FY2018 Public Health Regulations

May 2017

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SUMMARY

The purpose of the present report is to update the FY2017 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 CY2016 verification inspection results and will be implemented in FY2018. 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 public health related provisions of regulations that may be most informative for prioritizing FSAs.

The methodology used in developing the FY2018 PHR list is the same as that used for the FY2017 PHR list. For inclusion in the FY2018 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 action than in establishments without positives or enforcement actions. The analysis was based on one year of FSIS verification inspection results (January 1 –December 31, 2016) recorded in PHIS. The term "enforcement action" refers to a public health NOIE or suspension.

The final list of FY2018 PHRs consists of 57 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. This compares with 53 regulations that were identified in the FY2017 PHR list. The list of FY2018 PHRs is presented in Appendix A. Eighty one percent of the regulations on the FY2017 PHR list are also on the FY2018 PHR list.

The 57 FY2018 PHRs are composed of 11 regulations and 46 provisions of regulations. The 46 provisions fall under 22 different regulations. Thus, the 53 FY2018 PHRs represent 33 regulations, with the majority of FY2018 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 FY2018 PHR regulations three months before a pathogen positive or enforcement action is 13.43 times higher than the average FY2018 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action.

The FY2018 PHRs are one of seven public health based decision criteria that will be used in prioritizing Public Health Risk Evaluations (PHREs). Noncompliance with a single FY2018 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 FY2018 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 FY2018 cut points, the mean and standard deviation of the log transformed non-zero FY2018 PHR rates for each of the four quarters in CY2016 is computed (the log transform of the non-zero FY2018 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 FY2018 PHR cut points for the non-transformed PHR non-compliance data for each of the two establishment operation types. The FY2017 PHR cut points are included for comparison. (See Section 6 and Appendix F for more details.)

Table S-1 FY2018 PHR Tier 1 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	4.22%	4.81%
Combination	8.73%	9.46%

Table S-2 FY2018 PHR Tier 3 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	2.82%	3.16%
Combination	5.38%	5.82%

The cut points are used to determine when FSIS will send "early warning alerts" through PHIS or prioritize establishments for a PHRE. The cut points in Table S-1 are the upper cut points. When establishments exceed these cut points, based on a monthly evaluation of the prior 90 days, they will be prioritized for a "for cause" PHRE and an EIAO will make a determination whether to conduct an FSA or not. The cut points in Table S-2 are the lower cut points. For establishments that fall in between these two cut points, FSIS sends an alert to its in-plant inspection personnel to make them aware of the elevated non-compliance at these establishments. For establishments that fall below the cut points in Table S-2, no action is taken related to the PHR measure.

Table S-3 presents the number of establishments in each Tier for the time period from January 1 –March 31, 2017, based on the PHR criterion. The number of "for cause" PHREs, 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	56	13	69
Tier 2	80	29	109

Classification	Processing	Combination	Total
Tier 3	3,970	994	4,964
Total	4,106	1,036	5,142

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, 2017.

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	197	3.83%	6	8.70%
Turkey Slaughter	49	0.95%	1	1.45%
Beef Slaughter	637	12.39%	5	7.25%
Pork Slaughter	596	11.59%	2	2.90%
Beef Processing	1639	31.87%	14	20.29%
Chicken Processing	820	15.95%	17	24.64%
Turkey Processing	317	6.16%	4	5.80%
Pork Processing	1808	35.16%	10	14.49%
RTE	2531	49.22%	37	53.62%
Poultry Combination	396	7.70%	8	11.59%
Total Number of Establishments	5142		69	

The time period used for calculating the noncompliance rate of the PHRs was January 1 –March 31, 2017. 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.

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 FY2017 PHRs using current verification inspection results from the Public Health Information System (PHIS). The updated list is called the FY2018 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 FY2018 PHR list is the same as that used for the FY2017 PHR. Specifically, for inclusion in the FY2018 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, 2016) recorded in PHIS. Candidate regulations related to egg products are not included in the present report.

The final FY2018 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 or Enforcement Actions

The second step in selecting a list of PHRs is to determine which of the candidate regulations are related to a higher rate of noncompliance in the three months before the occurrence of a pathogen positive during FSIS sampling or an enforcement action. 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 action than the average noncompliance rate in establishments that do not have a *Salmonella, E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positive or enforcement action. The current analysis includes the six non-O157

STECs (O26, O45, O103, O111, O121, and O145) that FSIS has declared adulterants in beef trim.

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 (144) 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 144 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 OR ENFORCEMENT ACTIONS

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, 2016 through December 31, 2016. 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 or enforcement action is higher than the noncompliance rate for establishments with no positives or enforcement actions are selected as PHRs. The exact sequence of steps used to develop the list of PHRs is given in Appendix D.

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,096 establishments with *Salmonella* testing data, of which 793 had 2,978 *Salmonella* positives and 1,303 did not have *Salmonella* positives. There were 39,677 total *Salmonella* tests performed.

Table 4-1 presents the 19 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, 2016 to December 31, 2016.

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 FY2017 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)	No	6.04%	0.17%	1.12E-08	37.92
207	318.1(b)	No	0.10%	0.03%	4.17E-02	3.00
234	318.2(a)	Yes	0.47%	0.07%	4.21E-07	6.50
543	381.71(a)	Yes	23.05%	7.14%	6.72E-16	3.90
557	381.83	Yes	0.07%	0.01%	5.97E-05	13.25
589	416.13(a)	Yes	3.53%	0.77%	0.00E+00	4.74
590	416.13(b)	Yes	0.57%	0.18%	5.58E-163	3.15
591	416.13(c)	Yes	6.30%	1.28%	0.00E+00	5.19
592	416.14	Yes	1.02%	0.23%	0.00E+00	4.44
594	416.15(a)	Yes	5.11%	1.66%	3.10E-50	3.19
595	416.15(b)	Yes	8.99%	2.07%	6.07E-91	4.67
630	416.3(b)	Yes	2.65%	0.67%	2.40E-43	4.04
631	416.3(c)	Yes	4.88%	0.88%	3.36E-98	5.78
633	416.4(a)	Yes	20.74%	5.95%	0.00E+00	4.14
636	416.4(d)	Yes	27.92%	7.04%	0.00E+00	5.11
649	417.2(c)(4)	Yes	1.75%	0.41%	0.00E+00	4.35
717	310.18(a)	Yes	3.90%	1.07%	5.73E-275	3.75
1349	381.76(b)(6)(ii)(A)	Yes	1.11%	0.09%	2.26E-22	12.21
1444	311.14	No	0.27%	0.03%	2.38E-02	10.30

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 203 establishments with Intact Chicken *Salmonella* testing data, of which 129 had 347 *Salmonella* positives and 74 did not have *Salmonella* positives. There were 8,818 total Intact Chicken *Salmonella* tests performed.

Table 4-2 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 Intact Chicken *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Chicken *Salmonella* positive in the period January 1, 2016 to December 31, 2016.

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 FY2017 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	42.48%	3.98%	2.61E-106	17.83
557	381.83	Yes	0.14%	0.04%	6.45E-10	3.41
594	416.15(a)	Yes	8.81%	3.05%	1.97E-12	3.07
657	417.3(a)(1)	Yes	8.23%	1.45%	1.67E-15	6.09
659	417.3(a)(3)	Yes	16.84%	2.62%	3.90E-27	7.51
660	417.3(a)(4)	Yes	0.93%	0.21%	8.23E-05	4.41
666	417.3(c)	No	5.10%	1.24%	7.64E-06	4.30
668	417.4(a)	Yes	37.84%	0.24%	4.44E-19	254.13
689	417.5(f)	No	0.44%	0.03%	1.11E-03	13.96
1349	381.76(b)(6)(ii)(A)	Yes	1.46%	0.43%	2.58E-14	3.39

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Salmonella* testing data, of which 13 had 16 *Salmonella* positives and 32 did not have *Salmonella* positives. There were 1,841 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the 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 Intact Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Turkey *Salmonella* positive in the period January 1, 2016 to December 31, 2016.

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 FY2017 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
590	416.13(b)	Yes	1.20%	0.37%	2.62E-05	3.24

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,202 establishments with *Salmonella* testing data, of which 123 had 211 *Salmonella* positives and 1,079 did not have *Salmonella* positives. There were 11,426 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 5 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, 2016 to December 31, 2016.

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 FY2017 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	16.81%	1.54%	3.15E-13	12.88
99	310.22(f)(2)	Yes	1.12%	0.11%	1.51E-03	10.24
595	416.15(b)	Yes	6.56%	1.70%	1.26E-05	4.06
649	417.2(c)(4)	Yes	1.43%	0.39%	1.18E-51	3.75
717	310.18(a)	Yes	4.09%	1.31%	1.33E-55	3.21

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, 2016 to December 31, 2016. FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 855 establishments with Intact Beef *Salmonella* testing data, of which 82 had 128 *Salmonella* positives and 773 did not have *Salmonella* positives. There were 5,242 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 12 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, 2016 to December 31, 2016.

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 FY2017 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	5.21%	1.22%	3.42E-229	4.43
594	416.15(a)	Yes	7.41%	1.60%	1.65E-08	4.93
595	416.15(b)	Yes	16.81%	1.48%	5.03E-14	13.47
631	416.3(c)	Yes	2.22%	0.74%	4.62E-03	3.06
636	416.4(d)	Yes	25.92%	5.70%	1.28E-199	5.79
649	417.2(c)(4)	Yes	4.06%	0.31%	9.02E-252	13.59
658	417.3(a)(2)	Yes	1.82%	0.36%	1.93E-08	5.17
664	417.3(b)(3)	Yes	3.39%	0.48%	4.83E-03	7.21
665	417.3(b)(4)	Yes	4.59%	0.74%	1.97E-03	6.49
668	417.4(a)	Yes	20.59%	4.27%	6.83E-04	5.81
717	310.18(a)	Yes	5.82%	1.14%	1.61E-209	5.36
1331	381.65(f)	Yes	2.35%	0.32%	3.56E-02	7.58

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 104 establishments with Comminuted Chicken *Salmonella* testing data, of which 95 had 427 *Salmonella* positives and 9 did not have *Salmonella* positives. There were 1,330 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 11 regulations more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher 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, 2016 to December 31, 2016.

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 FY2017 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	3.87%	0.60%	2.60E-10	6.64
589	416.13(a)	Yes	3.62%	0.25%	7.69E-19	14.88
590	416.13(b)	Yes	0.33%	0.09%	1.38E-02	3.60
591	416.13(c)	Yes	4.50%	0.64%	3.43E-54	7.37
597	416.16(a)	Yes	0.28%	0.02%	3.59E-05	14.24
631	416.3(c)	Yes	3.92%	0.97%	3.07E-02	4.17
633	416.4(a)	Yes	19.75%	3.02%	1.84E-40	7.90
636	416.4(d)	Yes	26.03%	2.64%	1.57E-43	12.99
649	417.2(c)(4)	Yes	0.99%	0.14%	6.29E-10	7.24
659	417.3(a)(3)	Yes	12.29%	0.61%	4.71E-07	22.71
1331	381.65(f)	Yes	1.26%	0.11%	1.08E-11	11.93

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, 2016 to December 31, 2016. There are 60 establishments with Comminuted Turkey *Salmonella* testing data, of which 40 had 159 *Salmonella* positives and 20 did not have *Salmonella* positives. There were 978 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 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 Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Salmonella* positive in the period January 1, 2016 to December 31, 2016.

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 FY2017 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	1.92%	0.27%	3.23E-04	7.16
592	416.14	Yes	0.57%	0.11%	1.97E-07	5.17
594	416.15(a)	Yes	4.35%	0.19%	4.99E-08	24.26
681	417.5(a)(2)	Yes	0.18%	0.02%	3.56E-03	9.74

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, 2016 to December 31, 2016. There are 244 establishments with Intact Pork *Salmonella* testing data, of which 93 had 241 *Salmonella* positives and 151 did not have *Salmonella* positives. There were 1430 total Intact Pork *Salmonella* tests performed.

Table 4-8 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 Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Pork *Salmonella* positive in the period January 1, 2016 to December 31, 2016.

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 FY2017 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)	No	21.05%	1.32%	5.99E-04	20.00
527	381.65(a)	Yes	1.88%	0.14%	1.16E-02	13.47
631	416.3(c)	Yes	4.76%	1.18%	2.68E-09	4.19
649	417.2(c)(4)	Yes	1.30%	0.30%	4.80E-46	4.31
657	417.3(a)(1)	Yes	14.15%	2.78%	2.52E-06	5.77
659	417.3(a)(3)	Yes	47.62%	10.33%	1.42E-15	7.89
660	417.3(a)(4)	Yes	7.69%	1.57%	1.09E-03	5.22
664	417.3(b)(3)	Yes	20.00%	2.07%	6.36E-05	11.85
665	417.3(b)(4)	Yes	3.54%	0.81%	5.05E-03	4.49
666	417.3(c)	No	13.04%	3.85%	2.05E-02	3.75
717	310.18(a)	Yes	3.39%	0.010871502	2.0809E-42	3.19

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, 2016 to December 31, 2016. There are 361 establishments with Ground Pork *Salmonella* testing data, of which 146 had 342 *Salmonella* positives and 215 did not have *Salmonella* positives. There were 1,808 total Ground Pork *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 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, 2016 to December 31, 2016.

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 FY2017 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
152	316.6	Yes	4.55%	0.90%	3.57E-02	5.21

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, 2016 to December 31, 2016. There are 418 establishments with Chicken Parts *Salmonella* testing data, of which 313 had 1,107 *Salmonella* positives and 105 did not have *Salmonella* positives. There were 6,804 total Chicken Parts *Salmonella* tests performed.

Table 4-10 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 *Salmonella* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Salmonella* positive in the period January 1, 2016 to December 31, 2016.

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 FY2017 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
630	416.3(b)	Yes	3.31%	0.95%	3.85E-11	3.57
631	416.3(c)	Yes	6.78%	2.12%	2.51E-17	3.35
1349	381.76(b)(6)(ii)(A)	Yes	1.40%	0.38%	3.88E-14	3.75

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,933 establishments with *Salmonella* testing data, of which 10 had 13 *Salmonella* positives and 1,923 did not have *Salmonella* positives. There were 12,169 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, 2016 to December 31, 2016.

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 FY2017 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
636	416.4(d)	Yes	20.59%	4.97%	1.23E-03	4.96

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,202 establishments with *E. coli* O157:H7 testing data, of which 13 had 13 *E. coli* O157:H7 positives and 1,189 did not have *E. coli* O157:H7 positives. There were 15,533 total *E. coli* O157:H7 tests performed.

Table 4-12 presents the 5 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, 2016 to December 31, 2016.

Table 4-12 Comparison of Noncompliance Rates 3 Months before an E. coli O157:H7 Positive with Those for Establishments with No E. coli O157:H7 Positive

Reg ID	Regulation Verified	On FY2017 PHR List	Noncompliance Rate in 3 Months before a E Coli O157 Positive	Noncompliance Rate for Establishments with no E Coli O157 Positive	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Yes	47.06%	2.68%	2.60E-23	32.33
234	318.2(a)	Yes	1.18%	0.05%	4.39E-02	25.68
582	416.1	Yes	6.07%	2.02%	4.26E-07	3.14
592	416.14	Yes	0.86%	0.26%	3.32E-03	3.36
681	417.5(a)(2)	Yes	0.45%	0.00120144	2.44E-02	3.73

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 inMT55 (bench trim) and MT60 (beef or veal trim). FSIS has declared there are six non-O157 STEC adulterants in raw beef trim. 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- 157 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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 350 establishments with non-O157 STEC testing data, of which 23 had 58 non- O157 STEC positives and 327 did not have non-O157 STEC positives. There were 3,345 total non-O157 STEC tests performed.

Table 4-13 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 non- O157 STEC positive is higher than the average noncompliance rate for establishments with no non-O157 STEC positive in the period January 1, 2016 to December 31, 2016.

Table 4-13 Comparison of Noncompliance Rates 3 Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive

Reg ID	Regulation Verified	On FY2017 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
527	381.65(a)	Yes	5.26%	0.33%	1.16E-02	16.56
586	416.12(c)	Yes	2.56%	0.13%	8.78E-03	19.86
587	416.12(d)	Yes	2.56%	0.22%	1.80E-02	11.76
589	416.13(a)	Yes	2.82%	0.95%	6.25E-10	3.02
590	416.13(b)	Yes	0.90%	0.25%	7.34E-09	3.63
633	416.4(a)	Yes	16.22%	5.86%	5.51E-25	3.11
636	416.4(d)	Yes	29.98%	9.08%	1.00E-49	4.29
649	417.2(c)(4)	Yes	4.69%	0.78%	2.84E-71	6.30
717	310.18(a)	Yes	5.13%	1.68%	4.14E-50	3.18

4.3 *Listeria* monocytogenes

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,933 establishments with

Listeria monocytogenes testing data, of which 22 had 23 *Listeria monocytogenes* positives and 1,911 did not have *Listeria monocytogenes* positives. There were 12,174 total *Listeria monocyogenes* tests performed.

Table 4-14 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, 2016 to December 31, 2016.

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

Reg ID	Regulation Verified	On FY2017 PHR List	Noncompliance Rate in 3 Months before a Listeria monocytogenes Positive	Noncompliance Rate for Establishments with no Listeria monocytogenes Positive	Two-Sided Fisher Exact p Value	Odds Ratio
630	416.3(b)	Yes	8.51%	0.80%	5.73E-04	11.56

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 557 establishments with *Campylobacter* testing data, of which 274 had 826 *Campylobacter* positives and 283 did not have *Campylobacter* positives. There were 19,051 total *Campylobacter* tests performed.

Table 4-13 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 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, 2016 to December 31, 2016.

Table 4-15 Comparison of Noncompliance Rates 3 Months before a Campylobacter Positive with Those for Establishments with No 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
234	318.2(a)	Yes	1.28%	0.10%	4.14E-03	12.74
590	416.13(b)	Yes	1.08%	0.36%	1.87E-92	3.03
592	416.14	Yes	1.50%	0.37%	1.08E-146	4.12
631	416.3(c)	Yes	6.21%	2.04%	5.80E-27	3.18
641	416.6	No	12.12%	4.11%	1.08E-03	3.22
668	417.4(a)	Yes	10.06%	1.91%	4.36E-06	5.74
701	430.4(a)	Yes	0.19%	0.03%	3.15E-02	6.78
1348	381.69	No	10.45%	1.79%	1.93E-03	6.42
1349	381.76(b)(6)(ii)(A)	Yes	0.81%	0.08%	5.86E-22	10.64
1350	381.76(b)(6)(ii)(D)	No	10.39%	0.46%	1.53E-08	25.05

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 203 establishments with Intact Chicken *Campylobacter* testing data, of which 104 had 223 *Campylobacter* positives and 99 did not have *Campylobacter* positives. There were 8,435 total Intact Chicken *Campylobacter* tests performed.

Table 4-16 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, 2016 to December 31, 2016.

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

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
107	310.25(a)	Yes	2.36%	0.29%	3.33E-02	8.19
681	417.5(a)(2)	Yes	0.39%	0.08%	9.89E-19	5.11

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 45 establishments with *Campylobacter* testing data, of which 10 had 10 *Campylobacter* positives and 35 did not have *Campylobacter* positives. There were 1,758 total Intact Turkey *Campylobacter* tests performed.

Table 4-17 presents the 1 regulation which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher 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, 2016 to December 31, 2016.

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

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
1349	381.76(b)(6)(ii)(A)	Yes	1.56%	0.36%	3.70E-02	4.36

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 105 establishments with Comminuted Chicken *Campylobacter* testing data, of which 21 had 45 *Campylobacter* positives and 84 did not have *Campylobacter* positives. There were 1,328 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-18 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 Comminuted Chicken *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Chicken *Campylobacter* positive in the period January 1, 2016 to December 31, 2016.

Table 4-18 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 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
550	381.76(a)*	Yes	19.57%	0.77%	2.23E-10	31.29
565	381.91(b)	Yes	4.09%	1.09%	4.54E-03	3.87
659	417.3(a)(3)	Yes	50.00%	15.81%	5.47E-06	5.33

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 59 establishments with Comminuted Turkey *Campylobacter* testing data, of which 6 had 10 *Campylobacter* positives and 49 did not have *Campylobacter* positives. There were 973 total Comminuted Turkey *Campylobacter* tests performed.

There is one 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 Comminuted Turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Campylobacter* positive in the period January 1, 2016 to December 31, 2016.

Table 4-19 Comparison of Noncompliance Rates 3 Months before a Comminuted Turkey Campylobacter Positive with those for Establishments with No Comminuted Turkey Campylobacter Positive

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
681	417.5(a)(2)	Yes	0.33%	0.10%	2.73E-02	3.30

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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 419 establishments with Chicken Parts *Campylobacter* testing data, of which 209 had 538 *Campylobacter* positives and 210 did not have *Campylobacter* positives. There were 6,557 total Chicken Parts *Campylobacter* tests performed.

Table 4-20 presents the 6 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher 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, 2016 to December 31, 2016.

Table 4-20 Comparison of Noncompliance Rates 3 Months before a Chicken Parts Campylobacter Positive with Those for Establishments with No Chicken Parts Campylobacter Positive

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
234	318.2(a)	Yes	2.11%	0.18%	5.06E-03	12.03
557	381.83	Yes	0.07%	0.02%	2.07E-04	3.37
592	416.14	Yes	1.53%	0.51%	3.21E-78	3.03
668	417.4(a)	Yes	6.11%	1.92%	1.14E-02	3.32
1348	381.69	No	11.55%	1.01%	5.74E-04	12.80
1350	381.76(b)(6)(ii)(D)	No	11.15%	0.65%	1.60E-06	19.21

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 FY2018 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, 2016 to December 31, 2016. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,372 active meat and poultry establishments, of which 147 had 167 public health related NOIEs or suspensions and 5,225 did not have any public health related NOIEs or suspensions.

Table 4-21 presents the 35 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, 2016 to December 31, 2016.

Table 4-21 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
78	310.22(c)	No	2.59%	0.31%	1.96E-08	8.56
89	310.22(e)(2)	No	11.36%	1.85%	1.83E-03	6.79
90	310.22(e)(3)	Yes	9.76%	1.37%	2.38E-05	7.80
107	310.25(a)	Yes	6.35%	0.76%	3.23E-10	8.89
110	310.3	No	18.18%	5.82%	1.37E-03	3.59
178	317.24(a)	No	6.06%	0.42%	4.58E-04	15.35
207	318.1(b)	No	0.38%	0.02%	4.37E-03	23.07

582	416.1	Yes	9.25%	2.29%	2.69E-108	4.35
587	416.12(d)	Yes	1.22%	0.18%	1.09E-02	6.82
590	416.13(b)	Yes	1.18%	0.20%	4.81E-53	5.99
592	416.14	Yes	1.17%	0.28%	3.52E-33	4.18
594	416.15(a)	Yes	9.25%	1.74%	4.32E-12	5.77
595	416.15(b)	Yes	7.81%	2.53%	1.10E-06	3.26
597	416.16(a)	Yes	0.48%	0.16%	1.01E-16	3.05
630	416.3(b)	Yes	4.23%	0.99%	2.31E-07	4.43
631	416.3(c)	Yes	9.64%	1.44%	2.04E-20	7.30
633	416.4(a)	Yes	20.96%	8.03%	6.55E-84	3.04
636	416.4(d)	Yes	27.91%	9.15%	4.30E-136	3.85
641	416.6	No	11.86%	4.00%	4.08E-04	3.23
645	417.2(a)(1)	Yes	10.49%	1.49%	2.63E-35	7.70
649	417.2(c)(4)	Yes	2.87%	0.61%	1.62E-86	4.85
657	417.3(a)(1)	Yes	33.70%	4.65%	1.90E-18	10.42
658	417.3(a)(2)	Yes	4.61%	0.39%	2.04E-37	12.16
659	417.3(a)(3)	Yes	36.84%	9.50%	1.17E-12	5.55
660	417.3(a)(4)	Yes	4.65%	0.70%	5.88E-07	6.88
663	417.3(b)(2)	No	42.42%	3.84%	1.62E-11	18.44
664	417.3(b)(3)	Yes	2.01%	0.57%	0.0301	3.56
666	417.3(c)	No	30.56%	4.64%	5.38E-07	9.04
680	417.5(a)(1)	Yes	1.59%	0.31%	9.67E-48	5.14
681	417.5(a)(2)	Yes	0.98%	0.12%	2.86E-38	7.98
682	417.5(a)(3)	Yes	0.82%	0.26%	8.52E-16	3.12
704	430.4(b)(3)	Yes	9.89%	1.18%	1.67E-06	9.17
717	310.18(a)	Yes	7.71%	1.26%	4.39E-109	6.56
1174	418.3	No	3.03%	0.41%	0.0319	7.59
1352	381.76(b)(6)(ii)(B)	No	7.48%	0.21%	2.11E-10	37.37

5.0 LIST OF FY2018 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2018 PHR list. Table 5-1 presents the list of 57 FY2018 PHRs. These 57 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 57 FY2018 PHRs are composed of 11 regulations and 46 provisions of regulations. The 46 provisions fall under 22 different regulations. Thus, the 57 FY2018 PHRs represent 33 regulations, with the majority of FY2018 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 FY2018 PHRs

Reg ID	List of FY2018 PHRs	Description	On FY2017 PHR List	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Adulterated	Yes	3.15E-13	12.88
78	310.22(c)	Disposal of SRM	No	1.96E-08	8.56
89	310.22(e)(2)	Appropriate corrective actions	No	1.83E-03	6.79
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	2.38E-05	7.80
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	1.51E-03	10.24
107	310.25(a)	Verification criteria for E. coli testing meat	Yes	3.33E-02	8.19
110	310.3	Carcasses and parts in certain instances to be retained.	No	1.37E-03	3.59
152	316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	Yes	3.57E-02	5.21
178	317.24(a)	Packaging materials composed of poisonous or deleterious	No	1.12E-08	37.92

		substances			
207	318.1(b)	Only inspected and passed poultry product to enter official establishment	No	4.17E-02	3.00
234	318.2(a)	All products subject to reinspection by program employees	Yes	4.21E-07	6.50
406	381.1_Adulterated[1]	Adulterated	Yes		
527	381.65(a)	Clean and sanitary practices; products not adulterated	Yes	3.23E-04	7.16
543	381.71(a)	Condemnation on ante mortem inspection	Yes	6.72E-16	3.90
550	381.76(a)*	Post-mortem inspection, when required, extent.	Yes	2.23E-10	31.29
557	381.83	Septicemia or toxemia	Yes	5.97E-05	13.25
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	4.54E-03	3.87
582	416.1	Operate in a manner to prevent insanitary conditions	Yes	2.60E-10	6.64
586	416.12(c)	plan identifies procedures for pre-op	Yes	8.78E-03	19.86
587	416.12(d)	plan list frequency for each procedure & responsible individual	Yes	1.80E-02	11.76
589	416.13(a)	Conduct pre-op procedures	Yes	0.00E+00	4.74
590	416.13(b)	Conduct other procedures listed in the plan	Yes	5.58E-163	3.15
591	416.13(c)	Plant monitors implementation of SSOP procedures	Yes	0.00E+00	5.19
592	416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.00E+00	4.44
594	416.15(a)	Appropriate corrective actions	Yes	3.10E-50	3.19
595	416.15(b)	Corrective action, procedures for	Yes	6.07E-91	4.67
597	416.16(a)	Daily records required, responsible individual, initialed and dated	Yes	3.59E-05	14.24
630	416.3(b)	Constructed, located & operated in a manner that does	Yes	2.40E-43	4.04

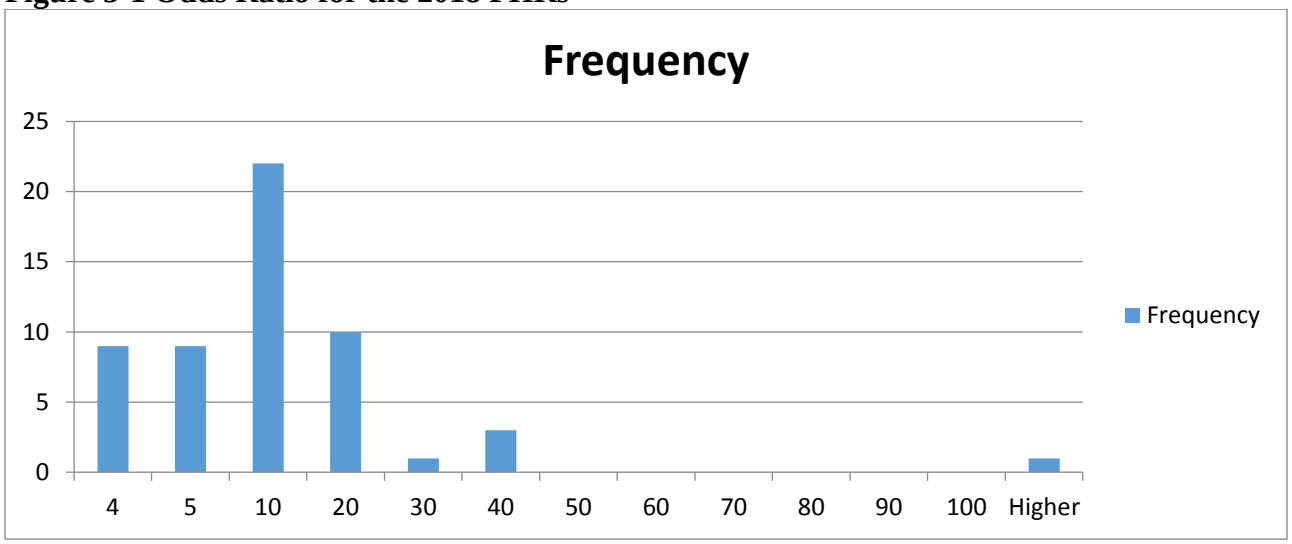
		not deter inspection			
631	416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	3.36E-98	5.78
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	0.00E+00	4.14
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	0.00E+00	5.11
641	416.6	Only FSIS program employee may remove "U.S. Rejected" tag	No	1.08E-03	3.22
645	417.2(a)(1)	Hazard analysis	Yes	2.64E-35	7.70
649	417.2(c)(4)	List of procedures & frequency	Yes	0.00E+00	4.35
657	417.3(a)(1)	Identify and eliminate the cause	Yes	1.67E-15	6.09
658	417.3(a)(2)	CCP is under control	Yes	1.93E-08	5.17
659	417.3(a)(3)	Establish measures to prevent recurrence	Yes	3.90E-27	7.51
660	417.3(a)(4)	No adulterated product enters commerce.	Yes	8.23E-05	4.41
663	417.3(b)(2)	Determine the acceptability of the affected product	No	1.62E-11	18.45
664	417.3(b)(3)	No adulterated product enters commerce	Yes	4.83E-03	7.21
665	417.3(b)(4)	Reassessment	Yes	5.05E-03	4.49
666	417.3(c)	Document corrective actions	No	7.64E-06	4.30
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	4.44E-19	254.13
680	417.5(a)(1)	Written hazard analysis	Yes	9.67E-48	5.14
681	417.5(a)(2)	Written HACCP plan	Yes	3.56E-03	9.74
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	8.52E-16	3.12
689	417.5(f)	Official Review	No	1.11E-03	13.96
701	430.4(a)	Lm, post-lethality exposed RTE	Yes	3.15E-02	6.78
704	430.4(b)(3)	Alternative 3	Yes	1.67E-06	9.17
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	5.73E-275	3.75

1174	418.3	Recall Plans	No	3.20E-02	7.59
1331	381.65(f)	Procedures for controlling visible fecal contamination	Yes	3.56E-02	7.58
1348	381.69	Maximum line speed rates under the New Poultry Inspection System	No	1.93E-03	6.42
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	Yes	2.26E-22	12.21
1350	381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS	No	1.53E-08	25.05
1352	381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage	No	2.11E-10	37.37
1444	311.14	Abrasions, bruises, abscesses, pus, etc.	No	2.38E-02	10.30

[1] 381.1 (adulteration in poultry) was not found to be significant from this analysis. However, the FY18 update did find 301.2 (adulteration in livestock) to be significant. FSIS has decided to include 381.1 on the final FY18 PHR list for consistency between livestock and poultry establishments

Figure 5-1 presents a histogram of the ratios (odds ratios) for each of the 57 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 13.43. 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 13.43 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 2018 PHRs



Forty three of the previous 53 FY2017 PHRs are mapped into these 57 FY2018 PHRs. Approximately 81% of the FY2017 PHRs are included in the FY2018 PHRs. There are 10 additional regulations that were on the FY2017 PHR list and are not in the FY2018 PHR list (See Appendix E).

Table 5-2 lists the number of regulations triggered by different events for inclusion in the FY2018 PHR list. Most regulations were triggered by multiple events.

Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2018 PHR list

Product	Number of Regulations	Percent
Campylobacter	10	6.84%
Campylobacter Intact Chicken	2	1.37%
Campylobacter Intact Turkey	1	0.68%
Campylobacter Chicken Parts	6	4.10%
Campylobacter Comminuted Chicken	3	2.05%

Product	Number of Regulations	Percent
Campylobacter Comminuted Turkey	1	0.68%
Enforcement Actions	35	23.97%
NonO157 STEC	5	3.42%
O157	4	2.74%
Listeria	1	0.68%
Salmonella	19	13.01%
Salmonella Ground Beef	5	3.42%
Salmonella Comminuted Chicken	11	7.53%
Salmonella Comminuted Turkey	4	2.74%
Salmonella Intact Beef	12	8.21%
Salmonella Intact Chicken	10	6.84%
Salmonella Intact Turkey	1	0.68%
Salmonella RTE	1	0.68%
Salmonella Intact Pork	11	7.53%
Salmonella Ground Pork	1	0.68%
Salmonella Chicken Parts	3	2.05%
Total	146	100.00%

There were nineteen regulations triggered by a single type of event. Eleven were from enforcement actions, two were from *Campylobacter* Comminuted Chicken, and one each were from Non O157 STEC All Products, *Salmonella*, *Salmonella* Ground Beef, *Salmonella* Ground Pork, *Campylobacter*, and *Salmonella* Intact Chicken. Table 5-3 presents the regulations triggered for inclusion in the FY2018 PHR list by only single event type.

Table 5-3 Regulations Triggered for Inclusion in the FY2018 PHR List by Only a Single Event

Reg ID	Regulations from a Single Event	Event
78	310.22(c)	Enforcements
89	310.22(e)(2)	Enforcements
90	310.22(e)(3)	Enforcements
99	310.22(f)(2)	Salmonella Ground Beef
110	310.3	Enforcements
152	316.6	Salmonella Ground Pork
550	381.76(a)*	Campylobacter Comminuted Chicken
565	381.91(b)	Campylobacter Comminuted Chicken
586	416.12(c)	NonO157
645	417.2(a)(1)	Enforcements
663	417.3(b)(2)	Enforcements
680	417.5(a)(1)	Enforcements

Reg ID	Regulations from a Single Event	Event
682	417.5(a)(3)	Enforcements
689	417.5(f)	Salmonella Intact Chicken
701	430.4(a)	Campylobacter
704	430.4(b)(3)	Enforcements
1174	418.3	Enforcements
1352	381.76(b)(6)(ii)(B)	Enforcements
1444	311.14	Salmonella

After the analysis was complete, one regulation was added to the PHR list for administrative reasons. Reg 381.1 (adulteration in poultry) was not found to be significant in the FY18 analysis. However, the FY18 update did find 301.2 (adulteration in livestock) to be significant. FSIS has decided to include 381.1 on the final FY18 PHR list for consistency between livestock and poultry establishments

6.0 CUT POINTS FOR FY2018 PHRS

The FY2018 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 FY2018 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 FY2018 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 FY2018 cut points, the mean and standard deviation of the natural log transformed non-zero FY2018 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 FY2018 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 FY2018 PHR Rate

	Mean of Natural Log FY2018 PHR Rate			**Standard Deviation FY2018 PHR Rate**	
Mean	Combination	Processing		Combination	Processing
Jan-Mar 2016	-4.43	-4.83		1.06	0.82
Apr-Jun 2016	-4.25	-4.59		0.88	0.79
July-Sep 2016	-4.36	-4.77		0.98	0.83
Oct-Dec 2016	-4.41	-4.85		1.06	0.84
Average	-4.38	-4.78		0.97	0.81

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 -4.78 + 2*0.81 = —4.78 + 1.61 = -3.17. (Rounding shows the standard deviation in 6-1 as 0.81, but it is closer to 0.806) The cut point of the original, non-transformed PHR non-compliance data is the antilog of -3.17 or Exp(-3.17) = 4.22%. Tables 6-2 and 6-3 present the FY2018 PHR upper and lower cut points for each of the two establishment operation types. The FY2017 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 2018.

Table 6-2 FY2018 PHR Tier 1 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	4.22%	4.89%
Combination	8.73%	9.70%

Table 6- 3 FY2018 PHR Tier 3 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	2.82%	3.23%
Combination	5.38%	5.97%

Table 6-4 presents the number of establishments in each Tier based solely on the FY2018 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 FY2018 PHRs, 69 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, 2017.

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

Classification	Number of Establishments
Tier 1	69
Tier 2	109
Tier 3	4,964
Total	5,142

Table 6-5 presents the number of establishments in each Tier based 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 FY2018 PHRs, 56 processing establishments are Tier 1 and are candidates to receive for cause FSAs. In total, 69 establishments are in Tier 1 based solely on non-compliances with the FY2018 PHRs. Table 6-4 is based on regulatory non-compliances during January 1 –March 31, 2017.

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

Classification	Processing	Combination
Tier 1	56	13
Tier 2	80	29
Tier 3	3,970	994
Total	4,106	1,036

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 FY2018 PHR regulations used to prioritize certain FY2018 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 FY2018 PHRs has 57 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 eighty one percent of the regulations on the FY2017 PHR list are also on the FY2018 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 FY2018 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 FY2017 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 FY2018 PHR Tier 1 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	4.22%	4.81%
Combination	8.73%	9.46%

Table 7- 2 FY2018 PHR Tier 3 Cut Points

Operation Type	FY2018 PHR Cut Points	FY2017 PHR Cut Points
Processing	2.82%	3.16%
Combination	5.38%	5.82%

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: FY2018 PHR REGULATIONS

Table A-1 presents the list of fifty seven FY2018 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates three months before a pathogen positive or enforcement action 13.43 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2018 PHRs

Reg ID	List of FY2018 PHRs	Description
29	301.2_Adulterated	Adulterated
78	310.22(c)	Disposal of SRM
89	310.22(e)(2)	Appropriate corrective actions
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
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
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
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
406	381.1_Adulterated[1]	Adulterated
527	381.65(a)	Clean and sanitary practices; products not adulterated
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
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
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
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
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.
663	417.3(b)(2)	Determine the acceptability of the affected product
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
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
701	430.4(a)	Lm, post-lethality exposed RTE
704	430.4(b)(3)	Alternative 3
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
1174	418.3	Recall Plans
1331	381.65(f)	Procedures for controlling visible fecal contamination
1348	381.69	Maximum line speed rates under the New Poultry Inspection System
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
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.

[1] 381.1 (adulteration in poultry) was not found to be significant from this analysis. However, the FY18 update did find 301.2 (adulteration in livestock) to be significant. FSIS has decided to include 381.1 on the final FY18 PHR list for consistency between livestock and poultry establishments

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 FY2018 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:

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

The PHR cut-points are defined as follows for each of the two plant types (Processing, and Slaughter/Processing Combination):

- For establishments with a PHR rate that is less than the lower cut point for all establishments with the same establishment type, they would not receive any early warnings or prioritized PHREs based on this criterion. These establishments are performing better on average than their peers with respect to compliance with FSIS regulations. These establishments would still be eligible for a routine PHRE or could be prioritized based on other public health criteria as explained in FSIS Directive 5100.4.
- For establishments with a PHR rate between the lower and upper cut points for all establishments with the same establishment type, the in-plant inspection personnel would receive an "early warning" alert through PHIS.
- 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 be prioritized for a PHRE to determine if a for cause FSA is appropriate.

APPENDIX C: FY2018 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, 2016 through December 31, 2016.

Table C-1 FY2018 Candidate regulations

Reg ID	FY2018 Candidate Regulation	FY2017 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
29	301.2_Adulterated	Yes	No	9496	258	2.65%
43	304.3(a)	No	No	1045	11	1.04%
45	304.3(c)	No	No	1177	8	0.68%
53	309.2(a)	No	No	976	5	0.51%
54	309.3	No	No	210	1	0.47%
55	309.4	No	No	188	2	1.05%
56	309.5	No	No	137	-	0.00%
57	309.9	No	No	129	-	0.00%
69	310.18	No	No	382	5	1.29%
77	310.22(b)	No	No	6013	16	0.27%
78	310.22(c)	No	Yes	54571	183	0.33%
84	310.22(d)(2)	No	No	67	-	0.00%
88	310.22(e)(1)	Yes	No	15148	176	1.15%
89	310.22(e)(2)	No	No	4816	52	1.07%
90	310.22(e)(3)	Yes	No	10023	123	1.21%
92	310.22(e)(4)(i)	Yes	No	92628	251	0.27%
99	310.22(f)(2)	Yes	No	19114	34	0.18%
101	310.22(g)(1)	No	No	2121	3	0.14%
104	310.22(g)(4)	No	No	4805	15	0.31%
107	310.25(a)	Yes	No	29319	274	0.93%
108	310.25(b)	No	No	206	4	1.90%
109	310.25(b)(3)(ii)	No	No	371	1	0.27%
110	310.3	No	No	3662	204	5.28%
114	311.16	No	No	171	10	5.52%
115	311.17	No	No	416	2	0.48%
116	311.24	No	No	96	-	0.00%
138	315.2	No	No	83	-	0.00%
152	316.6	Yes	No	11805	66	0.56%
178	317.24(a)	No	No	4165	16	0.38%
207	318.1(b)	No	No	93248	16	0.02%
215	318.10(b)	No	No	2412	11	0.45%
217	318.10(c)(1)	No	No	2669	2	0.07%
218	318.10(c)(2)	No	No	721	1	0.14%
219	318.10(c)(3)	No	No	414	1	0.24%
221	318.14(a)	No	No	86	-	0.00%

222	318.14(b)	No	No	906	-	0.00%
223	318.14(c)	No	No	40	1	2.44%
226	318.16(b)	No	No	537	-	0.00%
228	318.17(a)(1)(2)	Yes	No	3414	8	0.23%
229	318.17(b)	No	No	796	1	0.13%
230	318.17(c)	No	No	35	-	0.00%
234	318.2(a)	Yes	No	49100	61	0.12%
235	318.2(d)	No	No	8482	42	0.49%
239	318.23(b)(1)	No	No	372	4	1.06%
241	318.23(b)(3)	No	No	17	2	10.53%
242	318.23(c)(1)	No	No	163	1	0.61%
243	318.23(c)(2)	No	No	14	-	0.00%
245	318.23(c)(4)	No	No	35	-	0.00%
246	318.23(c)(5)	No	No	14	-	0.00%
247	318.24	No	No	2483	14	0.56%
251	318.303	No	Yes	8144	8	0.10%
256	318.308	No	Yes	5046	5	0.10%
268	318.6(b)(1)	No	No	2865	-	0.00%
273	318.6(b)(4)	No	No	9376	-	0.00%
274	318.6(b)(6)	No	No	12576	-	0.00%
275	318.6(b)(8)	No	No	484	1	0.21%
329	319.5(b)	No	No	168	-	0.00%
406	381.1_Adulterated	Yes	No	5694	66	1.15%
450	381.144(a)	No	No	2583	-	0.00%
457	381.150(a)	Yes	No	1816	6	0.33%
459	381.150(c)	No	No	77	-	0.00%
460	381.150(d)	No	No	6	1	14.29%
462	381.151(a)	No	No	47	-	0.00%
490	381.22(a)	No	No	411	1	0.24%
491	381.22(b)	No	No	1216	6	0.49%
492	381.22(c)	No	No	312	2	0.64%
503	381.310	No	Yes	4732	1	0.02%
504	381.311	No	Yes	4623	-	0.00%
506	381.37(a)	No	No	2195	13	0.59%
527	381.65(a)	Yes	No	80801	900	1.10%
543	381.71(a)	Yes	No	3302	290	8.07%
545	381.72(a)	No	No	156	-	0.00%
546	381.72(b)	No	No	2	-	0.00%
550	381.76(a)*	Yes	No	22860	375	1.61%
557	381.83	Yes	No	241150	135	0.06%
559	381.85	No	No	55	-	0.00%
564	381.91(a)	Yes	No	11756	25	0.21%

565	381.91(b)	Yes	No	29063	319	1.09%
572	381.94(b)	No	No	1	-	0.00%
582	416.1	Yes	Yes	640587	14974	2.28%
586	416.12(c)	Yes	No	48339	95	0.20%
587	416.12(d)	Yes	No	65328	127	0.19%
588	416.13 Implementation of SOP's	No	No	6246	15	0.24%
589	416.13(a)	Yes	Yes	733754	6878	0.93%
590	416.13(b)	Yes	Yes	1778040	3834	0.22%
591	416.13(c)	Yes	Yes	2575764	42929	1.64%
592	416.14	Yes	Yes	1582629	4485	0.28%
593	416.15 Corrective Actions	Yes	No	705	3	0.42%
594	416.15(a)	Yes	Yes	68218	1136	1.64%
595	416.15(b)	Yes	Yes	44141	1050	2.32%
597	416.16(a)	Yes	Yes	2808139	4951	0.18%
630	416.3(b)	Yes	No	78738	724	0.91%
631	416.3(c)	Yes	No	72856	1022	1.38%
633	416.4(a)	Yes	No	298538	24990	7.72%
636	416.4(d)	Yes	No	270721	26265	8.84%
640	416.5(c)	Yes	No	42547	27	0.06%
641	416.6	No	No	3826	165	4.13%
645	417.2(a)(1)	Yes	Yes	126657	2271	1.76%
648	417.2(c)	Yes	No	35830	117	0.33%
649	417.2(c)(4)	Yes	Yes	1332897	8216	0.61%
655	417.3 Corrective actions	No	No	445	2	0.45%
656	417.3(a)	No	No	1491	2	0.13%
657	417.3(a)(1)	Yes	No	11647	645	5.25%
658	417.3(a)(2)	Yes	No	141592	643	0.45%
659	417.3(a)(3)	Yes	No	6765	726	9.69%
660	417.3(a)(4)	Yes	No	30777	245	0.79%
662	417.3(b)(1)	No	No	3562	138	3.73%
663	417.3(b)(2)	No	No	2976	118	3.81%
664	417.3(b)(3)	Yes	No	22660	120	0.53%
665	417.3(b)(4)	Yes	Yes	27877	237	0.84%
666	417.3(c)	No	No	5909	335	5.37%
668	417.4(a)	Yes	No	6657	298	4.28%
669	417.4(a)(1)	Yes	No	4773	513	9.70%
675	417.4(b)	Yes	Yes	31176	103	0.33%
680	417.5(a)(1)	Yes	Yes	1343138	4443	0.33%
681	417.5(a)(2)	Yes	Yes	1195495	1706	0.14%
682	417.5(a)(3)	Yes	Yes	1399871	4197	0.30%

689	417.5(f)	No	No	87567	125	0.14%
690	417.6	No	No	436	137	23.91%
701	430.4(a)	Yes	Yes	294085	183	0.06%
702	430.4(b)(1)	No	No	1082	7	0.64%
703	430.4(b)(2)	No	No	13620	122	0.89%
704	430.4(b)(3)	Yes	No	27780	398	1.41%
705	430.4(c)(2)	No	Yes	284757	209	0.07%
706	430.4(c)(3)	No	Yes	295652	168	0.06%
707	430.4(c)(4)	No	No	2971	12	0.40%
708	430.4(c)(5)	No	No	6561	27	0.41%
709	430.4(c)(6)	No	No	6150	97	1.55%
717	310.18(a)	Yes	Yes	312597	3866	1.22%
718	310.18(b)	No	No	20015	4	0.02%
1173	418.2	No	No	1424	100	6.56%
1174	418.3	No	No	15018	70	0.46%
1241	354.242(b)	No	No	165	2	1.20%
1247	354.242(h)	No	No	112	2	1.75%
1250	354.243(a)	No	No	84	-	0.00%
1292	381.193(a)	No	No	233	14	5.67%
1331	381.65(f)	Yes	No	742919	9203	1.22%
1346	381.65(h)	No	No	12378	1	0.01%
1348	381.69	No	No	472	15	3.08%
1349	381.76(b)(6)(ii)(A)	Yes	No	36976	266	0.71%
1350	381.76(b)(6)(ii)(D)	No	No	1549	113	6.80%
1351	381.76(b)(6)(ii)(C)	No	No	312454	124	0.04%
1352	381.76(b)(6)(ii)(B)	No	No	29962	72	0.24%
1444	311.14	No	No	10265	7	0.07%

1. NC = Noncompliance

APPENDIX D: COMPARISON OF FY2018 PHR LIST WITH FY2017 PHR LIST

There are eleven regulations from the FY2017 PHR list that no longer appear in the FY2018 PHR list. These eleven regulations are shown in Table D-1.

Table D-1 Regulation from the FY2017 PHR list no longer on the FY2018 PHR list

Reg ID	List of FY2016 PHRs	Description
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
92	310.22(e)(4)(i)	Maintain daily records
228	318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef
457	381.150(a)	Lethality and Stabilization requirements for cooked poultry
530	381.65(e)*	Zero-tolerance for visible fecal matter entering chiller
564	381.91(a)	Certain contaminated carcasses to be condemned
593	416.15 Corrective Actions	Corrective Actions
640	416.5(c)	Employees who appear to have any abnormal source of microbial contamination
648	417.2(c)	Contents of HACCP Plan
669	417.4(a)(1)	Initial validation
675	417.4(b)	Reassessment of hazard analysis

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

The purpose of this Appendix is to explain how the 57 PHRs are used as one component of the overall decision tree methodology used to schedule FSAs.

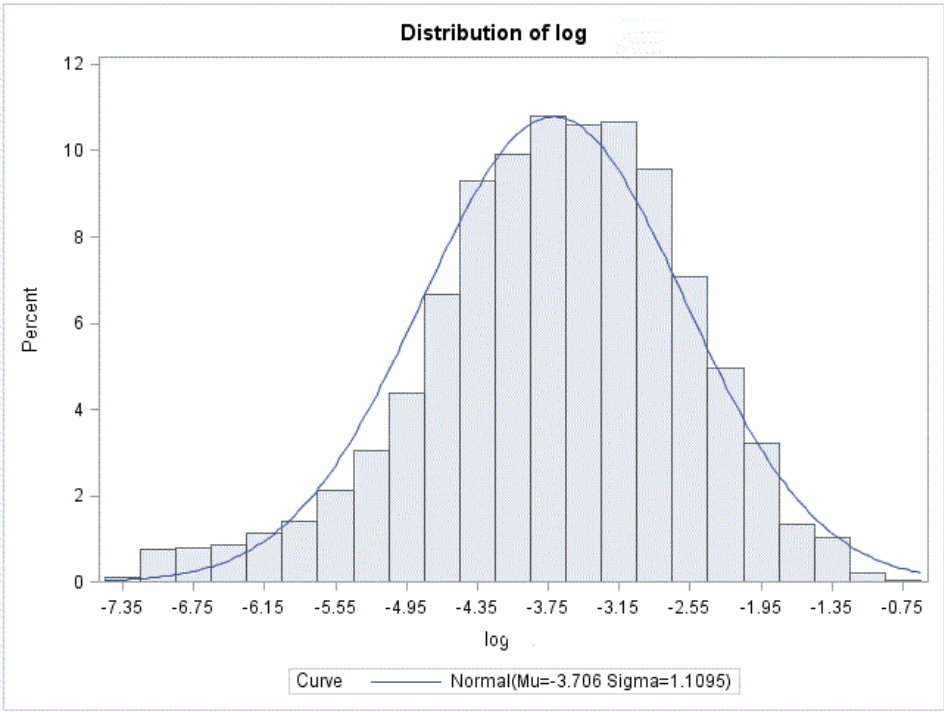
The PHR noncompliance rate is calculated by the following formula using the most recent three months of establishment verification inspection data:

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

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	0.02942787	Pr > D	<0.010
Cramer-von Mises	W-Sq	1.20153057	Pr > W-Sq	<0.005
Anderson-Darling	A-Sq	9.11623745	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)
Q1CY2016					Tier 1	**77**
Both	**1,035**	**-4.43**	**1.01**		Tier 2	**97**
Processing	**4,036**	**-4.84**	**0.82**		Tier 3	**4,897**
Q2CY2016					Tier 1	**66**
Both	**1,049**	**-4.27**	**0.88**		Tier 2	**69**
Processing	**4,047**	**-4.61**	**0.74**		Tier 3	**4,961**
Q3CY2016					Tier 1	**61**
Both	**1,046**	**-4.39**	**0.98**		Tier 2	**117**
Processing	**4,055**	**-4.81**	**0.83**		Tier 3	**4,923**
Q4CY2016					Tier 1	**65**
Both	**1,043**	**-4.42**	**1.01**		Tier 2	**100**
Processing	**4,064**	**-4.86**	**0.84**		Tier 3	**4,942**

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 2017 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	-4.38	-4.78
Standard Deviation	0.97	0.81

Table E-3 March 2017 Tier Distribution Based on the PHR Criteria Only

Classification	Plants
Tier 1	69
Tier 2	109
Tier 3	4,964
Total	5,142

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	197	3.83%	6	8.70%
Turkey Slaughter	49	0.95%	1	1.45%
Beef Slaughter	637	12.39%	5	7.25%
Pork Slaughter	596	11.59%	2	2.90%
Beef Processing	1639	31.87%	14	20.29%
Chicken Processing	820	15.95%	17	24.64%
Turkey Processing	317	6.16%	4	5.80%
Pork Processing	1808	35.16%	10	14.49%
RTE	2531	49.22%	37	53.62%
Poultry Combination	396	7.70%	8	11.59%
Total Number of Establishments	5142		69	