	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	218	0	0.00%
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2,490	12	0.48%
318.6(b)(1)	Requirements for use of casings, used as containers	No	No	2,095	2	0.10%
318.6(b)(4)	Detached spinal cords	No	No	9,783	0	0.00%
318.6(b)(6)	Tonsils	No	No	11,680	1	0.01%
318.6(b)(8)	Intestines as ingredients	No	No	348	0	0.00%
319.5(b)	Mechanically separated (beef) - prohibited for use in human food	No	No	204	0	0.00%
354.242(b)	All equipment and utensils clean and sanitary	No	No	62	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	31	0	0.00%
354.243(a)	No handling or storage of objectionable materials	No	No	15	0	0.00%
381.1_Adulterated	Adulterated	No	No	5,269	29	0.55%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	2,181	0	0.00%
381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	No	1,478	1	0.07%
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry	No	No	121	0	0.00%
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	27	0	0.00%
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	383	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
381.193(a)	Poultry not intended for human food in commerce	No	No	184	7	3.80%
381.22(a)	Develop written SSOP	No	No	228	0	0.00%
381.22(b)	Conduct hazard analysis & develop and validate HACCP plan	No	No	1,237	0	0.00%
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	527	1	0.19%
381.37(a)	Product not produced under supervision of program employee	No	No	1,845	18	0.98%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	34,571	245	0.71%
381.65(f)	Procedures for controlling visible fecal contamination	No	No	1,484,173	11,033	0.74%
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	Yes	No	120,126	995	0.83%
381.71(a)	Condemnation on ante mortem inspection	Yes	No	1,389	22	1.58%
381.72(a)	Poultry	No	No	258	0	0.00%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
381.72(b)	Ratites	No	No	2	0	0.00%
381.76(a)	Post-mortem inspection, when required, extent	No	No	10,973	176	1.60%
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	No	60,227	299	0.50%
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	No	76,233	74	0.10%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	No	1,256,847	143	0.01%
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	No	3,990	249	6.24%
381.83	Septicemia or toxemia	No	No	1,143,642	137	0.01%
381.85	Special Diseases (organisms or toxins dangerous to the consumer)	No	No	30	0	0.00%
381.91(a)	Certain contaminated carcasses to be condemned	No	No	3,768	4	0.11%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	No	11,177	175	1.57%
381.94(a)	Verification criteria for E. coli testing ratites	No	No	993	5	0.50%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
416.1	Operate in a manner to prevent insanitary conditions	Yes	Yes	607,961	5,770	0.95%
416.12(c)	Plan identifies procedures for pre-op	Yes	No	45,757	60	0.13%
416.12(d)	Plan list frequency for each procedure & responsible individual	No	No	63,333	75	0.12%
416.13(a)	Conduct pre-op procedures	Yes	Yes	749,910	13,611	1.82%
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	1,886,131	3,513	0.19%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2,701,496	38,358	1.42%
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	Yes	1,652,069	3,642	0.22%
416.15(a)	Appropriate corrective actions	Yes	Yes	63,512	995	1.57%
416.15(b)	Corrective action, procedures for	Yes	Yes	39,458	1,040	2.64%
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	Yes	2,905,631	4,183	0.14%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	No	80,649	524	0.65%
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	68,457	912	1.33%
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	No	279,852	13,687	4.89%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	267,088	17,608	6.59%
416.5(c)	Employees who appear to have any abnormal source of microbial contamination	No	No	37,002	20	0.05%
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2,614	106	4.06%
417.2(a)(1)	Hazard analysis	Yes	Yes	127,373	1,423	1.12%
417.2(c)	Contents of HACCP Plan	Yes	No	30,421	79	0.26%
417.2(c)(4)	List of procedures & frequency	Yes	Yes	1,320,027	5,318	0.40%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
417.3(a)(1)	Identify and eliminate the cause	Yes	No	9,403	514	5.47%
417.3(a)(2)	CCP is under control	Yes	No	131,023	638	0.49%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	No	6,611	652	9.86%
417.3(a)(4)	No adulterated product enters commerce	No	No	27,665	158	0.57%
417.3(b)(1)	Segregate and hold the affected product	Yes	No	3,243	74	2.28%
417.3(b)(2)	Determine the acceptability of the affected product	Yes	No	2,681	72	2.69%
417.3(b)(3)	No adulterated product enters commerce	Yes	No	17,897	79	0.44%
417.3(b)(4)	Reassessment	Yes	Yes	28,992	171	0.59%
417.3(c)	Document corrective actions	Yes	No	4,439	251	5.65%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	7,438	214	2.88%
417.4(a)(1)	Initial validation	No	No	6,280	302	4.81%
417.4(b)	Reassessment of hazard analysis	No	Yes	30,786	57	0.19%
417.5(a)(1)	Written hazard analysis	Yes	Yes	1,381,468	3,556	0.26%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1,223,486	1,300	0.11%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1,392,959	3,510	0.25%
417.5(f)	Official Review	Yes	No	87,292	97	0.11%
417.6	Inadequate HACCP systems	Yes	No	552	156	28.26%
418.2	Notification of adulterated or misbranded product in commerce	Yes	No	1,726	98	5.68%
418.3	Recall Plans	No	No	23,995	52	0.22%
430.4(a)	Lm, post-lethality exposed RTE	Yes	Yes	300,023	102	0.03%
430.4(b)(1)	Alternative 1	No	No	745	7	0.94%
430.4(b)(2)	Alternative 2	No	No	14,186	61	0.43%
430.4(b)(3)	Alternative 3	Yes	No	20,540	254	1.24%
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	Yes	293,422	156	0.05%
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Yes	Yes	296,943	154	0.05%
430.4(c)(4)	Lm, validate and verify control measures in HACCP plan	No	No	3,640	12	0.33%
430.4(c)(5)	Lm, evaluate control measures in Sanitation SOP	No	No	5,696	23	0.40%

Regulation	Description	FY2021 PHR	Mandatory Regulation¹	Total Regulations Verified	Total Non- compliant Regulations Verified	PHR Non- compliance Rate
430.4(c)(6)	Lm, prerequisite program requirements	No	No	5,081	51	1.00%
431.11	Personnel and training	No	No	68	0	0.00%
431.12	Recall procedure	No	No	62	0	0.00%
431.4	Critical factors and the application of the process schedule	No	Yes	10,427	8	0.08%
431.9(b)	Procedures for handling of process deviations	No	Yes	9,311	2	0.02%
431.9(c)(1)	Process deviations identified in-process	No	No	152	1	0.66%
431.9(c)(2)	Process deviations identified through record review	No	No	79	2	2.53%
431.9(d)	Process deviation file	No	No	165	0	0.00%

¹Mandatory Regulations are the regulatory requirements that must be verified each time IPP perform the task.

APPENDIX C: COMPARISON OF FY2022 PHR LIST WITH FY2021 PHR LIST

There are seven regulations from the FY2021 PHR list that no longer appear in the FY2022 PHR list. These are shown in Table C-1.

Table C-1 Regulations from the FY2021 PHR List That Are No Longer on the FY2022 PHR List

List of FY2021 PHRs	Description
310.22(e)(4)(i)	Maintain daily records
311.14	Abrasions, bruises, abscesses, pus, etc.
381.71(a)	Condemnation on ante mortem inspection
416.12(c)	Plan identifies procedures for pre-op
417.6	Inadequate HACCP systems
430.4(b)(3)	Alternative 3: The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product. There are separate requirements for deli meat and hot dogs under this alternative.
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis

There are 13 regulations on the FY2022 PHR list that were not on the FY2021 PHR list.

Table C-2 Regulations on the FY2022 PHR List That Were Not on the FY2021 PHR List

List of FY2022 PHRs	Description
310.18(c)	Written procedures to prevent contamination; all swine slaughter
310.18(d)	Daily records sufficient to document the implementation and monitoring of contamination control procedures
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations
318.1(b)	Only inspected and passed poultry product to enter official establishment
381.65(f)	Procedures for controlling visible fecal contamination
381.193(a)	Poultry not intended for human food in commerce
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(a)(4)	No adulterated product enters commerce.
417.4(a)(1)	Initial validation
418.3	Recall plans
430.4(b)(2)	Alternative 2: The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product or the establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements

APPENDIX D: METHODOLOGY AND CALCULATION OF PHR CUT POINTS

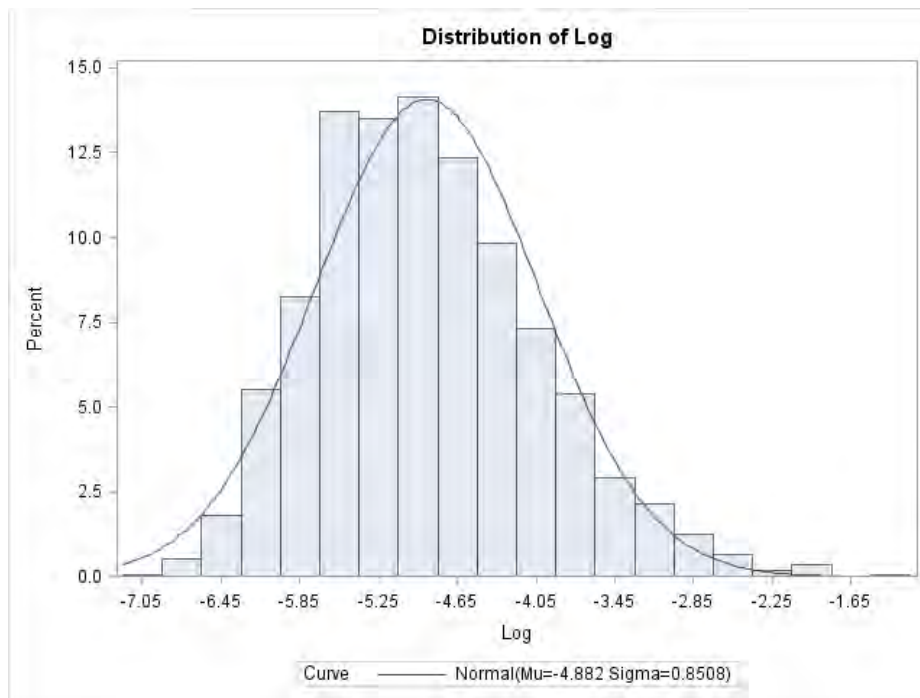
The purpose of this Appendix is to explain the methodology and calculations used to develop the PHR Cut Points. The PHR noncompliance rate is calculated by the following formula using the most recent 3 months of establishment verification inspection data:

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

Establishments are categorized into one of two plant types: (1) Processing Only and (2) Slaughter/Processing; named Processing, and Combination in the main body of the report). The plant 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 two noncompliances are considered.

Figure D-1 Log Transformed Non-Zero Noncompliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action



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

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

Goodness-of-Fit Tests for Normal Distribution				
Test	Statistic		p Value	
Kolmogorov-Smirnov	D	0.04327940	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.18116754	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	7.41746090	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 plants, mean and standard deviation for each plant 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/ Plant Type	Number of Establishments	Mean	Standard Deviation	Level	Tier Distribution (Number of Establishments)
Q1CY2020				Upper	64
Both	1,050	-4.51	0.96	Mid	98
Processing	4,260	-4.89	0.82	Lower	5,148
Q2CY2020				Upper	46
Both	1,055	-4.46	0.9	Mid	65
Processing	4,134	-4.72	0.74	Lower	5,078
Q3CY2020				Upper	61
Both	1,047	-4.52	0.98	Mid	93
Processing	4,213	-4.99	0.8	Lower	5,106
Q4CY2020				Upper	54
Both	1,034	-4.57	0.95	Mid	85
Processing	4,246	-5.01	0.81	Lower	5,141

Table D-2 shows the average mean and standard deviation of the log transformed non-zero PHR rate over four quarters for each plant type based on the quarterly data in Table D-1. Table D-3 shows the upper and lower cut points for FY2022 PHRs. Table D-4 show the distribution of establishments using data from January to March 2021 utilizing the proposed FY2022 PHRs.

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

Statistic	Combination	Processing
Mean	-4.51	-4.90
Standard Deviation	0.95	0.79

Table D-3 FY2022 Upper and Lower Cut Points

Operation Type	FY2022 PHR Upper Cut Points	FY2022 PHR Lower Cut Points
Processing	3.63%	2.44%
Combination	7.33%	4.60%

Table D-4 March 2021 Level Distribution Based on the PHR Criteria Only

(Note: Establishments with less than 20 verifications or establishments that have only one noncompliance are moved to the Mid Level Classification).

Classification	Plants
Upper	39
Mid	78
Lower	5,200
Total	5,317

REVISION HISTORY

Version	Date	Author	Change Description
1.0	7/1/2021	Kim Quigley Karyn Roark	Initial Document
2.0	11/22/2021	Kim Quigley Karyn Roark	<ul style="list-style-type: none"> Added Section 4.1.11 for <i>Salmonella</i> in RTE Added Section 4.4.4 and Table 4-18 for <i>Campylobacter</i> in Comminuted Turkey In Appendix Table B-1, FY2022 List of Candidate Regulations, the column was changed from “Total FSIS Verifications”, that included only compliant regulations, to “Total Regulations Verified” which includes compliant and noncompliant regulations. This change simplifies the calculation of the PHR noncompliance rate for the reader. Updated text and tables in Appendix D to be consistent with text in the body of the report Updated the PHR noncompliance formula in Appendix D from ‘Number of PHR Noncompliances divided by Total Number of PHR Inspection Procedures’ to ‘Total Noncompliant PHRs divided by Total PHRs Verified’ to emphasize this rate is based on regulations verified, not individual inspection tasks. Minor edits to text and formats, such as updating the Table of Contents and List of Figures