FY2019 Public Health Regulations

May 2018

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SUMMARY

The purpose of the present report is to update the FY2018 list of Public Health Regulations (PHRs) used by the Food Safety and Inspection Service (FSIS) for prioritizing Food Safety Assessments (FSAs). The updated list of PHRs is based on CY2017 verification inspection results and will be implemented in FY2019. If an establishment is prioritized for an FSA, the District Office first performs a Public Health Risk Evaluation (PHRE), as described in FSIS Directive 5100.4, to review the operational and compliance history of the establishment to decide if an FSA is appropriate.

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 FSAs.

The methodology used in developing the FY2019 PHR list is the same as that used for the FY2018 PHR list. For inclusion in the FY2019 PHR list, each candidate 9 CFR regulation in the candidate list was evaluated to determine whether noncompliance with the regulation had occurred more frequently 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. The analysis was based on one year of FSIS verification inspection results (January 1 –December 31, 2017) recorded in PHIS. The term "enforcement action" refers to a public health NOIE or suspension.

The final list of FY2019 PHRs consists of 63 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. This compares with 57 regulations that were identified in the FY2018 PHR list. The list of FY2019 PHRs is presented in Appendix A. Seventy eight percent of the regulations on the FY2018 PHR list are also on the FY2019 PHR list.

The 63 FY2019 PHRs are composed of 10 regulations and 53 provisions of regulations. The 53 provisions fall under 18 different regulations. Thus, the 63 FY2019 PHRs represent 28 regulations, with the majority of FY2019 PHRs actually 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 FY2019 PHR regulations three months before a pathogen positive or enforcement action is 9.57 times higher than the average FY2019 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action.

The FY2019 PHRs are one of seven public health based decision criteria that will be used in prioritizing Food Safety Assessments (FSAs). Noncompliance with a single FY2019 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 FY2019 PHR noncompliance rate by

establishments is evaluated and compared to cut points that have been set for two broad categories of establishment operations: Processing Only, and Slaughter/Processing (Named Processing, and Combination in the main body of the report).

To compute the set of FY2019 cut points, the mean and standard deviation of the log transformed non-zero FY2019 PHR rates for each of the four quarters in CY2017 is computed (the log transform of the non-zero FY2019 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 non-compliance 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" FSA if they have not had an FSA in the last six months. Tables S-1 and S-2 present the upper and lower FY2019 PHR cut points for the non-transformed PHR non-compliance data for each of the two establishment operation types. The FY2018 PHR cut points are included for comparison. (See Section 6 and Appendix F for more details.)

Table S-1 FY2019 PHR Tier 1 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	4.40%	4.22%
Combination	9.40%	8.73%

Table S-2 FY2019 PHR Tier 3 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	2.90%	2.82%
Combination	5.64%	5.38%

Table S-3 presents the number of establishments in each Tier for the time period from January 1 –March 31, 2018, based on the PHR criterion. The number of "for cause" FSAs, for Tier 1 establishments will be 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	53	10	63
Tier 2	49	19	68
Tier 3	4,066	1,036	5,102
Total	4,168	1,065	5,233

Table S-4 presents the distribution of Tier 1 establishments (as determined using only the PHR criterion) among different product categories, for the time period from January 1 –March 31, 2018.

Table S-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	201	3.84%	5	7.94%
Turkey Slaughter	54	1.03%	1	1.59%
Beef Slaughter	652	12.46%	1	1.59%
Pork Slaughter	610	11.66%	2	3.17%
Beef Processing	1646	31.45%	14	22.22%
Chicken Processing	805	15.38%	14	22.22%
Turkey Processing	310	5.92%	3	4.76%
Pork Processing	1812	34.63%	13	20.63%
RTE	2550	48.73%	38	60.32%
Poultry Combination	390	7.45%	8	12.70%
Total Number of Establishments	5233		63	

When establishments have had an FSA in the past six months, Tier 1 establishments are not automatically scheduled to receive a PHRE. Instead, the District is notified that such establishments have received a Tier 1 classification and it is up to the District to determine if the establishment should receive an additional PHRE and possible FSA. The time period used for calculating the noncompliance rate of the PHRs was January 1 –March 31, 2018.

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 Food Safety Assessments (FSAs). 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 an FSA is to review an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements. If an establishment is prioritized for an FSA, the District Office first performs a Public Health Risk Evaluation (PHRE), as described in FSIS Directive 5100.4, to review the operational and compliance history of the establishment to decide if an FSA is appropriate.

The subset of 9 CFR regulations used to schedule FSAs were initially called W3NR regulations to indicate they are the most serious non-compliances. 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 were 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 the present report is to update the list of FY2018 PHRs using current verification inspection results from the Public Health Information System (PHIS). The updated list is called the FY2019 PHRs.

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 public health-related provisions of regulations that may be most informative for prioritizing FSAs.

The methodology used in developing the FY2019 PHR list is the same as that used for the FY2018 PHR. Specifically, for inclusion in the FY2019 PHR list, each candidate 9 CFR regulation was evaluated to determine whether noncompliance with the regulation had occurred more frequently 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. The analysis was based on one year of FSIS verification inspection results (January 1 –December 31, 2017) recorded in PHIS. Candidate regulations related to egg products or siluriformes are not included in the present report.

The final FY2019 PHR list is presented in Appendix A. Appendix B describes how non-compliance with PHR regulations has been used in the past to prioritize scheduling of FSAs.

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 those 9 CFR regulations with which noncompliance occurs more frequently 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, to facilitate the analysis and to focus on the most relevant 9 CFR regulations, first the list of 9 CFR regulations is narrowed to those regulations 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.

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 for the production of safe, wholesome food. To make the selection process more transparent, a set of four criteria were developed to assist in selecting the list of candidate regulations.

FSIS requires that establishments develop HAACP plans for controlling food safety hazards that can affect their products. These plans delineate a system of process control for each establishment's particular 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 will be 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 will also be included. Inclusion of 9 CFR regulations in the list of candidate regulations should err on the side of inclusiveness.

2.2 Relationship with Pathogen Positives

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. The three month time period is chosen to be long enough to have sufficient FSIS verification data for analysis and short enough to be indicative of establishment operating conditions before a pathogen positive. 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

The purpose of this section is to use the above criteria to select a list of candidate regulations. The purpose of the candidate list is to narrow the list of all 9 CFR regulations to those related to verifying HACCP food safety process control in order to make the analysis of relationship to pathogen positives manageable. All regulations in 9 CFR were individually reviewed to determine if they satisfied any of the 4 criteria delineated in Section 2.1. A set of one hundred forty eight (148) 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 148 candidate regulations that are indicators of a potential loss of HACCP food safety process control are presented in Appendix C.

4.0 RELATIONSHIP BETWEEN CANDIDATE REGULATIONS AND PATHOGEN POSITIVES

The purpose of this section is to investigate the relationship between the list of candidate regulations and *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Listeria monocytogenes, Campylobacter* positives or enforcement actions during FSIS verification testing. The noncompliance rate of each of the 144 candidate regulations in establishments three months before 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 in the period January 1, 2017 through December 31, 2017. 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 Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments in the three months before a pathogen positive is higher than the noncompliance rate for establishments with no positives are selected as PHRs.

A few candidate regulations have 30 or less verifications three months before a specific pathogen positive or enforcement action. These candidate regulations 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 that have more the 30 verifications).

An odds ratio (OR) is one of several statistics useful as an effect-size measure, especially when statistical significance of dichotomous data is computed using the Fisher 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 non-compliance 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 non-compliance 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 noncompliance rate of each of the 144 candidate regulations in establishments three months before a *Salmonella* positive was compared with the average noncompliance rate of establishments that received *Salmonella* FSIS verification testing, but had no *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,132 establishments with *Salmonella* testing data, of which 797 had 3,313 *Salmonella* positives and 1,335 did not have *Salmonella* positives. There were 42,122 total *Salmonella* tests performed.

Table 4-1 presents the 36 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 Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments 3 months before a *Salmonella* positive is higher than the average noncompliance rate for establishments with no *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Yes	9.32%	2.88%	6.19E-15	3.47
69	310.18	No	3.86%	1.23%	8.76E-06	3.22
78	310.22(c)	Yes	0.76%	0.20%	1.71E-07	3.83
88	310.22(e)(1)	No	3.04%	0.88%	4.88E-08	3.53
90	310.22(e)(3)	Yes	2.38%	0.68%	1.94E-05	3.58
178	317.24(a)	Yes	5.23%	0.21%	4.00E-06	25.86
234	318.2(a)	Yes	0.48%	0.10%	2.17E-06	4.56
406	381.1_Adulterated	Yes	2.91%	0.55%	3.71E-03	5.46
527	381.65(a)	Yes	2.25%	0.50%	5.40E-34	4.59
543	381.71(a)	Yes	13.35%	0.71%	1.89E-07	21.42
582	416.1	Yes	5.97%	1.28%	0.00E+00	4.88
586	416.12(c)	Yes	0.41%	0.10%	2.49E-05	4.07
588	416.13 Implementation of SOP's	No	0.46%	0.03%	4.39E-02	13.86
589	416.13(a)	Yes	4.50%	0.53%	0.00E+00	8.88
590	416.13(b)	Yes	0.69%	0.13%	0.00E+00	5.13
591	416.13(c)	Yes	8.05%	1.05%	0.00E+00	8.27
592	416.14	Yes	1.31%	0.17%	0.00E+00	7.79
594	416.15(a)	Yes	7.80%	1.96%	6.38E-101	4.24

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
595	416.15(b)	Yes	10.95%	2.15%	4.25E-126	5.59
597	416.16(a)	Yes	0.43%	0.12%	6.34E-235	3.53
630	416.3(b)	Yes	3.43%	0.51%	2.70E-78	6.90
631	416.3(c)	Yes	5.50%	0.87%	8.09E-128	6.60
633	416.4(a)	Yes	28.85%	4.48%	0.00E+00	8.65
636	416.4(d)	Yes	34.64%	4.83%	0.00E+00	10.45
641	416.6	Yes	8.89%	2.06%	6.29E-09	4.64
648	417.2(c)	No	0.52%	0.17%	1.37E-04	3.10
649	417.2(c)(4)	Yes	1.63%	0.28%	0.00E+00	5.82
657	417.3(a)(1)	Yes	8.60%	1.58%	5.25E-111	5.85
659	417.3(a)(3)	Yes	11.70%	1.99%	2.21E-135	6.54
662	417.3(b)(1)	No	1.91%	0.53%	4.61E-10	3.65
663	417.3(b)(2)	Yes	1.64%	0.41%	6.44E-09	4.01
665	417.3(b)(4)	Yes	1.70%	0.48%	4.71E-16	3.62

4.1.1 *Salmonella* in Intact Chicken

The noncompliance rate of each of the 144 candidate regulations in establishments three months before an Intact Chicken *Salmonella* positive was compared with the average noncompliance rate of establishments that received Intact Chicken *Salmonella* FSIS verification testing, but had no Intact Chicken *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 205 establishments with Intact Chicken *Salmonella* testing data, of which 159 had 514 *Salmonella* positives and 46 did not have *Salmonella* positives. There were 9,126 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 11 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 Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Intact Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Chicken *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
543	381.71(a)	Yes	20.32%	1.07%	1.16E-31	23.67
557	381.83	Yes	0.11%	0.02%	3.67E-13	4.77
590	416.13(b)	Yes	1.35%	0.32%	2.01E-52	4.23
592	416.14	Yes	2.47%	0.73%	2.03E-66	3.46
594	416.15(a)	Yes	18.52%	4.47%	2.36E-38	4.86
657	417.3(a)(1)	Yes	9.75%	1.04%	9.59E-19	10.33
659	417.3(a)(3)	Yes	12.73%	2.53%	9.97E-18	5.62
664	417.3(b)(3)	Yes	0.57%	0.12%	4.32E-03	4.87
669	417.4(a)(1)	No	14.58%	2.50%	8.88E-05	6.66
717	310.18(a)	Yes	2.58%	0.43%	7.85E-04	6.08
1351	381.76(b)(6)(ii)(C)	No	0.09%	0.02%	6.48E-12	4.42

4.1.2 *Salmonella* in Intact Turkey

The noncompliance rate of each of the candidate regulations in establishments three months before an Intact Turkey *Salmonella* positive was compared with the average noncompliance rate of establishments that received Intact Turkey *Salmonella* FSIS verification testing, but had no Intact Turkey *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Salmonella* testing data, of which 12 had 16 *Salmonella* positives and 33 did not have *Salmonella* positives. There were 1,904 total Intact Turkey *Salmonella* tests performed.

Table 4-3 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 Exact p value of less than 0.05) that the noncompliance rate of the regulations in establishments three months before an Intact Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Turkey *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
649	417.2(c)(4)	Yes	2.34%	0.71%	5.66E-13	3.35
682	417.5(a)(3)	Yes	0.79%	0.25%	5.08E-05	3.21

4.1.3 *Salmonella* in Ground Beef

The noncompliance rate of each of the candidate regulations in establishments three months before a Ground Beef *Salmonella* positive was compared with the average noncompliance rate of establishments that received Ground Beef *Salmonella* FSIS verification testing, but had no Ground Beef *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,250 establishments with *Salmonella* testing data, of which 117 had 166 *Salmonella* positives and 1,133 did not have *Salmonella* positives. There were 11,182 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 6 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 Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Ground Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ground Beef *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
90	310.22(e)(3)	Yes	4.94%	1.31%	2.45E-02	3.91
594	416.15(a)	Yes	5.77%	1.44%	8.19E-05	4.20
648	417.2(c)	No	7.79%	0.26%	1.67E-07	32.44
657	417.3(a)(1)	Yes	5.88%	1.54%	1.33E-05	4.01
662	417.3(b)(1)	No	4.81%	0.47%	2.05E-06	10.62
663	417.3(b)(2)	Yes	3.66%	0.42%	6.83E-05	9.04

4.1.4 *Salmonella* in Intact Beef

The noncompliance rate of each of the candidate regulations in establishments three months before an Intact Beef *Salmonella* positive was compared with the average noncompliance rate of establishments that received Intact Beef *Salmonella* FSIS verification testing, but had no Intact Beef *Salmonella* positives in the period January 1, 2017 to December 31, 2017. FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 911 establishments with Intact Beef *Salmonella* testing data, of which 68 had 109 *Salmonella* positives and 843 did not have *Salmonella* positives. There were 5,188 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 15 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability, as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Intact Beef *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Beef *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Yes	19.76%	2.60%	9.50E-28	9.24
69	310.18		3.70%	1.22%	1.01E-02	3.11
78	310.22(c)	Yes	1.55%	0.21%	2.41E-12	7.39
88	310.22(e)(1)		7.09%	1.00%	1.72E-13	7.53
89	310.22(e)(2)	Yes	12.50%	4.09%	1.94E-02	3.35
90	310.22(e)(3)	Yes	9.24%	0.64%	2.36E-13	15.81
99	310.22(f)(2)	Yes	0.53%	0.09%	2.51E-02	5.75
588	416.13 Implementation of SOP's		0.78%	0.03%	1.62E-02	24.63
589	416.13(a)	Yes	2.11%	0.55%	1.93E-24	3.89
590	416.13(b)	Yes	0.50%	0.16%	1.19E-10	3.06
591	416.13(c)	Yes	5.04%	1.09%	3.38E-244	4.83
630	416.3(b)	Yes	2.26%	0.45%	9.87E-03	5.12
636	416.4(d)	Yes	17.58%	4.71%	3.97E-107	4.31
649	417.2(c)(4)	Yes	2.30%	0.28%	2.61E-114	8.47
717	310.18(a)	Yes	4.16%	0.95%	5.55E-128	4.54

4.1.5 *Salmonella* in Comminuted Chicken

The noncompliance rate of each of the candidate regulations in establishments three months before a Comminuted Chicken *Salmonella* positive was compared with the average noncompliance rate of establishments that received Comminuted Chicken *Salmonella* FSIS verification testing, but had no Comminuted Chicken *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 105 establishments with Comminuted Chicken *Salmonella* testing data, of which 83 had 513 *Salmonella* positives and 22 did not have *Salmonella* positives. There were 1,665 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 12 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
527	381.65(a)	Yes	2.03%	0.09%	1.56E-07	23.05
550	381.76(a)*	Yes	6.66%	0.56%	4.72E-09	12.72
591	416.13(c)	Yes	5.89%	1.75%	3.34E-107	3.50
594	416.15(a)	Yes	11.38%	2.21%	2.38E-04	5.69
595	416.15(b)	Yes	16.44%	1.53%	9.74E-08	12.69
630	416.3(b)	Yes	3.44%	1.08%	4.15E-02	3.27
633	416.4(a)	Yes	29.97%	7.68%	7.61E-97	5.14
636	416.4(d)	Yes	31.63%	13.04%	4.20E-52	3.09
657	417.3(a)(1)	Yes	14.53%	1.44%	1.31E-12	11.65
658	417.3(a)(2)	Yes	1.80%	0.25%	4.46E-14	7.47
659	417.3(a)(3)	Yes	19.12%	0.74%	3.47E-20	31.92
664	417.3(b)(3)	Yes	0.56%	0.14%	1.36E-02	4.00

4.1.6 *Salmonella* in Comminuted Turkey

The noncompliance rate of each of the candidate regulations in establishments three months before a Comminuted Turkey *Salmonella* positive was compared with the average noncompliance rate of establishments that received Comminuted Turkey *Salmonella* FSIS

verification testing, but had no Comminuted Turkey *Salmonella* positives in the period January 1, 2017 to December 31, 2017. There are 56 establishments with Comminuted Turkey *Salmonella* testing data, of which 37 had 184 *Salmonella* positives and 19 did not have *Salmonella* positives. There were 1208 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the 11 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
589	416.13(a)	Yes	1.81%	0.44%	5.85E-08	4.22
592	416.14	Yes	0.93%	0.22%	3.53E-09	4.30
594	416.15(a)	Yes	6.38%	1.47%	1.57E-05	4.57
595	416.15(b)	Yes	12.67%	0.28%	2.51E-16	51.06
597	416.16(a)	Yes	0.42%	0.09%	2.70E-09	4.60
645	417.2(a)(1)	Yes	3.35%	1.06%	3.37E-03	3.22
649	417.2(c)(4)	Yes	1.64%	0.43%	6.58E-17	3.84
657	417.3(a)(1)	Yes	23.08%	2.47%	5.07E-07	11.85
658	417.3(a)(2)	Yes	2.51%	0.54%	9.81E-04	4.72
659	417.3(a)(3)	Yes	35.02%	1.18%	7.34E-14	45.27
717	310.18(a)	Yes	3.78%	1.12%	2.26E-02	3.48

4.1.7 *Salmonella* in Intact Pork

The noncompliance rate of each of the candidate regulations in establishments three months before an Intact Pork *Salmonella* positive was compared with the average noncompliance rate of establishments that received Intact Pork *Salmonella* FSIS verification testing, but had no Intact Pork *Salmonella* positives in the period January 1, 2017 to December 31, 2017. There are 262 establishments with Intact Pork *Salmonella* testing data, of which 86 had 192 *Salmonella* positives and 176 did not have *Salmonella* positives. There were 1389 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the 9 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
582	416.1	Yes	6.03%	1.37%	9.90E-61	4.62
592	416.14	Yes	0.64%	0.19%	3.93E-12	3.45
630	416.3(b)	Yes	4.22%	0.32%	2.65E-12	13.58
631	416.3(c)	Yes	5.30%	0.81%	5.11E-12	6.88
649	417.2(c)(4)	Yes	1.30%	0.36%	2.03E-27	3.65
657	417.3(a)(1)	Yes	19.35%	0.87%	7.92E-07	27.24
659	417.3(a)(3)	Yes	59.49%	1.56%	2.35E-45	92.98
660	417.3(a)(4)	Yes	23.40%	0.32%	5.73E-15	95.64
666	417.3(c)	Yes	29.55%	1.67%	5.40E-11	24.74

4.1.8 *Salmonella* in Ground Pork

The noncompliance rate of each of the candidate regulations in establishments three months before a Ground Pork *Salmonella* positive was compared with the average noncompliance rate of establishments that received Ground Pork *Salmonella* FSIS verification testing, but had no Ground Pork *Salmonella* positives in the period January 1, 2017 to December 31, 2017. There are 341 establishments with Ground Pork *Salmonella* testing data, of which 161 had 456 *Salmonella* positives and 180 did not have *Salmonella* positives. There were 2,537 total Ground Pork *Salmonella* tests performed.

There are 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 Exact p value of less than 0.05) that for which the noncompliance rate of the regulation in establishments three months before an Ground Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ground Pork *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
178	317.24(a)	Yes	16.67%	1.64%	7.42E-03	12.00
631	416.3(c)	Yes	3.52%	1.02%	1.55E-07	3.55
665	417.3(b)(4)	Yes	3.27%	0.63%	2.38E-03	5.32

4.1.9 *Salmonella* in Chicken Parts

The noncompliance rate of each of the candidate regulations in establishments three months before a Chicken Parts *Salmonella* positive was compared with the average noncompliance rate of establishments that received Chicken Parts *Salmonella* FSIS verification testing, but had no Chicken Parts *Salmonella* positives in the period January 1, 2017 to December 31, 2017. There are 432 establishments with Chicken Parts *Salmonella* testing data, of which 315 had 1,153 *Salmonella* positives and 117 did not have *Salmonella* positives. There were 7,742 total Chicken Parts *Salmonella* tests performed.

Table 4-10 presents the 10 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
557	381.83	Yes	0.08%	0.00%	6.96E-14	19.88
582	416.1	Yes	6.47%	1.76%	2.50E-131	3.87
589	416.13(a)	Yes	6.52%	2.01%	1.68E-122	3.39
591	416.13(c)	Yes	10.04%	2.94%	0.00E+00	3.68
592	416.14	Yes	1.61%	0.54%	1.51E-69	3.03
633	416.4(a)	Yes	34.48%	14.74%	4.03E-281	3.05

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
657	417.3(a)(1)	Yes	4.71%	1.51%	5.05E-06	3.22
659	417.3(a)(3)	Yes	5.86%	0.41%	2.51E-14	15.03
665	417.3(b)(4)	Yes	2.22%	0.46%	2.54E-04	4.87
1351	381.76(b)(6)(ii)(C)	No	0.06%	0.00%	4.51E-12	17.33

4.1.10 *Salmonella* in Ready to Eat

The noncompliance rate of each of the candidate regulations in establishments three months before an Ready to Eat *Salmonella* positive was compared with the average noncompliance rate of establishments that received Ready to Eat *Salmonella* FSIS verification testing, but had no Ready to Eat *Salmonella* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1837establishments with *Salmonella* testing data, of which 1 had 1 *Salmonella* positives and 1,836 did not have *Salmonella* positives. There were 12,318 total Ready to Eat *Salmonella* tests performed.

There is 1 regulation 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 Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Ready to Eat *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ready to Eat *Salmonella* positive in the period January 1, 2017 to December 31, 2017.

Table 4-11 Comparison of Noncompliance Rates 3 Months before a Ready to Eat *Salmonella* Positive with those for Establishments with No Ready to Eat *Salmonella* Positive

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Salmonella* Positive	Noncompliance Rate for Establishments with no *Salmonella* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
591	416.13(c)	Yes	8.65%	1.05%	1.73E-06	8.94

4.2 *E. Coli*

4.2.1 *E. coli* O157:H7

The purpose of this section is to investigate the relationship 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 noncompliance rate of each of the candidate regulations in the three months before an *E. coli* O157:H7 positive was compared with the average noncompliance rate of establishments that received FSIS *E. coli* O157:H7 verification testing, but had no *E. coli* O157:H7 positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1177 establishments with *E. coli* O157:H7 testing data, of which 16 had 16 *E. coli* O157:H7 positives and 1,161 did not have *E. coli* O157:H7 positives. There were 14725 total *E. coli* O157:H7 tests performed.

There were no 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 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 in the period January 1, 2017 to December 31, 2017.

4.2.2 Non-O157 STEC

The purpose of this section is to investigate the relationship 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 noncompliance rate of each of the candidate regulations in the three months before a non-O157 STEC positive was compared with the average noncompliance rate of establishments that received FSIS non-O157 STEC verification testing, but had no non-O157 STEC positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 373 establishments with non-O157 STEC testing data, of which 15 had 31 non- O157 STEC positives and 358 did not have non-O157 STEC positives. There were 3,105 total non-O157 STEC tests performed.

Table 4-12 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Non-O157 STEC Positive	Noncompliance Rate for Establishments with no Non-O157 STEC Positive	Two-Sided Fisher Exact p Value	Odds Ratio
78	310.22(c)	Yes	1.37%	0.44%	1.62E-02	3.11
88	310.22(e)(1)	No	7.69%	2.16%	7.63E-03	3.77

4.3 *Listeria monocytognes*

The noncompliance rate of each of the candidate regulations in the three months before a *Listeria monocytogenes* positive was compared with the average noncompliance rate of establishments that received FSIS *Listeria monocytogenes* verification testing, but had no *Listeria monocytogenes* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1837 establishments with *Listeria monocytogenes* testing data, of which 19 had 20 *Listeria monocytogenes* positives and 1818 did not have *Listeria monocytogenes* positives. There were 12,319 total *Listeria monocyogenes* tests performed.

Table 4-13 presents the 1 regulation that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a *Listeria monocytognes* Positive	Noncompliance Rate for Establishments with no *Listeria monocytognes* Positive	Two-Sided Fisher Exact p Value	Odds Ratio
717	310.18(a)	Yes	3.06%	0.83%	4.89E-02	3.78

4.4 *Campylobacter*

The purpose of this section is to investigate the relationship between the candidate regulations and *Campylobacter* positives. The noncompliance rate of each of the candidate regulations in the three months before a *Campylobacter* positive was compared with the average noncompliance rate of establishments that received FSIS *Campylobacter* verification testing, but had no

Campylobacter positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 577 establishments with *Campylobacter* testing data, of which 206 had 479 *Campylobacter* positives and 371 did not have *Campylobacter* positives. There were 21,229 total *Campylobacter* tests performed.

Table 4-14 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 95% probability (as determined by a two-sided Fisher 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 in the period January 1, 2017 to December 31, 2017.

Table 4-94 Comparison of Noncompliance Rates 3 Months before a Campylobacter Positive with Those for Establishments with No Campylobacter Positive

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
234	318.2(a)	Yes	4.55%	0.30%	1.01E-06	15.84
668	417.4(a)	Yes	19.92%	3.19%	4.83E-18	7.55
669	417.4(a)(1)	No	19.23%	6.53%	1.58E-04	3.41
689	417.5(f)	Yes	0.39%	0.12%	6.02E-03	3.27

4.4.1 *Campylobacter* in Intact Chicken

The noncompliance rate of each of the candidate regulations in the three months before an Intact Chicken *Campylobacter* positive was compared with the average noncompliance rate of establishments that received FSIS *Campylobacter* verification testing, but had no Intact Chicken *Campylobacter* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 204 establishments with Intact Chicken *Campylobacter* testing data, of which 96 had 187 *Campylobacter* positives and 108 did not have *Campylobacter* positives. There were 8978 total Intact Chicken *Campylobacter* tests performed.

Table 4-15 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 95% probability (as determined by a two-sided Fisher 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
668	417.4(a)	Yes	46.36%	1.86%	3.50E-39	45.70
669	417.4(a)(1)	No	34.29%	8.67%	2.49E-04	5.50

4.4.2 *Campylobacter* in Intact Turkey

The noncompliance rate of each of the candidate regulations in the three months before an Intact Turkey *Campylobacter* positive was compared with the average noncompliance rate of establishments that received FSIS *Campylobacter* verification testing, but had no Intact Turkey *Campylobacter* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Campylobacter* testing data, of which 4 had 4 *Campylobacter* positives and 41 did not have *Campylobacter* positives. There were 1852 total Intact Turkey *Campylobacter* tests performed.

Table 4-16 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 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulations in the three months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
591	416.13(c)	Yes	13.66%	4.60%	2.08E-16	3.28
594	416.15(a)	Yes	11.36%	3.80%	2.94E-02	3.25
597	416.16(a)	Yes	1.43%	0.29%	8.72E-04	4.91
649	417.2(c)(4)	Yes	4.29%	1.11%	6.63E-07	3.98

4.4.3 *Campylobacter* in Comminuted Chicken

The noncompliance rate of each of the candidate regulations in establishments three months before a Comminuted Chicken *Campylobacter* positive was compared with the average noncompliance rate of establishments that received Comminuted Chicken *Campylobacter* FSIS verification testing, but had no Comminuted Chicken *Campylobacter* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 105 establishments with Comminuted Chicken *Campylobacter* testing data, of which 22 had 60 *Campylobacter* positives and 83 did not have *Campylobacter* positives. There were 1,651 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-17 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
550	381.76(a)*	Yes	8.42%	2.61%	6.81E-03	3.43
657	417.3(a)(1)	Yes	21.57%	1.28%	8.19E-39	21.24
658	417.3(a)(2)	Yes	1.99%	0.28%	8.33E-17	7.14
659	417.3(a)(3)	Yes	27.72%	4.82%	8.78E-26	7.57

4.4.4 *Campylobacter* in Comminuted Turkey

The noncompliance rate of each of the candidate regulations in establishments three months before a Comminuted Turkey *Campylobacter* positive was compared with the average noncompliance rate of establishments that received Comminuted Turkey *Campylobacter* FSIS verification testing, but had no Comminuted Turkey *Campylobacter* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 56 establishments with Comminuted Turkey *Campylobacter* testing data, of which 4 had 6 *Campylobacter* positives and 52 did not have *Campylobacter* positives. There were 1201 total Comminuted Turkey *Campylobacter* tests performed.

There are three 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2018 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
594	416.15(a)	Yes	10.00%	2.77%	2.76E-02	3.90
636	416.4(d)	Yes	36.25%	15.42%	6.20E-06	3.12
689	417.5(f)	Yes	1.24%	0.17%	4.98E-02	7.54

4.4.5 *Campylobacter* in Chicken Parts

The noncompliance rate of each of the candidate regulations in establishments three months before a Chicken Parts *Campylobacter* positive was compared with the average noncompliance rate of establishments that received Chicken Parts *Campylobacter* FSIS verification testing, but had no Chicken Parts *Campylobacter* positives in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 432 establishments with Chicken Parts *Campylobacter* testing data, of which 129 had 222 *Campylobacter* positives and 303 did not have *Campylobacter* positives. There were 7547 total Chicken Parts *Campylobacter* tests performed.

Table 4-19 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2017 PHR List	Noncompliance Rate in 3 Months before a Campylobacter Positive	Noncompliance Rate for Establishments with no Campylobacter Positive	Two-Sided Fisher Exact p Value	Odds Ratio
207	318.1(b)	Yes	0.29%	0.03%	1.65E-02	8.87
234	318.2(a)	Yes	9.78%	0.23%	3.56E-09	46.05
717	310.18(a)	Yes	7.65%	1.01%	2.28E-02	8.12

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. Food Safety Inspection Service (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.

A public-health related NOIE or suspension is one that results 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 FY2019 PHRs. The enforcement action list will consist of candidate 9 CFR regulations in which non-compliances occur more frequently in establishments in the three month period before a Notice of Intended Enforcement Action (NOIE) or suspension than in establishments without a NOIE or suspension in the period January 1, 2017 to December 31, 2017. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,492 active meat and poultry establishments, of which 129 had 222 public health related NOIEs or suspensions and 5,354 did not have any public health related NOIEs or suspensions.

Table 4-20 presents the 38 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 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 in the period January 1, 2017 to December 31, 2017.

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

Reg ID	Regulation Verified	On FY2017 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Two-Sided Fisher Exact p Value	Odds Ratio
88	310.22(e)(1)	No	11.11%	1.70%	1.05E-03	7.22
92	310.22(e)(4)(i)	No	2.97%	0.15%	1.03E-06	20.16
107	310.25(a)	Yes	3.57%	0.60%	6.38E-04	6.17
234	318.2(a)	Yes	1.12%	0.11%	1.92E-02	9.92
235	318.2(d)	No	2.94%	0.55%	2.18E-02	5.44
530	381.65(e)*	No	4.94%	1.27%	2.16E-02	4.03
587	416.12(d)	Yes	0.90%	0.20%	2.93E-02	4.64

Reg ID	Regulation Verified	On FY2017 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Two-Sided Fisher Exact p Value	Odds Ratio
589	416.13(a)	Yes	3.10%	0.97%	2.92E-27	3.26
590	416.13(b)	Yes	1.24%	0.19%	9.53E-55	6.59
592	416.14	Yes	0.96%	0.26%	1.20E-21	3.72
594	416.15(a)	Yes	7.73%	1.90%	8.42E-10	4.33
595	416.15(b)	Yes	10.19%	2.88%	4.37E-07	3.83
597	416.16(a)	Yes	0.60%	0.14%	4.31E-27	4.16
630	416.3(b)	Yes	2.65%	0.86%	1.99E-03	3.13
645	417.2(a)(1)	Yes	11.99%	1.41%	1.58E-39	9.54
649	417.2(c)(4)	Yes	1.94%	0.64%	7.48E-27	3.09
657	417.3(a)(1)	Yes	21.03%	2.77%	1.14E-25	9.35
658	417.3(a)(2)	Yes	1.88%	0.52%	5.51E-07	3.66
659	417.3(a)(3)	Yes	23.61%	3.87%	6.62E-25	7.68
660	417.3(a)(4)	Yes	3.94%	0.46%	2.77E-09	8.96
662	417.3(b)(1)	No	9.76%	0.86%	7.75E-07	12.46
663	417.3(b)(2)	Yes	8.97%	0.70%	1.81E-06	14.01
664	417.3(b)(3)	Yes	3.78%	0.32%	3.40E-06	12.28
665	417.3(b)(4)	Yes	6.44%	0.56%	2.72E-10	12.30
666	417.3(c)	Yes	12.50%	1.80%	2.42E-08	7.79
668	417.4(a)	Yes	56.25%	3.69%	1.09E-25	33.54
669	417.4(a)(1)	No	51.43%	8.05%	3.64E-11	12.10
675	417.4(b)	No	1.59%	0.25%	4.01E-02	6.57
680	417.5(a)(1)	Yes	2.10%	0.32%	7.53E-71	6.74
681	417.5(a)(2)	Yes	0.84%	0.12%	2.23E-26	6.94
682	417.5(a)(3)	Yes	1.15%	0.25%	7.59E-31	4.75
689	417.5(f)	Yes	0.67%	0.12%	1.76E-02	5.68
701	430.4(a)	Yes	0.40%	0.03%	1.80E-05	11.95
703	430.4(b)(2)	No	4.76%	0.62%	5.90E-04	8.05
704	430.4(b)(3)	Yes	3.54%	0.95%	9.19E-04	3.83
705	430.4(c)(2)	No	0.21%	0.04%	1.86E-02	5.55
1174	418.3	Yes	5.41%	0.56%	9.43E-04	10.15
1349	381.76(b)(6)(ii)(A)	Yes	3.33%	0.51%	3.83E-02	6.72

5.0 LIST OF FY2019 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2019 PHR list. Table 5-1 presents the list of 63 FY2019 PHRs. These 63 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 63 FY2019 PHRs are composed of 10 regulations and 53 provisions of regulations. The 53 provisions fall under 18 different regulations. Thus, the 63 FY2019 PHRs represent 28 regulations, with the majority of FY2019 PHRs actually 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 FY2019 PHRs

Reg ID	List of FY2019 PHRs	Description	On FY2018 PHR List	Average Two-Sided Fisher Exact p Value	Average Odds Ratio
29	301.2_Adulterated	Adulterated	Yes	3.10E-15	6.35
69	310.18	Contamination of carcasses, organs, or other parts	No	5.03E-03	3.16
78	310.22(c)	Disposal of SRM	Yes	5.41E-03	4.78
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	No	2.17E-03	5.51
89	310.22(e)(2)	Appropriate corrective actions	Yes	1.94E-02	3.35
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	8.16E-03	7.76
92	310.22(e)(4)(i)	Maintain daily records	No	1.03E-06	20.16
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	2.51E-02	5.75
107	310.25(a)	Verification criteria for *E. coli* testing meat	Yes	6.38E-04	6.17
178	317.24(a)	Packaging materials composed of poisonous or deleterious substances	Yes	3.71E-03	18.93

Reg ID	List of FY2019 PHRs	Description	On FY2018 PHR List	Average Two-Sided Fisher Exact p Value	Average Odds Ratio
207	318.1(b)	Only inspected and passed poultry product to enter official establishment	Yes	1.65E-02	8.87
234	318.2(a)	All products subject to reinspection by program employees	Yes	4.79E-03	19.09
235	318.2(d)	Removal of U.S. retained by authorized Program employees only	No	2.18E-02	5.44
406	381.1_Adulterated	Adulterated	Yes	3.71E-03	5.46
527	381.65(a)	Clean and sanitary practices; products not adulterated	Yes	7.82E-08	13.82
530	381.65(e)*	Zero-tolerance for visible fecal material entering chiller	No	2.16E-02	4.03
543	381.71(a)	Condemnation on ante mortem inspection	Yes	9.44E-08	22.55
550	381.76(a)*	Post-mortem inspection, when required, extent.	Yes	3.40E-03	8.07
557	381.83	Septicemia or toxemia	Yes	2.19E-13	12.32
582	416.1	Operate in a manner to prevent insanitary conditions	Yes	3.30E-61	4.46
586	416.12(c)	plan identifies procedures for pre-op	Yes	2.49E-05	4.07
587	416.12(d)	plan list frequency for each procedure & responsible individual	Yes	2.93E-02	4.64
588	416.13 Implementation of SOP's	Implementation of SSOP	No	3.01E-02	19.25
589	416.13(a)	Conduct pre-op procedures	Yes	1.17E-08	4.73
590	416.13(b)	Conduct other procedures listed in the plan	Yes	2.97E-11	4.75
591	416.13(c)	Plant monitors implementation of SSOP procedures	Yes	2.88E-07	5.42
592	416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	5.90E-10	4.29
594	416.15(a)	Appropriate corrective actions	Yes	7.17E-03	4.38

Reg ID	List of FY2019 PHRs	Description	On FY2018 PHR List	Average Two-Sided Fisher Exact p Value	Average Odds Ratio
595	416.15(b)	Corrective action, procedures for	Yes	1.34E-07	18.29
597	416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	2.18E-04	4.30
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	1.07E-02	6.40
631	416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.16E-08	5.68
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	2.54E-97	5.61
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	1.55E-06	5.24
641	416.6	Only FSIS program employee may remove "U.S. Rejected" tag	Yes	6.29E-09	4.64
645	417.2(a)(1)	Hazard analysis	Yes	1.68E-03	6.38
648	417.2(c)	Contents of HACCP Plan	No	6.88E-05	17.77
649	417.2(c)(4)	List of procedures & frequency	Yes	9.48E-08	4.60
657	417.3(a)(1)	Identify and eliminate the cause	Yes	2.18E-06	11.64
658	417.3(a)(2)	CCP is under control	Yes	2.45E-04	5.75
659	417.3(a)(3)	Establish measures to prevent recurrence	Yes	1.23E-14	26.58
660	417.3(a)(4)	No adulterated product enters commerce.	Yes	1.38E-09	52.30
662	417.3(b)(1)	Segregate and hold the affected product	No	9.43E-07	8.91
663	417.3(b)(2)	Determine the acceptability of the affected product	Yes	2.34E-05	9.02
664	417.3(b)(3)	No adulterated product enters commerce	Yes	5.97E-03	7.05
665	417.3(b)(4)	Reassessment	Yes	6.59E-04	6.52
666	417.3(c)	Document corrective actions	Yes	1.21E-08	16.26

Reg ID	List of FY2019 PHRs	Description	On FY2018 PHR List	Average Two-Sided Fisher Exact p Value	Average Odds Ratio
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	1.21E-18	23.51
669	417.4(a)(1)	Initial validation	No	1.24E-04	6.91
675	417.4(b)	Reassessment of hazard analysis	No	4.01E-02	6.57
680	417.5(a)(1)	Written hazard analysis	Yes	7.53E-71	6.74
681	417.5(a)(2)	Written HACCP plan	Yes	2.23E-26	6.94
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	2.54E-05	3.98
689	417.5(f)	Official Review	Yes	2.45E-02	5.50
690	417.6	Inadequate HACCP systems	No	1.51E-19	12.85
701	430.4(a)	Lm, post-lethality exposed RTE	Yes	1.80E-05	11.95
703	430.4(b)(2)	Alternative 2	No	5.90E-04	8.05
704	430.4(b)(3)	Alternative 3	Yes	9.19E-04	3.83
705	430.4(c)(2)	Alternative 3	No	1.86E-02	5.55
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	1.59E-02	4.90
1174	418.3	Recall Plans	Yes	9.43E-04	10.15
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	1.92E-02	10.05
1351	381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia	No	5.50E-12	10.88

Figure 5-1 presents a histogram of the ratios (odds ratios) for each of the 63 PHRs between the odds of a non-compliance 3 months before a pathogen positive versus the odds of a non-compliance of the regulations for establishments with no pathogen positive. The average odds ratio is 9.57. That is, for a given PHR, the ratio of non-compliances to compliances for that regulation in establishments 3 months before a positive pathogen or enforcement action is on average 9.57 times higher than the ratio of non-compliances to compliances for that regulation in establishments with no pathogen positive or enforcement action.

Figure 5-1 Odds Ratio for the 2019 PHRs
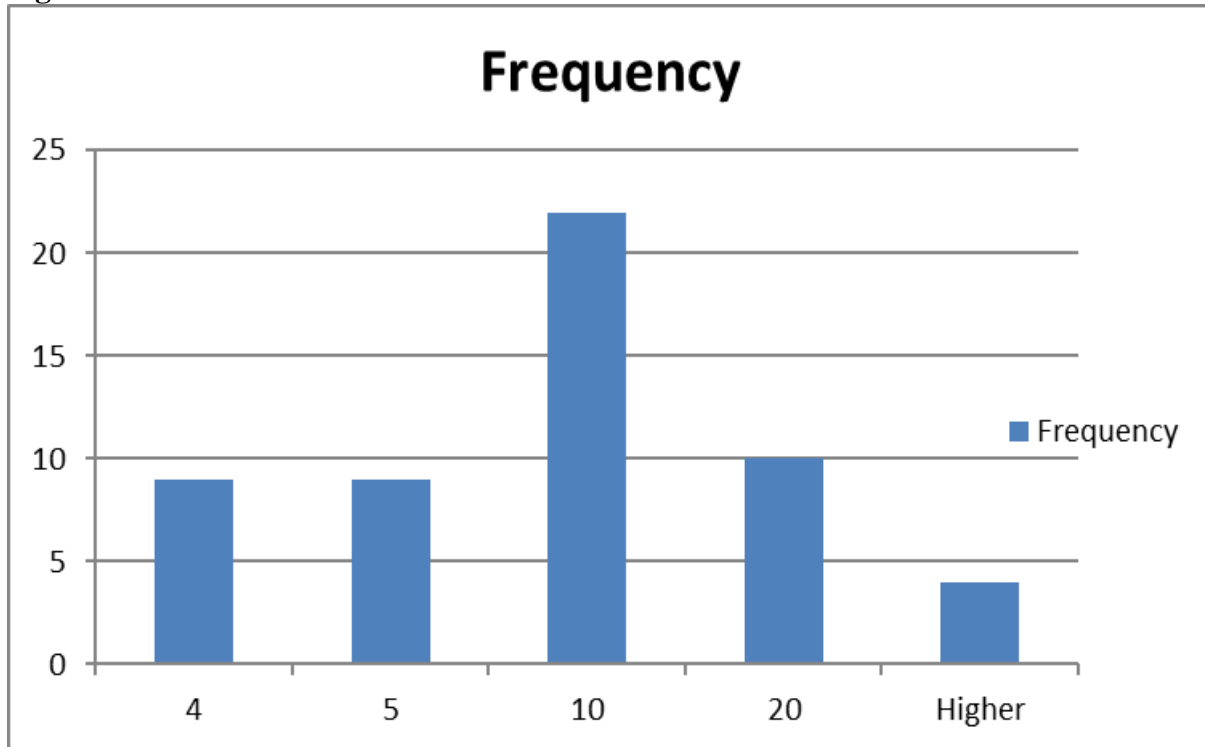
Forty nine of the previous 57 FY2018 PHRs are mapped into these 63 FY2019 PHRs. Approximately 86% of the FY2018 PHRs are included in the FY2019 PHRs. There are 8 additional regulations that were on the FY2018 PHR list and are not in the FY2019 PHR list (See Appendix E).

Table 5-2 lists the number of regulations triggered by different events for inclusion in the FY2019 PHR list. Most regulations were triggered by multiple events.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2019 PHR list

Product	Number of Regulations	Percent
Campylobacter	4	2.26%
Chicken Parts Campylobacter	3	1.69%
Chicken Parts *Salmonella*	10	5.65%
Enforcements	38	21.47%
Ground Beef *Salmonella*	6	3.39%
Ground Chicken Campylobacter	4	2.26%
Ground Chicken *Salmonella*	12	6.78%
Ground Pork *Salmonella*	3	1.69%
Ground Turkey Campylobacter	3	1.69%
Ground Turkey *Salmonella*	11	6.21%
Intact Beef *Salmonella*	15	8.47%
Intact Chicken Campylobacter	2	1.13%
Intact Chicken *Salmonella*	11	6.21%
Intact Pork *Salmonella*	9	5.08%
Intact Turkey Campylobacter	4	2.26%
Intact Turkey *Salmonella*	2	1.13%
Listeria	1	0.56%
Non-O157 Ecoli	2	1.13%
RTE *Salmonella*	1	0.56%
Salmonella	36	20.34%
Grand Total	177	100.00%

There were twenty regulations triggered by a single type of event. Thirteen were from enforcement actions, four were from *Salmonella*, two were from *Salmonella* in Intact Beef and one was from *Campylobacter* in Chicken Parts. Table 5-3 presents the regulations triggered for inclusion in the FY2019 PHR list by only single event type.

Table 5-3 Regulations Triggered for Inclusion in the FY2019 PHR List by Only a Single Event

Reg ID	Regulations from a Single Event	Event
89	310.22(e)(2)	Intact Beef *Salmonella*
92	310.22(e)(4)(i)	Enforcements
99	310.22(f)(2)	Intact Beef *Salmonella*
107	310.25(a)	Enforcements
207	318.1(b)	Chicken Parts Campylobacter
235	318.2(d)	Enforcements
406	381.1_Adulterated	*Salmonella*
530	381.65(e)*	Enforcements
586	416.12(c)	*Salmonella*
587	416.12(d)	Enforcements
641	416.6	*Salmonella*
675	417.4(b)	Enforcements
680	417.5(a)(1)	Enforcements
681	417.5(a)(2)	Enforcements
690	417.6	*Salmonella*
701	430.4(a)	Enforcements
703	430.4(b)(2)	Enforcements
704	430.4(b)(3)	Enforcements
705	430.4(c)(2)	Enforcements
1174	418.3	Enforcements

6.0 CUT POINTS FOR FY2019 PHRS

The FY2019 PHRs are one of seven public health based decision criteria that are used in prioritizing Food Safety Assessments (FSAs). 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 FY2019 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 of the PHR regulations in a 90 day period together into a single aggregate ratio. The aggregate FY2019 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).

The aggregate non-zero PHR non-compliance rates are approximately log normally distributed. That means that the natural logarithm of the non-zero PHR non-compliance rates are approximately normally distributed. Only establishments with greater than or equal to 20 verifications and at least two non-compliances were considered when developing cut points.

To determine a set of annual FY2019 cut points, the mean and standard deviation of the natural log transformed non-zero FY2019 PHR rate (for establishments having more than 20 verifications in the past 90 days and at least two non-compliances) for each of four quarters and each of the two types of establishment operation is computed (the log transform of the non-zero FY2019 PHR rates is taken to obtain an approximately normal distribution, see Appendix F). 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 non-compliance rates). The standard deviations are positive.

Table 6-1 Mean and Standard Deviation of Quarterly FY2019 PHR Rate

	Mean of Natural Log FY2019 PHR Rate			Standard Deviation FY2019 PHR Rate	
	Combination	Processing		Combination	Processing
Jan-Mar 2017	-4.47	-4.84		1.03	0.85
Apr-Jun 2017	-4.29	-4.61		1.01	0.79
July-Sep 2017	-4.40	-4.88		1.03	0.87
Oct-Dec 2017	-4.47	-4.86		1.02	0.84
Average	-4.41	-4.80		1.02	0.84

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 FSA. For example, the upper cut point for the log transformed data for Processing establishments is -4.80 + 2*0.84 = -4.80 + 1.67 = -3.12. (Rounding shows the standard deviation in 6-1 as 0.84, but it is closer to 0.837) The cut point of the original, non-transformed PHR non-compliance data is the antilog of -3.12 or Exp(-3.12) = 4.40%. Tables 6-2 and 6-3 present the FY2019 PHR upper and lower cut points for each of the two establishment operation types. The FY2018 PHR cut points are included for comparison. (See Appendix F for more details). The cut points are determined once a year. The next update to the cut points is planned for October 2019.

Table 6-2 FY2019 PHR Tier 1 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	4.40%	4.22%
Combination	9.40%	8.73%

Table 6-3 FY2019 PHR Tier 3 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	2.90%	2.82%
Combination	5.64%	5.38%

Table 6-4 presents the number of establishments in each Tier based solely on the FY2019 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 non-compliance are moved to Tier 2. The other six decision criteria used in determining establishment Tiers were not used. Based solely on noncompliance rate with FY2019 PHRs, 63 establishments are in Tier 1 and candidates to receive for cause FSAs. These establishments are scheduled for a PHRE. Table 6-3 is based on regulatory non-compliances for the period January 1 – March 31, 2018.

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

Classification	Number of Establishments
Tier 1	63
Tier 2	68
Tier 3	5,102
Total	5,233

Table 6-5 presents the number of establishments in each Tier based on establishment operation type and only the PHR criterion. The other six decision criteria used in determining an establishment's Tier classification were not used. For example for processing establishments, based solely on non-compliances with the FY2019 PHRs, 53 processing establishments are Tier 1 and are candidates to receive for cause FSAs. In total, 63 establishments are in Tier 1 based solely on non-compliances with the FY2019 PHRs. Table 6-4 is based on regulatory non-compliances during January 1 –March 31, 2018.

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

Classification	Processing	Combination
Tier 1	53	10
Tier 2	49	19
Tier 3	4,066	1,036
Total	4,168	1,065

In using the decision tree methodology and the seven decision criteria to schedule Food Safety Assessments (FSA), a new FSA is not automatically scheduled if the establishment has received an FSA in the past six months. Instead, the District is notified that the establishment has received a Tier 1 classification and it is up to the District to determine if the establishment should receive an additional PHRE and possible FSA. The number of Tier 1 establishments that are eligible for FSAs is approximately the same as in recent years.

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2019 PHR regulations used to prioritize certain FY2019 FSIS inspection activities.

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 higher in establishments three months before a *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm, Campylobacter* positive or enforcement action than in establishments without positives or enforcement actions.

The list of FY2019 PHRs has 63 regulations whose individual noncompliance rates are higher in establishments three months before *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm, Campylobacter* positives or enforcement action than in establishments without positives or enforcement actions. About seventy eight percent of the regulations on the FY2018 PHR list are also on the FY2019 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 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 Public Health Risk Evaluation (PHRE), described in FSIS Directive 5100.4.

Tables 7-1 and 7-2 present the FY2019 PHR upper and lower cut points (the upper cut points are equal to antilog of the mean plus two times the standard deviation of the log transformed non-zero PHR rate for similar establishments). The FY2018 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 FY2019 PHR Tier 1 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	4.40%	4.22%
Combination	9.40%	8.73%

Table 7-2 FY2019 PHR Tier 3 Cut Points

Operation Type	FY2019 PHR Cut Points	FY2018 PHR Cut Points
Processing	2.90%	2.82%
Combination	5.64%	5.38%

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: FY2019 PHR REGULATIONS

Table A-1 presents the list of sixty three FY2019 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates three months before a pathogen positive or enforcement action 9.57 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2019 PHRs

Reg ID	List of FY2019 PHRs	Description
29	301.2_Adulterated	Adulterated
69	310.18	Contamination of carcasses, organs, or other parts
78	310.22(c)	Disposal of SRM
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
89	310.22(e)(2)	Appropriate corrective actions
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
92	310.22(e)(4)(i)	Maintain daily records
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
107	310.25(a)	Verification criteria for *E. coli* testing meat
178	317.24(a)	Packaging materials composed of poisonous or deleterious substances
207	318.1(b)	Only inspected and passed poultry product to enter official establishment
234	318.2(a)	All products subject to reinspection by program employees
235	318.2(d)	Removal of U.S. retained by authorized Program employees only
406	381.1_Adulterated	Adulterated
527	381.65(a)	Clean and sanitary practices; products not adulterated
530	381.65(e)*	Zero-tolerance for visible fecal material entering chiller
543	381.71(a)	Condemnation on ante mortem inspection
550	381.76(a)*	Post-mortem inspection, when required, extent.
557	381.83	Septicemia or toxemia

Reg ID	List of FY2019 PHRs	Description
582	416.1	Operate in a manner to prevent insanitary conditions
586	416.12(c)	plan identifies procedures for pre-op
587	416.12(d)	plan list frequency for each procedure & responsible individual
588	416.13 Implementation of SOP's	Implementation of SSOP
589	416.13(a)	Conduct pre-op procedures
590	416.13(b)	Conduct other procedures listed in the plan
591	416.13(c)	Plant monitors implementation of SSOP procedures
592	416.14	Evaluate effectiveness of SSOP's & maintain plan
594	416.15(a)	Appropriate corrective actions
595	416.15(b)	Corrective action, procedures for
597	416.16(a)	Daily records required, responsible individual, initialed and dated
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection
631	416.3(c)	Receptacles for storing inedible material must identify permitted use
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
641	416.6	Only FSIS program employee may remove "U.S. Rejected" tag
645	417.2(a)(1)	Hazard analysis
648	417.2(c)	Contents of HACCP Plan
649	417.2(c)(4)	List of procedures & frequency
657	417.3(a)(1)	Identify and eliminate the cause
658	417.3(a)(2)	CCP is under control
659	417.3(a)(3)	Establish measures to prevent recurrence
660	417.3(a)(4)	No adulterated product enters commerce.
662	417.3(b)(1)	Segregate and hold the affected product
663	417.3(b)(2)	Determine the acceptability of the affected product

Reg ID	List of FY2019 PHRs	Description
664	417.3(b)(3)	No adulterated product enters commerce
665	417.3(b)(4)	Reassessment
666	417.3(c)	Document corrective actions
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards
669	417.4(a)(1)	Initial validation
675	417.4(b)	Reassessment of hazard analysis
680	417.5(a)(1)	Written hazard analysis
681	417.5(a)(2)	Written HACCP plan
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
689	417.5(f)	Official Review
690	417.6	Inadequate HACCP systems
701	430.4(a)	Lm, post-lethality exposed RTE
703	430.4(b)(2)	Alternative 2
704	430.4(b)(3)	Alternative 3
705	430.4(c)(2)	Alternative 3
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
1174	418.3	Recall Plans
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
1351	381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia

APPENDIX B: PAST USE OF PUBLIC HEALTH REGULATIONS

The purpose of this Appendix is to explain how the list of Public Health regulations had been used to prioritize scheduling for Food Safety Assessments (FSAs).

If a pattern of public health related non-compliances occurs, it indicates an establishment's food safety system may not be in control and may not be able to prevent adulterated product from entering commerce. The list of FY2019 PHRs is presented in Appendix A.

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

$$\text{PHR NC Rate} = \frac{\textbf{Number of PHR Non-compliances}}{\textbf{Total Number of PHR Inspection Verifications}}$$

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 and routine FSAs every four years. These establishments are performing better on average than their peers with respect to compliance with FSIS regulations.

- Establishments with a PHR rate between the lower and upper cut points for all establishments with the same establishment type would continue to receive routine inspection procedures and, in addition, be prioritized for routine FSAs.

- Establishments with a PHR rate greater than the upper cut point for establishments with the same establishment type that have not had a FSA in the last six months would continue to receive routine inspection procedures plus a PHRE to determine if a for cause FSA is appropriate.

APPENDIX C: FY2019 CANDIDATE REGULATIONS

Table C-1 presents the list of 144 candidate regulations. The noncompliance rates in Table C-1 are based on PHIS data for January 1, 2017 through December 31, 2017.

Table C-1 FY2019 Candidate regulations

Reg ID	FY2019 Candidate Regulation	FY2018 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
29	301.2_Adulterated	Yes	No	8231	215	2.55%
43	304.3(a)	No	No	867	7	0.80%
45	304.3(c)	No	No	1062	9	0.84%
53	309.2(a)	No	No	881	0	0.00%
54	309.3	No	No	331	2	0.60%
55	309.4	No	No	255	0	0.00%
56	309.5	No	No	240	0	0.00%
57	309.9	No	No	233	0	0.00%
69	310.18	No	Yes	5535	82	1.46%
77	310.22(b)	No	No	5538	7	0.13%
78	310.22(c)	Yes	Yes	56616	157	0.28%
84	310.22(d)(2)	No	No	92	0	0.00%
88	310.22(e)(1)	No	No	15345	214	1.38%
89	310.22(e)(2)	Yes	No	3502	58	1.63%
90	310.22(e)(3)	Yes	No	9437	132	1.38%
92	310.22(e)(4)(i)	No	No	87789	218	0.25%
99	310.22(f)(2)	Yes	No	18612	24	0.13%
101	310.22(g)(1)	No	No	1674	4	0.24%
104	310.22(g)(4)	No	No	4292	15	0.35%
107	310.25(a)	Yes	No	29535	248	0.83%
108	310.25(b)	No	No	161	4	2.42%
109	310.25(b)(3)(ii)	No	No	134	1	0.74%
110	310.3	Yes	No	3651	252	6.46%
114	311.16	No	No	243	9	3.57%
115	311.17	No	No	571	7	1.21%
116	311.24	No	No	186	0	0.00%
138	315.2	No	No	68	0	0.00%
152	316.6	Yes	No	12816	59	0.46%
178	317.24(a)	Yes	No	2723	20	0.73%
207	318.1(b)	Yes	No	95580	19	0.02%
215	318.10(b)	No	No	2378	10	0.42%
217	318.10(c)(1)	No	No	2445	3	0.12%
218	318.10(c)(2)	No	No	760	1	0.13%
219	318.10(c)(3)	No	No	490	2	0.41%

Reg ID	FY2019 Candidate Regulation	FY2018 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
221	318.14(a)	No	No	110	2	1.79%
222	318.14(b)	No	No	621	0	0.00%
223	318.14(c)	No	No	83	0	0.00%
226	318.16(b)	No	No	289	0	0.00%
228	318.17(a)(1)(2)	No	No	3402	6	0.18%
229	318.17(b)	No	No	666	1	0.15%
230	318.17(c)	No	No	22	0	0.00%
234	318.2(a)	Yes	No	48140	53	0.11%
235	318.2(d)	No	No	8569	46	0.53%
239	318.23(b)(1)	No	No	501	3	0.60%
241	318.23(b)(3)	No	No	30	1	3.23%
242	318.23(c)(1)	No	No	230	2	0.86%
243	318.23(c)(2)	No	No	19	0	0.00%
245	318.23(c)(4)	No	No	55	0	0.00%
246	318.23(c)(5)	No	No	53	0	0.00%
247	318.24	No	No	2701	10	0.37%
251	318.303	No	Yes	8073	3	0.04%
256	318.308	No	Yes	5146	3	0.06%
268	318.6(b)(1)	No	No	3036	0	0.00%
273	318.6(b)(4)	No	No	9401	1	0.01%
274	318.6(b)(6)	No	No	12931	1	0.01%
275	318.6(b)(8)	No	No	433	1	0.23%
329	319.5(b)	No	No	322	0	0.00%
406	381.1_Adulterated	Yes	No	4518	68	1.48%
450	381.144(a)	No	No	2331	0	0.00%
457	381.150(a)	No	No	1759	8	0.45%
459	381.150(c)	No	No	129	0	0.00%
460	381.150(d)	No	No	7	0	0.00%
462	381.151(a)	No	No	77	0	0.00%
490	381.22(a)	No	No	362	1	0.28%
491	381.22(b)	No	No	1028	12	1.15%
492	381.22(c)	No	No	263	2	0.75%
503	381.310	No	Yes	4642	1	0.02%
504	381.311	No	Yes	4597	0	0.00%
506	381.37(a)	No	No	1931	18	0.92%
527	381.65(a)	Yes	No	65238	633	0.96%
530	381.65(e)*	No	Yes	7326	97	1.31%
543	381.71(a)	Yes	No	2331	223	8.73%
545	381.72(a)	No	No	252	0	0.00%
546	381.72(b)	No	No	11	0	0.00%

Reg ID	FY2019 Candidate Regulation	FY2018 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
550	381.76(a)*	Yes	No	20245	338	1.64%
557	381.83	Yes	No	389952	185	0.05%
559	381.85	No	No	139	0	0.00%
564	381.91(a)	No	No	9435	23	0.24%
565	381.91(b)	Yes	No	25335	303	1.18%
571	381.94(a)*	No	No	52	1	1.89%
582	416.1	Yes	Yes	642693	11512	1.76%
586	416.12(c)	Yes	No	53920	85	0.16%
587	416.12(d)	Yes	No	68469	137	0.20%
588	416.13 Implementation of SOP's	No	No	6281	7	0.11%
589	416.13(a)	Yes	Yes	748815	6871	0.91%
590	416.13(b)	Yes	Yes	1847746	3506	0.19%
591	416.13(c)	Yes	Yes	2652621	44877	1.66%
592	416.14	Yes	Yes	1627582	4082	0.25%
593	416.15 Corrective Actions	No	No	677	3	0.44%
594	416.15(a)	Yes	Yes	74738	1200	1.58%
595	416.15(b)	Yes	Yes	48293	1211	2.45%
597	416.16(a)	Yes	Yes	2892951	4693	0.16%
630	416.3(b)	Yes	No	80068	662	0.82%
631	416.3(c)	Yes	No	72299	987	1.35%
633	416.4(a)	Yes	No	292553	24889	7.84%
636	416.4(d)	Yes	No	271364	25979	8.74%
640	416.5(c)	No	No	40780	24	0.06%
641	416.6	Yes	No	3432	123	3.46%
645	417.2(a)(1)	Yes	Yes	125410	1995	1.57%
648	417.2(c)	No	No	33990	115	0.34%
649	417.2(c)(4)	Yes	Yes	1358531	7933	0.58%
655	417.3 Corrective actions	No	No	451	1	0.22%
656	417.3(a)	No	No	536	1	0.19%
657	417.3(a)(1)	Yes	Yes	27138	827	2.96%
658	417.3(a)(2)	Yes	Yes	163105	814	0.50%
659	417.3(a)(3)	Yes	Yes	23098	947	3.94%
660	417.3(a)(4)	Yes	Yes	50229	236	0.47%
662	417.3(b)(1)	No	Yes	17547	151	0.85%
663	417.3(b)(2)	Yes	Yes	16366	112	0.68%
664	417.3(b)(3)	Yes	Yes	39611	121	0.30%
665	417.3(b)(4)	Yes	Yes	43276	257	0.59%
666	417.3(c)	Yes	Yes	16058	293	1.79%

Reg ID	FY2019 Candidate Regulation	FY2018 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
668	417.4(a)	Yes	No	6980	296	4.07%
669	417.4(a)(1)	No	No	6424	596	8.49%
674	417.4(a)(3)	No	No	7	0	0.00%
675	417.4(b)	No	Yes	32241	93	0.29%
680	417.5(a)(1)	Yes	Yes	1371552	4681	0.34%
681	417.5(a)(2)	Yes	Yes	1222781	1729	0.14%
682	417.5(a)(3)	Yes	Yes	1428606	4162	0.29%
689	417.5(f)	Yes	No	91067	125	0.14%
690	417.6	No	No	331	136	29.12%
701	430.4(a)	Yes	Yes	303822	160	0.05%
702	430.4(b)(1)	No	No	989	5	0.50%
703	430.4(b)(2)	No	No	15530	114	0.73%
704	430.4(b)(3)	Yes	No	29120	392	1.33%
705	430.4(c)(2)	No	Yes	293596	157	0.05%
706	430.4(c)(3)	No	Yes	303338	187	0.06%
707	430.4(c)(4)	No	No	3332	22	0.66%
708	430.4(c)(5)	No	No	7167	22	0.31%
709	430.4(c)(6)	No	No	6275	80	1.26%
717	310.18(a)	Yes	Yes	313208	3808	1.20%
718	310.18(b)	No	No	20793	1	0.00%
1173	418.2	No	No	1414	127	8.24%
1174	418.3	Yes	No	14857	87	0.58%
1241	354.242(b)	No	No	101	0	0.00%
1247	354.242(h)	No	No	58	0	0.00%
1250	354.243(a)	No	No	42	0	0.00%
1292	381.193(a)	No	No	256	9	3.40%
1331	381.65(f)	Yes	No	878764	10158	1.14%
1346	381.65(h)	No	No	12642	0	0.00%
1349	381.76(b)(6)(ii)(A)	Yes	No	50333	280	0.55%
1350	381.76(b)(6)(ii)(D)	Yes	No	1777	118	6.23%
1351	381.76(b)(6)(ii)(C)	No	No	481064	199	0.04%
1352	381.76(b)(6)(ii)(B)	Yes	No	50243	101	0.20%
1444	311.14	Yes	No	18601	15	0.08%

1. NC = Noncompliance

APPENDIX D: COMPARISON OF FY2019 PHR LIST WITH FY2018 PHR LIST

There are eight regulations from the FY2018 PHR list that no longer appear in the FY2019 PHR list. These eight regulations are shown in Table D-1.

Table D-1 Regulation from the FY2018 PHR list no longer on the FY2019 PHR list

Reg ID	List of FY2018 PHRs	Description
110	310.3	Carcasses and parts in certain instances to be retained.
152	316.6	Products not to be removed from official establishments unless marked in accordance with the regulations
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
1331	381.65(f)	Procedures for controlling visible fecal contamination
1348	381.69	Maximum line speed rates under the New Poultry Inspection System
1350	381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
1352	381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage
1444	311.14	Abrasions, bruises, abscesses, pus, etc.

APPENDIX E: USE OF PUBLIC HEALTH REGULATIONS IN SCHEDULING FOOD SAFETY ASSESSMENTS

The purpose of this Appendix is to explain how the 63 PHRs are used as one component of the overall decision tree methodology used to schedule FSAs.

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 non-compliance rates are approximately log normally distributed. That means that the natural logarithm of the non-zero PHR non-compliance rates is approximately normally distributed. Figure E-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 non-compliances are considered.

Figure E-1 Log Transformed Non-zero Non-Compliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action
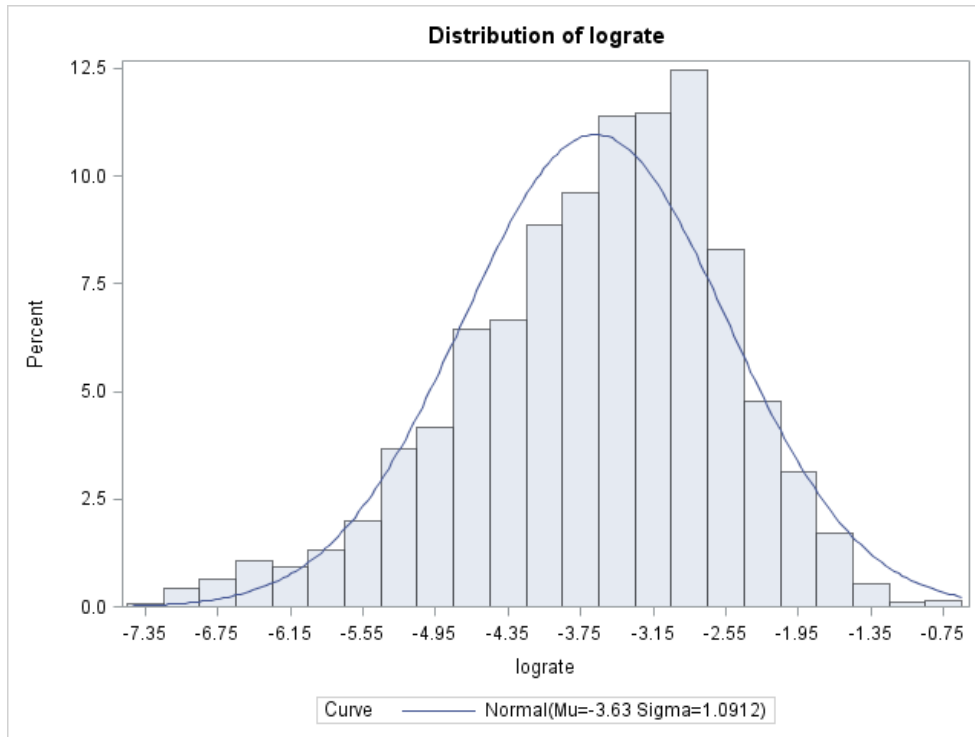
This distribution is approximately normally distributed. Three goodness of fit tests within SAS, shown in Figure E-2, indicate near-normality.

Figure E-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	0.05368	Pr > D	<0.010
Cramer-von Mises	W-Sq	3.13714	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	18.5995	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 non-compliance data). Table E-1 shows the number of plants, mean and standard deviation for each plant type as well as the Tier distribution (based only on PHR non-compliances) using the quarterly cut points.

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

	Number of Establishments	Mean	Standard Deviation			Tier Distribution (Number of Establishments)
Q1CY2017					Tier 1	68
Both	1,036	-4.47	1.03		Tier 2	122
Processing	4,104	-4.84	0.85		Tier 3	4,950
Q2CY2017					Tier 1	57
Both	1,055	-4.29	1.01		Tier 2	76
Processing	4,106	-4.61	0.79		Tier 3	5,028
Q3CY2017					Tier 1	69
Both	1,079	-4.40	1.03		Tier 2	108
Processing	4,140	-4.88	0.87		Tier 3	5,042
Q4CY2017					Tier 1	65
Both	1,076	-4.47	1.02		Tier 2	95
Processing	4,172	-4.86	0.84		Tier 3	5,088

Table E-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 E-1. Table E-3 shows the Tier distribution (based only on PHR non-compliances) using the cut points in Table E-2. Table E-4 shows how many Tier 1 establishments in March 2018 are within certain product categories.

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

	Combination	Processing
Mean	-4.41	-4.80
Standard Deviation	1.02	0.84

Table E-3 March 2018 Tier Distribution Based on the PHR Criteria Only

Classification	Plants
Tier 1	63
Tier 2	68
Tier 3	5,102
Total	5,233

Table E-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	201	3.84%	5	7.94%
Turkey Slaughter	54	1.03%	1	1.59%
Beef Slaughter	652	12.46%	1	1.59%
Pork Slaughter	610	11.66%	2	3.17%
Beef Processing	1646	31.45%	14	22.22%
Chicken Processing	805	15.38%	14	22.22%
Turkey Processing	310	5.92%	3	4.76%
Pork Processing	1812	34.63%	13	20.63%
RTE	2550	48.73%	38	60.32%
Poultry Combination	390	7.45%	8	12.70%
Total Number of Establishments	5233		63	