FY2016 Public Health Regulations

June 8, 2014

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SUMMARY

The purpose of the present report is to update the current list of Public Health Regulations (PHRs) used by the Food Safety and Inspection Service (FSIS) for prioritizing Food Safety Assessments (FSAs). The current list of PHRs was based on 2013 FSIS verification inspection results and used for FSA scheduling in FY2015. The updated list of PHRs is based on 2014 verification inspection results and will be implemented in FY2016. The updated list is called FY2016 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 list of PHRs contains both regulations and specific provisions of regulations. The inclusion of provisions of regulations in the PHR list allows FSIS to focus on specific health related provisions of regulations that may be most informative for prioritizing FSAs.

The methodology used in developing the FY2016 PHR list is the same as that used for the FY2015 PHR list. A new approach is employed to develop the cut points between Tier 1, Tier 2, and Tier 3 establishments. Rather than apply the means and standard deviations directly to the aggregate PHR non-compliance rates, the non-zero, aggregate PHR non-compliances are first log transformed to obtain an approximately normal distribution. The cut points are then the mean plus 1.5 standard deviations and the mean plus 2.0 standard deviations of the log-transformed normal distribution.

Regulations that have higher noncompliance rates in establishments three months before a public health related Notice of Intended Enforcement (NOIE) or suspension than in establishments without a public health related NOIE or suspension are included in the derivation of the FY2016 PHRs. A public health related NOIE or suspension is one that results from a Sanitation Standard Operating Procedure (Sanitation SOP), HACCP, or Sanitation Performance Standards (SPS) violation. There were 166 public health related NOIE or suspensions issued in CY2014. The public health related NOIE and suspensions are simply referred to as enforcement actions in the rest of the report. The enforcement action list of regulations was selected from the same list of 134 candidate regulations used to select the other FY2016 PHRs.

For inclusion in the FY2016 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 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, 2014) recorded in PHIS.

The final list of FY2016 PHRs consists of 54 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. This compares with 48 regulations that were identified in the FY2015 PHR list. The list of FY2016 PHRs is presented in Appendix A. Eighty five percent of regulations on the FY2015 PHR list are also on the FY2016 PHR list.

The 54 FY2016 PHRs are composed of 6 regulations and 48 provisions of regulations. The 48 provisions fall under 21 different regulations. Thus, the 54 FY2016 PHRs represent 27 regulations, with the majority of FY2016 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 FY2016 PHR regulations three months before a pathogen positive or enforcement action is 5.4 times higher than the average FY2016 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action.

The FY2016 PHRs fall into one of 5 broad regulatory categories (see Table S-1). PHRs may fall into more than one category.

Table S- 1 Regulatory Categories of FY2016 PHRs

FY2016 PHR Category	Percent of FY2015 PHRs	Percent of FY2016 PHRs
Prevent insanitary conditions and ensure product is not adulterated (Sanitation SOP/SPS)	45.8%	53.7%
Perform initial hazard analysis, develop HACCP plan and verify adequacy of HACCP plans (HACCP)	29.2%	24.1%
Maintain adequate records	8.3%	9.3%
Monitor Critical Control Points and critical limits	6.3%	3.7%
Identify corrective actions and prevent recurrence	10.4%	9.3%
Total	100%	100.0%

Table S-2 lists the number of regulations triggered by each type of event for inclusion in the FY2015 PHR list. A regulation may be triggered by multiple events. There were fourteen regulations triggered by a single type of event.

Table S- 2 Events That Triggered Inclusion of a Regulation in the FY2016 PHR list

Type of Event	Number of FY2015 PHR Regulations	Number of FY2016 PHR Regulations	Percent
Campylobacter All Products	15	16	7.84%
Campylobacter Comminuted Chicken	0	12	5.88%
Campylobacter Comminuted Turkey	0	7	3.43%
Campylobacter Intact Chicken	12	13	6.37%
Campylobacter Intact Turkey	5	4	1.96%
Enforcement Actions	38	40	19.61%
NonO157 STEC All Products	12	8	3.92%
O157 All Products	10	5	2.45%
Salmonella All Products	22	30	14.71%

Type of Event	Number of FY2015 PHR Regulations	Number of FY2016 PHR Regulations	Percent
Salmonella Ground Beef	10	15	7.35%
Salmonella Comminuted Chicken	2	7	3.43%
Salmonella Comminuted Turkey	1	8	3.92%
Salmonella Intact Beef	0	15	7.35%
Salmonella Intact Chicken	14	16	7.84%
Salmonella Intact Turkey	8	6	2.94%
Salmonella RTE	1	2	0.98%
Total	155	204	100.00%

The FY2016 PHRs are one of seven public health based decision criteria that will be used in prioritizing Food Safety Assessments (FSAs). Noncompliance with a single FY2016 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 FY2016 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 FY2016 cut points, the mean and standard deviation of the log transformed non-zero FY2016 PHR rates for each of the four quarters in CY2014 is computed (the log transform of the non-zero FY2016 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 receive a "for cause" FSA if they have not had an FSA in the last six months. Table S-3 presents the FY2016 PHR cut points for the non-transformed PHR non-compliance data for each of the two establishment operation types. The FY2015 PHR cut points are included for comparison. (See Section 6 and Appendix F for more details.)

Table S- 3 FY2016 PHR Upper Cut Points

Operation Type	FY2016 PHR Cut Points	FY2015 PHR Cut Points
Processing	4.80%	6.55%
Combination	9.25%	9.37%

Table S-4 presents the number of establishments in each Tier based on all seven decision criteria, including the PHR criterion. The time period used for calculating the noncompliance rate of the PHRs was December 1, 2014 – February 28, 2015.

Table S- 4 Number of Establishments in Tiers Based on all Seven Decision Criteria

Classification	Processing	Combination	Total
Tier 1	63	7	70
Tier 2	88	26	114
Tier 3	3,849	1,000	4,849
Total	4,000	1,033	5,033

Table S-5 presents the distribution of Tier 1 establishments (as determined using only the PHR criterion) among different product categories. There is a statistically significant difference between the percentage of establishments producing a given product category and the percentage of establishments in Tier 1 for that product category for Beef Slaughter, Pork Slaughter and Ground Pork.

The product type "Poultry Combination" was included to determine if establishments that slaughter poultry only or slaughter and process poultry might receive a higher percentage of Tier 1 classifications. Analysis indicates that they do not; there is not a statistically significant difference between the percentage of establishments in the Poultry Combination product category and the percentage of establishments in Tier 1 for that product category.

Table S- 5 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	Statistical Difference
Chicken Slaughter	197	3.93%	2	3.57%	No
Turkey Slaughter	51	1.02%	-	0.00%	No
Beef Slaughter	621	12.37%	2	3.57%	Yes
Pork Slaughter	589	11.74%	-	0.00%	Yes
Ground Beef	1,597	31.82%	12	21.43%	No
Comminuted Chicken	803	16.00%	10	17.86%	No
Comminuted Turkey	313	6.24%	3	5.36%	No
Ground Pork	1,721	34.29%	11	19.64%	Yes
RTE	2,495	49.71%	31	55.36%	No
Poultry Combination	395	7.87%	4	7.14%	No
Total Number of Establishments	5,019		56		

When establishments have had an FSA in the past six months, Tier 1 establishments are not automatically scheduled to receive a for cause FSA. 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 FSA. Table S-6 presents the number of establishments in each Tier based on all seven decision criteria that have not had an FSA in the past six months. The time period used for calculating the noncompliance rate of the PHRs was December 1, 2014 – February 28, 2015. Sixty establishments would receive a "for cause" FSA after removing establishments that have had an FSA in the past six months.

Table S- 6 Number of Establishments in Each Tier without an FSA in Past Six Months Based on the all Seven Decision Criteria Level

Classification	Processing	Combination	Total
Tier 1	53	7	60
Tier 2	74	22	96
Tier 3	3,691	954	4,645
Total	3,818	983	4,801

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 subset of 9 CFR regulations used to schedule FSAs was 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 was called Public Health Regulations (PHRs). In January, 2013, FSIS submitted to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) its plans to implement the PHRs. NACMPI endorsed the use of PHRs, and suggested that the PHR list be updated annually (NACMPI 2013). The list of FY2014 PHRs was published in July 2013 (FSIS 2013). The list of FY2015 PHRs was published in July 2014 (FSIS 2014). The purpose of the present report is to update the list of FY2015 PHRs using current verification inspection results from the Public Health Information System (PHIS). The updated list is called FY2016 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 list of PHRs contains both regulations and specific provisions of regulations. 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 FY2016 PHR list is the same as that used for the FY2015 PHR. Specifically, for inclusion in the FY2015 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, 2014) recorded in PHIS. Candidate regulations related to egg products are not included in the present report. FSIS has developed a proposed list of candidate regulations for egg products and may include egg products in the next update of the PHR list.

FSIS has been collecting *Campylobacter* samples on young chicken carcasses since July 2011. In addition, FSIS began testing beef trim for the six non-O157 Shiga toxin-producing *Escherichia coli* (STEC) (O26, O45, O103, O111, O121, and O145) that FSIS declared adulterants in non-intact raw beef products and product components in June 2012. The *Campylobacter* and the six non-O157 STEC data will be added to the pathogens used to update the list of PHRs. The report does not address possible health impacts from allergens or residues. The final FY2016 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.

In the second step of the process, the final list of public health regulations will consist of that subset of candidate regulations that are associated with higher noncompliance rates in establishments in the three months before a *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm,* or *Campylobacter* positive or enforcement actions than in establishments without pathogen positives or enforcement actions. These regulations will be called PHRs and are considered to be indicators of potential public health impact.

2.2 Relationship with Pathogen Positives

The second step in selecting a list of PHRs is to determine which of the candidate regulations are related to a higher rate of noncompliance in the three months before the occurrence of a pathogen positive during FSIS sampling. The three month time period is chosen to be long enough to have sufficient FSIS verification data for analysis and short enough to be indicative of establishment

operating conditions before a pathogen positive. A candidate regulation will be included in the final list of PHRs if the noncompliance rate for the regulation is higher in establishments in the three months before a *Salmonella, E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positive or enforcement actions than the average noncompliance rate in establishments that do not have a *Salmonella, E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positive or enforcement action. The current analysis includes the six non-O157 STECs (O26, O45, O103, O111, O121, and O145) that FSIS has declared adulterants in non-intact raw beef products and product components.

3.0 CANDIDATE REGULATIONS

The purpose of this section is to use the above criteria to select a list of candidate regulations. The purpose of the candidate list is to narrow the list of all 9 CFR regulations to those related to verifying HACCP food safety process control in order to make the analysis of relationship to pathogen positives manageable. All regulations in 9 CFR were individually reviewed to determine if they satisfied any of the 4 criteria delineated in Section 2.1. A set of one hundred forty three (143) 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. These 143 regulations map to 134 regulations in PHIS. Some of the 143 map directly to regulations in PHIS and others are verified under higher order regulations in PHIS. For example, 381.1(i)-381.1(iv) (all of which are on the original W3NR list) are verified under 381.1. The list of 134 candidate regulations that are indicators of a potential loss of HACCP food safety process control are presented in Appendix C.

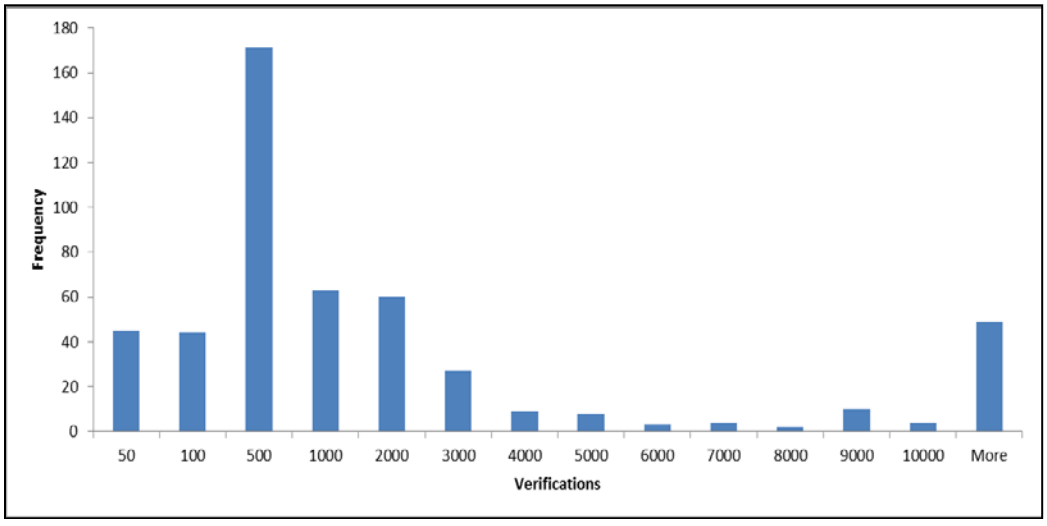
4.0 RELATIONSHIP BETWEEN CANDIDATE REGULATIONS AND PATHOGEN POSITIVES

The purpose of this section is to investigate the relationship between the list of candidate regulations and *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Listeria monocytogenes, Campylobacter* positives or enforcement actions during FSIS verification testing. The noncompliance rate of each of the 134 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, 2014 through December 31, 2014. Those with more than 30 verifications in a year, an effect size of 0.5 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments in the three months before a pathogen positive is higher than the noncompliance rate for establishments with no positives are selected as PHRs. 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). For candidate regulations with more than 30 verifications, the average number of verifications of candidate regulations 3 months before a pathogen positive or verification for candidate regulations with more than 30 verifications is 4,395.

Figure 4-1 presents a histogram of the number of verifications of candidate regulations 3 months before a pathogen positive or enforcement action. Only pathogen positives or enforcement actions with greater than 30 verifications were considered in constructing the figure.

Figure 4- 1 Number of Verifications of Candidate Regulations 3 Months before a Pathogen Positive or Enforcement Action



An effect size is the difference between the means of two groups divided by their combined (pooled) standard deviation. Effect size indicates how many pooled standard deviations there are between the means of the two groups; for example, an effect size of 0.75 indicates that the mean of one group is three quarters of a standard deviation from the mean of the other group. In general an effect size of 0.2 is considered small; an effect size of 0.5 is considered medium and above 0.8 is large. However, there is no definitive rule for determining a meaningful effect size. In this report, an effect size of 0.5 is taken as the threshold for a meaningful separation between two means.

4.1 *Salmonella*

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,550 establishments with *Salmonella* testing data, of which 393 had 2,880 *Salmonella* positives and 1,157 did not have *Salmonella* positives. There were 32,350 total *Salmonella* tests performed.

Table 4-1 presents the 31 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
310.18	Yes	3.33%	1.38%	8.78E-19	0.90
310.18(a)	No	3.76%	0.67%	3.29E-182	5.25
310.22(c)	No	0.54%	0.26%	5.40E-03	1.27
310.22(e)(1)	No	4.91%	0.97%	1.03E-12	0.72
318.10(b)	No	3.95%	0.64%	3.12E-02	0.59
381.1_Adulterated	Yes	7.19%	2.01%	1.65E-49	2.74
381.193(a)	No	15.47%	2.50%	3.50E-02	2.67
381.65(f)[1]	Yes	1.34%	1.28%	9.02E-03	43.02
381.71(a)	No	29.01%	1.97%	1.69E-182	1.42
381.83	No	0.08%	0.02%	4.16E-12	72.09
381.91(a)	No	2.01%	0.27%	3.26E-21	1.42

Regulation Verified	On FY2015 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	Cohen Effect Size
381.94(a)*	Yes	0.35%	0.07%	2.87E-03	6.82
416.1	Yes	12.03%	5.02%	0.00E+00	11.60
416.14	Yes	0.96%	0.43%	2.73E-135	15.50
416.15(a)	Yes	4.88%	3.10%	7.52E-12	6.03
416.15(b)	Yes	8.50%	4.26%	7.63E-32	6.08
416.16(a)	Yes	0.56%	0.21%	2.48E-187	20.44
416.3(b)	Yes	3.87%	0.83%	3.97E-63	2.73
416.3(c)	Yes	3.02%	1.24%	1.07E-31	4.38
416.4(a)	Yes	21.08%	9.27%	0.00E+00	7.98
416.4(d)	Yes	24.21%	9.95%	0.00E+00	8.10
417.2(c)(4)	Yes	2.00%	0.96%	0.00E+00	17.83
417.3(a)(3)	Yes	15.05%	1.68%	1.86E-280	0.74
417.3(a)(4)	Yes	1.30%	0.96%	1.90E-03	0.86
417.3(b)(1)	Yes	6.84%	2.94%	8.86E-07	2.25
417.3(b)(4)	Yes	3.79%	1.56%	1.11E-08	1.61
417.4(b)	Yes	0.75%	0.41%	4.51E-02	1.52
417.5(a)(1)	Yes	0.49%	0.38%	4.58E-11	14.43
417.5(a)(3)	Yes	0.48%	0.29%	2.55E-41	17.91
430.4(b)(2)	Yes	3.99%	0.83%	2.73E-08	3.09
430.4(c)(3)	Yes	0.15%	0.07%	4.84E-03	8.81

1 In December 2014, FSIS retired regulation 381.65(e)* and replaced it with regulation 381.65(f). Non-compliances with 381.65(e)* were used in the current analysis to determine that 381.65(e)*satisfied the PHR conditions. However, the regulations 381.65(f) is listed above as the PHR since that regulation name will be used in the future. The "*" on regulations 381.65(e)* and 381.94(a)* is part of the regulation name. Regulation 381.83 was not included in the final list of PHRs since it is restricted to HIMP establishments only.

4.1.1 *Salmonella* in Intact Chicken

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 182 establishments with Intact Chicken *Salmonella* testing data, of which 83 had 320 *Salmonella* positives and 99 did not have *Salmonella* positives. There were 8,799 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 16 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
381.71(a)	No	16.15%	3.19%	2.40E-21	2.30
381.91(a)	No	0.92%	0.28%	6.30E-03	5.12
381.94(a)*	Yes	0.69%	0.05%	5.91E-06	5.92
417.3(a)(1)	Yes	12.17%	1.28%	1.26E-23	7.66
417.3(a)(3)	Yes	17.21%	1.48%	2.03E-37	7.55
417.3(a)(4)	Yes	3.64%	1.05%	8.71E-09	8.41
417.3(b)(1)	Yes	13.33%	2.21%	3.92E-08	2.43
417.3(b)(2)	Yes	9.55%	1.17%	5.01E-09	2.97
417.3(b)(3)	Yes	4.10%	1.01%	5.43E-06	3.93
417.3(b)(4)	Yes	6.94%	2.98%	1.42E-02	1.21
417.3(c)	Yes	16.41%	8.46%	8.82E-03	2.49
417.5(a)(1)	Yes	0.78%	0.40%	1.88E-09	25.53
417.5(a)(2)	Yes	0.29%	0.11%	9.59E-07	25.54
417.5(a)(3)	Yes	0.44%	0.26%	3.71E-07	21.16
430.4(c)(2)	Yes	2.17%	0.00%	1.07E-05	5.93
430.4(c)(3)	Yes	2.30%	0.07%	2.09E-05	8.52

4.1.2 *Salmonella* in Intact Turkey

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 40 establishments with *Salmonella* testing data, of which 17 had 32 *Salmonella* positives and 23 did not have *Salmonella* positives. . There were 1,912 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the 6 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
381.65(a)	Yes	2.50%	0.59%	1.26E-05	7.60
381.65(f)	Yes	1.32%	0.73%	2.22E-06	31.47
381.91(a)	No	1.14%	0.07%	3.45E-02	4.34
381.91(b)	Yes	2.25%	0.72%	1.55E-02	5.76
381.94(a)*	Yes	2.25%	0.22%	1.35E-03	5.18
416.1	Yes	14.26%	7.18%	1.95E-14	10.33

4.1.3 *Salmonella* in Ground Beef

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,179 establishments with *Salmonella* testing data, of which 136 had 274 *Salmonella* positives and 1,043 did not have *Salmonella* positives. There were 15,020 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 15 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
310.18	Yes	3.57%	0.86%	6.03E-28	5.28
310.18(a)	No	5.06%	0.58%	2.39E-173	5.42
310.22(c)	No	0.51%	0.20%	1.41E-02	1.82
310.22(e)(1)	No	5.25%	0.92%	1.25E-08	0.71
416.1	Yes	3.89%	2.90%	6.76E-07	4.68
416.15(a)	Yes	10.44%	1.56%	8.99E-21	1.24
416.15(b)	Yes	4.66%	1.84%	1.21E-03	1.03
416.4(a)	Yes	7.15%	4.62%	1.29E-10	2.84
416.4(d)	Yes	11.24%	4.00%	5.68E-75	1.90
417.2(c)(4)	Yes	1.98%	0.16%	9.92E-231	5.53
417.3(a)(2)	Yes	3.17%	0.24%	2.76E-23	2.57
417.3(b)(1)	Yes	7.95%	2.14%	1.39E-03	1.10
417.3(b)(2)	Yes	6.71%	2.38%	1.63E-02	1.06
417.3(b)(4)	Yes	5.73%	0.95%	2.59E-06	0.54
417.5(a)(1)	Yes	0.47%	0.36%	1.62E-02	6.44

4.1.4 Salmonella in Intact Beef

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 354 establishments with Intact Beef *Salmonella* testing data, of which 52 had 78 *Salmonella* positives and 302 did not have *Salmonella* positives. There were 1,952 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 15 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
310.18	Yes	5.21%	1.69%	9.44E-06	11.40
310.18(a)	No	3.44%	0.86%	1.98E-68	1.00
310.22(c)	No	1.00%	0.31%	1.34E-03	6.45
310.22(e)(1)	No	6.45%	0.98%	9.82E-07	2.70
416.1	Yes	6.73%	3.46%	8.41E-23	4.15
416.13 Implementation of SOP's	No	0.99%	0.21%	2.38E-02	0.76
416.14	Yes	0.59%	0.33%	1.35E-03	7.54
416.3(c)	Yes	2.99%	1.12%	1.53E-02	2.18
416.4(a)	Yes	9.67%	7.29%	8.71E-05	0.77
416.4(d)	Yes	16.55%	6.47%	7.09E-51	1.32
417.2(c)(4)	Yes	1.63%	0.47%	6.06E-29	8.52
417.3(a)(1)	Yes	7.09%	2.05%	2.58E-03	1.09
417.3(a)(2)	Yes	0.72%	0.27%	6.33E-03	2.54
417.3(a)(4)	Yes	1.52%	0.23%	1.94E-02	2.06
417.5(f)	Yes	1.43%	0.13%	1.87E-03	1.64

4.1.5 *Salmonella* in Comminuted Chicken

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 117 establishments with Comminuted Chicken *Salmonella* testing data, of which 104 had 1,834 *Salmonella* positives and 13 did not have *Salmonella* positives. There were 3,082 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 7 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
416.1	Yes	13.56%	3.82%	1.08E-37	32.57
416.14	Yes	1.13%	0.29%	7.91E-10	43.51
416.16(a)	Yes	0.66%	0.17%	6.39E-10	58.78
416.4(a)	Yes	23.27%	5.18%	1.27E-49	20.39
416.4(d)	Yes	26.33%	5.32%	4.69E-52	20.67
417.2(c)(4)	Yes	2.07%	0.30%	1.61E-25	50.41
417.5(a)(3)	Yes	0.56%	0.28%	8.24E-3	47.05

4.1.6 *Salmonella* in Comminuted Turkey

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. There are 58 establishments with Comminuted Turkey *Salmonella* testing data, of which 43 had 342 *Salmonella* positives and 15 did not have *Salmonella* positives. There were 1,582 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the 8 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
416.1	Yes	6.97%	2.27%	2.60E-20	15.67
416.16(a)	Yes	0.39%	0.04%	1.83E-11	27.66
416.3(b)	Yes	3.44%	0.27%	1.69E-04	1.56
416.3(c)	Yes	2.93%	0.97%	1.81E-02	3.26
416.4(a)	Yes	17.50%	4.92%	1.12E-42	3.56
416.4(d)	Yes	22.63%	5.02%	2.82E-63	4.27
417.2(c)(4)	Yes	1.48%	0.21%	1.76E-18	28.77
417.5(a)(1)	Yes	0.63%	0.29%	1.37E-03	23.98

4.1.7 *Salmonella* in Ready to Eat

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,077 establishments with *Salmonella* testing data, of which 5 had 5 *Salmonella* positives and 2,072 did not have *Salmonella* positives. There were 12,203 total Ready to Eat *Salmonella* tests performed.

Table 4-8 presents the 2 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 8 Comparison of Noncompliance Rates 3 Months before a Ready to Eat *Salmonella* Positive with Those for Establishments with No Ready to Eat *Salmonella* Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
430.4(a)	Yes	1.92%	0.05%	2.84E-02	14.62
430.4(c)(2)	Yes	3.92%	0.07%	5.63E-04	13.83

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 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,319 establishments with *E. coli* O157:H7 testing data, of which 17 had 17 *E. coli* O157:H7 positives and 1,302 did not have *E. coli* O157:H7 positives. There were 16,094 total *E. coli* O157:H7 tests performed.

Table 4-9 presents the 5 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 9 Comparison of Noncompliance Rates 3 Months before an *E. coli* O157:H7 Positive with Those for Establishments with No *E. coli* O157:H7 Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
310.18(a)	No	2.66%	1.08%	1.86E-04	8.57
416.1	Yes	11.20%	3.13%	8.14E-19	10.57
416.4(d)	Yes	12.04%	5.30%	1.67E-05	5.12
417.2(c)(4)	Yes	0.73%	0.29%	1.53E-02	17.18

Regulation Verified	On FY2015 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	Cohen Effect Size
417.5(a)(3)	Yes	0.68%	0.28%	1.47E-02	20.16

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 non-intact beef products and product components. On June 4, 2012, FSIS began testing for these six non-O157 STECs in beef manufacturing trimmings. The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 342 establishments with non-O157 STEC testing data, of which 12 had 19 non-O157 STEC positives and 330 did not have non-O157 STEC positives. There were 2,665 total non-O157 STEC tests performed.

Table 4-10 presents the 8 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 10 Comparison of Noncompliance Rates 3 Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
310.18	Yes	12.55%	1.86%	1.43E-29	9.21
310.22(c)	No	1.32%	0.23%	6.19E-03	7.04
310.22(e)(1)	No	16.22%	1.22%	6.98E-06	3.10
310.22(e)(3)	No	5.88%	0.77%	3.00E-02	2.62
310.22(f)(2)	Yes	3.05%	0.17%	1.19E-04	4.57
416.14	Yes	0.94%	0.40%	1.34E-02	18.38
416.4(d)	Yes	15.87%	8.56%	1.01E-03	6.75
417.5(a)(1)	Yes	0.80%	0.39%	4.74E-02	17.78

4.3 *Listeria* monocytogenes

The purpose of this section is to investigate the relationship between the candidate regulations and *Listeria monocytogenes* positives. The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,085 establishments with *Listeria monocytogenes* testing data, of which 40 had 43 *Listeria monocytogenes* positives and 2,045 did not have *Listeria monocytogenes* positives. There were 12,713 total *Listeria monocyogenes* tests performed.

There are no regulations that had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 331 establishments with *Campylobacter* testing data, of which 129 had 903 *Campylobacter* positives and 202 did not have *Campylobacter* positives. There were 15,372 total *Campylobacter* tests performed.

Table 4-11 presents the 17 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 11 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Positive with Those for Establishments with No *Campylobacter* Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
318.2(a)	No	2.22%	0.08%	3.80E-03	1.65
381.1_Adulterated	Yes	7.81%	1.68%	1.51E-32	3.72
381.65(a)	Yes	1.97%	1.50%	2.99E-05	1.60
381.65(f)	Yes	1.22%	1.16%	1.93E-02	8.31
381.71(a)	No	14.86%	2.52%	2.37E-36	1.87
381.83	No	0.07%	0.02%	5.69E-09	22.26
381.91(a)	No	1.03%	0.20%	7.23E-08	0.61
416.14	Yes	1.02%	0.88%	2.58E-03	4.87
417.3(a)(1)	Yes	5.30%	1.20%	6.38E-20	4.94
417.3(a)(2)	Yes	0.68%	0.53%	4.03E-02	7.09
417.3(a)(3)	Yes	11.15%	1.42%	1.93E-63	4.63
417.3(a)(4)	Yes	1.79%	0.92%	4.81E-05	4.71
417.4(a)	Yes	22.86%	1.51%	5.70E-13	2.99
417.5(a)(1)	Yes	0.55%	0.44%	1.39E-03	1.57
417.5(a)(3)	Yes	0.37%	0.30%	1.03E-02	1.37
430.4(b)(2)	Yes	7.41%	1.19%	6.57E-04	1.78
430.4(c)(3)	Yes	0.33%	0.02%	8.16E-04	2.72

4.4.1 *Campylobacter* in Intact Chicken

The purpose of this section is to investigate the relationship between the candidate regulations and *Campylobacter* positives. The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 182 establishments with Intact Chicken *Campylobacter* testing data, of which 70 had 522 *Campylobacter* positives and 112 did not have *Campylobacter* positives. There were 8,804 total Intact Chicken *Campylobacter* tests performed

Table 4-12 presents the 13 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 12 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Intact Chicken Positive with Those for Establishments with No *Campylobacter* Intact Chicken Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
381.65(f)	Yes	1.40%	1.24%	2.14E-04	50.40
381.94(a)*	Yes	0.68%	0.06%	6.38E-07	1.02
416.16(a)	Yes	0.69%	0.54%	1.72E-04	4.51
417.2(c)	Yes	2.24%	0.34%	6.02E-08	3.02
417.3(a)(1)	Yes	13.12%	1.11%	9.88E-27	7.28
417.3(a)(2)	Yes	1.25%	0.48%	1.04E-09	13.47
417.3(a)(3)	Yes	16.67%	1.36%	1.03E-33	6.93
417.3(a)(4)	Yes	4.11%	0.88%	2.12E-12	7.89
417.3(b)(2)	Yes	5.11%	1.21%	2.17E-04	1.65
417.3(c)	Yes	26.32%	5.43%	8.60E-10	2.93
417.5(a)(1)	Yes	0.69%	0.42%	1.02E-07	10.34
417.5(a)(2)	Yes	0.21%	0.14%	8.20E-03	12.00
417.5(a)(3)	Yes	0.66%	0.21%	8.02E-38	11.37

4.4.2 *Campylobacter* in Intact Turkey

The purpose of this section is to investigate the relationship between the candidate regulations and *Campylobacter* positives. The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 40 establishments with *Campylobacter* testing data, of which 12 had 38 *Campylobacter* positives and 28 did not have *Campylobacter* positives. There were 1,911 total Intact Turkey *Campylobacter* tests performed.

Table 4-13 presents the 4 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 13 Comparison of Noncompliance Rates 3 Months before a *Campylobacter* Intact Turkey Positive with Those for Establishments with No *Campylobacter* Intact Turkey Positive

Regulation Verified	On FY2015 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	Cohen Effect Size
416.3(b)	Yes	9.23%	0.76%	5.46E-05	5.29
416.4(d)	Yes	30.37%	18.40%	3.73E-07	10.28
417.3(a)(2)	Yes	0.98%	0.40%	4.79E-02	5.87
417.3(a)(4)	Yes	6.67%	0.75%	7.29E-03	6.13

4.4.3 *Campylobacter* in Comminuted Chicken

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 118 establishments with Comminuted Chicken *Campylobacter* testing data, of which 53 had 333 *Campylobacter* positives and 65 did not have *Campylobacter* positives. There were 3,081 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-14 presents the 12 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
381.65(a)	Yes	2.45%	0.46%	8.73E-17	6.23
381.71(a)	No	28.11%	1.61%	4.05E-07	1.55
381.76(a)*	No	3.60%	0.41%	3.67E-20	32.78
381.91(b)	Yes	2.23%	0.00%	3.31E-03	3.89

Regulation Verified	On FY2015 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	Cohen Effect Size
416.1	Yes	12.36%	10.16%	1.07E-08	13.51
416.14	Yes	1.07%	0.28%	1.15E-29	15.48
416.15(a)	Yes	4.28%	1.44%	1.48E-06	4.61
416.3(b)	Yes	6.10%	2.40%	2.97E-04	0.86
416.4(a)	Yes	20.73%	16.44%	3.52E-10	9.59
416.4(d)	Yes	23.69%	18.18%	3.17E-15	7.23
417.2(c)(4)	Yes	1.53%	0.53%	1.74E-43	28.50
430.4(b)(3)	Yes	3.30%	0.44%	2.00E-02	1.56

4.4.4 *Campylobacter* in Comminuted Turkey

The noncompliance rate of each of the 134 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 58 establishments with Comminuted Turkey *Campylobacter* testing data, of which 7 had 10 *Campylobacter* positives and 51 did not have *Campylobacter* positives. There were 1,576 total Comminuted Turkey *Campylobacter* tests performed.

Table 4-15 presents the 7 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

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

Regulation Verified	On FY2015 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	Cohen Effect Size
381.65(f)	Yes	2.77%	0.64%	1.30E-21	39.58
381.91(b)	Yes	7.32%	0.91%	2.83E-04	8.81
416.3(c)	Yes	7.69%	1.85%	3.96E-02	4.80
416.4(a)	Yes	31.43%	11.77%	1.12E-07	11.21

Regulation Verified	On FY2015 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	Cohen Effect Size
416.4(d)	Yes	47.56%	12.52%	1.97E-14	12.08
417.2(c)(4)	Yes	4.28%	0.78%	6.26E-29	13.52
417.5(a)(1)	Yes	2.36%	0.41%	1.11E-10	21.24

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 134 candidate regulations used to select all other FY2016 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, 2014 to December 31, 2014. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,297 active meat and poultry establishments, of which 155 had 166 public health related NOIEs or suspensions and 5,142 did not have any public health related NOIEs or suspensions.

Table 4-16 presents the 40 regulations which had more than 30 verifications in a year, an effect size of 0.5 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, 2014 to December 31, 2014.

Table 4- 16 Comparison of Noncompliance Rates 3 Months before an Enforcement Action with Those for Establishments with No Enforcement Action

Regulation Verified	On FY2015 PHR List	Noncompliance Rate in 3 Months before a NOIE/ Suspension	Noncompliance Rate for Establishments with no NOIE/ Suspension	Two-Sided Fisher Exact p Value	Cohen Effect Size
301.2_Adulterated	Yes	17.43%	2.17%	6.81E-12	2.14
310.18	Yes	7.63%	1.41%	1.39E-36	5.37
310.18(a)	No	2.97%	0.93%	1.57E-13	7.24
310.22(c)	No	1.89%	0.22%	5.96E-08	3.11
310.22(e)(1)	No	10.23%	1.08%	7.60E-07	2.32
310.22(e)(4)(i)	Yes	1.92%	0.14%	4.63E-10	3.06
310.25(a)	Yes	2.73%	0.64%	8.16E-04	5.29
318.2(a)	No	1.22%	0.23%	2.15E-02	2.57
381.65(a)	Yes	5.88%	1.40%	2.29E-06	4.04
381.65(f)	Yes	1.88%	1.26%	1.60E-04	36.21
381.71(a)	No	48.48%	5.53%	5.66E-12	1.83
381.91(b)	Yes	5.68%	0.95%	1.71E-03	6.16
416.1	Yes	11.26%	4.42%	5.55E-77	9.51
416.12(c)	No	6.36%	0.28%	7.88E-12	2.22
416.12(d)	No	2.33%	0.33%	2.54E-04	2.03
416.14	Yes	0.98%	0.31%	5.52E-20	18.57
416.15(a)	Yes	8.73%	2.08%	6.80E-09	2.83
416.15(b)	Yes	15.36%	2.71%	7.95E-19	2.42
416.16(a)	Yes	0.51%	0.17%	5.41E-17	26.87
416.3(b)	Yes	2.15%	1.03%	3.21E-02	1.76
416.3(c)	Yes	2.42%	1.32%	3.56E-02	1.90
416.4(a)	Yes	12.15%	7.86%	7.59E-12	5.37
416.4(d)	Yes	17.25%	8.42%	4.44E-39	5.30
417.2(c)	Yes	2.29%	0.58%	1.01E-02	1.75
417.2(c)(4)	Yes	1.40%	0.73%	2.65E-12	9.10
417.3(a)(1)	Yes	35.24%	2.45%	3.90E-32	1.36
417.3(a)(2)	Yes	2.34%	0.63%	1.75E-07	2.24
417.3(a)(3)	Yes	28.57%	3.16%	7.38E-18	1.27
417.3(a)(4)	Yes	4.17%	1.19%	1.32E-03	1.58
417.3(b)(1)	Yes	19.35%	5.37%	5.93E-03	0.99
417.3(b)(3)	Yes	3.79%	1.03%	1.31E-02	1.31
417.3(b)(4)	Yes	14.29%	1.27%	5.26E-11	0.99
417.5(a)(1)	Yes	2.20%	0.36%	1.21E-80	13.29
417.5(a)(2)	Yes	1.08%	0.15%	9.27E-42	11.94
417.5(a)(3)	Yes	1.37%	0.32%	5.70E-42	13.58

Regulation Verified	On FY2015 PHR List	Noncompliance Rate in 3 Months before a NOIE/ Suspension	Noncompliance Rate for Establishments with no NOIE/ Suspension	Two-Sided Fisher Exact p Value	Cohen Effect Size
430.4(a)	Yes	0.66%	0.06%	2.58E-09	9.73
430.4(b)(2)	Yes	3.95%	1.05%	4.80E-02	1.59
430.4(b)(3)	Yes	10.95%	1.14%	1.08E-10	2.84
430.4(c)(2)	Yes	0.39%	0.07%	3.11E-04	9.22
430.4(c)(3)	Yes	0.45%	0.04%	4.61E-07	9.15

5.0 LIST OF FY2016 PHRS

The purpose of this section is to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2016 PHR list. Table 5-1 presents the list of 54 FY2016 PHRs. These 54 PHRs were selected since they were verified more than 30 times in a year, had an effect size of 0.5 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 54 FY2016 PHRs are composed of 6 regulations and 48 provisions of regulations. The 48 provisions fall under 21 different regulations. Thus, the 54 FY2016 PHRs represent 27 regulations, with the majority of FY2016 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 FY2016 PHRs

List of FY2016 PHRs	Description	On List of FY2015 PHRs	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Plants with no Pathogen Positive	Two-Sided Fisher Exact p Value	Cohen Effect Size
310.18	Contamination of carcasses, organs, or other parts	Yes	7.63%	1.41%	1.39E-36	5.37
416.1	Operate in a manner to prevent insanitary conditions	Yes	12.03%	5.02%	0.00E+00	11.60
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.96%	0.43%	2.73E-135	15.50
301.2_Adulterated	Adulterated	Yes	17.43%	2.17%	6.81E-12	2.14
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	No	3.76%	0.67%	3.29E-182	5.25
310.22(c)	Disposal of SRM	No	1.89%	0.22%	5.96E-08	3.11
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	No	4.91%	0.97%	1.03E-12	0.72

List of FY2016 PHRs	Description	On List of FY2015 PHRs	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Plants with no Pathogen Positive	Two-Sided Fisher Exact p Value	Cohen Effect Size
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation and disposition of SRMs	No	5.88%	0.77%	3.00E-02	2.62
310.22(e)(4)(i)	Maintain daily records	Yes	1.92%	0.14%	4.63E-10	3.06
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	3.05%	0.17%	1.19E-04	4.57
310.25(a)	Verification criteria for E. coli testing meat	Yes	2.73%	0.64%	8.16E-04	5.29
318.10(b)	Products requiring treatment to destroy trichinae	No	3.95%	0.64%	3.12E-02	0.59
318.2(a)	All products subject to reinspection by program employees	No	2.22%	0.08%	3.80E-03	1.65
381.1_Adulterated	Adulterated	Yes	7.19%	2.01%	1.65E-49	2.74
381.193(a)	Poultry not intended for human food in commerce	No	15.47%	2.50%	3.50E-02	2.67
381.65(a)	Clean and sanitary practices; products not adulterated	Yes	2.45%	0.46%	8.73E-17	6.23
381.65(f)	Zero-tolerance for visible fecal material entering chiller	Yes	2.77%	0.64%	1.30E-21	39.58
381.71(a)	Condemnation on ante mortem inspection	No	29.01%	1.97%	1.69E-182	1.42
381.76(a)*	Post-mortem inspection, when required, extent.	No	3.60%	0.41%	3.67E-20	32.78

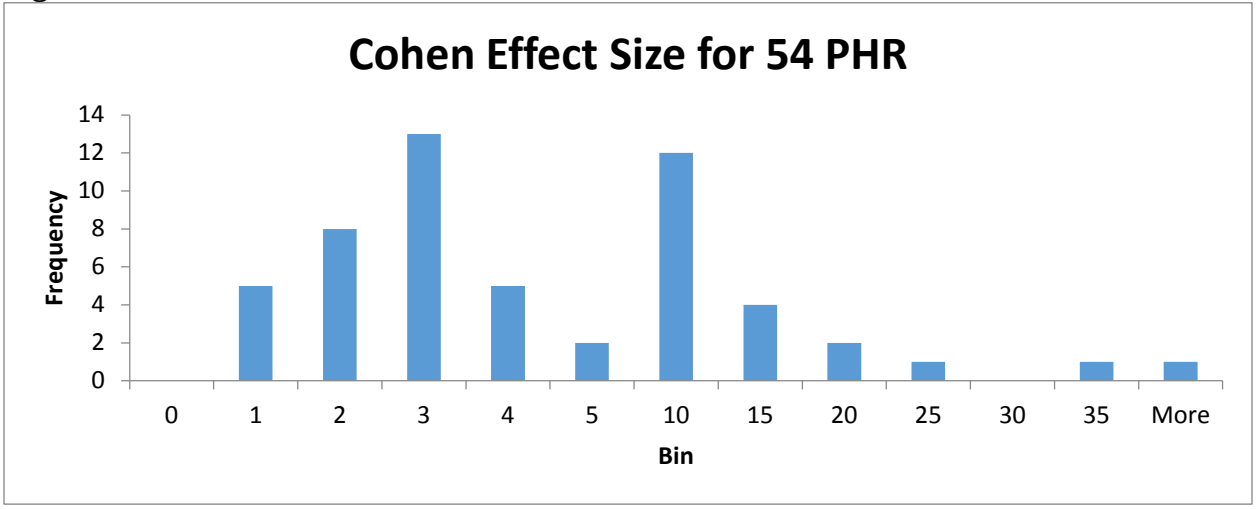
List of FY2016 PHRs	Description	On List of FY2015 PHRs	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Plants with no Pathogen Positive	Two-Sided Fisher Exact p Value	Cohen Effect Size
381.91(a)	Certain contaminated carcasses to be condemned	No	2.01%	0.27%	3.26E-21	1.42
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	7.32%	0.91%	2.83E-04	8.81
381.94(a)*	Verification criteria for E. coli testing poultry	Yes	0.68%	0.06%	6.38E-07	1.02
416.12(c)	plan identifies procedures for pre-op	No	6.36%	0.28%	7.88E-12	2.22
416.12(d)	plan list frequency for each procedure & responsible individual	No	2.33%	0.33%	2.54E-04	2.03
416.13 Implementation of SOP's	Implementation of SSOP	No	0.99%	0.21%	2.38E-02	0.76
416.15(a)	Appropriate corrective actions	Yes	10.44%	1.56%	8.99E-21	1.24
416.15(b)	Corrective action, procedures for	Yes	8.50%	4.26%	7.63E-32	6.08
416.16(a)	daily records required, responsible individual, initialed and dated	Yes	0.56%	0.21%	2.48E-187	20.44
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	3.87%	0.83%	3.97E-63	2.73

List of FY2016 PHRs	Description	On List of FY2015 PHRs	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Plants with no Pathogen Positive	Two-Sided Fisher Exact p Value	Cohen Effect Size
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	3.02%	1.24%	1.07E-31	4.38
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	21.08%	9.27%	0.00E+00	7.98
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	24.21%	9.95%	0.00E+00	8.10
417.2(c)	Contents of HACCP Plan	Yes	2.24%	0.34%	6.02E-08	3.02
417.2(c)(4)	List of procedures & frequency	Yes	2.00%	0.96%	0.00E+00	17.83
417.3(a)(1)	Identify and eliminate the cause	Yes	35.24%	2.45%	3.90E-32	1.36
417.3(a)(2)	CCP is under control	Yes	3.17%	0.24%	2.76E-23	2.57
417.3(a)(3)	Establish measures to prevent recurrence	Yes	15.05%	1.68%	1.86E-280	0.74
417.3(a)(4)	No adulterated product enters commerce.	Yes	4.11%	0.88%	2.12E-12	7.89
417.3(b)(1)	Segregate and hold the affected product	Yes	13.33%	2.21%	3.92E-08	2.43
417.3(b)(2)	Determine the acceptability of the affected product	Yes	9.55%	1.17%	5.01E-09	2.97
417.3(b)(3)	No adulterated product enters commerce	Yes	4.10%	1.01%	5.43E-06	3.93
417.3(b)(4)	Reassessment	Yes	14.29%	1.27%	5.26E-11	0.99
417.3(c)	Document corrective actions	Yes	26.32%	5.43%	8.60E-10	2.93

List of FY2016 PHRs	Description	On List of FY2015 PHRs	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Plants with no Pathogen Positive	Two-Sided Fisher Exact p Value	Cohen Effect Size
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	22.86%	1.51%	5.70E-13	2.99
417.4(b)	Reassessment of hazard analysis	Yes	0.75%	0.41%	4.51E-02	1.52
417.5(a)(1)	Written hazard analysis	Yes	2.20%	0.36%	1.21E-80	13.29
417.5(a)(2)	Written HACCP plan	Yes	1.08%	0.15%	9.27E-42	11.94
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	1.37%	0.32%	5.70E-42	13.58
417.5(f)	Official Review	Yes	1.43%	0.13%	1.87E-03	1.64
430.4(a)	Lm, post-lethality exposed RTE	Yes	0.66%	0.06%	2.58E-09	9.73
430.4(b)(2)	Alternative 2	Yes	3.99%	0.83%	2.73E-08	3.09
430.4(b)(3)	Alternative 3	Yes	10.95%	1.14%	1.08E-10	2.84
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes	2.17%	0.00%	1.07E-05	5.93
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Yes	0.45%	0.04%	4.61E-07	9.15

Figure 5-1 presents a histogram for the 54 PHRs of the Cohen effect sizes for difference between the non-compliance rate 3 months before a pathogen positive and the non-compliance rate of establishments with no pathogen positive. The average effect size is 6.2.

Figure 5- 1 Cohen Effect Sizes for 54 PHRs



Forty one of the previous 48 FY2015 PHRs are mapped into these 54 FY2016 PHRs. Thus, approximately 85% of the FY2015 PHRs are included in the FY2016 PHRs. There are 13 additional regulations that are not in the previous PHR list (See Appendix E).

Table 5-2 lists the number of regulations triggered by different events for inclusion in the FY2016 PHR list. Most regulations were triggered by multiple events.

Table 5- 2 Events That Triggered Inclusion of a Regulation in the FY2016 PHR list

Type of Event	Number of Regulations	Percent
Campylobacter	16	7.84%
Campylobacter Comminuted Chicken	12	5.88%
Campylobacter Comminuted Turkey	7	3.43%
Campylobacter Intact Chicken	13	6.37%
Campylobacter Intact Turkey	4	1.96%
Enforcement Actions	40	19.61%
NonO157 STEC	8	3.92%
O157	5	2.45%
Salmonella	30	14.71%
Salmonella Ground Beef	15	7.35%
Salmonella Comminuted Chicken	7	3.43%
Salmonella Comminuted Turkey	8	3.92%
Salmonella Intact Beef	15	7.35%
Salmonella Intact Chicken	16	7.84%
Salmonella Intact Turkey	6	2.94%
Salmonella RTE	2	0.98%
Total	204	100.00%

There were fourteen regulations triggered by a single type of event. Five were from enforcement actions, three were from *Salmonella* All Products, two were from NonO157 STEC All Products, two were from *Salmonella* Intact Beef and one each were from *Campylobacter* All Products and *Campylobacter* Comminuted Chicken. Table 5-3 presents the regulations triggered for inclusion in the FY2016 PHR list by only single event type.

Table 5- 3 Regulations Triggered for Inclusion in the FY2016 PHR List by Only a Single Event

Regulations Triggered by Single Event	Event
301.2_Adulterated	Enforcements
310.22(e)(3)	NonO157
310.22(e)(4)(i)	Enforcements
310.22(f)(2)	NonO157
310.25(a)	Enforcements
318.10(b)	Salmonella
381.193(a)	Salmonella
381.76(a)*	Campylobacter Comminuted Chicken
416.12(c)	Enforcements
416.12(d)	Enforcements
416.13 Implementation of SOP's	Salmonella Intact Beef
417.4(a)	Campylobacter
417.4(b)	Salmonella
417.5(f)	Salmonella Intact Beef

6.0 CUT POINTS FOR FY2016 PHRS

The FY2016 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 FY2016 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 FY2016 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 40 verifications and at least one non-compliance were considered when developing cut points.

To determine a set of annual FY2016 cut points, the mean and standard deviation of the natural log transformed non-zero FY2016 PHR rate (for establishments having more than 40 verifications in the past 90 days and at least one non-compliance) for each of four quarters and each of the two types of establishment operation is computed (the log transform of the non-zero FY2016 PHR rates is taken to obtain an approximately normal distribution). 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 FY2016 PHR Rate

	Mean of Natural Log FY2016 PHR Rate			**Standard Deviation of FY2016 PHR Rate**	
Mean	Combination	Processing		Combination	Processing
Jan-Mar 2014	-4.55	-4.92		1.11	0.98
Apr-Jun 2014	-4.54	-4.92		1.11	0.98
July-Sep 2014	-4.63	-4.94		1.11	0.96
Oct-Dec 2014	-4.66	-5.05		1.09	0.92
Average	-4.60	-4.96		1.11	0.96

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 -4.96 + 2*0.96 = -4.96 + 1.92 = -3.04. The cut point of the original, non-transformed PHR non-compliance data is the antilog of -3.04 or Exp (-3.04) = 4.80%. Table 6-2 presents the FY2016 PHR upper cut points for each of the two establishment operation types. The FY2015 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 2016.

Table 6- 2 FY2016 PHR Tier 1 Cut Points

Operation Type	FY2016 PHR Cut Points	FY2015 PHR Cut Points
Processing	4.80%	6.55%
Combination	9.25%	9.37%

Table 6-3 presents the number of establishments in each Tier based solely on the FY2016 PHR criterion and the cut points in Table 6-2. When applying the cut points to establishments with less than 40 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 FY2016 PHRs, 56 establishments are in Tier 1 and candidates to receive for cause FSAs. Table 6-3 is based on regulatory non-compliances for the period December 1, 2014 – February 28, 2015.

Table 6- 3 Tier Classification of Establishments Based Solely on the PHR Criterion

Classification	Number of Establishments
Tier 1	56
Tier 2	115
Tier 3	4,848
Total	5,019

Table 6-4 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 FY2016 PHRs, 49 processing establishments are Tier 1 and are candidates to receive for cause FSAs. Table 6-4 is based on regulatory non-compliances during December1, 2014 – February 28, 2015.

Table 6- 4 Tier Classification of Establishments Based on Operation Type and Only the PHR Criterion

Classification	Processing	Combination
Tier 1	49	7
Tier 2	88	27
Tier 3	3,849	999
Total	3,986	1,033

Table 6-5 presents the number of establishments in each Tier based on all seven decision criteria, including the PHR criterion. The time period used for calculating the noncompliance rate of the PHRs was December 1, 2014 – February 28, 2015.

Table 6- 5 Tier Classification of Establishments Based on the all Seven Decision Criteria

Classification	Processing	Combination	Total
Tier 1	63	7	70
Tier 2	88	26	114
Tier 3	3,849	1,000	4,849
Total	4,000	1,033	5,033

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 FSA. Table 6-6 presents the number of establishments without an FSA in the past six months in each Tier based on all seven decision criteria. The time period used for calculating the noncompliance rate of the PHRs was December 1, 2014 – February 28, 2015. Sixty establishments would receive a "for cause" FSA based on this data. The district may schedule additional for cause FSAs at additional establishments based on other considerations.

Table 6- 6 Tier Classification of Establishments without an FSA in Past Six Months Based on the all Seven Decision Criteria

Classification	Processing	Combination	Total
Tier 1	53	7	60
Tier 2	74	22	96
Tier 3	3,691	954	4,645
Total	3,818	983	4,801

7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting 9 CFR regulations used to prioritize certain 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 FY2016 PHRs has 54 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. Eighty five percent of the regulations on the FY2015 PHR list are also on the FY2016 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. Table 7-1 presents the FY2016 PHR upper 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 FY2015 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 FY2016 PHR Upper Cut Points

Operation Type	FY2016 PHR Cut Points	FY2015 PHR Cut Points
Processing	4.80%	6.55%
Combination	9.25%	9.37%

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: FY2016 PHR REGULATIONS

Table A-1 presents the list of fifty four FY2016 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates three months before a pathogen positive or enforcement action 5.4 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

Table A-1 List of FY2016 PHRs

List of FY2016 PHRs	Description
310.18	Contamination of carcasses, organs, or other parts
416.1	Operate in a manner to prevent insanitary conditions
416.14	Evaluate effectiveness of SSOP's & maintain plan
301.2_Adulterated	Adulterated
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
310.22(c)	Disposal of SRM
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation,and disposition of SRMs
310.22(e)(4)(i)	Maintain daily records
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
310.25(a)	Verification criteria for E. coli testing meat
318.10(b)	Products requiring treatment to destroy trichinae
318.2(a)	All products subject to reinspection by program employees
381.1_Adulterated	Adulterated
381.193(a)	Poultry not intended for human food in commerce
381.65(a)	Clean and sanitary practices; products not adulterated
381.65(f)	Zero-tolerance for visible fecal material entering chiller
381.71(a)	Condemnation on ante mortem inspection
381.76(a)*	Post-mortem inspection, when required, extent.
381.91(a)	Certain contaminated carcasses to be condemned
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
381.94(a)*	Verification criteria for E. coli testing poultry
416.12(c)	plan identifies procedures for pre-op
416.12(d)	plan list frequency for each procedure & responsible individual
416.13 Implementation of SOP's	Implementation of SSOP
416.15(a)	Appropriate corrective actions
416.15(b)	Corrective action, procedures for
416.16(a)	daily records required, responsible individual, initialed and dated

List of FY2016 PHRs	Description
416.3(b)	Constructed, located & operated in a manner that does not deter inspection
416.3(c)	Receptacles for storing inedible material must identify permitted use
416.4(a)	Food contact surface, cleaning & sanitizing as frequency
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
417.2(c)	Contents of HACCP Plan
417.2(c)(4)	List of procedures & frequency
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(a)(4)	No adulterated product enters commerce.
417.3(b)(1)	Segregate and hold the affected product
417.3(b)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions
417.4(a)	Adequacy of HACCP in controlling food safety hazards
417.4(b)	Reassessment of hazard analysis
417.5(a)(1)	Written hazard analysis
417.5(a)(2)	Written HACCP plan
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
417.5(f)	Official Review
430.4(a)	Lm, post-lethality exposed RTE
430.4(b)(2)	Alternative 2
430.4(b)(3)	Alternative 3
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment

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 FY2016 PHRs is presented in Appendix A. The list of FY2015 PHRs is presented in FSIS (2014).

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):

- Any establishment with a PHR rate that is less than the lower cut point for all establishments with the same establishment type would continue to receive routine inspection procedures and routine FSAs every four years. These establishments are performing better on average than their peers with respect to compliance with FSIS regulations.
- Establishments with a PHR rate between the lower and upper cut points for all establishments with the same establishment type would continue to receive routine inspection procedures and, in addition, be prioritized for routine FSAs.
- Establishments with a PHR rate greater than the upper cut point for establishments with the same establishment type that have not had a FSA in the last six months would continue to receive routine inspection procedures plus a for-cause FSA.

APPENDIX C: FY2016 CANDIDATE REGULATIONS

Table C-1 presents the list of 134 candidate regulations. The noncompliance rates in Table C-1 are based on PHIS data for January 1, 2014 through December 31, 2014.

Table C- 1 FY2016 Candidate regulations

FY2016 Candidate regulations	FY2015 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
301.2_Adulterated	Yes		10,736	267	2.49%
304.3(a)			849	1	0.12%
304.3(c)			1,099	11	1.00%
309.2(a)			857	9	1.05%
309.3			160	-	0.00%
309.4			131	1	0.76%
309.5			21	-	0.00%
309.9			19	-	0.00%
310.18	Yes	Yes	111,174	1,383	1.24%
310.18(a)		Yes	177,448	1,367	0.77%
310.18(b)			14,372	3	0.02%
310.22(b)			10,970	30	0.27%
310.22(c)		Yes	63,633	145	0.23%
310.22(d)(2)			191	-	0.00%
310.22(e)(1)			14,763	164	1.11%
310.22(e)(2)			7,373	64	0.87%
310.22(e)(3)			9,253	58	0.63%
310.22(e)(4)(i)	Yes		114,717	267	0.23%
310.22(f)(2)	Yes		24,302	35	0.14%
310.22(g)(1)			2,520	5	0.20%
310.22(g)(4)			2,240	11	0.49%
310.25(a)	Yes		30,517	250	0.82%
310.25(b)			335	1	0.30%
310.25(b)(3)(ii)			262	-	0.00%
310.3	Yes		3,778	152	4.02%
311.16			123	6	4.88%
311.17			133	1	0.75%
311.24			10	-	0.00%
315.2			106	-	0.00%
316.6			11,264	69	0.61%
317.24(a)			4,885	17	0.35%
318.1(b)			91,453	23	0.03%
318.10(b)			2,384	15	0.63%
318.10(c)(1)			2,968	5	0.17%
318.10(c)(2)			976	4	0.41%

FY2016 Candidate regulations	FY2015 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
318.10(c)(3)			629	4	0.64%
318.14(a)			179	2	1.12%
318.14(b)			947	-	0.00%
318.14(c)			52	-	0.00%
318.16(b)			436	-	0.00%
318.17(a)(1)(2)			4,218	15	0.36%
318.17(b)			915	3	0.33%
318.17(c)			41	-	0.00%
318.2(a)			50,886	115	0.23%
318.2(d)	Yes		8,162	35	0.43%
318.23(b)(1)			595	11	1.85%
318.23(b)(3)			20	2	10.00%
318.23(c)(1)			142	1	0.70%
318.23(c)(2)			19	-	0.00%
318.23(c)(4)			45	-	0.00%
318.23(c)(5)			23	-	0.00%
318.24			2,147	6	0.28%
318.303		Yes	8,165	8	0.10%
318.308		Yes	4,636	9	0.19%
318.6(b)(1)			4,238	1	0.02%
318.6(b)(4)			7,617	-	0.00%
318.6(b)(6)			12,089	1	0.01%
318.6(b)(8)			396	-	0.00%
319.5(b)			118	-	0.00%
354.242(b)			135	1	0.74%
354.242(h)			52	-	0.00%
354.243(a)			27	-	0.00%
381.1_Adulterated	Yes		14,401	254	1.76%
381.144(a)			1,926	2	0.10%
381.150(a)			2,072	26	1.25%
381.150(c)			115	2	1.74%
381.150(d)			9	1	11.11%
381.151(a)			64	1	1.56%
381.193(a)			141	7	4.96%
381.22(a)			387	-	0.00%
381.22(b)			1,378	6	0.44%
381.22(c)	Yes		421	2	0.48%
381.310		Yes	4,677	1	0.02%
381.311		Yes	4,550	-	0.00%
381.37(a)			1,892	9	0.48%

FY2016 Candidate regulations	FY2015 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
381.65(a)	Yes		85,204	1,192	1.40%
381.65(f)	Yes	Yes	685,989	8,601	1.25%
381.71(a)			4,681	289	6.17%
381.72(a)			255	-	0.00%
381.72(b)			3	-	0.00%
381.76(a)*			24,800	543	2.19%
381.83	Yes		207,242	64	0.03%
381.85			414	-	0.00%
381.91(a)		Yes	11,771	36	0.31%
381.91(b)	Yes	Yes	21,658	221	1.02%
381.94(a)*	Yes		10,855	40	0.37%
381.94(b)	Yes		552	2	0.36%
381.94(b)(3)(ii)			94	-	0.00%
416.1	Yes	Yes	671,607	27,662	4.12%
416.12(c)			48,437	139	0.29%
416.12(d)			60,414	201	0.33%
416.13 Implementation of SOP's			10,199	23	0.23%
416.14	Yes	Yes	1,572,946	4,793	0.30%
416.15 Corrective Actions			742	7	0.94%
416.15(a)	Yes	Yes	60,614	1,285	2.12%
416.15(b)	Yes	Yes	43,360	1,201	2.77%
416.16(a)	Yes	Yes	2,825,726	5,214	0.18%
416.3(b)	Yes	Yes	72,359	717	0.99%
416.3(c)	Yes	Yes	70,304	928	1.32%
416.4(a)	Yes	Yes	310,531	23,099	7.44%
416.4(d)	Yes	Yes	293,529	24,001	8.18%
416.5(c)	Yes	Yes	35,683	18	0.05%
416.6			2,944	170	5.77%
417.2(c)	Yes		35,631	220	0.62%
417.2(c)(4)	Yes	Yes	1,389,469	9,076	0.65%
417.3 Corrective actions			454	-	0.00%
417.3(a)			1,516	3	0.20%
417.3(a)(1)	Yes	Yes	30,011	790	2.63%
417.3(a)(2)	Yes	Yes	148,936	883	0.59%
417.3(a)(3)	Yes	Yes	26,634	876	3.29%
417.3(a)(4)	Yes	Yes	47,735	544	1.14%
417.3(b)(1)	Yes	Yes	3,943	203	5.15%
417.3(b)(2)	Yes	Yes	4,750	189	3.98%

FY2016 Candidate regulations	FY2015 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs[1]	NC[1] Rate
417.3(b)(3)	Yes	Yes	18,989	184	0.97%
417.3(b)(4)	Yes	Yes	18,407	247	1.34%
417.3(c)	Yes	Yes	5,582	380	6.81%
417.4(a)	Yes	Yes	8,276	269	3.25%
417.4(a)(1)	Yes	Yes	3,828	133	3.47%
417.4(a)(3)			3	-	0.00%
417.4(b)	Yes	Yes	21,427	110	0.51%
417.5(a)(1)	Yes	Yes	1,290,988	4,708	0.36%
417.5(a)(2)	Yes	Yes	1,196,755	1,967	0.16%
417.5(a)(3)	Yes	Yes	1,453,547	5,102	0.35%
417.5(f)	Yes		92,466	110	0.12%
417.6			529	164	31.00%
430.4(a)	Yes	Yes	291,241	211	0.07%
430.4(b)(1)			1,637	3	0.18%
430.4(b)(2)	Yes		13,117	139	1.06%
430.4(b)(3)	Yes		25,156	336	1.34%
430.4(c)(2)	Yes	Yes	276,296	240	0.09%
430.4(c)(3)	Yes	Yes	294,820	167	0.06%
430.4(c)(4)			2,524	17	0.67%
430.4(c)(5)			5,417	32	0.59%
430.4(c)(6)			5,945	116	1.95%

1. NC = Noncompliance

APPENDIX D: STEPS USED TO DEVELOP PHR LIST

The following steps are used to determine the list of PHRs:

1. Obtain the PHIS noncompliance data for the period October 1, 2013 to December 31, 2014.
2. Develop the list of establishments with at least one *Salmonella* positive in the four month period January 1, 2014 to December 31, 2014.
3. For each candidate regulation and each establishment on the list in step 2 above, determine the number of compliant and noncompliant inspection findings three months before the occurrence of a *Salmonella* positive.
4. For each candidate regulation, sum the number of compliant and noncompliant verification inspections three months before the occurrence of a *Salmonella* positive across all establishments and all *Salmonella* positives. The result is the total number of compliant and noncompliant verification inspections for a given candidate regulation.
5. Repeat the above process for *E. coli* O157:H7, Non- O157 STEC, *Lm, Campylobacter* and enforcement actions.
6. Remove any regulations that have 30 or less total inspections in the three months before a positive or for establishments without any positives.
7. For each candidate regulation, determine if the noncompliance rate three months before the occurrence of a *Salmonella* positive is statistically higher (as measured by a two-sided Fisher Exact $p \leq 0.05$) than the noncompliance rate for establishments without any *Salmonella* positives.
8. For each candidate regulation, determine if the Cohen effect size is 0.5 or greater.
9. The final list of FY2015 PHRs is the combination of the lists for *Salmonella*, *E. coli* O157:H7, Non- O157 STEC, *Lm, Campylobacter* and enforcement actions determined through the above steps.

APPENDIX E: COMPARISON OF FY2016 PHR LIST WITH FY2015 PHR LIST

Table E-1 presents a comparison of the FY2016 PHR list with the FY2015 PHR list (See FSIS (2014) for the FY2015 PHR list)). Eighty five percent of the regulations on the FY2015 PHR list are also on the FY2016 PHR list.

Table E- 1 Comparison of FY2016 Public Health Regulations with FY2015 PHR List

List of FY2016 PHRs	Description	On FY2015 PHR List
310.18	Contamination of carcasses, organs, or other parts	Yes
416.1	Operate in a manner to prevent insanitary conditions	Yes
416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes
301.2_Adulterated	Adulterated	Yes
310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	No
310.22(c)	Disposal of SRM	No
310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	No
310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation,and disposition of SRMs	No
310.22(e)(4)(i)	Maintain daily records	Yes
310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes
310.25(a)	Verification criteria for E. coli testing meat	Yes
318.10(b)	Products requiring treatment to destroy trichinae	No
318.2(a)	All products subject to reinspection by program employees	No
381.1_Adulterated	Adulterated	Yes
381.193(a)	Poultry not intended for human food in commerce	No
381.65(a)	Clean and sanitary practices; products not adulterated	Yes
381.65(f)	Zero-tolerance for visible fecal material entering chiller	Yes
381.71(a)	Condemnation on ante mortem inspection	No
381.76(a)*	Post-mortem inspection, when required, extent.	No
381.91(a)	Certain contaminated carcasses to be condemned	No
381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes
381.94(a)*	Verification criteria for E. coli testing poultry	Yes
416.12(c)	plan identifies procedures for pre-op	No

List of FY2016 PHRs	Description	On FY2015 PHR List
416.12(d)	plan list frequency for each procedure & responsible individual	No
416.13 Implementation of SOP's	Implementation of SSOP	No
416.15(a)	Appropriate corrective actions	Yes
416.15(b)	Corrective action, procedures for	Yes
416.16(a)	daily records required, responsible individual, initialed and dated	Yes
416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes
416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes
416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes
417.2(c)	Contents of HACCP Plan	Yes
417.2(c)(4)	List of procedures & frequency	Yes
417.3(a)(1)	Identify and eliminate the cause	Yes
417.3(a)(2)	CCP is under control	Yes
417.3(a)(3)	Establish measures to prevent recurrence	Yes
417.3(a)(4)	No adulterated product enters commerce.	Yes
417.3(b)(1)	Segregate and hold the affected product	Yes
417.3(b)(2)	Determine the acceptability of the affected product	Yes
417.3(b)(3)	No adulterated product enters commerce	Yes
417.3(b)(4)	Reassessment	Yes
417.3(c)	Document corrective actions	Yes
417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes
417.4(b)	Reassessment of hazard analysis	Yes
417.5(a)(1)	Written hazard analysis	Yes
417.5(a)(2)	Written HACCP plan	Yes
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes
417.5(f)	Official Review	Yes
430.4(a)	Lm, post-lethality exposed RTE	Yes
430.4(b)(2)	Alternative 2	Yes
430.4(b)(3)	Alternative 3	Yes

List of FY2016 PHRs	Description	On FY2015 PHR List
430.4(c)(2)	Lm, documentation that supports decision in hazard analysis	Yes
430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment	Yes

There are seven regulations from the FY2015 PHR list that no longer appear in the FY2016 PHR list. These seven regulations are shown in Table E-2.

Table E- 2 Regulation from the FY2015 PHR list no longer on the FY2016 PHR list

Regulation	Description
310.3	Carcasses and parts in certain instances to be retained.
381.83	(HIMP ONLY) Septicemia or toxemia
318.2(d)	Removal of U.S. retained by authorized Program employees only
381.22(c)	Conduct hazard analysis & develop HACCP plan for new product
381.94(b)	Exceeds Pathogen reduction performance standards for Salmonella
416.5(c)	Employees who appears to have any abnormal source of microbial contamination
417.4(a)(1)	Initial validation

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

The purpose of this Appendix is to explain how the 54 PHRs are used as one component of the overall decision tree methodology used to schedule FSAs.

F-1 Calculating the Cut Points

This section discusses the derivation of the cut-points for the *PHR* noncompliance criteria.

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 F-1 and Figure F-2 present histograms for processing and combination for the log transformed non-zero PHR noncompliance data. Only establishments with greater than or equal to 40 verifications and at least one non-compliance are considered.

Figure F- 1 Log Transformed Non-zero Non-Compliance Rates of PHRs with 40 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Processing Establishments

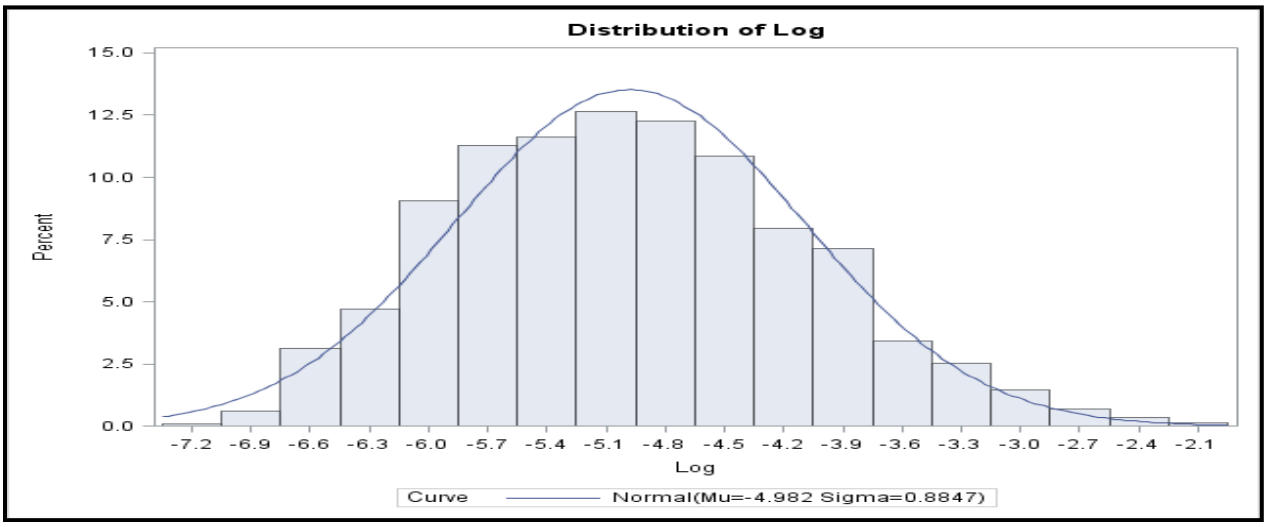
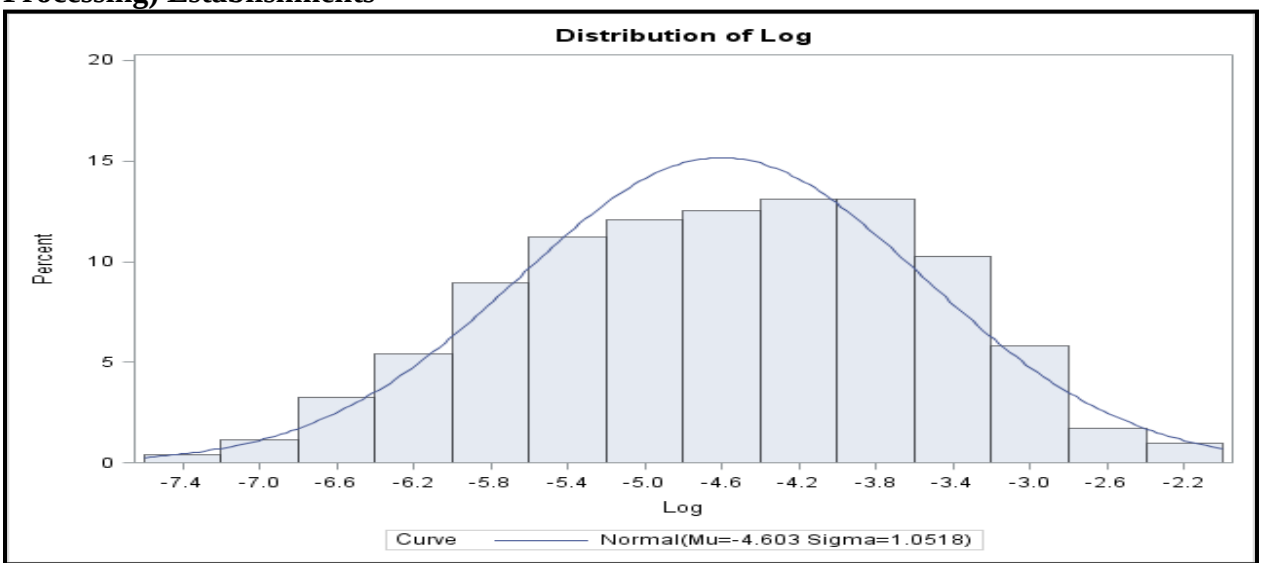


Figure F- 2 Regulatory Non-Compliance Rate of PHRs with 40 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Both (Slaughter and Processing) Establishments



These distributions are approximately normally distributed. The Shapiro-Wilk test for normality W statistics for the two distributions are 0.991 and 0.990, respectively, which indicates near-normality (The test statistic W takes values between 0 and 1, with values close to 1 indicating near-normality).

A visual test for near-normality is the Q-Q plot where the quantiles of a dataset are plotted against the quantiles that would be expected from a normal distribution. If the two set of points come from a population with the same distribution, the points should fall approximately along a 45^0 line.

Figure F- 3 Q-Q Plot of the Log Transformed Non-Zero Non-Compliance Rates of PHRs with 40 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Processing Establishments

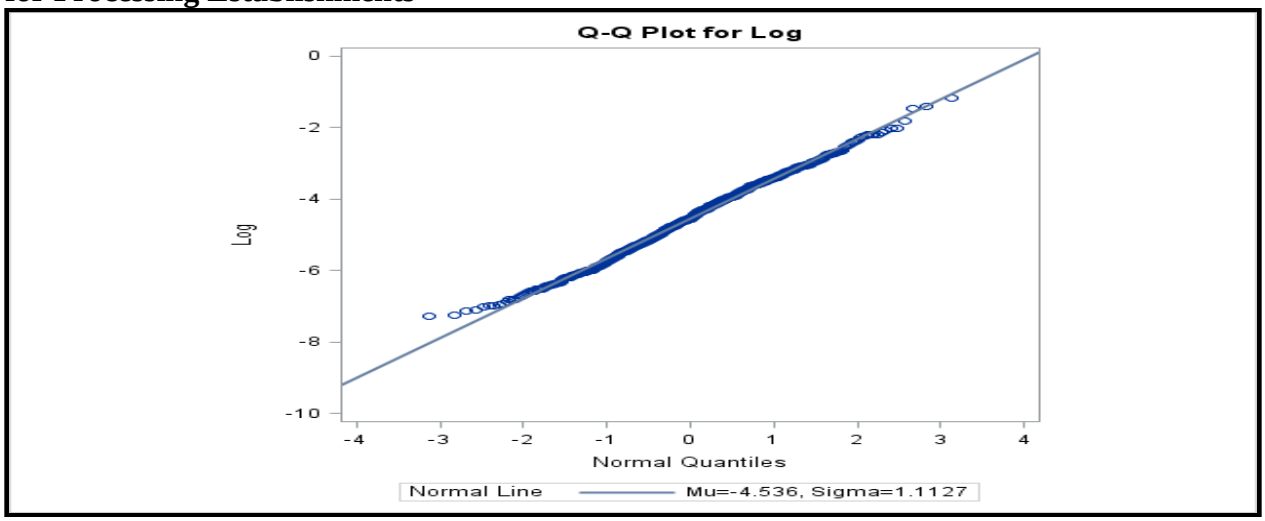
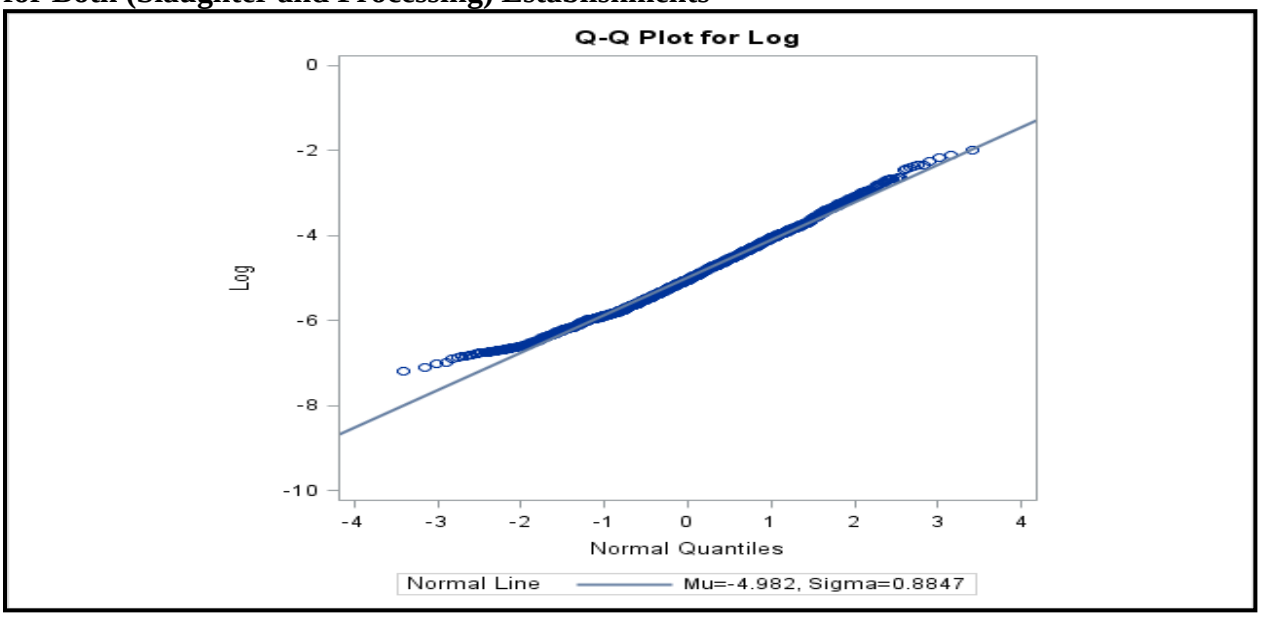


Figure F- 4 Q-Q Plot of the Log Transformed Non-Zero Non-Compliance Rates of PHRs with 40 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Both (Slaughter and Processing) Establishments



For each of the two plant types, the mean and standard deviation of the log transformed non-zero PHR noncompliance rates (hereafter called the PHR rate) are calculated separately for all establishments with 40 or more PHR verification inspections and at least one noncompliance.

For each of the two plant types, there are two cut points for the log-transformed data: one is two times the standard deviation plus the mean of the log transformed non-zero PHR rate and the

other is one and a half times the standard deviation plus the mean of the log transformed non-zero PHR rate.

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 F-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. Across the four quarters, there is an average of 83 Tier 1 establishments per month based solely on the PHR criteria. The subset of the 83 establishments that have not had an FSA in the past 6 months will receive a for cause FSA.

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

	Number of Establishments	Mean	Standard Deviation			Tier Distribution (Number of Establishments)
Q1CY2014					Tier1	90
Both	1,020	-4.55	1.11		Tier2	157
Processing	4,018	-4.92	0.98		Tier3	4,791
Q2CY2014					Tier1	90
Both	1,020	-4.54	1.11		Tier2	155
Processing	4,018	-4.92	0.98		Tier3	4,793
Q3CY2014					Tier1	84
Both	1,031	-4.63	1.11		Tier2	137
Processing	4,020	-4.94	0.96		Tier3	4,830
Q4CY2014					Tier1	66
Both	1,039	-4.66	1.09		Tier2	132
Processing	3,994	-5.05	0.92		Tier3	4,835

Table F-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 F-1. Table F-3 shows the Tier distribution (based only on PHR non-compliances) using the cut points in Table F-2. There are 56 for cause FSAs in the February 2015 ranking based on PHRs only.

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

	Combination	Processing
Mean	-4.60	-4.96
Standard Deviation	1.11	0.96

Table F- 3 February 2015 Tier Distribution Based on the PHR Criteria Only

Classification	Plants
Tier 1	56
Tier 2	115
Tier 3	4,848
Total	5,019

F-2 Scheduling FSAs Using Seven Criteria

Table F-4 presents the Tier distribution of establishments when using all seven decision criteria, including the FY2016 PHR regulations and the cut points defined from Table F-2. The table is derived from data for the three month period December 1, 2014 – February 28, 2015. The second column represents the number of establishments in each of the Tier categories. When scheduling FSAs, establishments that have had an FSA in the past six months are not automatically scheduled for another FSA. 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 FSA. The third column in Table F-4 represents to number of establishments in each of the Tier 1 categories when establishments with an FSA in the past six months are removed.

Table F- 4 FSA Scheduling for February 2015 Using All Seven Decision Criteria

	Number Plants in Each Tier Using all 7 Decision Criteria	Number Plants in Each Tier without FSA in Past 6 Months
Tier 1	70	60
Tier 2	114	96
Tier 3	4,849	4,645
Total	5,033	4,801

Table F-5 presents the distribution of Tier 1 establishments among different establishment types. There is no statistically significant difference between the percentage of Tier 1 processing and combination establishments with their representation among all establishments.

Table F- 5 Distribution of Tier 1 Establishments among Different Plant Types

Plant Type	Number Plants	Percent Plants	Number Tier 1 Plants	Percent Tier 1 Plants	Statistical Difference with Representation Among All Plants
Processing	4,000	79.48%	63	90.00%	Yes
Combination	1,033	20.52%	7	10.00%	Yes
Totals	5,033	100.00%	70	100.00%	

Table F-6 presents the distribution of Tier 1 establishments (as determined using only the PHR criteria) among different product categories. There is a statistically significant difference between the percentage of establishments producing a given product category and the percentage

of establishments in Tier 1 for that product category in Beef Slaughter, Pork Slaughter and Ground Pork.

The product type "Poultry Combination" was included since it was suspected that establishments that slaughter only or slaughter and process poultry may receive a higher percentage of Tier 1 classifications. The analysis indicates that there is not a statistically significant difference between the percentage of establishments classified as Poultry Combination and the percentage of establishments in Tier 1 for that product category

Table F- 6 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	Statistical Difference
Chicken Slaughter	197	3.93%	2	3.57%	No
Turkey Slaughter	51	1.02%	-	0.00%	No
Beef Slaughter	621	12.37%	2	3.57%	Yes
Pork Slaughter	589	11.74%	-	0.00%	Yes
Ground Beef	1,597	31.82%	12	21.43%	No
Comminuted Chicken	803	16.00%	10	17.86%	No
Comminuted Turkey	313	6.24%	3	5.36%	No
Ground Pork	1,721	34.29%	11	19.64%	Yes
RTE	2,495	49.71%	31	55.36%	No
Poultry Combination	395	7.87%	4	7.14%	No
Total Number of Establishments	5,019		56		