

FY2021 Public Health Regulations

July 2020

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SUMMARY

Public Health Regulations (PHRs) are verified regulations¹ with statistically higher individual noncompliance rates in establishments in the three 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 time period October 1, 2020, to September 30, 2021 (FY2021) to prioritize certain FY2021 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 PHRs is based on January 1, 2019, to December 31, 2019, (CY2019) verification inspection results and will be implemented in FY2021. 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 Public Health Risk Evaluation Methodology, to review the operational and compliance history of the establishment to decide if a Food Safety Assessment (FSA) or enforcement action is appropriate. For inclusion in the FY2021 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 FY2021 PHRs consists of 56 regulations that have higher rates of noncompliance 3 months before a pathogen positive or enforcement action. This compares with 49 regulations that were identified in the October 1, 2019, to September 30, 2020, (FY2020) PHR list. The list of FY2021 PHRs is presented in Appendix A. Forty-three regulations from the FY2020 PHR list are included in the FY2021 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 56 FY2021 PHRs comprise 8 regulations and 48 provisions of regulations. The 48 provisions fall under 19 different regulations. Thus, the 56 FY2021 PHRs represent 27 regulations, with the majority of FY2021 PHRs being provisions of regulations that provide greater specificity as to the nature of the noncompliance associated with a regulation violation. The average noncompliance rate of FY2021 PHR regulations 3 months before a pathogen positive or enforcement action is 9.92 times higher than the average FY2021 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action. Noncompliance with a single FY2021 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 FY2021 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 FY2021 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2021 PHR rates for each of the four quarters in CY2019 (the log transform of the non-zero FY2021 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 Tier 1 and are considered for a “for cause” PHRE if they have not had an 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 Tier 3. Establishments with a PHR noncompliance rate between the Tier 1 and Tier 3 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 FY2021 PHR cut points for the non-transformed PHR noncompliance data for each of the two establishment operation types. The FY2020 PHR cut points are included for comparison. (See Section 6 and Appendix D for more details.)

Table S-1 FY2021 PHR Tier 1 Cut Points

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

Table S-2 FY2021 PHR Tier 3 Cut Points

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

Table S-3 presents the number of establishments in each tier from January 1, 2020, to March 31, 2020, based on the PHR criterion. The period used for calculating the noncompliance rate of the

PHRs was January 1, 2020, to March 31, 2020. The number of “for cause” PHREs for Tier 1 establishments is approximately the same as in previous years.

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

Classification	Processing	Combination	Total
Tier 1	51	8	59
Tier 2	62	30	92
Tier 3	4,148	1,012	5,160
Total	4,261	1,050	5,311

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 to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) its plans 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 FY2021 PHRs (PHRs that will be used for the time period October 1, 2020, to September 30, 2021).

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 FY2021 PHR list is the same as that used for the FY2020 PHR list. For inclusion in the FY2021 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, 2019 (CY2019). Candidate regulations related to egg products are not included in the present 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

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.

of PHRs and section five explains the calculation of the cut points used for notifying districts of establishments that need to be scheduled for an FSA or PHRE. The final FY2021 PHR list is presented in Appendix A. Appendix B lists the candidate regulations evaluated to determine PHRs. Appendix C describes the differences between the FY2021 PHR list and FY2020 PHR list. Appendix D explains the methodology and calculations used to determine the PHR cut points.

2.0 SELECTION OF PHRS

The purpose of this section is to outline the process for 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. However, 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.
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 and consist of four elements that are used as the criteria for selecting the list of candidate regulations.

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
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. The current analysis

includes the six non-O157 STECs (O26, O45, O103, O111, O121, and O145) that FSIS has declared adulterants in non-intact raw beef products and product components.

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 134 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 134 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 134 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 CY2019. 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 2,110 establishments with *Salmonella* testing data, of which 771 had 3,519 *Salmonella* positives and 1,339 did not have *Salmonella* positives. There were 51,234 total *Salmonella* tests performed.

Table 4-1 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 an 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 CY2019.

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 FY2020 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	35.56%	1.65%	32.94	7.49E-193
310.22(b)	Inedible and prohibited SRM for use as human food	No	1.06%	0.09%	11.79	5.30E-03
310.22(c)	Disposal of SRM	Yes	3.92%	0.35%	11.76	4.00E-81
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	12.30%	1.51%	9.13	4.24E-62
310.22(e)(2)	Appropriate corrective actions	Yes	5.34%	1.16%	4.81	5.11E-06
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	15.07%	0.85%	20.64	4.81E-80
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	1.31%	0.18%	7.45	1.23E-07
318.2(a)	All products subject to reinspection by program employees	Yes	0.36%	0.06%	5.83	7.32E-08
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	1.38%	0.31%	4.57	1.09E-18

Regulation Verified	Description	On FY2020 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
381.71(a)	Condemnation on ante mortem inspection	Yes	6.80%	0.25%	29.12	2.93E-10
416.13(a)	Conduct pre-op procedures	Yes	7.10%	1.55%	4.87	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.60%	0.15%	4.10	3.93E-257
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	6.11%	1.19%	5.41	0.00E+00
416.15(b)	Corrective action, procedures for	Yes	10.76%	2.69%	4.36	9.61E-93
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	2.73%	0.54%	5.21	1.11E-52
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.52%	0.98%	5.88	3.16E-117
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	21.00%	4.08%	6.25	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	27.48%	5.34%	6.72	0.00E+00

Regulation Verified	Description	On FY2020 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
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	14.51%	3.32%	4.95	3.18E-12
417.2(c)	Contents of HACCP Plan	No	0.85%	0.17%	5.16	1.73E-10
417.2(c)(4)	List of procedures & frequency	Yes	1.30%	0.24%	5.44	0.00E+00
417.3(a)(1)	Identify and eliminate the cause	Yes	17.16%	2.06%	9.87	4.34E-96
417.3(a)(2)	CCP is under control	Yes	1.35%	0.29%	4.75	1.30E-59
417.3(a)(3)	Establish measures to prevent recurrence	Yes	26.53%	4.70%	7.33	7.02E-81
417.3(b)(2)	Determine the acceptability of the affected product	Yes	7.23%	1.19%	6.47	4.79E-10
417.3(b)(4)	Reassessment	Yes	1.64%	0.53%	3.11	1.99E-08
417.6	Inadequate HACCP systems	No	24.18%	7.42%	3.98	9.85E-05
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.34%	1.08%	4.16	0.00E+00
418.2	Notification of adulterated or misbranded product in commerce	No	15.24%	3.51%	4.94	1.53E-06
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	9.57%	2.60%	3.97	9.15E-05
311.14	Abrasions, bruises, abscesses, pus, etc.	No	0.40%	0.01%	38.45	3.40E-09

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 155 had 420 *Salmonella* positives and 51 did not have *Salmonella* positives. There were 9,307 total Intact Chicken *Salmonella* tests performed.

Table 4-2 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 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 CY2019.

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

Reg ID	Regulation Verified	Description	On FY2020 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
680	417.5(a)(1)	Written hazard analysis	Yes	0.52%	0.17%	3.13	2.88E-15
1332	381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	No	1.76%	0.59%	3.03	1.68E-33

4.1.2 *Salmonella* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with Intact Turkey *Salmonella* testing data, of which 9 had 10 *Salmonella* positives and 36 did not have *Salmonella* positives. There were 1,826 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the one regulation 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 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 CY2019.

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

Reg ID	Regulation Verified	Description	On FY2020 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
527	381.65(a)	Clean and sanitary practices; products not adulterated	Yes	2.14%	0.42%	5.20	1.21E-02

4.1.3 *Salmonella* in Ground Beef

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,222 establishments with Ground Beef *Salmonella* testing data, of which 111 had 163 *Salmonella* positives and 1,111 did not have *Salmonella* positives. There were 11,198 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the seven 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 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 CY2019.

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 FY2020 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	31.15%	2.25%	19.65	1.08E-15
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	8.26%	1.40%	6.34	8.53E-09
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	3.03%	0.25%	12.29	1.40E-07
416.15(b)	Corrective action, procedures for	Yes	16.96%	3.08%	6.44	4.09E-09

Regulation Verified	Description	On FY2020 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	2.25%	0.22%	10.23	5.09E-164
417.3(b)(3)	No adulterated product enters commerce	Yes	2.56%	0.35%	7.43	3.86E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.49%	0.99%	5.84	8.98E-139

4.1.4 *Salmonella* in Intact Beef

FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 908 establishments with Intact Beef *Salmonella* testing data, of which 72 had 147 *Salmonella* positives and 836 did not have *Salmonella* positives. There were 6,489 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 28 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 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 CY2019.

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

Reg ID	Regulation Verified	Description	On FY2020 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
29	301.2 Adulterated	Adulterated	Yes	33.41%	1.93%	25.52	6.11E-121
77	310.22(b)	Inedible and prohibited SRM for use as human food	No	2.82%	0.21%	13.77	9.73E-04
78	310.22(c)	Disposal of SRM	Yes	5.01%	0.38%	13.69	4.22E-66
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	17.66%	1.62%	13.04	3.55E-72
89	310.22(e)(2)	Appropriate corrective actions	Yes	23.36%	0.78%	38.85	5.61E-20
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	20.16%	0.94%	26.73	1.76E-72

Reg ID	Regulation Verified	Description	On FY2020 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
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.93%	0.20%	4.65	2.52E-03
234	318.2(a)	All products subject to reinspection by program employees	Yes	0.71%	0.06%	12.22	9.27E-05
235	318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	1.99%	0.10%	19.80	2.06E-03
591	416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.71%	0.99%	6.05	0.00E+00
594	416.15(a)	Appropriate corrective actions	Yes	22.04%	1.23%	22.73	6.84E-66

Reg ID	Regulation Verified	Description	On FY2020 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
595	416.15(b)	Corrective action, procedures for	Yes	50.00%	1.73%	56.81	5.17E-117
597	416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.51%	0.13%	3.86	1.20E-30
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	2.11%	0.45%	4.80	6.47E-05
631	416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	2.56%	0.84%	3.09	5.15E-04

Reg ID	Regulation Verified	Description	On FY2020 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
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	15.48%	3.91%	4.50	3.10E-192
641	416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	28.57%	3.02%	12.87	1.06E-06
648	417.2(c)	Contents of HACCP Plan	No	5.52%	0.21%	28.04	5.93E-15
649	417.2(c)(4)	List of procedures & frequency	Yes	1.87%	0.25%	7.51	7.54E-127
657	417.3(a)(1)	Identify and eliminate the cause	Yes	7.41%	1.98%	3.97	4.29E-05
658	417.3(a)(2)	CCP is under control	Yes	1.19%	0.29%	4.15	3.28E-05

Reg ID	Regulation Verified	Description	On FY2020 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
659	417.3(a)(3)	Establish measures to prevent recurrence	Yes	19.90%	4.27%	5.57	4.07E-12
664	417.3(b)(3)	No adulterated product enters commerce	Yes	1.24%	0.20%	6.37	2.37E-02
680	417.5(a)(1)	Written hazard analysis	Yes	0.87%	0.25%	3.56	1.28E-25
705	430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	Yes	2.59%	0.06%	47.09	3.45E-07
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.71%	0.99%	6.06	8.86E-296
1332	381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	No	6.85%	0.89%	8.18	1.03E-03

Reg ID	Regulation Verified	Description	On FY2020 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
1444	311.14	Abrasions, bruises, abscesses, pus, etc.	No	0.46%	0.01%	44.14	1.87E-05

4.1.5 *Salmonella* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 95 establishments with Comminuted Chicken *Salmonella* testing data, of which 82 had 663 *Salmonella* positives and 13 did not have *Salmonella* positives. There were 2,245 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 13 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 Comminuted Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Salmonella* positive for CY2019.

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 FY2020 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	2.83%	0.24%	12.29	2.72E-15
416.13(a)	Conduct pre-op procedures	Yes	7.48%	2.04%	3.88	1.38E-26
416.13(b)	Conduct other procedures listed in the plan	Yes	0.78%	0.13%	6.29	3.91E-11

Regulation Verified	Description	On FY2020 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(c)	Plant monitors implementation of SSOP procedures	Yes	5.47%	1.02%	5.62	1.06E-100
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.39%	0.12%	3.23	1.17E-03
416.15(a)	Appropriate corrective actions	Yes	12.61%	2.08%	6.78	2.23E-02
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.27%	0.07%	4.08	3.66E-05
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	7.16%	0.36%	21.37	3.37E-07
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	30.67%	3.41%	12.53	6.73E-83
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	34.19%	11.35%	4.06	2.05E-49
417.5(a)(1)	Written hazard analysis	Yes	0.57%	0.17%	3.41	6.02E-04
417.5(a)(2)	Written HACCP plan	Yes	0.34%	0.03%	10.84	5.60E-04
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	No	1.47%	0.29%	5.12	5.01E-04

4.1.6 *Salmonella* in Comminuted Turkey

There are 57 establishments with Comminuted Turkey *Salmonella* testing data, of which 47 had 339 *Salmonella* positives and 10 did not have *Salmonella* positives. There were 1,562 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the four 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 Comminuted Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Salmonella* positive for CY2019.

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 FY2020 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	7.33%	0.74%	10.64	4.87E-27
416.15(b)	Corrective action, procedures for	Yes	10.99%	1.54%	7.90	1.17E-02
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.35%	0.09%	3.74	6.42E-04
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	21.30%	5.88%	4.33	3.77E-22

4.1.7 *Salmonella* in Intact Pork

There are 161 establishments with Intact Pork *Salmonella* testing data, of which 57 had 235 *Salmonella* positives and 104 did not have *Salmonella* positives. There were 2,463 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the seven 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 CY2019.

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 FY2020 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
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.19%	0.32%	13.51	8.66E-14
417.2(c)	Contents of HACCP Plan	No	5.28%	0.18%	30.48	7.02E-09
417.2(c)(4)	List of procedures & frequency	Yes	0.82%	0.25%	3.30	4.11E-24
417.3(a)(1)	Identify and eliminate the cause	Yes	22.97%	1.63%	17.96	4.05E-11
417.3(a)(2)	CCP is under control	Yes	1.48%	0.28%	5.29	6.09E-04
417.3(a)(3)	Establish measures to prevent recurrence	Yes	21.21%	7.81%	3.18	4.54E-02
417.5(f)	Official Review	Yes	0.39%	0.08%	4.65	4.44E-02

4.1.8 *Salmonella* in Comminuted Pork

There are 223 establishments with Comminuted Pork *Salmonella* testing data, of which 117 had 575 *Salmonella* positives and 106 did not have *Salmonella* positives. There were 2,360 total Comminuted Pork *Salmonella* tests performed.

Table 4-9 presents the four 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 an Comminuted Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Pork *Salmonella* positive for CY2019.

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 FY2020 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	25.22%	9.80%	3.10	1.29E-02
310.22(c)	Disposal of SRM	Yes	8.13%	0.06%	141.63	1.09E-18
416.1	Operate in a manner to prevent insanitary conditions	Yes	2.97%	1.01%	3.01	6.03E-34
417.2(c)	Contents of HACCP Plan	No	0.82%	0.08%	10.69	6.40E-03

4.1.9 *Salmonella* in Chicken Parts

There are 479 establishments with Chicken Parts *Salmonella* testing data, of which 346 had 949 *Salmonella* positives and 133 did not have *Salmonella* positives. There were 10,900 total Chicken Parts *Salmonella* tests performed.

Table 4-10 presents the 10 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 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 *Salmonella* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Salmonella* positive for CY2019.

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 FY2020 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
381.71(a)	Condemnation on ante mortem inspection	Yes	15.74%	1.28%	14.45	5.25E-09
417.2(c)(4)	List of procedures & frequency	Yes	1.59%	0.33%	4.89	7.84E-130
417.3(a)(3)	Establish measures to prevent recurrence	Yes	12.58%	3.74%	3.70	1.91E-07
417.3(b)(1)	Segregate and hold the affected product	No	19.87%	3.85%	6.20	1.44E-04
417.3(b)(2)	Determine the acceptability of the affected product	Yes	16.67%	2.40%	8.13	4.01E-05
417.3(b)(3)	No adulterated product enters commerce	Yes	1.43%	0.24%	5.99	3.30E-04
417.3(b)(4)	Reassessment	Yes	3.30%	0.60%	5.70	1.48E-04
417.3(c)	Document corrective actions	No	8.64%	2.69%	3.42	4.30E-04

Regulation Verified	Description	On FY2020 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) (A)	NPIS Sorting, Trimming, and Reprocessing	Yes	1.27%	0.41%	3.12	7.54E-14
381.76(b)(6)(ii) (D)	Ready-to-Cook verification in NPIS	Yes	8.47%	2.39%	3.79	3.36E-06

4.1.10 *Salmonella* in Siluriformes

There are 74 establishments with Siluriformes *Salmonella* testing data, of which 13 had 18 *Salmonella* positives and 61 did not have *Salmonella* positives. There were 632 total Siluriformes *Salmonella* tests performed.

Table 4-11 presents the one regulation 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 CY2019.

Table 4-11 Comparison of Noncompliance Rates Three Months before a Siluriformes *Salmonella* Positive with those for Establishments with No Siluriformes *Salmonella* Positive

Regulation Verified	Description	On FY2020 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
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	13.79%	3.79%	4.06	1.71E-04

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 1,376 establishments with *E. coli* O157:H7 testing data, of which 12 had 13 *E. coli* O157:H7 positives and 1,364 did not have *E. coli* O157:H7 positives. There were 17,690 total *E. coli* O157:H7 tests performed.

Table 4-12 presents the five 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 CY2019.

Table 4-12 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 FY2020 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	35.59%	3.04%	17.65	2.92E-16
310.22(c)	Disposal of SRM	Yes	7.77%	0.52%	16.25	9.44E-08
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.15%	0.21%	5.56	5.38E-05
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.76%	0.13%	6.02	1.07E-05
417.5(a)(2)	Written HACCP plan	Yes	0.36%	0.08%	4.67	2.80E-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 34 had 73 Non-O157 STEC positives and 449 did not have Non-O157 STEC positives. There were 4,038 total Non-O157 STEC tests performed.

Table 4-13 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 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 Non-O157 STEC positive is higher than the average noncompliance rate for establishments with no Non-O157 STEC positive for CY2019.

Table 4-13 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 FY2020 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
417.3(b)(3)	No adulterated product enters commerce	Yes	1.63%	0.08%	20.41	1.03E-04
417.5(a)(2)	Written HACCP plan	Yes	0.29%	0.07%	4.07	9.51E-05

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 2,255 establishments with *Listeria monocytogenes* testing data, of which 3 had three *Listeria monocytogenes* positives and 2,252 did not have *Listeria monocytogenes* positives. There were 2,255 total *Listeria monocytogenes* tests performed.

Table 4-14 presents the four 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 CY2019.

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

Regulation Verified	Description	On FY2020 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
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	2.90%	0.95%	3.12	1.41E-16
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.29%	0.11%	2.65	1.27E-02
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	9.39%	3.69%	2.71	4.82E-05

Regulation Verified	Description	On FY2020 PHR List	Noncompliance Rate in 3 Months before a <i>Listeria monocytognes</i> Positive	Noncompliance Rate for Establishments with no <i>Listeria monocytognes</i> Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	10.67%	3.97%	2.89	5.64E-07

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 610 establishments with *Campylobacter* testing data, of which 457 had 4,126 *Campylobacter* positives and 153 did not have *Campylobacter* positives. There were 25,765 total *Campylobacter* tests performed.

Table 4-15 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 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 CY2019.

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

Regulation Verified	Description	On FY2020 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher Exact p Value
381.71(a)	Condemnation on ante mortem inspection	Yes	8.06%	0.55%	15.87	1.03E-05
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	3.38%	0.57%	6.16	1.09E-06
416.1	Operate in a manner to prevent insanitary conditions	Yes	4.58%	1.40%	3.38	1.00E-103
416.13(b)	Conduct other procedures listed in the plan	Yes	0.90%	0.20%	4.52	3.44E-94
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.20%	0.13%	9.48	8.16E-150
416.15(a)	Appropriate corrective actions	Yes	7.93%	2.44%	3.44	3.46E-12
416.16(a)	Daily records required,	Yes	0.50%	0.10%	5.30	4.16E-88

Regulation Verified	Description	On FY2020 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher Exact p Value
	responsible individual, initialed and dated					
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.50%	0.52%	11.18	3.20E-32
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	11.18%	2.96%	4.12	7.09E-30
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	34.79%	3.97%	12.89	2.76E-16
417.2(c)(4)	List of procedures & frequency	Yes	1.68%	0.12%	14.80	3.11E-237
417.3(a)(3)	Establish measures to prevent recurrence	Yes	11.41%	2.98%	4.19	6.33E-06

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 198 had 1,907 *Campylobacter* positives and 8 did not have *Campylobacter* positives. There were 9,281 total Intact Chicken *Campylobacter* tests performed.

Table 4-16 presents the four 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 CY2019.

Table 4-16 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 FY2020 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
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	2.99%	0.27%	11.30	3.99E-04
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	33.69%	12.11%	3.69	1.24E-23
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	45.13%	8.68%	8.66	1.19E-65
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	7.52%	1.10%	7.32	1.39E-02

4.4.2 *Campylobacter* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with Intact Turkey *Campylobacter* testing data, of which 17 had 39 *Campylobacter* positives and 28 did not have *Campylobacter* positives. There were 1,827 total Intact Turkey *Campylobacter* tests performed.

Table 4-17 presents the one 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 CY2019.

Table 4-17 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 FY2020 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
417.2(c)(4)	List of procedures & frequency	Yes	1.45%	0.46%	3.20	9.68E-13

4.4.3 *Campylobacter* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 95 establishments with Comminuted Chicken *Campylobacter* testing data, of which 47 had 182 *Campylobacter* positives and 48 did not have *Campylobacter* positives. There were 2,232 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-18 presents the four 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 Comminuted Chicken *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Campylobacter* positive for CY2019.

Table 4-18 Comparison of Noncompliance Rates 3Months before a Comminuted Chicken Campylobacter Positive with Those for Establishments with No Comminuted Chicken Campylobacter Positive

Regulation Verified	Description	On FY2020 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher Exact p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.75%	0.17%	4.50	6.01E-16
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	11.59%	2.17%	5.93	8.42E-08
417.3(a)(3)	Establish measures to prevent recurrence	Yes	15.79%	3.26%	5.56	4.40E-03
417.5(a)(2)	Written HACCP plan	Yes	0.60%	0.13%	4.75	8.69E-14

4.4.4 *Campylobacter* in Comminuted Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 57 establishments with Comminuted Turkey *Campylobacter* testing data, of which 19 had 71 *Campylobacter* positives and 38 did not have *Campylobacter* positives. There were 1,547 total Comminuted Turkey *Campylobacter* tests performed.

Table 4-19 presents the five 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 regulations in establishments 3 months before an Comminuted Turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Campylobacter* positive for CY2019.

Table 4-19 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 FY2020 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
318.2(a)	All products subject to reinspection by program employees	Yes	8.33%	0.15%	1.16E-06	61.45
416.15(a)	Appropriate corrective actions	Yes	8.05%	2.39%	1.14E-04	3.58
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	7.60%	1.12%	1.71E-05	7.24
417.3(a)(3)	Establish measures to prevent recurrence	Yes	19.78%	5.42%	1.81E-05	4.30
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	0.57%	0.04%	1.96E-03	12.94

4.4.5 *Campylobacter* in Chicken Parts

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 479 establishments with Chicken Parts *Campylobacter* testing data, of which 373 had 1,927 *Campylobacter* positives and 106 did not have *Campylobacter* positives. There were 10,878 total Chicken Parts *Campylobacter* tests performed.

Table 4-20 presents the nine 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 CY2019.

Table 4-20 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 FY2020 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	3.95%	0.19%	4.86E-08	21.42
416.1	Operate in a manner to prevent insanitary conditions	Yes	4.57%	1.12%	3.55E-78	4.22
416.13(b)	Conduct other procedures listed in the plan	Yes	0.90%	0.15%	5.75E-76	6.24
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.21%	0.11%	9.28E-103	10.76
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.49%	0.10%	7.58E-53	4.92
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.39%	0.90%	7.99E-10	5.03

Regulation Verified	Description	On FY2020 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	10.52%	3.10%	4.02E-14	3.68
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	29.39%	6.68%	3.15E-240	5.82
417.2(c)(4)	List of procedures & frequency	Yes	1.70%	0.12%	3.83E-157	14.95

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 FY2020 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 CY2019. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,300 active meat and poultry establishments, of which 138 had 121 enforcement actions and 5,179 did not have any enforcement actions.

Table 4-21 presents the 34 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 CY2019.

Table 4-21 Comparison of Noncompliance Rates 3 Months before an Enforcement Action with Those for Establishments with No Enforcement Action

Regulation Verified	Description	On FY2020 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
310.22(c)	Disposal of SRM	Yes	2.56%	0.47%	5.55	1.13E-05
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	8.47%	1.59%	5.75	2.60E-05
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	11.76%	1.56%	8.40	1.47E-05
310.22(e)(4)(i)	Maintain daily records	No	1.85%	0.18%	10.58	3.65E-05
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	No	2.83%	0.66%	4.37	1.64E-03
310.3	Carcasses and parts in certain instances to be retained.	No	24.24%	6.98%	4.27	1.78E-03
318.2(d)	Removal of U.S. retained by authorized program employees only	Yes	5.88%	0.52%	11.93	1.46E-02

Regulation Verified	Description	On FY2020 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
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.02%	1.25%	4.18	3.85E-41
416.12(c)	Plan identifies procedures for pre-op	No	2.16%	0.17%	12.83	7.07E-05
416.13(a)	Conduct pre-op procedures	Yes	5.90%	1.96%	3.13	3.66E-42
416.13(b)	Conduct other procedures listed in the plan	Yes	0.98%	0.19%	5.20	6.07E-33
416.15(a)	Appropriate corrective actions	Yes	12.04%	1.89%	7.10	1.63E-13
416.15(b)	Corrective action, procedures for	Yes	9.05%	2.93%	3.29	1.87E-05
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.64%	0.14%	4.56	1.70E-28
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.91%	0.80%	7.80	1.29E-08
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	4.64%	1.40%	3.43	1.46E-05

Regulation Verified	Description	On FY2020 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	16.12%	6.00%	3.01	1.04E-52
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	22.28%	8.27%	3.18	3.52E-67
417.2(a)(1)	Hazard analysis	Yes	8.59%	1.15%	8.08	3.96E-24
417.2(c)	Contents of HACCP Plan	No	2.78%	0.26%	10.93	3.20E-03
417.2(c)(4)	List of procedures & frequency	Yes	2.24%	0.47%	12.51	2.71E-51
417.3(a)(1)	Identify and eliminate the cause	Yes	39.39%	4.94%	9.33	2.83E-09
417.3(a)(3)	Establish measures to prevent recurrence	Yes	50.91%	10.00%	4.86	4.51E-14
417.3(b)(3)	No adulterated product enters commerce	Yes	2.15%	0.45%	5.18	1.13E-02
417.3(b)(4)	Reassessment	Yes	2.94%	0.58%	20.77	2.28E-02
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	35.00%	2.53%	5.08	9.48E-13
417.5(a)(1)	Written hazard analysis	Yes	1.33%	0.27%	5.72	1.38E-33
417.5(a)(2)	Written HACCP plan	Yes	0.53%	0.09%	12.51	8.82E-15

Regulation Verified	Description	On FY2020 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
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	1.55%	0.23%	6.76	4.55E-53
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	0.17%	0.03%	6.17	4.39E-02
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE - Alternative 3	No	2.94%	0.90%	3.33	3.65E-02
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	Yes	0.25%	0.04%	6.10	1.44E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.55%	1.47%	3.93	2.68E-55
381.76(b)(6)(ii)(A)	NPIS sorting, trimming, and reprocessing	Yes	2.17%	0.66%	3.34	2.13E-03

5.0 LIST OF FY2021 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2021 PHR list. Table 5-1 presents the complete list of the 56 FY2021 PHRs. These 56 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 56 FY2021 PHRs are composed of eight regulations and 48 provisions of regulations. The 48 provisions fall under 19 different regulations. Thus, the 56 FY2021 PHRs represent 27 regulations, with the majority of FY2021 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 FY2021 PHRs

Regulation Verified	Description	On FY2020 PHR List	Average Odds Ratio	Average Two-Sided Fisher Exact p Value
301.2 Adulterated	Adulterated	Yes	19.77	2.57E-03
310.22(b)	Inedible and prohibited SRM for use as human food	No	12.78	3.14E-03
310.22(c)	Disposal of SRM	Yes	37.77	2.28E-06
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	8.56	6.51E-06
310.22(e)(2)	Appropriate corrective actions	Yes	21.83	2.56E-06
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	18.59	4.91E-06
310.22(e)(4)(i)	Maintain daily records	No	10.58	3.65E-05
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	8.13	8.39E-04
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	No	4.37	1.64E-03
310.3	Carcasses and parts in certain instances to be retained.	No	4.27	1.78E-03
318.2(a)	All products subject to reinspection by program employees	Yes	26.50	3.13E-05

Regulation Verified	Description	On FY2020 PHR List	Average Odds Ratio	Average Two- Sided Fisher Exact p Value
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	15.86	8.34E-03
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	4.88	6.05E-03
381.71(a)	Condemnation on ante mortem inspection	Yes	19.82	3.43E-06
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	12.96	1.34E-04
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.41	5.44E-16
416.12(c)	Plan identifies procedures for pre-op	No	12.83	7.07E-05
416.13(a)	Conduct pre-op procedures	Yes	5.63	4.66E-27
416.13(b)	Conduct other procedures listed in the plan	Yes	5.27	7.83E-12
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.05	3.53E-17
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	6.71	2.45E-04
416.15(a)	Appropriate corrective actions	Yes	8.73	4.49E-03
416.15(b)	Corrective action, procedures for	Yes	15.76	2.34E-03
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	4.39	1.67E-03
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	7.82	1.17E-05
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	6.78	7.57E-05
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	5.44	3.13E-05
416.4(d)	Product processing, handling, storage, loading, unloading,	Yes	4.90	8.06E-08

Regulation Verified	Description	On FY2020 PHR List	Average Odds Ratio	Average Two- Sided Fisher Exact p Value
	and during transportation must be protected			
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	10.24	3.53E-07
417.2(a)(1)	Hazard analysis	Yes	8.08	3.96E-24
417.2(c)	Contents of HACCP Plan	No	17.06	1.92E-03
417.2(c)(4)	List of procedures & frequency	Yes	7.68	1.08E-13
417.3(a)(1)	Identify and eliminate the cause	Yes	11.08	1.07E-05
417.3(a)(2)	CCP is under control	Yes	4.73	2.14E-04
417.3(a)(3)	Establish measures to prevent recurrence	Yes	5.40	6.23E-03
417.3(b)(1)	Segregate and hold the affected product	No	6.20	1.44E-04
417.3(b)(2)	Determine the acceptability of the affected product	Yes	7.30	2.00E-05
417.3(b)(3)	No adulterated product enters commerce	Yes	9.01	1.48E-02
417.3(b)(4)	Reassessment	Yes	4.66	7.66E-03
417.3(c)	Document corrective actions	No	3.42	4.30E-04
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	20.77	9.48E-13
417.5(a)(1)	Written hazard analysis	Yes	3.80	1.50E-04
417.5(a)(2)	Written HACCP plan	Yes	6.01	5.74E-03
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	6.76	4.55E-53
417.5(f)	Official Review	Yes	4.65	4.44E-02
417.6	Inadequate HACCP systems	No	3.98	9.85E-05
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	6.17	4.39E-02
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE - Alternative 3	No	3.33	3.65E-02

Regulation Verified	Description	On FY2020 PHR List	Average Odds Ratio	Average Two-Sided Fisher Exact p Value
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	Yes	26.60	7.22E-03
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	12.94	1.96E-03
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.00	6.70E-56
418.2	Notification of adulterated or misbranded product in commerce	No	4.94	1.53E-06
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	No	5.44	5.10E-04
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	3.23	1.07E-03
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	5.02	4.65E-03
311.14	Abrasions, bruises, abscesses, pus, etc.	No	41.29	9.36E-06

Forty-three of the previous 49 FY2020 PHRs are included in the FY2021 PHRs. There are six regulations on the FY2020 PHR list that are not in the FY2021 PHR list (See Appendix C). There are 13 regulations that are on the FY2021 PHR list that were not on the FY2020 PHR list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2021 PHR list. Most regulations were triggered by multiple events. Similar to the FY2020 PHR list, salmonella pathogen positives and enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2021 PHR List

Product	Number of Regulations
Campylobacter	12
Campylobacter Chicken Parts	9
Campylobacter Ground Chicken	4
Campylobacter Ground Turkey	5
Campylobacter Intact Chicken	4
Campylobacter Intact Turkey	1
Enforcements	34
Listeria	4
Non-O157 <i>E. coli</i>	2
O157 <i>E. coli</i>	5
Salmonella	31
Salmonella Chicken Parts	10
Salmonella Ground Beef	7
Salmonella Ground Chicken	13
Salmonella Ground Pork	4
Salmonella Ground Turkey	4
Salmonella Intact Beef	28
Salmonella Intact Chicken	2
Salmonella Intact Pork	7
Salmonella Intact Turkey	1
Salmonella Siluriformes	1

There were 10 regulations triggered by a single type of event: Four were from Enforcement Actions, two were from *Salmonella*, two were from *Salmonella* in Chicken Parts, one was from *Salmonella* in Intact Beef, and one was from *Campylobacter* in Comminuted Turkey. Table 5-3 presents the regulations triggered for inclusion in the FY2021 PHR list by only single pathogen product or enforcement action type.

Table 5-3 Regulations Triggered for Inclusion in the FY2021 PHR List by Only a Single Event

Regulation Verified	Description	Event
310.22(e)(4)(i)	Maintain daily records	Enforcements
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	Enforcements
416.12(c)	Plan identifies procedures for pre-op	Enforcements
417.3(b)(1)	Segregate and hold the affected product	Salmonella Chicken Parts
417.3(c)	Document corrective actions	Salmonella Chicken Parts
417.6	Inadequate HACCP systems	Salmonella
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Salmonella Intact Beef
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE - Alternative 3	Enforcements
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Campylobacter Ground Turkey
418.2	Notification of adulterated or misbranded product in commerce	Salmonella

6.0 CUT POINTS FOR FY2021 PHRS

The FY2021 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 FY2021 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 FY2021 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 FY2021 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 FY2021 PHR Rate

	Mean of Natural Log FY2021 PHR Rate			Standard Deviation FY2021 PHR Rate	
	Processing	Combination		Processing	Combination
Jan-Mar 2019	-4.96	-4.48		0.82	1.05
Apr-Jun 2019	-4.72	-4.26		0.75	0.95
July-Sept 2019	-4.92	-4.42		0.83	1.10
Oct-Dec 2019	-4.98	-4.43		0.82	1.06
Average	-4.90	-4.40		0.80	1.04

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 Tier 1 and are candidates to receive a for cause PHRE. For example⁴, the upper cut point for the log transformed data for Combination establishments is $-4.40 + 2 \times 1.04 = -4.40 + 2.08 = -2.32$. The cut point of the original, non-transformed PHR noncompliance data is the antilog of -2.32 or $\text{Exp}(-2.32) = 9.84\%$. Establishments that are below the Tier 1 threshold but meet or exceed the lower Tier 3 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 (Processing, and Slaughter/Processing Combination):

- Any establishment with a PHR rate that is less than the lower cut point for all establishments with the same establishment type would continue to receive routine inspection procedures. These establishments are performing better on average than their peers with respect to compliance with the PHR regulations.
- Establishments with a PHR rate that is greater than or equal to the lower cut point but less than the upper cut point for all establishments with the same establishment type would continue to receive routine inspection procedures and be alerted through inspection personnel of elevated PHR noncompliance levels.
- Establishments with a PHR rate greater than the upper cut point for establishments with the same establishment type that have not had an FSA in the last six months receive a PHRE to determine if a for-cause FSA is appropriate.

Tables 6-2 and 6-3 present the FY2021 PHR upper and lower cut points for each of the two establishment operation types. The FY2020 PHR cut points are included for comparison. (See

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

Appendix D for more details). The cut points are determined once a year. The next update to the cut points is planned for October 2020.

Table 6-2 FY2021 PHR Tier 1 Cut Points

Operation Type	FY2021 PHR Cut Points	FY2020 PHR Cut Points	FY2019 PHR Cut Points
Processing	3.73%	3.86%	4.40%
Combination	9.84%	8.83%	9.40%

Table 6-3 FY2021 PHR Tier 3 Cut Points

Operation Type	FY2021 PHR Cut Points	FY2020 PHR Cut Points	FY2019 PHR Cut Points
Processing	2.50%	2.58%	2.90%
Combination	5.85%	5.42%	5.64%

Table 6-4 presents the number of establishments in each Tier based solely on the FY2021 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 Tier 1 but only have one noncompliance are moved to Tier 2. Based solely on the noncompliance rate for the FY2021 PHRs, 59 establishments are in Tier 1 and candidates to receive for cause PHREs. Table 6-4 is based on regulatory noncompliances for the period January 1-March 31, 2020.

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

Classification	Number of Establishments
Tier 1	59
Tier 2	92
Tier 3	5,160
Total	5,311

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

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

Classification	Processing	Combination
Tier 1	51	8
Tier 2	62	30
Tier 3	4,148	1,012
Total	4,261	1,050

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2021 PHR regulations used to prioritize certain FY2021 FSIS inspection activities. This process involves 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 using this subset to determine cut points to determine which establishments should be flagged for a PHRE or an alert throughout the year.

The list of FY2021 PHRs has 56 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-three regulations on the FY2020 PHR list are also on the FY2021 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, described in [FSIS Directive 5100.4](#).

Tables 7-1 and 7-2 present the FY2021 PHR upper and lower cut points. The FY2020 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 FY2021 PHR Tier 1 Cut Points

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

Table 7-2 FY2021 PHR Tier 3 Cut Points

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

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 \(FSIS\) 2019, FY2020 Public Health Regulations.](#)
4. [National Advisory Committee on Meat and Poultry Inspection \(NACMPI\) 2013, Subcommittee Two, Issue Two: Data Analysis.](#)

APPENDIX A: FY2021 PHR REGULATIONS

Table A-1 presents the list of 56 FY2021 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates 3 months prior to a pathogen positive or enforcement action that is 9.92 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2021 PHRs

Regulation	Description
301.2 Adulterated	Adulterated
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(c)	Disposal of SRM
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
310.22(e)(2)	Appropriate corrective actions
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
310.22(e)(4)(i)	Maintain daily records
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
310.25(a)	Verification criteria for <i>E. coli</i> testing meat
310.3	Carcasses and parts in certain instances to be retained.
318.2(a)	All products subject to reinspection by program employees
318.2(d)	Removal of U.S. retained by authorized Program employees only
381.65(a)	Clean and sanitary practices; products not adulterated
381.71(a)	Condemnation on ante mortem inspection
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
416.1	Operate in a manner to prevent insanitary conditions
416.12(c)	Plan identifies procedures for pre-op
416.13(a)	Conduct pre-op procedures
416.13(b)	Conduct other procedures listed in the plan
416.13(c)	Plant monitors implementation of SSOP procedures
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.15(a)	Appropriate corrective actions
416.15(b)	Corrective action, procedures for
416.16(a)	Daily records required, responsible individual, initialed and dated

Regulation	Description
416.3(b)	Constructed, located & operated in a manner that does not deter inspection
416.3(c)	Receptacles for storing inedible material must identify permitted use
416.4(a)	Food contact surface, cleaning & sanitizing as frequency
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
416.6	Only FSIS program employee may remove "U.S. Rejected" tag
417.2(a)(1)	Hazard analysis
417.2(c)	Contents of HACCP Plan
417.2(c)(4)	List of procedures & frequency
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(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
417.5(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
417.6	Inadequate HACCP systems
430.4(a)	<i>Lm</i> , post-lethality exposed RTE
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE - Alternative 3
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
418.2	Notification of adulterated or misbranded product in commerce
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation

Regulation	Description
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
311.14	Abrasions, bruises, abscesses, pus, etc.

APPENDIX B: FY2021 CANDIDATE REGULATIONS

Table B-1 presents the list of candidate regulations. The noncompliance rates in Table B-1 are based on PHIS data for January 1, 2019, through December 31, 2019.

Table B-1 FY2021 Candidate Regulations

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
301.2 Adulterated	Adulterated	Yes	No	6058	208	3.32%
304.3(a)	Develop written SSOP	No	No	628	2	0.32%
304.3(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	1468	7	0.47%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	579	13	2.20%
309.3	(HIMP ONLY) Dead, dying, disabled or diseased and similar livestock.	No	No	214	0	0.00%
309.4	(HIMP ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases	No	No	223	3	1.33%
309.5	(HIMP ONLY) Swine; disposal because of hog cholera	No	No	203	0	0.00%
309.9	(HIMP ONLY) Swine erysipelas	No	No	207	0	0.00%
310.18	Contamination of carcasses, organs, or other parts	No	No	435	5	1.14%
310.22(b)	Inedible and prohibited SRM for use as human food	No	No	4217	11	0.26%
310.22(c)	Disposal of SRM	Yes	Yes	54500	204	0.37%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar US products	No	No	123	0	0.00%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	15877	267	1.65%
310.22(e)(2)	Appropriate corrective actions	Yes	No	3619	53	1.44%
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	9778	154	1.55%
310.22(e)(4)(i)	Maintain daily records	No	No	77402	210	0.27%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	No	15988	37	0.23%
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	No	1255	6	0.48%
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	No	4232	14	0.33%
310.25(a)	Verification criteria for <i>E. coli</i> testing meat	No	No	29229	255	0.86%
310.25(b)	Pathogen reduction performance standards; Salmonella	No	No	216	0	0.00%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	58	1	1.69%
310.3	Carcasses and parts in certain instances to be retained.	No	No	3012	233	7.18%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
311.16	(HIMP ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.	No	No	202	6	2.88%
311.17	(HIMP ONLY) Necrobacillosis, pyemia, septicemia.	No	No	519	1	0.19%
311.24	(HIMP ONLY) Hogs affected with tapeworm cysts.	No	No	201	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	87	0	0.00%
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	No	12733	48	0.38%
317.24(a)	Packaging materials composed of poisonous or deleterious substances	No	No	2996	14	0.47%
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	No	101717	13	0.01%
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	401	0	0.00%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	844	1	0.12%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision	No	No	192	0	0.00%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
318.16(b)	Pesticides chemicals & other residues in products not to exceed FD&C Act levels - Meat ingredients	No	No	364	1	0.27%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	2670	1	0.04%
318.17(b)	Lethality and Stabilization processes other than HACCP for cooked beef	No	No	678	0	0.00%
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	39	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	50128	59	0.12%
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	9015	46	0.51%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully cooked meat patties	No	No	436	2	0.46%
318.23(b)(3)	Heat deviations for meat patties	No	No	32	1	3.03%
318.23(c)(1)	Stabilization requirements for meat patties	No	No	389	0	0.00%
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	24	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	331	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	164	0	0.00%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2558	16	0.62%
318.6(b)(1)	Requirements for use of casings, used as containers	No	No	2030	1	0.05%
318.6(b)(4)	Detached spinal cords	No	No	9998	0	0.00%
318.6(b)(6)	Tonsils	No	No	12555	2	0.02%
318.6(b)(8)	Intestines as ingredients	No	No	306	0	0.00%
319.5(b)	Mechanically separated (beef) - prohibited for use in human food	No	No	269	0	0.00%
381.1 Adulterated	Adulterated	Yes	No	3785	22	0.58%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	2546	1	0.04%
381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	No	1631	3	0.18%
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry	No	No	63	0	0.00%
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	4	0	0.00%
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	167	0	0.00%
381.22(a)	Develop written SSOP	No	No	258	1	0.39%
381.22(b)	Conduct hazard analysis & develop and validate HACCP plan	No	No	1249	1	0.08%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	402	1	0.25%
381.37(a)	Product not produced under supervision of program employee	No	No	2000	12	0.60%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	44145	342	0.77%
381.71(a)	Condemnation on ante mortem inspection	Yes	No	1972	81	3.95%
381.72(a)	Poultry	No	No	148	0	0.00%
381.72(b)	Ratites	No	No	2	0	0.00%
381.76(a)*	Post-mortem inspection, when required, extent.	Yes	No	8286	145	1.72%
381.83	Septicemia or toxemia	Yes	No	884160	125	0.01%
381.85	Special Diseases (organisms or toxins dangerous to the consumer)	No	No	64	0	0.00%
381.91(a)	Certain contaminated carcasses to be condemned	No	No	5974	4	0.07%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	No	15201	199	1.29%
416.1	Operate in a manner to prevent insanitary conditions	Yes	Yes	608967	7774	1.26%
416.12(c)	Plan identifies procedures for pre-op	No	No	48387	83	0.17%
416.12(d)	Plan list frequency for each procedure & responsible individual	No	No	65813	91	0.14%
416.13(a)	Conduct pre-op procedures	Yes	Yes	741929	13387	1.77%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	1897363	3575	0.19%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2695599	43501	1.59%
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	Yes	1658091	4044	0.24%
416.15(a)	Appropriate corrective actions	Yes	Yes	64913	1009	1.53%
416.15(b)	Corrective action, procedures for	Yes	Yes	41108	1037	2.46%
416.16(a)	daily records required, responsible individual, initialed and dated	Yes	Yes	2942578	4564	0.15%
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	No	80261	606	0.75%
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	68919	936	1.34%
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	No	274664	16735	5.74%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	250748	21063	7.75%
416.5(c)	Employees who appears to have any abnormal source of microbial contamination	No	No	32164	17	0.05%
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2304	113	4.68%
417.2(a)(1)	Hazard analysis	Yes	Yes	126162	1714	1.34%
417.2(c)	Contents of HACCP Plan	No	No	29248	88	0.30%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
417.2(c)(4)	List of procedures & frequency	Yes	Yes	1352938	6125	0.45%
417.3(a)	Corrective action after deviation from CCP	No	No	285	2	0.70%
417.3(a)(1)	Identify and eliminate the cause	Yes	No	8520	488	5.42%
417.3(a)(2)	CCP is under control	Yes	No	127741	657	0.51%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	No	5200	596	10.28%
417.3(a)(4)	No adulterated product enters commerce	No	No	30265	181	0.59%
417.3(b)(1)	Segregate and hold the affected product	No	No	3509	90	2.50%
417.3(b)(2)	Determine the acceptability of the affected product	Yes	No	2292	96	4.02%
417.3(b)(3)	No adulterated product enters commerce	Yes	No	21758	97	0.44%
417.3(b)(4)	Reassessment	Yes	Yes	28163	184	0.65%
417.3(c)	Document corrective actions	No	No	4679	213	4.35%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	8228	234	2.77%
417.4(a)(1)	Initial validation	No	No	6097	402	6.19%
417.4(b)	Reassessment of hazard analysis	No	Yes	30599	90	0.29%
417.5(a)(1)	Written hazard analysis	Yes	Yes	1398408	3967	0.28%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1244575	1316	0.11%
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1424289	3973	0.28%
417.5(f)	Official Review	Yes	No	90784	106	0.12%
417.6	Inadequate HACCP systems	No	No	388	89	18.66%
430.4(a)	<i>Lm</i> , post-lethality exposed RTE	Yes	Yes	308853	117	0.04%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
430.4(b)(1)	<i>Lm</i> , post-lethality exposed RTE - Alternative 1	No	No	784	6	0.76%
430.4(b)(2)	<i>Lm</i> , post-lethality exposed RTE - Alternative 2	No	No	13994	76	0.54%
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE - Alternative 3	No	No	22203	298	1.32%
430.4(c)(2)	<i>Lm</i> , documentation that supports decision in hazard analysis	Yes	Yes	300217	170	0.06%
430.4(c)(3)	<i>Lm</i> , maintain sanitation in post-lethality processing environment	Yes	Yes	305736	163	0.05%
430.4(c)(4)	<i>Lm</i> , validate and verify control measures in HACCP plan	No	No	3525	12	0.34%
430.4(c)(5)	<i>Lm</i> , evaluate control measures in Sanitation SOP	No	No	6176	22	0.35%
430.4(c)(6)	<i>Lm</i> , prerequisite program requirements	No	No	5584	51	0.91%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	319299	4280	1.32%
310.18(b)	Brains, cheek meat, head trimmings from animals slaughtered by gunshot	No	No	20890	1	0.00%
418.2	Notification of adulterated or misbranded product in commerce	No	No	1443	109	7.02%
418.3	Recall Plans	Yes	No	20510	79	0.38%
354.242(b)	All equipment and utensils clean and sanitary	No	No	72	1	1.37%
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	24	0	0.00%

FY2021 Candidate Regulation	Description	FY2020 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs¹	NC¹ Rate
354.243(a)	No handling or storage of objectionable materials	No	No	17	0	0.00%
381.193(a)	Poultry not intended for human food in commerce	No	No	245	6	2.39%
381.65(f)	Procedures for controlling visible fecal contamination	No	No	1285450	11150	0.86%
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation	No	No	130728	1208	0.92%
381.76(a)	Post-mortem inspection, when required, extent	No	No	6109	117	1.88%
381.94(a)	Verification criteria for <i>E. coli</i> testing ratites	No	No	1172	9	0.76%
381.65(h)	Recordkeeping requirements	No	No	11201	0	0.00%
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	No	56665	384	0.67%
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	Yes	No	3110	225	6.75%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	No	1007485	126	0.01%
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Yes	No	80615	112	0.14%
311.14	Abrasions, bruises, abscesses, pus, etc.	No	No	24510	21	0.09%

¹NC = Noncompliance

APPENDIX C: COMPARISON OF FY2021 PHR LIST WITH FY2020 PHR LIST

There are six regulations from the FY2020 PHR list that no longer appear in the FY2021 PHR list. These are shown in Table C-1.

Table C-1 Regulations from the FY2020 PHR list no longer on the FY2021 PHR list

List of FY2020 PHRs	Description
318.1(b)	Only inspected and passed poultry product to enter official establishment
381.1 Adulterated	Adulterated
381.76(a)*	Post-mortem inspection, when required, extent.
381.83	Septicemia or toxemia
418.3	Recall Plans
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage

* The asterisk is part of the regulation name.

There are 13 regulations on the FY2021 PHR list that were not on the FY2020 PHR list. These regulations, shown in Table C-2, were candidate regulations analyzed in both years.

Table C-2 Regulations on the FY2021 PHR list that were not on the FY2020 PHR list

List of FY2021 PHRs	Description
310.22(b)	Inedible and prohibited SRM for use as human food
310.22(e)(4)(i)	Maintain daily records
310.25(a)	Verification criteria for <i>E. coli</i> testing meat
310.3	Carcasses and parts in certain instances to be retained.
416.12(c)	Plan identifies procedures for pre-op
417.2(c)	Contents of HACCP Plan
417.3(b)(1)	Segregate and hold the affected product
417.3(c)	Document corrective actions
417.6	Inadequate HACCP systems
430.4(b)(3)	<i>Lm</i> , post-lethality exposed RTE -Alternative 3
418.2	Notification of adulterated or misbranded product in commerce
381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation
311.14	Abrasions, bruises, abscesses, pus, etc.

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.

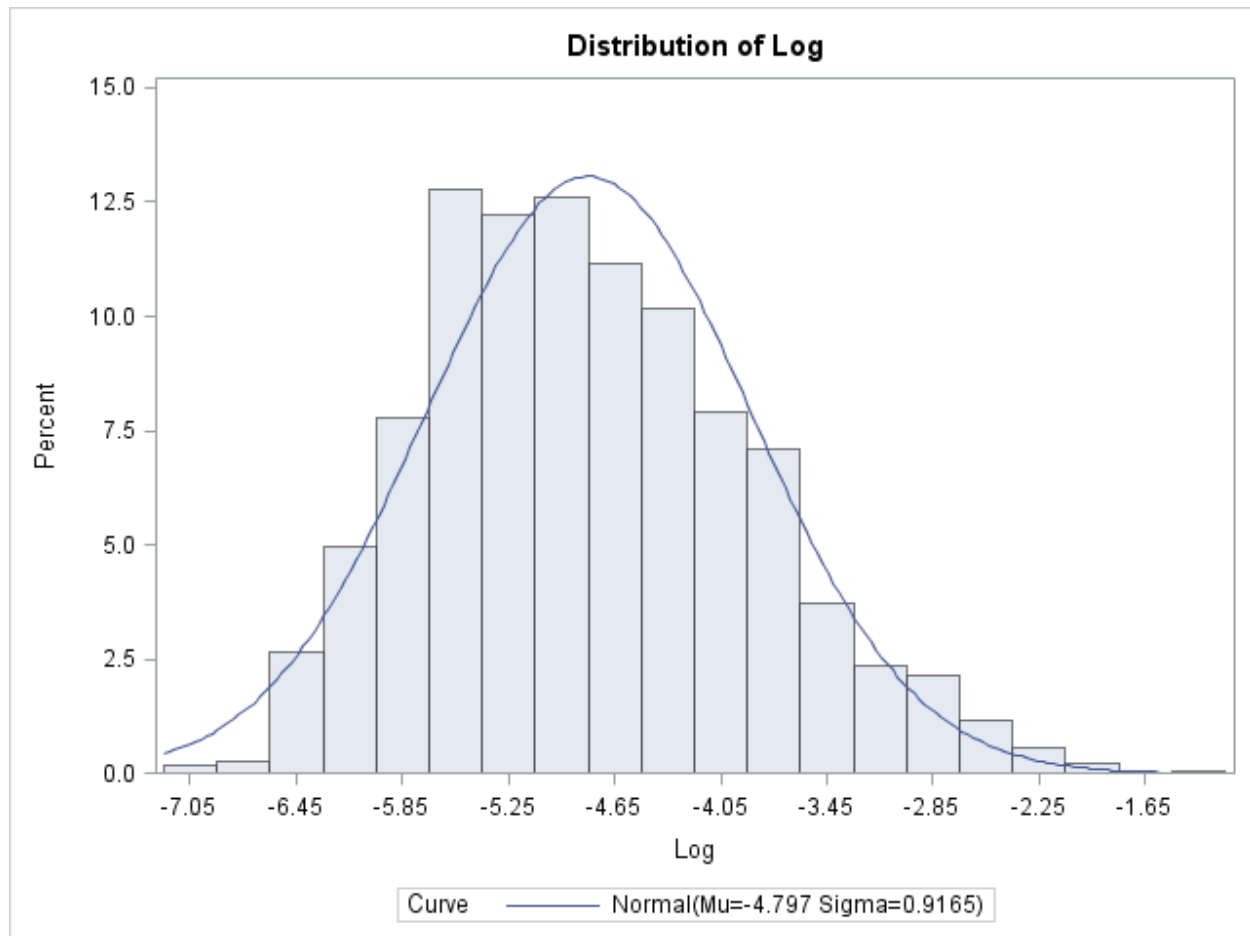
The PHR noncompliance rate is calculated by the following formula using the most recent 3 months of establishment verification inspection data:

$$PHR\ Noncompliance\ Rate = \frac{Number\ of\ PHR\ Noncompliances}{Total\ Number\ of\ PHR\ Inspection\ Procedures}$$

Establishments are categorized into one of two plant types (Processing Only and 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 within SAS, 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	0.04215	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.26553	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	7.81831	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 Tier distribution (based only on PHR noncompliances) using the quarterly cut points.

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

	Number of Establishments	Mean	Standard Deviation			Tier Distribution (Number of Establishments)
Q1CY2019					Tier 1	75
Both	1,051	-4.48	1.05		Tier 2	100
Processing	4,229	-4.96	0.82		Tier 3	5,105
Q2CY2019					Tier 1	54
Both	1,060	-4.26	0.95		Tier 2	77
Processing	4,231	-4.72	0.75		Tier 3	5,160
Q3CY2019					Tier 1	73
Both	1,061	-4.42	1.10		Tier 2	85
Processing	4,230	-4.92	0.83		Tier 3	5,133
Q4CY2019					Tier 1	63
Both	1,063	-4.43	1.06		Tier 2	96
Processing	4,235	-4.98	0.82		Tier 3	5,139

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 Tier distribution (based only on PHR noncompliances) using the cut points in Table D-2. Table D-4 shows how many Tier 1 establishments in March 2020 are within certain product categories.

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

	Combination	Processing
Mean	-4.40	-4.90
Standard Deviation	1.04	0.80

Table D-3 March 2020 Tier Distribution Based on the PHR Criteria Only

Classification	Plants
Tier 1	61
Tier 2	103
Tier 3	5,147
Total	5,311

Table D-4 Distribution of Tier 1 Establishments among Different Product Categories

Product Type	Number Plants Producing Product Type	Percent of all Plants	Number Tier 1 Plants	Percent Tier 1 Plants
Chicken Slaughter	196	3.69%	3	4.84%
Turkey Slaughter	44	0.83%	2	3.23%
Beef Slaughter	1104	20.79%	7	11.29%
Pork Slaughter	1020	19.21%	3	4.84%
Beef Processing	0	0.00%	0	0.00%
Chicken Processing	2015	37.94%	12	19.35%
Turkey Processing	932	17.55%	14	22.58%
Pork Processing	336	6.33%	5	8.06%
Siluriformes Processing	26	0.49%	0	0.00%
RTE	2168	40.82%	13	20.97%
Poultry Combination	0	0.00%	0	0.00%
Total Number of Establishments	5311		62	