FY2020 Public Health Regulations

July 2019

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SUMMARY

Public Health Regulations (PHRs) are verified regulations[1] 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 actions[2]. 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, 2019 to September 30, 2020 (FY2020) to prioritize certain FY2020 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, 2018 to December 31, 2018 (CY2018) verification inspection results and will be implemented in FY2020. 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 FY2020 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 three-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 FY2020 PHRs consists of 49 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. This compares

[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.

with 63 regulations that were identified in the October 1, 2018 to September 30, 2019 (FY2019) PHR list. The list of FY2020 PHRs is presented in Appendix A. Forty-five regulations from the FY2019 PHR list are included in the FY2020 PHR list.

The 49 FY2020 PHRs comprise 7 regulations and 42 provisions of regulations. The 42 provisions fall under 19 different regulations. Thus, the 49 FY2020 PHRs represent 26 regulations, with the majority of FY2020 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 FY2020 PHR regulations three months before a pathogen positive or enforcement action is 7.33 times higher than the average FY2020 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action. Noncompliance with a single FY2020 PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the three-month rolling average noncompliance rate for all similar establishments. The aggregate FY2020 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 FY2020 cut points are computed by determining the mean and standard deviation of the log transformed non-zero FY2020 PHR rates for each of the four quarters in CY2018 (the log transform of the non-zero FY2020 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 six 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 FY2020 PHR cut points for the non-transformed PHR noncompliance data for each of the two establishment operation types. The FY2019 PHR cut points are included for comparison. (See Section 6 and Appendix D for more details.)

Table S-1 FY2020 PHR Tier 1 Cut Points

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

Table S-2 FY2020 PHR Tier 3 Cut Points

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

Table S-3 presents the number of establishments in each tier for from January 1, 2019 to March 31, 2019, based on the PHR criterion. The period used for calculating the noncompliance rate of the PHRs was January 1, 2019 to March 31, 2019. 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	58	12	70
Tier 2	69	31	100
Tier 3	4,102	1,008	5,110
Total	4,229	1,051	5,280

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 FY2020 PHRs (PHRs that will be used for the time period October 1, 2019 to September 30, 2020).

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 FY2020 PHR list is the same as that used for the FY2019 PHR list. For inclusion in the FY2020 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 three-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 actions[3]. The analysis was based on one year of FSIS verification inspection results recorded in PHIS from January 1 to December 31, 2018 (CY2018). Candidate regulations related to egg products or Siluriformes 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 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 FY2020 PHR list is presented in Appendix A. Appendix B lists the candidate regulations evaluated to determine PHRs. Appendix C describes the differences between the FY2020 PHR list and FY2019 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 list will consist of verified 9 CFR regulations with which noncompliance occurs at a more frequent rate than in establishments in the three-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:

- Develop a candidate list of 9 CFR regulations related to verifying HACCP food safety process control.
- From this list, select the subset of regulations whose individual noncompliance rates are statistically higher in establishments in the three 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 three-month rolling average noncompliance rate for all similar establishments.

[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.

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. A set of four criteria were developed to assist in selecting the list of candidate regulations.

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. If 1) the design of the plan is effective in eliminating food safety hazards, and if the establishment executes the plan's design properly, including 2) maintaining sanitary conditions, 3) preventing adulteration, and 4) taking corrective action when appropriate, then the resulting product should be safe for the consumer. These four elements of HACCP are essential for maintaining an effective process control system and will be 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:

- Establish and Maintain HACCP plan and Critical Control Points (CCPs)
- Establish and Maintain Sanitary Conditions
- Prevent Adulteration
- 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 three months before the occurrence of a pathogen positive during FSIS sampling or enforcement action. The three-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 three 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 one hundred forty-five (145) 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 145 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 145 candidate regulations in establishments three 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 CY2018. Those with 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 in

the three 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 three 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 the 30 verifications.

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

4.1 *Salmonella*

The purpose of this section is to provide the results of the analysis between the list of candidate regulations and *Salmonella* positives. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,988 establishments with *Salmonella* testing data, of which 714 had 3,304 *Salmonella* positives and 1,274 did not have *Salmonella* positives. There were 43,671 total *Salmonella* tests performed.

Table 4-1 presents the 26 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 Test *p* value of less than 0.05) that the noncompliance rate of the regulation in establishments three months prior to a *Salmonella* positive is higher than the average noncompliance rate for establishments with no *Salmonella* positive for CY2018.

Table 4-2 Comparison of Noncompliance Rates Three Months before a *Salmonella* Positive with Those for Establishments with No *Salmonella* Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
301.2_Adulterated	Adulterated	Yes	24.64%	2.56%	12.43	7.60E-92
310.22(c)	Disposal of SRM	Yes	0.89%	0.26%	3.44	8.31E-10
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	3.41%	0.91%	3.84	9.55E-11
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.92%	0.24%	3.85	3.15E-05
318.2(a)	All products subject to reinspection by program employees	Yes	0.27%	0.06%	4.12	3.31E-04
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	2.52%	0.37%	6.94	4.13E-53
416.1	Operate in a manner to prevent insanitary conditions	Yes	4.47%	1.18%	3.90	0.00E+00
416.13(a)	Conduct pre-op procedures	Yes	5.73%	0.95%	6.33	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.62%	0.16%	3.81	1.17E-229
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	7.20%	1.20%	6.40	0.00E+00
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.09%	0.18%	6.03	0.00E+00
416.15(a)	Appropriate corrective actions	Yes	7.17%	2.03%	3.73	3.36E-75
416.15(b)	Corrective action, procedures for	Yes	10.86%	2.08%	5.74	1.98E-121

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.40%	0.12%	3.30	2.36E-192
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	2.91%	0.48%	6.16	1.94E-61
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.99%	0.97%	6.47	4.27E-125
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	22.98%	4.30%	6.65	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	31.51%	5.75%	7.54	0.00E+00
417.2(c)(4)	List of procedures & frequency	Yes	1.43%	0.30%	4.90	0.00E+00
417.3(a)(1)	Identify and eliminate the cause	Yes	12.01%	3.81%	3.45	3.13E-34
417.3(a)(2)	CCP is under control	Yes	1.06%	0.32%	3.33	5.79E-35
417.3(a)(3)	Establish measures to prevent recurrence	Yes	21.63%	6.22%	4.16	5.52E-46
417.3(b)(2)	Determine the acceptability of the affected product	Yes	3.84%	0.89%	4.45	3.74E-06
417.3(b)(3)	No adulterated product enters commerce	Yes	0.66%	0.14%	4.64	9.39E-06
417.3(b)(4)	Reassessment	Yes	2.68%	0.44%	6.21	2.55E-24
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	3.57%	0.97%	3.78	3.29E-294

4.1.1 *Salmonella* in Intact Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 202 establishments with Intact Chicken *Salmonella* testing data, of which 150 had 465 *Salmonella* positives and 52 did not have *Salmonella* positives. There were 9,054 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 4 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 three months prior to an Intact Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Chicken *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
417.3(b)(3)	No adulterated product enters commerce	Yes	1.05%	0.19%	5.58	3.63E-04
417.3(b)(4)	Reassessment	Yes	6.12%	1.18%	5.48	2.06E-04
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	8.68%	0.96%	9.77	6.64E-08
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	No	10.31%	3.44%	3.23	5.93E-05

4.1.2 *Salmonella* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Salmonella* testing data, of which 10 had 14 *Salmonella* positives and 35 did not have *Salmonella* positives. There were 1,903 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the 3 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 Test *p* value of less than 0.05) that the noncompliance rate of the

regulations in establishments three months prior to an Intact Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Turkey *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	2.36%	0.42%	5.77	1.99E-02
417.2(c)(4)	List of procedures & frequency	Yes	2.28%	0.61%	3.80	2.15E-10
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.44%	0.13%	3.43	4.65E-03

4.1.3 *Salmonella* in Ground Beef

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1229 establishments with *Salmonella* testing data, of which 127 had 229 *Salmonella* positives and 1,102 did not have *Salmonella* positives. There were 11,124 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 11 regulations with 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 three months prior to a Ground Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ground Beef *Salmonella* positive for CY2018.

Table 4-5 Comparison of Noncompliance Rates Three Months before a Ground Beef *Salmonella* Positive with Those for Establishments with No Ground Beef *Salmonella* Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
301.2_Adulterated	Adulterated	Yes	18.72%	2.10%	10.72	1.52E-22
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	4.31%	1.19%	3.72	1.00E-04
310.22(e)(2)	Appropriate corrective actions	Yes	15.22%	2.48%	7.06	5.35E-04
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	5.42%	0.89%	6.42	7.33E-09
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	0.42%	0.01%	67.09	2.48E-03
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	2.91%	0.88%	3.38	1.60E-189
416.15(a)	Appropriate corrective actions	Yes	4.78%	1.56%	3.16	2.36E-07
416.15(b)	Corrective action, procedures for	Yes	4.98%	1.56%	3.30	1.88E-03
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	10.56%	3.63%	3.13	1.14E-73
417.2(c)(4)	List of procedures & frequency	Yes	1.34%	0.21%	6.57	4.08E-101
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	3.06%	0.78%	4.04	6.96E-77

4.1.4 Salmonella in Intact Beef

FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 864 establishments with Intact Beef *Salmonella* testing data, of which 71 had 168 *Salmonella* positives and 793 did not have *Salmonella* positives. There were 5,935 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 13 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability, as determined by a two-sided Fisher's Exact Test *p* value of less than 0.05) that the noncompliance rate of the regulation in establishments three months prior to an Intact Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Beef *Salmonella* positive for CY2018.

Table 4-6 Comparison of Noncompliance Rates Three Months before an Intact Beef *Salmonella* Positive with Those for Establishments with No Intact Beef *Salmonella* Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
301.2_Adulterated	Adulterated	Yes	38.29%	3.57%	16.78	1.16E-88
310.22(c)	Disposal of SRM	Yes	1.07%	0.28%	3.79	5.22E-08
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	4.94%	1.55%	3.29	1.34E-07
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	2.05%	0.24%	8.76	1.98E-10
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.88%	1.00%	5.08	0.00E+00
416.15(a)	Appropriate corrective actions	Yes	9.15%	1.84%	5.38	3.45E-20
416.15(b)	Corrective action, procedures for	Yes	9.90%	1.93%	5.59	2.20E-14

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	13.11%	4.79%	3.00	1.10E-87
417.2(a)(1)	Hazard analysis	Yes	4.71%	1.54%	3.16	1.32E-07
417.2(c)(4)	List of procedures & frequency	Yes	1.71%	0.24%	7.18	2.46E-116
417.3(b)(3)	No adulterated product enters commerce	Yes	2.14%	0.21%	10.54	1.82E-07
417.3(b)(4)	Reassessment	Yes	5.92%	0.49%	12.74	1.56E-07
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.52%	0.89%	5.29	3.64E-223

4.1.5 *Salmonella* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 96 establishments with Comminuted Chicken *Salmonella* testing data, of which 80 had 566 *Salmonella* positives and 16 did not have *Salmonella* positives. There were 2,028 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 11 regulations 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 three months before an Comminuted Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	3.70%	0.91%	4.19	2.43E-12
416.13(a)	Conduct pre-op procedures	Yes	5.52%	0.65%	8.97	9.85E-33
416.13(b)	Conduct other procedures listed in the plan	Yes	0.66%	0.10%	6.57	5.00E-10
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	5.01%	1.29%	4.03	1.33E-71
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.21%	0.15%	8.47	3.91E-16
416.15(a)	Appropriate corrective actions	Yes	12.20%	3.23%	4.17	3.81E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.07%	0.80%	6.63	1.15E-03
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	28.35%	3.50%	10.91	1.34E-90
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	32.02%	12.02%	3.45	2.82E-52
417.2(c)(4)	List of procedures & frequency	Yes	0.97%	0.31%	3.17	1.43E-06
417.5(a)(2)	Written HACCP plan	Yes	0.25%	0.08%	3.28	2.50E-02

4.1.6 *Salmonella* in Comminuted Turkey

There are 63 establishments with Comminuted Turkey *Salmonella* testing data, of which 43 had 298 *Salmonella* positives and 20 did not have *Salmonella* positives. There were 1,598 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the 6 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 three months before an Comminuted Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Salmonella* positive for CY2018.

Table 4-8 Comparison of Noncompliance Rates Three Months before a Comminuted Turkey *Salmonella* Positive with Those for Establishments with No Comminuted Turkey *Salmonella* Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.13(a)	Conduct pre-op procedures	Yes	3.19%	0.89%	3.67	9.85E-33
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.80%	1.59%	3.12	1.33E-71
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.75%	0.26%	6.82	2.68E-02
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.80%	1.66%	3.64	6.13E-04
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	20.30%	5.09%	4.75	4.53E-48
417.2(c)(4)	List of procedures & frequency	Yes	0.71%	0.19%	3.80	1.87E-06

4.1.7 *Salmonella* in Intact Pork

There are 126 establishments with Intact Pork *Salmonella* testing data, of which 41 had 137 *Salmonella* positives and 85 did not have *Salmonella* positives. There were 1,290 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the 7 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 three months before an Intact Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Pork *Salmonella* positive for CY2018.

Table 4-9 Comparison of Noncompliance Rates Three Months before an Intact Pork *Salmonella* Positive with Those for Establishments with No Intact Pork *Salmonella* Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	6.56%	2.11%	3.25	9.79E-166
416.15(b)	Corrective action, procedures for	Yes	13.46%	2.51%	6.03	2.58E-07
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.60%	0.10%	6.25	6.05E-31
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.10%	0.51%	6.27	4.18E-06
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	3.42%	0.82%	4.26	3.87E-06
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	25.41%	9.29%	3.33	5.64E-88
417.3(a)(2)	CCP is under control	Yes	3.00%	0.43%	7.09	2.12E-04

4.1.8 *Salmonella* in Comminuted Pork

There are 163 establishments with Comminuted Pork *Salmonella* testing data, of which 95 had 405 *Salmonella* positives and 68 did not have *Salmonella* positives. There were 2,793 total Comminuted Pork *Salmonella* tests performed.

Table 4-9 presents the 5 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 for which the noncompliance rate of the regulation in establishments three months before an Comminuted Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Pork *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	3.93%	1.02%	3.96	1.19E-42
416.13(b)	Conduct other procedures listed in the plan	Yes	0.50%	0.13%	3.93	7.33E-18
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.88%	0.55%	3.47	1.58E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	4.21%	0.84%	5.16	3.47E-07
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	15.21%	4.76%	3.59	9.19E-76

4.1.9 *Salmonella* in Chicken Parts

There are 449 establishments with Chicken Parts *Salmonella* testing data, of which 313 had 1022 *Salmonella* positives and 136 did not have *Salmonella* positives. There were 7,946 total Chicken Parts *Salmonella* tests performed.

Table 4-10 presents the 6 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 three months before an Chicken Parts *Salmonella* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	3.50%	1.06%	3.37	4.46E-34
381.83	Septicemia or toxemia	Yes	0.03%	0.01%	3.30	2.59E-02
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.49%	0.15%	3.31	5.35E-47
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	8.70%	2.61%	3.56	4.26E-17
417.3(b)(4)	Reassessment	Yes	7.85%	0.67%	12.59	7.61E-13
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	6.20%	0.79%	8.33	1.12E-05

4.1.10 *Salmonella* in Ready to Eat (RTE)

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,247 establishments with *Salmonella* testing data, of which 1 had 1 *Salmonella* positive and 2,246 did not have *Salmonella* positives. There were 14,457 total RTE *Salmonella* tests performed.

Table 4-11 presents the 2 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 three months before an RTE *Salmonella* positive is higher than the average noncompliance rate for establishments with no RTE *Salmonella* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
430.4(a)	Lm, post-lethality exposed RTE	Yes	1.05%	0.03%	34.28	2.94E-02
430.4(c)(2)	Lm, post-lethality exposed RTE – Alternative 3	Yes	1.05%	0.05%	20.60	4.82E-02

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 1,382 establishments with *E. coli* O157:H7 testing data, of which 13 had 14 *E. coli* O157:H7 positives and 1369 did not have *E. coli* O157:H7 positives. There were 17,048 total *E. coli* O157:H7 tests performed.

Table 4-12 presents the 10 regulations which 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 three 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 CY2018.

Table 4-12 Comparison of Noncompliance Rates Three Months before an *E. coli* O157:H7 Positive with Those for Establishments with *E. coli* O157:H7 Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
310.22(c)	Disposal of SRM	Yes	2.36%	0.37%	6.59	1.32E-03
416.13(a)	Conduct pre-op procedures	Yes	6.67%	0.87%	8.10	4.21E-15
416.13(b)	Conduct other procedures listed in the plan	Yes	0.80%	0.15%	5.41	1.65E-04
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.51%	1.10%	4.25	5.11E-21
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.00%	0.51%	10.25	1.99E-04
417.2(a)(1)	Hazard analysis	Yes	6.67%	1.55%	4.54	3.30E-02
417.2(c)(4)	List of procedures & frequency	Yes	1.40%	0.29%	4.92	9.58E-07
417.5(a)(1)	Written hazard analysis	Yes	0.79%	0.26%	3.08	9.13E-03
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	No	1.06%	0.04%	28.79	3.73E-02
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.34%	1.31%	3.41	3.57E-11

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 480 establishments with Non-O157 STEC testing data, of which 10 had 21 Non- O157 STEC positives and 470 did not have Non-O157 STEC positives. There were 3,726 total Non-O157 STEC tests performed.

Table 4-13 presents the 2 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 three months before an Non-O157 STEC positive is higher than the average noncompliance rate for establishments with no Non-O157 STEC positive for CY2018.

Table 4-13 Comparison of Noncompliance Rates Three Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive

Regulation Verified	Description	On FY2019 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's Exact p Value
310.22(c)	Disposal of SRM	Yes	3.00%	0.48%	6.35	5.49E-04
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	25.00%	7.41%	4.16	2.66E-13

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 2,250 establishments with *Listeria monocytogenes* testing data, of which 3 had 3 *Listeria monocytogenes* positives and 2,247 did not have *Listeria monocytogenes* positives. There were 14,470 total *Listeria monocytogenes* tests performed.

Table 4-14 presents the 2 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher's Exact p value of less than 0.05) that the noncompliance rate of the regulation in the three months before a *Listeria monocytogenes* positive is higher than the noncompliance rate for establishments with no *Listeria monocytogenes* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a *Listeria monocytogenes* Positive	Noncompliance Rate for Establishments with no *Listeria monocytogenes* Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	14.29%	4.49%	3.54	5.69E-09
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	0.58%	0.05%	11.73	2.43E-03

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 590 establishments with *Campylobacter* testing data, of which 325 had 1,315 *Campylobacter* positives and 265 did not have *Campylobacter* positives. There were 22,513 total *Campylobacter* tests performed.

Table 4-15 presents the 18 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 three months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	11.43%	0.67%	19.23	5.25E-04
381.71(a)	Condemnation on ante mortem inspection	Yes	11.42%	0.20%	64.87	1.66E-20
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.21%	1.76%	3.06	5.89E-142
416.13(a)	Conduct pre-op procedures	Yes	11.37%	1.68%	7.49	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.80%	0.18%	4.52	1.44E-112
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	9.83%	2.00%	5.33	0.00E+00
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.48%	0.29%	5.13	2.85E-183
416.15(b)	Corrective action, procedures for	Yes	14.44%	4.76%	3.37	1.12E-37
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.46%	0.14%	3.33	2.70E-72
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.71%	1.27%	3.84	1.17E-17
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	10.90%	2.11%	5.68	7.19E-56

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	30.97%	7.31%	5.69	0.00E+00
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	45.72%	9.59%	7.94	0.00E+00
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	29.36%	5.53%	7.10	5.79E-09
417.2(c)(4)	List of procedures & frequency	Yes	1.87%	0.32%	5.94	0.00E+00
417.3(b)(4)	Reassessment	Yes	4.30%	0.53%	8.43	2.57E-18
417.5(f)	Official Review	Yes	0.25%	0.02%	15.49	1.05E-04
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	No	0.24%	0.03%	8.09	1.13E-03

4.4.1 *Campylobacter* in Intact Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 202 establishments with Intact Chicken *Campylobacter* testing data, of which 169 had 623 *Campylobacter* positives and 33 did not have *Campylobacter* positives. There were 9,052 total Intact Chicken *Campylobacter* tests performed.

Table 4-16 presents the one regulation 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 three months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive for CY2018.

Table 4-16 Comparison of Noncompliance Rates Three Months before a Campylobacter Intact Chicken Positive with Those for Establishments with No Campylobacter Intact Chicken Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.94%	1.72%	3.61	1.09E-47

4.4.2 *Campylobacter* in Intact Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Campylobacter* testing data, of which 7 had 9 *Campylobacter* positives and 38 did not have *Campylobacter* positives. There were 1,899 total Intact Turkey *Campylobacter* tests performed.

Table 4-17 presents the 3 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 regulations in the three months before an Intact Turkey *Campylobacter* positive is higher than the noncompliance rate for establishments with no Intact Turkey *Campylobacter* positive for CY2018.

Table 4-17 Comparison of Noncompliance Rates Three Months before a Campylobacter Intact Turkey Positive with Those for Establishments with No Campylobacter Intact Turkey Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	No	3.13%	0.46%	6.96	3.95E-02
416.1	Operate in a manner to prevent insanitary conditions	Yes	12.42%	2.76%	4.99	2.59E-13
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	6.00%	1.49%	4.23	4.77E-02

4.4.3 *Campylobacter* in Comminuted Chicken

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 96 establishments with Comminuted Chicken *Campylobacter* testing data, of which 38 had 114 *Campylobacter* positives and 58 did not have *Campylobacter* positives. There were 2,022 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-18 presents the 2 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 three months before an Comminuted Chicken *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Campylobacter* positive for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
381.76(a)	Post-mortem inspection, when required, extent.	Yes	7.14%	1.56%	4.86	1.18E-02
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	0.50%	0.05%	9.62	3.74E-05

4.4.4 *Campylobacter* in Comminuted Turkey

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 63 establishments with Comminuted Turkey *Campylobacter* testing data, of which 12 had 30 *Campylobacter* positives and 51 did not have *Campylobacter* positives. There were 1,597 total Comminuted Turkey *Campylobacter* tests performed.

Table 4-19 presents the 4 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 regulations in establishments three months before an Comminuted Turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Campylobacter* positive for CY2018.

Table 4-19 Comparison of Noncompliance Rates Three Months before a Comminuted Turkey Campylobacter Positive with those for Establishments with No Comminuted Turkey Campylobacter Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	15.09%	2.69%	6.42	1.70E-04
417.3(b)(3)	No adulterated product enters commerce	Yes	1.22%	0.11%	10.84	3.03E-02
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	5.26%	0.46%	12.09	3.72E-09
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	2.07%	0.22%	9.73	3.46E-04

4.4.5 *Campylobacter* in Chicken Parts

The dataset used in the analysis consists of candidate PHR noncompliance rates for the 449 establishments with Chicken Parts *Campylobacter* testing data, of which 233 had 539 *Campylobacter* positives and 216 did not have *Campylobacter* positives. There were 7,943 total Chicken Parts *Campylobacter* tests performed.

Table 4-20 presents the 13 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher's Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Chicken Parts *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Campylobacter* positive for CY2018.

Table 4-20 Comparison of Noncompliance Rates Three Months before a Chicken Parts Campylobacter Positive with Those for Establishments with No Chicken Parts Campylobacter Positive

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
381.1_Adulterated	NRs review, NRs cite for quality (OCP), not being used as public health- related	Yes	2.65%	0.16%	17.36	2.35E-06
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	1.87%	0.52%	3.67	4.34E-19
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	No	2.68%	0.16%	16.84	1.73E-33
416.13(a)	Conduct pre-op procedures	Yes	13.13%	2.48%	5.95	0.00E+00
416.13(b)	Conduct other procedures listed in the plan	Yes	0.78%	0.19%	4.06	2.04E-68
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	10.36%	3.31%	3.38	0.00E+00
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	1.59%	0.32%	4.98	3.56E-130
416.15(a)	Appropriate corrective actions	Yes	10.08%	3.13%	3.47	6.92E-23
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	11.52%	2.97%	4.25	2.41E-26
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	46.12%	18.82%	3.69	0.00E+00

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Odds Ratio	Two-Sided Fisher's Exact p Value
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	45.45%	19.18%	3.51	3.29E-03
417.2(c)(4)	List of procedures & frequency	Yes	1.91%	0.50%	3.90	2.64E-187
417.3(b)(4)	Reassessment	Yes	5.83%	0.80%	7.63	7.78E-10

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 will be selected from the same list of candidate regulations used to select all other FY2020 PHRs. The enforcement action list will consist of candidate 9 CFR regulations in which noncompliances occurs at a more frequent rate in establishments in the three-month period prior to an NOIE or suspension than in establishments without an NOIE or suspension for CY2018. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,336 active meat and poultry establishments, of which 113 had 122 enforcement actions and 5,223 did not have any enforcement actions.

Table 4-21 presents the 29 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 three months before an enforcement action is higher than the noncompliance rate for establishments with no enforcement action for CY2018.

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

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher's Exact p Value
310.22(c)	Disposal of SRM	Yes	3.42%	0.38%	9.31	1.16E-03
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	20.00%	1.66%	14.85	3.27E-07
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	9.09%	0.30%	33.55	1.25E-05
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	14.40%	0.84%	19.80	3.73E-31
416.1	Operate in a manner to prevent insanitary conditions	Yes	5.34%	1.52%	3.65	1.63E-38
416.13(a)	Conduct pre-op procedures	Yes	4.87%	1.31%	3.86	1.71E-39
416.13(b)	Conduct other procedures listed in the plan	Yes	1.04%	0.17%	6.03	1.19E-38
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	6.54%	1.71%	4.02	3.86E-215

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher's Exact p Value
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.82%	0.24%	3.47	7.44E-15
416.15(a)	Appropriate corrective actions	Yes	7.84%	1.95%	4.27	1.76E-14
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	0.60%	0.14%	4.33	9.52E-24
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.16%	0.75%	4.34	3.63E-04
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	6.05%	1.47%	4.31	9.37E-08
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	25.40%	7.04%	4.50	2.31E-93
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	27.33%	8.78%	3.91	1.54E-108
417.2(a)(1)	Hazard analysis	Yes	4.09%	1.19%	3.54	9.94E-07
417.2(c)(4)	Hazard analysis	Yes	1.85%	0.53%	3.54	1.62E-26
417.3(a)(2)	CCP is under control	Yes	2.10%	0.46%	4.66	2.25E-08
417.3(b)(3)	No adulterated product enters commerce	Yes	1.37%	0.44%	3.13	1.60E-02
417.5(a)(1)	Written hazard analysis	Yes	1.41%	0.28%	5.07	9.80E-31
417.5(a)(2)	Written HACCP plan	Yes	0.37%	0.11%	3.29	1.17E-05

Regulation Verified	Description	On FY2019 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Odds Ratio	Two-Sided Fisher's Exact p Value
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	0.99%	0.24%	4.14	6.78E-19
430.4(a)	Lm, post-lethality exposed RTE	Yes	0.38%	0.03%	12.10	4.28E-04
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	1.05%	0.05%	22.67	9.73E-12
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	No	1.11%	0.06%	20.33	2.82E-11
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	6.25%	1.32%	4.99	1.01E-35
418.3	Lm, maintain sanitation in post-lethality processing environment	Yes	4.35%	0.25%	18.29	6.52E-03
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	3.61%	0.51%	7.36	2.53E-07
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	No	18.18%	5.12%	4.12	1.94E-03

5.0 LIST OF FY2020 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2020 PHR list. Table 5-1 presents the complete list of the 49 FY2020 PHRs. These 49 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 three 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 49 FY2020 PHRs are composed of 7 regulations and 42 provisions of regulations. The 42 provisions fall under 19 different regulations. Thus, the 49 FY2020 PHRs represent 26 regulations, with the majority of FY2020 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 FY2020 PHRs

Regulation Verified	Description	On FY2019 PHR List	Average Odds Ratio	Average Two-Sided Fisher's Exact p Value
301.2_Adulterated	Adulterated	Yes	13.31	5.06E-23
310.22(c)	Disposal of SRM	Yes	5.90	6.04E-04
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	9.29	5.03E-05
310.22(e)(2)	Appropriate corrective actions	Yes	7.06	5.35E-04
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	4.52	4.72E-08
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	15.38	1.47E-05
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	67.09	2.48E-03
318.2(a)	All products subject to reinspection by program employees	Yes	4.12	3.31E-04
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	19.23	5.25E-04
381.1_Adulterated	Adulterated	Yes	17.36	2.35E-06

Regulation Verified	Description	On FY2019 PHR List	Average Odds Ratio	Average Two-Sided Fisher's Exact p Value
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	7.91	3.97E-03
381.71(a)	Condemnation on ante mortem inspection	Yes	64.87	1.66E-20
381.76(a)	Post-mortem inspection, when required, extent.	Yes	4.86	1.18E-02
381.83	Septicemia or toxemia	Yes	3.30	2.59E-02
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	No	11.90	1.97E-02
416.1	Operate in a manner to prevent insanitary conditions	Yes	3.91	3.84E-13
416.13(a)	Conduct pre-op procedures	Yes	6.34	4.83E-13
416.13(b)	Conduct other procedures listed in the plan	Yes	4.90	2.35E-05
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	4.22	6.38E-22
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	5.62	1.57E-15
416.15(a)	Appropriate corrective actions	Yes	4.03	6.35E-03
416.15(b)	Corrective action, procedures for	Yes	4.81	3.76E-04
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	4.10	1.90E-24
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	5.67	9.58E-03
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.04	1.94E-04
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	5.81	1.14E-09

Regulation Verified	Description	On FY2019 PHR List	Average Odds Ratio	Average Two-Sided Fisher's Exact p Value
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	4.49	3.32E-14
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	5.30	1.65E-03
417.2(a)(1)	Hazard analysis	Yes	3.75	1.10E-02
417.2(c)(4)	List of procedures & frequency	Yes	4.77	4.72E-07
417.3(a)(1)	Identify and eliminate the cause	Yes	3.45	3.13E-34
417.3(a)(2)	CCP is under control	Yes	5.03	7.07E-05
417.3(a)(3)	Establish measures to prevent recurrence	Yes	4.16	5.52E-46
417.3(b)(2)	Determine the acceptability of the affected product	Yes	4.45	3.74E-06
417.3(b)(3)	No adulterated product enters commerce	Yes	6.95	9.34E-03
417.3(b)(4)	Reassessment	Yes	8.85	3.44E-05
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	9.05	5.61E-06
417.5(a)(1)	Written hazard analysis	Yes	4.07	4.54E-03
417.5(a)(2)	Written HACCP plan	Yes	3.28	1.25E-02
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	3.78	2.32E-03
417.5(f)	Official Review	Yes	15.49	1.05E-04
430.4(a)	Lm, post-lethality exposed RTE	Yes	23.19	1.49E-02
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	18.33	1.69E-02
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	No	19.07	1.28E-02

Regulation Verified	Description	On FY2019 PHR List	Average Odds Ratio	Average Two-Sided Fisher's Exact p Value
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.30	7.14E-12
418.3	Recall Plans	Yes	18.29	6.52E-03
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	9.69	1.25E-05
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	No	3.68	1.00E-03
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	9.73	3.46E-04

Forty-five of the previous 63 FY2019 PHRs are included in the FY2020 PHRs. There are 18 regulations on the FY2019 PHR list that are not in the FY2020 PHR list (See Appendix C). Vice versa, there are 4 regulations that are on the FY2020 PHR list that were not on the FY2019 PHR list.

Table 5-2 lists the number of regulations triggered by different pathogens or enforcement actions for inclusion in the FY2020 PHR list. Most regulations were triggered by multiple events. Similar to the FY2019 PHR list, enforcement actions triggered the most regulations.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2020 PHR list

Product	Number of Regulations
Campylobacter	18
Comminuted Chicken Campylobacter	2
Comminuted Chicken Salmonella	11
Comminuted Pork Salmonella	5
Comminuted Turkey Campylobacter	4
Comminuted Turkey Salmonella	6
Chicken Parts Campylobacter	13
Chicken Parts Salmonella	6
Enforcements	29
Ground Beef Salmonella	11
Intact Beef Salmonella	13
Intact Chicken Campylobacter	1
Intact Chicken Salmonella	4
Intact Pork Salmonella	7
Intact Turkey Campylobacter	7
Intact Turkey Salmonella	3
Listeria	2
Non-O157 E.coli	2
O157 E.coli	10
RTE Salmonella	2
Salmonella	26

There were three regulations triggered by a single type of event. One was from *Salmonella* in one Ground Beef, one was from *Campylobacter* in Comminuted Chicken, and one was from *Campylobacter* in Comminuted Turkey. Table 5-3 presents the regulations triggered for inclusion in the FY2020 PHR list by only single pathogen product or enforcement action type.

Table 5-3 Regulations Triggered for Inclusion in the FY2020 PHR List by Only a Single Event

Regulation Verified	Description	Event
318.1(b)	Only inspected and passed poultry product to enter official establishment	Ground Beef Salmonella
381.76(a)	Post-mortem inspection, when required, extent.	Comminuted Chicken Campylobacter
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	Comminuted Turkey Campylobacter

6.0 CUT POINTS FOR FY2020 PHRS

The FY2020 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 FY2020 PHR does not indicate a loss of process control. The aggregate set of PHRs is used to identify establishments that significantly deviate from the three-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 FY2020 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 FY2020 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 FY2020 PHR Rate

	Mean of Natural Log FY2020 PHR Rate			Standard Deviation FY2020 PHR Rate	
	Combination	Processing		Combination	Processing
Jan-Mar 2018	-4.43	-4.89		0.99	0.82
Apr-Jun 2018	-4.23	-4.69		0.93	0.75
July-Sep 2018	-4.41	-4.94		1.01	0.82
Oct-Dec 2018	-4.44	-4.92		0.97	0.82
Average	-4.38	-4.86		0.97	0.80

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 example, the upper cut point for the log transformed data for Processing establishments is -4.86 + 2*0.80 = -4.86 + 1.60 = -3.26. The cut point of the original, non-transformed PHR noncompliance data is the antilog of -3.26 or Exp(-3.26) = 3.86%. 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 FY2020 PHR upper and lower cut points for each of the two establishment operation types. The FY2019 PHR cut points are included for comparison. (See Appendix D for more details). The cut points are determined once a year. The next update to the cut points is planned for October 2020.

Table 6-2 FY2020 PHR Tier 1 Cut Points

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

Table 6-3 FY2020 PHR Tier 3 Cut Points

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

Table 6-4 presents the number of establishments in each Tier based solely on the FY2020 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 FY2020 PHRs, 70 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, 2019.

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

Classification	Number of Establishments
Tier 1	70
Tier 2	100
Tier 3	5,110
Total	5,280

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	58	12
Tier 2	69	31
Tier 3	4,102	1,008
Total	4,229	1,051

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2020 PHR regulations used to prioritize certain FY2020 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 three 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 FY2020 PHRs has 49 regulations whose individual noncompliance rates are higher in establishments three 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-five regulations on the FY2019 PHR list are also on the FY2020 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 FY2020 PHR upper and lower cut points. The FY2019 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 FY2020 PHR Tier 1 Cut Points

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

Table 7-2 FY2020 PHR Tier 3 Cut Points

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

8.0 REFERENCES

1. Food Safety and Inspection Service (FSIS) 2010, Data-Driven Inspection for Processing and Slaughter Establishments, Public Health Decision Criteria. (http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Public_Health_Decsion_Criteria_Report.pdf)
2. Food Safety and Inspection Service (FSIS) 2013, FSIS Data Analysis and Reporting: Public Health Regulations, http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting/public-health-regulations
3. Food Safety and Inspection Service (FSIS) 2014, FY2015 Public Health Regulations. http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting/public-health-regulations
4. National Advisory Committee on Meat and Poultry Inspection (NACMPI) 2013, Subcommittee Two, Issue Two: Data Analysis. http://www.fsis.usda.gov/wps/wcm/connect/9ee42a72-a1fc-4045-982b-b4dfe7e7a43f/NACMPI_Transcript_Subcmt2_011613.pdf?MOD=AJPERES

APPENDIX A: FY2020 PHR REGULATIONS

Table A-1 presents the list of forty-nine FY2020 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates three months prior to a pathogen positive or enforcement action that is 7.33 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2020 PHRs

Regulation	Description
301.2_Adulterated	Adulterated
310.22(c)	Disposal of SRM
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
310.22(e)(2)	Appropriate corrective actions
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
318.1(b)	Only inspected and passed poultry product to enter official establishment
318.2(a)	All products subject to reinspection by program employees
318.2(d)	Removal of U.S. retained by authorized Program employees only
381.1_Adulterated	Adulterated
381.65(a)	Clean and sanitary practices; products not adulterated
381.71(a)	Condemnation on ante mortem inspection
381.76(a)	Post-mortem inspection, when required, extent.
381.83	Septicemia or toxemia
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
416.1	Operate in a manner to prevent insanitary conditions
416.13(a)	Conduct pre-op procedures
416.13(b)	Conduct other procedures listed in the plan
416.13(c)	Plant monitors implementation of SSOP procedures
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.15(a)	Appropriate corrective actions
416.15(b)	Corrective action, procedures for
416.16(a)	Daily records required, responsible individual, initialed and dated
416.3(b)	Constructed, located & operated in a manner that does not deter inspection
416.3(c)	Receptacles for storing inedible material must identify permitted use

Regulation	Description
416.4(a)	Food contact surface, cleaning & sanitizing as frequency
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
416.6	Only FSIS program employee may remove "U.S. Rejected" tag
417.2(a)(1)	Hazard analysis
417.2(c)(4)	List of procedures & frequency
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(b)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
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
430.4(a)	Lm, post-lethality exposed RTE
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
418.3	Recall Plans
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage

APPENDIX B: FY2020 CANDIDATE REGULATIONS

Table B-1 presents the list of 145 candidate regulations. The noncompliance rates in Table B-1 are based on PHIS data for January 1, 2018 through December 31, 2018.

Table B-1 FY2020 Candidate regulations

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
301.2_Adulterated	Adulterated	Yes	No	5777	188	3.15%
304.3(a)	Develop written SSOP	No	No	593	2	0.34%
304.3(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	821	5	0.61%
309.2(a)	Livestock suspected of being diseased or affected with certain conditions; identifying suspects	No	No	611	4	0.65%
309.3	(HIMP ONLY) Dead, dying, disabled or diseased and similar livestock.	No	No	241	2	0.82%
309.4	(HIMP ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases	No	No	220	2	0.90%
309.5	(HIMP ONLY) Swine; disposal because of hog cholera	No	No	215	0	0.00%
309.9	(HIMP ONLY) Swine erysipelas	No	No	216	0	0.00%
310.18	Contamination of carcasses, organs, or other parts	Yes	No	338	9	2.59%
310.22(b)	Inedible and prohibited SRM for use as human food	No	No	4139	4	0.10%
310.22(c)	Disposal of SRM	Yes	Yes	53792	158	0.29%
310.22(d)(2)	Exports have equivalent level of protection from human exposure to BSE as similar US products	No	No	98	0	0.00%
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	No	14491	196	1.33%
310.22(e)(2)	Appropriate corrective actions	Yes	No	2622	50	1.87%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	No	8926	142	1.57%
310.22(e)(4)(i)	Maintain daily records	Yes	No	72199	161	0.22%
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	No	16447	41	0.25%
310.22(g)(1)	Maintain positive control of beef carcasses with the vertebral columns to another federal inspected establishment	No	No	1366	2	0.15%
310.22(g)(4)	Maintain records of official establishment showing proper disposition of vertebral columns	No	No	4294	25	0.58%
310.25(a)	Verification criteria for *E. coli* testing meat	Yes	No	28770	241	0.83%
310.25(b)	Pathogen reduction performance standards; Salmonella	No	No	123	2	1.60%
310.25(b)(3)(ii)	PR livestock - Failure to maintain adequate HACCP Plan	No	No	33	0	0.00%
310.3	Carcasses and parts in certain instances to be retained.	No	No	2938	222	7.03%
311.16	(HIMP ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.	No	No	208	9	4.15%
311.17	(HIMP ONLY) Necrobacillosis, pyemia, septicemia.	No	No	527	3	0.57%
311.24	(HIMP ONLY) Hogs affected with tapeworm cysts.	No	No	200	0	0.00%
315.2	Carcasses and parts passed for cooking	No	No	82	0	0.00%
316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	No	11805	40	0.34%
317.24(a)	Packaging materials composed of poisonous or deleterious substances	Yes	No	2840	13	0.46%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	No	98561	13	0.01%
318.10(b)	Products requiring treatment to destroy trichinae	No	No	2411	3	0.12%
318.10(c)(1)	Destruction of trichinae through heating	No	No	2338	0	0.00%
318.10(c)(2)	Destruction of trichinae through refrigeration	No	No	903	1	0.11%
318.10(c)(3)	Destruction of trichinae through curing	No	No	815	0	0.00%
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	82	0	0.00%
318.14(b)	Establishment shall be thoroughly cleaned and disinfected under FSIS supervision	No	No	542	0	0.00%
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision	No	No	124	0	0.00%
318.16(b)	Pesticides chemicals & other residues in products not to exceed FD&C Act levels - Meat ingredients	No	No	41	0	0.00%
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	No	3067	7	0.23%
318.17(b)	Lethality and Stabilization processes other than HACCP for cooked beef	No	No	706	0	0.00%
318.17(c)	Validation of new or altered process schedules (for cooked beef)	No	No	34	0	0.00%
318.2(a)	All products subject to reinspection by program employees	Yes	No	49324	42	0.09%
318.2(d)	Removal of U.S. retained by authorized Program employees only	Yes	No	8303	39	0.47%
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully-cooked meat patties	No	No	400	2	0.50%
318.23(b)(3)	Heat deviations for meat patties	No	No	16	1	5.88%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
318.23(c)(1)	Stabilization requirements for meat patties	No	No	195	1	0.51%
318.23(c)(2)	Stabilization processes for meat patties other than HACCP	No	No	10	0	0.00%
318.23(c)(4)	Labeling statement for partially cooked patties	No	No	118	0	0.00%
318.23(c)(5)	Labeling statement for char-marked patties	No	No	102	0	0.00%
318.24	Product prepared using advanced meat/bone separation machinery; process control	No	No	2564	20	0.77%
318.303	Critical factors and the application of the process schedule	No	Yes	5071	1	0.02%
318.308	Deviation in processing	No	Yes	3212	1	0.03%
318.6(b)(1)	Requirements for use of casings, used as containers	No	No	2648	0	0.00%
318.6(b)(4)	Detached spinal cords	No	No	9612	0	0.00%
318.6(b)(6)	Tonsils	No	No	12741	0	0.00%
318.6(b)(8)	Intestines as ingredients	No	No	295	0	0.00%
319.5(b)	Mechanically separated (species)	No	No	283	0	0.00%
381.1_Adulterated	Adulterated	Yes	No	5233	25	0.48%
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance	No	No	2248	1	0.04%
381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	No	1620	2	0.12%
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry	No	No	185	1	0.54%
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)	No	No	3	0	0.00%
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned	No	No	67	0	0.00%
381.22(a)	Develop written SSOP	No	No	269	5	1.82%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
381.22(b)	Conduct hazard analysis & develop and validate HACCP plan	No	No	919	3	0.33%
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product	No	No	217	2	0.91%
381.310	Personnel and training	No	Yes	2360	0	0.00%
381.311	Recall procedure	No	Yes	2348	0	0.00%
381.37(a)	Product not produced under supervision of program employee	No	No	1932	18	0.92%
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	No	57442	546	0.94%
381.65(e)	Zero-tolerance for visible fecal material entering chiller	No	No	0	0	0.00%
381.71(a)	Condemnation on ante mortem inspection	Yes	No	2127	103	4.62%
381.72(a)	Poultry	No	No	214	0	0.00%
381.72(b)	Ratites	No	No	2	0	0.00%
381.76(a)	Post-mortem inspection, when required, extent.	Yes	No	17536	290	1.63%
381.83	Septicemia or toxemia	Yes	No	573872	122	0.02%
381.85	Special Diseases (organisms or toxins dangerous to the consumer)	No	No	128	0	0.00%
381.91(a)	Certain contaminated carcasses to be condemned	No	No	8467	26	0.31%
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	No	No	22309	276	1.22%
381.94(a)	Verification criteria for E. coli testing poultry	No	No	0	0	0.00%
416.1	Operate in a manner to prevent insanitary conditions	Yes	No	606860	9154	1.49%
416.12(c)	plan identifies procedures for pre-op	Yes	No	51170	85	0.17%
416.12(d)	plan list frequency for each procedure & responsible individual	Yes	No	65329	105	0.16%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
416.13 Implementation of SOP's	Implementation of SSOP	Yes	No	5701	16	0.28%
416.13(a)	Conduct pre-op procedures	Yes	Yes	746132	9444	1.25%
416.13(b)	Conduct other procedures listed in the plan	Yes	Yes	1873365	3308	0.18%
416.13(c)	Plant monitors implementation of SSOP procedures	Yes	Yes	2678666	44076	1.62%
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	Yes	1636948	3888	0.24%
416.15 Corrective Actions	Corrective actions	No	No	559	3	0.53%
416.15(a)	Appropriate corrective actions	Yes	Yes	68002	1153	1.67%
416.15(b)	Corrective action, procedures for	Yes	Yes	46351	1121	2.36%
416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	Yes	2926480	4559	0.16%
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	No	80117	595	0.74%
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	No	68297	979	1.41%
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	No	281260	20025	6.65%
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	No	254980	23045	8.29%
416.5(c)	Employees who appears to have any abnormal source of microbial contamination	No	No	34457	17	0.05%
416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	No	2535	124	4.66%
417.2(a)(1)	Hazard analysis	Yes	Yes	122293	1686	1.36%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
417.2(c)	Contents of HACCP Plan	Yes	No	28213	94	0.33%
417.2(c)(4)	List of procedures & frequency	Yes	Yes	1356468	6573	0.48%
417.3 Corrective Actions	Corrective actions	No	No	336	0	0.00%
417.3(a)	Corrective action after deviation from CCP	No	No	266	2	0.75%
417.3(a)(1)	Identify and eliminate the cause	Yes	No	8389	544	6.09%
417.3(a)(2)	CCP is under control	Yes	No	127492	717	0.56%
417.3(a)(3)	Establish measures to prevent recurrence	Yes	No	5136	642	11.11 %
417.3(a)(4)	No adulterated product enters commerce.	Yes	No	32212	207	0.64%
417.3(b)(1)	Segregate and hold the affected product	Yes	No	4238	110	2.53%
417.3(b)(2)	Determine the acceptability of the affected product	Yes	No	2944	86	2.84%
417.3(b)(3)	No adulterated product enters commerce	Yes	No	25665	107	0.42%
417.3(b)(4)	Reassessment	Yes	Yes	28313	258	0.90%
417.3(c)	Document corrective actions	Yes	No	6946	249	3.46%
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	No	7980	224	2.73%
417.4(a)(1)	Initial validation	Yes	No	6817	388	5.39%
417.4(a)(3)	Reassessment, at least annually or when necessary	No	No	0	0	0.00%
417.4(b)	Reassessment of hazard analysis	Yes	Yes	31505	118	0.37%
417.5(a)(1)	Written hazard analysis	Yes	Yes	1381680	4217	0.30%
417.5(a)(2)	Written HACCP plan	Yes	Yes	1229633	1462	0.12%
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	Yes	1421504	3851	0.27%
417.5(f)	Official Review	Yes	No	92050	108	0.12%
417.6	Inadequate HACCP systems	Yes	No	364	116	24.17 %

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
430.4(a)	Lm, post-lethality exposed RTE	Yes	Yes	308727	130	0.04%
430.4(b)(1)	Lm, post-lethality exposed RTE - Alternative 1	No	No	878	6	0.68%
430.4(b)(2)	Lm, post-lethality exposed RTE - Alternative 2	Yes	No	14607	93	0.63%
430.4(b)(3)	Lm, post-lethality exposed RTE - Alternative 3	Yes	No	24658	312	1.25%
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	Yes	299753	181	0.06%
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	No	Yes	306736	185	0.06%
430.4(c)(4)	Lm, validate and verify control measures in HACCP plan	No	No	4057	16	0.39%
430.4(c)(5)	Lm, evaluate control measures in Sanitation SOP	No	No	7178	20	0.28%
430.4(c)(6)	Lm, prerequisite program requirements	No	No	6013	70	1.15%
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	Yes	306889	3443	1.11%
310.18(b)	Brains, cheek meat, head trimmings from animals slaughtered by gunshot	No	No	19926	0	0.00%
418.2	Notification of adulterated or misbranded product in commerce	No	No	1141	107	8.57%
418.3	Recall Plans	Yes	No	14770	50	0.34%
354.242(b)	All equipment and utensils clean and sanitary	No	No	94	2	2.08%
354.242(h)	Tools and equipment used in preparation to be kept clean and sanitary	No	No	42	1	2.33%
354.243(a)	No handling or storage of objectionable materials	No	No	30	0	0.00%
381.193(a)	Poultry not intended for human food in commerce	No	No	409	8	1.92%
381.65(f)	Procedures for controlling visible fecal contamination	No	No	1027214	10349	1.00%
381.65(h)	Recordkeeping requirements	No	No	13545	0	0.00%

FY2020 Candidate Regulation	Description	FY2019 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	No	48905	355	0.72%
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	No	No	2132	163	7.10%
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	Yes	No	666150	154	0.02%
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	No	58959	87	0.15%
311.14	Abrasions, bruises, abscesses, pus, etc.	No	No	21071	21	0.10%

[1]NC = Noncompliance

APPENDIX C: COMPARISON OF FY2020 PHR LIST WITH FY2019 PHR LIST

There are 18 regulations from the FY2019 PHR list that no longer appear in the FY2020 PHR list. These 18 regulations are shown in Table C-1.

Table C-1 Regulations from the FY2019 PHR list no longer on the FY2020 PHR list

List of FY2019 PHRs	Description
310.18	Contamination of carcasses, organs, or other parts
310.22(e)(4)(i)	Maintain daily records
310.25(a)	Verification criteria for E. coli testing meat
317.24(a)	Packaging materials composed of poisonous or deleterious substances
381.65(e)	Zero-tolerance for visible fecal material entering chiller
416.12(c)	plan identifies procedures for pre-op
416.12(d)	plan list frequency for each procedure & responsible individual
416.13 Implementation of SOP's	Implementation of SSOP
417.2(c)	Contents of HACCP Plan
417.3(a)(4)	No adulterated product enters commerce.
417.3(b)(1)	Segregate and hold the affected product
417.3(c)	Document corrective actions
417.4(a)(1)	Initial validation
417.4(b)	Reassessment of hazard analysis
417.6	Inadequate HACCP systems
430.4(b)(2)	Lm, post-lethality exposed RTE – Alternative 2
430.4(b)(3)	Lm, post-lethality exposed RTE – Alternative 3
381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia

There are 4 regulations on the FY2020 PHR list that were not on the FY2019 PHR list. These regulations, shown in Table C-2, were candidate regulations analyzed in both years.

Table C-2 Regulations on the FY2020 PHR list that were not on the FY2019 PHR list

List of FY2020 PHRs	Description
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment
381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage

APPENDIX D: METHODOLGY 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.

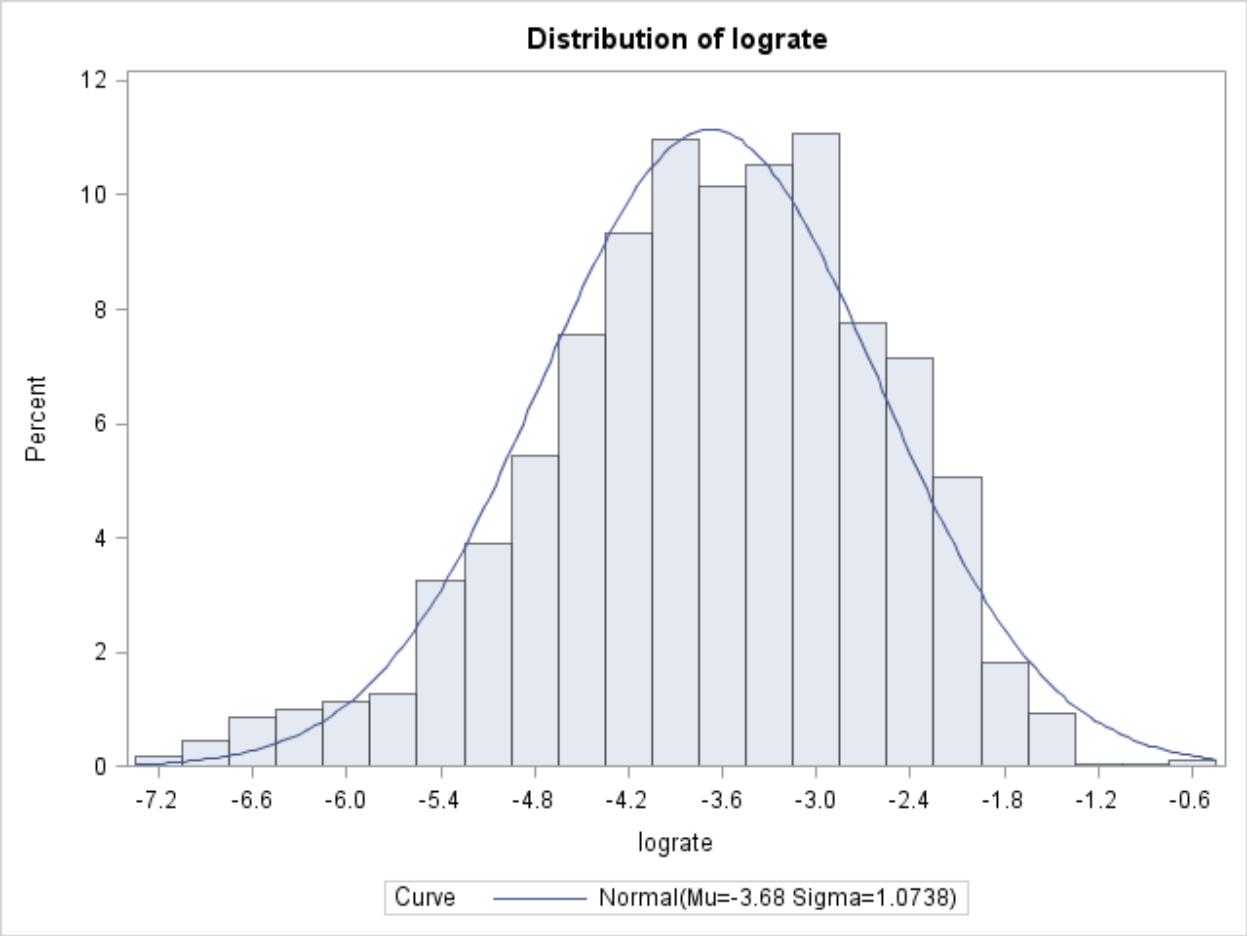
The PHR noncompliance rate is calculated by the following formula using the most recent three months of establishment verification inspection data:

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

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	0.03731	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.55238	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	11.53728	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)
Q1CY2018					Tier 1	66
Both	1,065	-4.43	0.99		Tier 2	95
Processing	4,169	-4.89	0.82		Tier 3	5073
Q2CY2018					Tier 1	60
Both	1,064	-4.23	0.93		Tier 2	68
Processing	4,213	-4.69	0.75		Tier 3	5149
Q3CY2018					Tier 1	67
Both	1,056	-4.41	1.01		Tier 2	89
Processing	4,143	-4.94	0.82		Tier 3	5043
Q4CY2018					Tier 1	61
Both	1,069	-4.44	0.97		Tier 2	87
Processing	4,221	-4.92	0.82		Tier 3	5142

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 2019 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	-4.38	-4.86
Standard Deviation	0.97	0.80

Table D-3 March 2019 Tier Distribution Based on the PHR Criteria Only

Classification	Plants
Tier 1	70
Tier 2	100
Tier 3	5,110
Total	5,280

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	202	3.83%	2	2.78%
Turkey Slaughter	50	0.95%	1	1.39%
Beef Slaughter	1090	20.65%	4	5.56%
Pork Slaughter	1031	19.53%	2	2.78%
Beef Processing	1960	37.13%	11	15.28%
Chicken Processing	896	16.97%	12	16.67%
Turkey Processing	346	6.55%	3	4.17%
Pork Processing	2135	40.44%	14	19.44%
RTE	0	0.00%	0	0.00%
Poultry Combination	383	7.26%	4	5.56%
Total Number of Establishments	5279		72	