

**FY2017 Public Health Regulations**

**June 2016**

## Table of Contents

Summary .....	6
1.0 Introduction.....	10
2.0 Selection of PHRs .....	12
2.1 Criteria for Selection of Candidate Regulations .....	12
2.2 Relationship with Pathogen Positives.....	13
3.0 Candidate Regulations .....	15
4.0 Relationship Between Candidate regulations and Pathogen Positives .....	16
4.1 <i>Salmonella</i> .....	17
4.1.1 <i>Salmonella</i> in Intact Chicken .....	18
4.1.2 <i>Salmonella</i> in Intact Turkey.....	19
4.1.3 <i>Salmonella</i> in Ground Beef.....	19
4.1.4 <i>Salmonella</i> in Intact Beef.....	20
4.1.5 <i>Salmonella</i> in Comminuted Chicken .....	21
4.1.6 <i>Salmonella</i> in Comminuted Turkey.....	22
4.1.7 <i>Salmonella</i> in Intact Pork.....	23
4.1.8 <i>Salmonella</i> in Ground Pork.....	23
4.1.9 <i>Salmonella</i> in Chicken Parts .....	24
4.1.10 <i>Salmonella</i> in Ready to Eat.....	25
4.2 <i>E. Coli</i> .....	25
4.2.1 <i>E. coli</i> O157:H7 .....	25
4.2.2 Non-O157 STEC.....	26
4.3 <i>Listeria monocytogenes</i> .....	27
4.4 <i>Campylobacter</i> .....	27
4.4.1 <i>Campylobacter</i> in Intact Chicken .....	28
4.4.2 <i>Campylobacter</i> in Intact Turkey .....	29
4.4.3 <i>Campylobacter</i> in Comminuted Chicken.....	30
4.4.4 <i>Campylobacter</i> in Comminuted Turkey .....	30
4.4.5 <i>Campylobacter</i> in Chicken Parts .....	31
4.5 Enforcement Actions .....	31
5.0 List of FY2017 PHRs.....	34
6.0 Cut Points for FY2017 PHRs.....	41
7.0 Conclusion .....	44
8.0 References.....	45
Appendix A: FY2017 PHR Regulations.....	46
Appendix B: Past Use of Public Health regulations .....	48
Appendix C: FY2017 Candidate regulations .....	49
Appendix D: Steps Used to Develop PHR List .....	54

Appendix E: Comparison of FY2017 PHR List with FY2016 PHR List.....	55
Appendix F: Use of Public Health Regulations in Scheduling Food Safety Assessments.....	58
F-1 Calculating the Cut Points.....	58
F-2 Scheduling FSAs Using Seven Criteria.....	63

## List of Figures and Tables

Figure 4-1 Number of Verifications of Candidate Regulations 3 Months before a Pathogen Positive or Enforcement Action.....	16
Figure 5-1 Odds Ratio for 54 PHRs.....	39
Figure F-1 Log Transformed Non-zero Non-Compliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Processing Establishments .....	59
Figure F-2 Regulatory Non-Compliance Rate of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Both (Slaughter and Processing) Establishments .....	59
Figure F-3 Q-Q Plot of the Log Transformed Non-Zero Non-Compliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Processing Establishments .....	60
Figure F-4 Q-Q Plot of the Log Transformed Non-Zero Non-Compliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Both (Slaughter and Processing) Establishments .....	61
Table S-1 Regulatory Categories of FY2017 PHRs .....	7
Table S-2 FY2017 PHR Tier 1 Cut Points.....	8
Table S-3 FY2017 PHR Tier 2 Cut Points.....	8
Table S-4 Number of Establishments in Tiers Based on all Seven Decision Criteria .....	8
Table S-5 Distribution of Tier 1 Establishments Among Different Product Categories .....	9
Table S-6 Number of Establishments in Each Tier without an FSA in Past Six Months Based on the all Seven Decision Criteria Level .....	9
Table 4-1 Comparison of Noncompliance Rates 3 Months before a <i>Salmonella</i> Positive with Those for Establishments with No <i>Salmonella</i> Positive.....	17
Table 4-2 Comparison of Noncompliance Rates 3 Months before an Intact Chicken <i>Salmonella</i> Positive with Those for Establishments with No Intact Chicken <i>Salmonella</i> Positive.....	18
Table 4-3 Comparison of Noncompliance Rates 3 Months before an Intact Turkey <i>Salmonella</i> Positive with Those for Establishments with No Intact Turkey <i>Salmonella</i> Positive .....	19
Table 4-4 Comparison of Noncompliance Rates 3 Months before a Ground Beef <i>Salmonella</i> Positive with Those for Establishments with No Ground Beef <i>Salmonella</i> Positive .....	20
Table 4-5 Comparison of Noncompliance Rates 3 Months before an Intact Beef <i>Salmonella</i> Positive with Those for Establishments with No Intact Beef <i>Salmonella</i> Positive .....	20
Table 4-6 Comparison of Noncompliance Rates 3 Months before a Comminuted Chicken <i>Salmonella</i> Positive with Those for Establishments with No Comminuted Chicken <i>Salmonella</i> Positive.....	22
Table 4-7 Comparison of Noncompliance Rates 3 Months before a Comminuted Turkey <i>Salmonella</i> Positive with Those for Establishments with No Comminuted Turkey <i>Salmonella</i> Positive.....	22
Table 4-8 Comparison of Noncompliance Rates 3 Months before an Intact Pork <i>Salmonella</i> Positive with Those for Establishments with No Intact Pork <i>Salmonella</i> Positive .....	23
Table 4-9 Comparison of Noncompliance Rates 3 Months before a Chicken Parts <i>Salmonella</i> Positive with Those for Establishments with No Chicken Parts <i>Salmonella</i> Positive.....	24

Table 4-10 Comparison of Noncompliance Rates 3 Months before an <i>E. coli</i> O157:H7 Positive with Those for Establishments with No <i>E. coli</i> O157:H7 Positive.....	25
Table 4-11 Comparison of Noncompliance Rates 3 Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive.....	26
Table 4-12 Comparison of Noncompliance Rates 3 Months before a <i>Listeria monocytogenes</i> Positive with Those for Establishments with No <i>Listeria monocytogenes</i> Positive.....	27
Table 4-13 Comparison of Noncompliance Rates 3 Months before a <i>Campylobacter</i> Positive with Those for Establishments with No <i>Campylobacter</i> Positive .....	28
Table 4-14 Comparison of Noncompliance Rates 3 Months before a <i>Campylobacter</i> Intact Chicken Positive with Those for Establishments with No <i>Campylobacter</i> Intact Chicken Positive .....	29
Table 4-15 Comparison of Noncompliance Rates 3 Months before a <i>Campylobacter</i> Intact Turkey Positive with Those for Establishments with No <i>Campylobacter</i> Intact Turkey Positive	29
Table 4-16 Comparison of Noncompliance Rates 3 Months before a Comminuted Chicken <i>Campylobacter</i> Positive with Those for Establishments with No Comminuted Chicken <i>Campylobacter</i> Positive .....	30
Table 4-17 Comparison of Noncompliance Rates 3 Months before a Chicken Parts <i>Campylobacter</i> Positive with Those for Establishments with No Chicken Parts <i>Campylobacter</i> Positive.....	31
Table 4-18 Comparison of Noncompliance Rates 3 Months before an Enforcement Action with Those for Establishments with No Enforcement Action .....	32
Table 5-1 List of FY2017 PHRs .....	34
Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2017 PHR list.....	39
Table 6-1 Mean and Standard Deviation of Quarterly FY2017 PHR Rate .....	41
Table 6-2 FY2017 PHR Tier 1 Cut Points.....	42
Table 6- 3 FY2017 PHR Tier 2 Cut Points.....	42
Table 6-4 Tier Classification of Establishments Based Solely on the PHR Criterion.....	42
Table 6-5 Tier Classification of Establishments Based on Operation Type and Only the PHR Criterion .....	43
Table 6-6 Tier Classification of Establishments Based on the all Seven Decision Criteria.....	43
Table 6-7 Tier Classification of Establishments without an FSA in Past Six Months Based on the all Seven Decision Criteria .....	43
Table 7- 1 FY2017 PHR Tier 1 Cut Points.....	44
Table 7- 2 FY2017 PHR Tier 2 Cut Points.....	44
Table A-1 List of FY2017 PHRs .....	46
Table C-1 FY2017 Candidate Regulations .....	49
Table C-2 New Candidate Regulations Added.....	53
Table E-1 Comparison of FY2017 Public Health Regulations with FY2016 PHR List .....	55
Table E-2 Regulation from the FY2016 PHR list no longer on the FY2017 PHR list.....	57
Table F-1 Quarterly PHR Mean, Standard Deviation and Tier Distribution.....	62
Table F-2 Average Mean and Standard Deviation of Log Transformed Non-Zero PHR Rates by Plant Type .....	62
Table F-3 March 2016 Tier Distribution Based on the PHR Criteria Only.....	62
Table F-4 FSA Scheduling for March 2016 Using All Seven Decision Criteria.....	63
Table F-5 Distribution of Tier 1 Establishments among Different Plant Types.....	63
Table F-6 Distribution of Tier 1 Establishments Among Different Product Categories .....	64

## SUMMARY

The purpose of the present report is to update the FY2016 list of Public Health Regulations (PHRs) used by the Food Safety and Inspection Service (FSIS) for prioritizing Food Safety Assessments (FSAs). The FY2016 list of PHRs was based on 2014 FSIS verification inspection results and used for FSA scheduling in FY2016. The updated list of PHRs is based on 2015 verification inspection results and will be implemented in FY2017. The updated list is called FY2017 PHRs. If an establishment is prioritized for an FSA, the District Office first performs a Public Health Risk Evaluation (PHRE), as described in FSIS Directive 5100.4, to review the operational and compliance history of the establishment to decide if an FSA is appropriate.

The term “regulation” is meant to include both regulations and the provisions of regulations. The Code of Federal Regulations (CFR) is composed of a set of regulations and the provisions of the regulations that define in greater detail the specific requirements of a regulation. The 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 FY2017 PHR list is the same as that used for the FY2016 PHR list. As in FY2016, 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. The antilog is then taken to obtain the cut points of the non-transformed PHR non-compliance data.

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 FY2017 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 161 public health related NOIE or suspensions issued in CY2015. 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 possible PHR regulations was selected from the same list of 149 candidate regulations used to select the other FY2017 PHRs.

For inclusion in the FY2017 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, 2015) recorded in PHIS.

The final list of FY2017 PHRs consists of 54 regulations that have higher rates of noncompliance three months before a pathogen positive or enforcement action. This compares

with 54 regulations that were identified in the FY2016 PHR list. The list of FY2017 PHRs is presented in Appendix A. Seventy six percent of the regulations on the FY2016 PHR list are also on the FY2017 PHR list.

The 54 FY2017 PHRs are composed of 7 regulations and 47 provisions of regulations. The 47 provisions fall under 22 different regulations. Thus, the 54 FY2017 PHRs represent 29 regulations, with the majority of FY2017 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 FY2017 PHR regulations three months before a pathogen positive or enforcement action is 6.4 times higher than the average FY2017 PHR noncompliance rate for establishments with no pathogen positive and no enforcement action.

The FY2017 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 FY2017 PHRs**

<b>FY2017 PHR Category</b>	<b>Percent of FY2016 PHRs</b>	<b>Percent of FY2017 PHRs</b>
Prevent insanitary conditions and ensure product is not adulterated (Sanitation SOP/SPS)	53.7%	44.4%
Perform initial hazard analysis, develop HACCP plan and verify adequacy of HACCP plans (HACCP)	24.1%	31.5%
Maintain adequate records	9.3%	7.4%
Monitor Critical Control Points and critical limits	3.7%	7.4%
Identify corrective actions and prevent recurrence	9.3%	9.3%
Total	100.0%	100.0%

The FY2017 PHRs are one of seven public health based decision criteria that will be used in prioritizing Food Safety Assessments (FSAs). Noncompliance with a single FY2017 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 FY2017 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 FY2017 cut points, the mean and standard deviation of the log transformed non-zero FY2017 PHR rates for each of the four quarters in CY2015 is computed (the log transform of the non-zero FY2017 PHR rates is taken to obtain an approximately normal distribution). The mean and standard deviation are averaged over the four quarters and the upper cut point is defined as the mean plus two times the standard deviation of the log transformed non-zero PHR rates. The antilog is then taken to obtain the upper cut point of the non-transformed PHR non-compliance data. Establishments that have PHR noncompliance rates higher than the upper cut point for similar establishments are classified as Tier 1 and are

considered for a PHRE if they have not had an FSA in the last six months. Tables S-2 and S-3 present the Tier 1 and Tier 2 FY2017 PHR cut points for the non-transformed PHR non-compliance data for each of the two establishment operation types. Anything below the Tier 2 cut points would be in Tier 3. The FY2016 PHR cut points are included for comparison. (See Section 6 and Appendix F for more details.)

**Table S-2 FY2017 PHR Tier 1 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	4.81%	4.80%
Combination	9.46%	9.25%

**Table S-3 FY2017 PHR Tier 2 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	3.16%	2.97%
Combination	5.82%	5.32%

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 January 1 –March 31, 2016.

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

Classification	Processing	Combination	Total
Tier 1	83	18	101
Tier 2	191	147	338
Tier 3	3,793	870	4,663
Total	4,067	1,035	5,102

Table S-5 presents the distribution of Tier 1 establishments (as determined using only the PHR criterion) among different product categories. The percentage of all plants and Tier 1 plants adds up to more than 100% since a plant may produce more than one product. There is no 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 except for Ground Beef, Pork Slaughter, Ground Pork and RTE.

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**

<b>Product Type</b>	<b>Number Plants Producing Product Type</b>	<b>Percent of all Plants</b>	<b>Number Tier 1 Plants</b>	<b>Percent Tier 1 Plants</b>	<b>Statistical Difference</b>
Chicken Slaughter	193	3.81%	4	6.67%	No
Turkey Slaughter	46	0.91%	-	0.00%	No
Beef Slaughter	639	12.60%	7	11.67%	No
Pork Slaughter	596	11.75%	1	1.67%	Yes
Ground Beef	1,622	31.99%	9	15.00%	Yes
Ground Chicken	808	15.93%	9	15.00%	No
Ground Turkey	315	6.21%	2	3.33%	No
Ground Pork	1,799	35.48%	9	15.00%	Yes
RTE	2,030	40.03%	33	55.00%	Yes
Poultry Combination	390	7.69%	5	8.33%	No
Total Number of Establishments	5,071		60		

When establishments have had an FSA in the past six months, Tier 1 establishments are not automatically scheduled to receive a PHRE. Instead, the District is notified that such establishments have received a Tier 1 classification and it is up to the District to determine if the establishment should receive an additional PHRE and possible FSA. 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 January 1 –March 31, 2016. Seventy two establishments would receive a PHRE 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**

<b>Classification</b>	<b>Processing</b>	<b>Combination</b>	<b>Total</b>
Tier 1	58	14	72
Tier 2	155	110	265
Tier 3	3,240	713	3,953
Total	3,453	837	4,290

## 1.0 INTRODUCTION

In January 2008, the Food Safety and Inspection Service (FSIS) published a decision tree methodology and a set of seven public health based decision criteria for use in prioritizing Food Safety Assessments (FSAs). The decision criteria include factors such as pathogen testing results, recalls, outbreaks, regulatory findings, and a record of noncompliance with certain 9 CFR regulations. These criteria are described in detail in FSIS' Public Health Decision Criteria Report (FSIS 2010). The purpose of an FSA is to review an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements.

In May, 2015, FSIS issued Directive 5100.4, "Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology" and revised Directive 5100.1, "Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology - Revision 4". Directive 5100.4 introduced a Public Health Risk Evaluation (PHRE) that EIAOs would conduct based on a set of public health decision criteria. These criteria include the original criteria from 2008 and additional criteria that FSIS has identified. The PHRE is an assessment by an EIAO of available data on an establishment, including non-compliances, testing data and enforcement actions. Based on this assessment, the EIAO will make a determination whether to conduct an FSA, proceed directly to an enforcement action, or take no action. The public health decision criteria now inform the PHRE assessment which in turn determines if an FSA is needed.

The subset of 9 CFR regulations used to schedule FSAs was initially called W3NR regulations to indicate they are the most serious non-compliances. In January 2012, FSIS developed a more transparent and data-driven approach to refine the list of W3NR regulations (FSIS 2012). The updated list of regulations 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 list of FY2016 PHRs was published in July 2015 (FSIS 2015). The purpose of the present report is to update the list of FY2016 PHRs using current verification inspection results from the Public Health Information System (PHIS). The updated list is called FY2017 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 FY2017 PHR list is the same as that used for the FY2016 PHR. Specifically, for inclusion in the FY2017 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, 2015) recorded in PHIS.

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. In March 2015, FSIS began testing for *Salmonella* and *Campylobacter* on raw chicken parts. In May 2015, FSIS began testing for *Salmonella* in both intact and ground pork products. The *Campylobacter*, the six non-O157 STEC data, the *Salmonella* on raw chicken parts, and the *Salmonella* in pork products 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 FY2017 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 HACCP 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 nine (149) 9 CFR regulations were selected as being indicators of a potential loss of food safety process control. The list of 149 candidate regulations that are indicators of a potential loss of HACCP food safety process control are presented in Appendix C.

The FY2017 list of candidate regulations is the same as the FY2016 list of candidate regulations except for the addition of 14 regulations. Nine (9) of these regulations are new regulations in PHIS related to the New Poultry Inspection System (NPIS) and fecal contamination. Four (4) of the regulations are propositions of a regulation in the FY2016 candidate list, and thus offer more specificity than in FY2016. A complete list of the 14 additional FY2017 candidate regulations is presented in Appendix C.

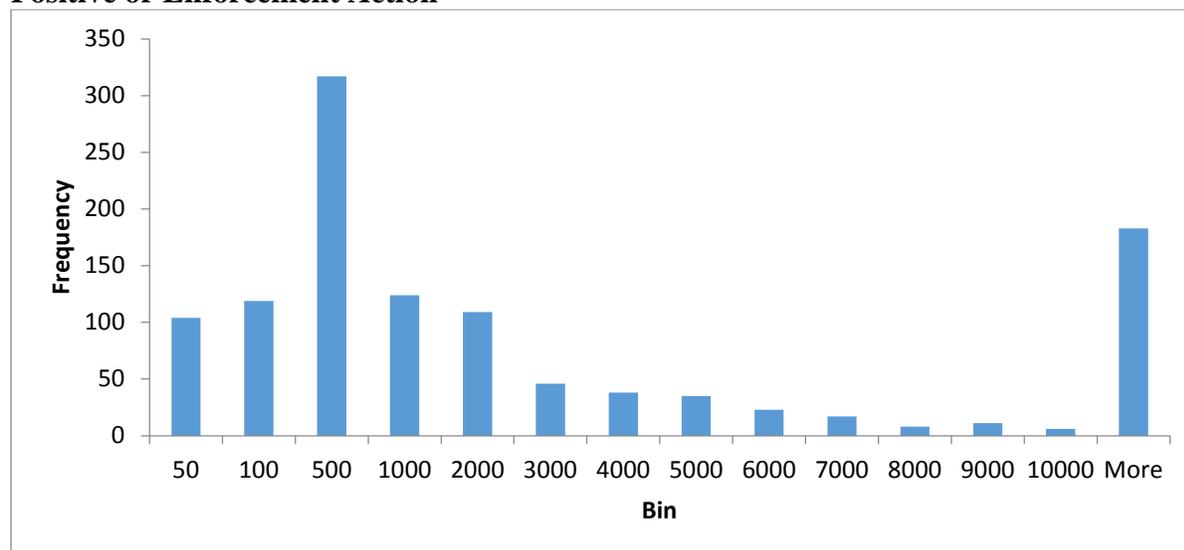
## 4.0 RELATIONSHIP BETWEEN CANDIDATE REGULATIONS AND PATHOGEN POSITIVES

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 149 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, 2015 through December 31, 2015. Those with more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher 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 where the regulations has 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 11,479.

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

#### 4.1 *Salmonella*

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,082 establishments with *Salmonella* testing data, of which 715 had 2,672 *Salmonella* positives and 1,367 did not have *Salmonella* positives. There were 31,883 total *Salmonella* tests performed.

Table 4-1 presents the 15 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
99	310.22(f)(2)	Yes	0.39%	0.11%	2.24E-02	3.45
527	381.65(a)	Yes	1.94%	0.59%	1.39E-38	3.31
543	381.71(a)	Yes	13.20%	1.10%	6.60E-20	13.72
589	416.13(a)	No	3.74%	0.78%	0.00E+00	4.97
590	416.13(b)	No	0.58%	0.16%	5.65E-193	3.67
591	416.13(c)	No	5.67%	1.34%	0.00E+00	4.44
592	416.14	Yes	0.71%	0.23%	4.55E-172	3.18
594	416.15(a)	Yes	5.87%	2.03%	9.86E-61	3.00
595	416.15(b)	Yes	13.82%	2.55%	1.56E-192	6.14

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
597	416.16(a)	Yes	0.43%	0.14%	8.31E-177	3.08
630	416.3(b)	Yes	4.48%	0.88%	1.01E-84	5.32
631	416.3(c)	Yes	5.20%	0.98%	2.37E-115	5.53
633	416.4(a)	Yes	19.86%	6.15%	0.00E+00	3.78
636	416.4(d)	Yes	23.02%	6.61%	0.00E+00	4.22
649	417.2(c)(4)	Yes	1.66%	0.38%	0.00E+00	4.40

#### 4.1.1 *Salmonella* in Intact Chicken

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 201 establishments with Intact Chicken *Salmonella* testing data, of which 71 had 151 *Salmonella* positives and 130 did not have *Salmonella* positives. There were 6,572 total Intact Chicken *Salmonella* tests performed.

Table 4-2 presents the 4 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
406	381.1_Adulterated	Yes	4.03%	0.78%	1.60E-03	5.33
1349	381.76(b)(6)(ii)(A)	No	2.49%	0.25%	8.64E-06	10.27
664	417.3(b)(3)	Yes	1.95%	0.53%	5.34E-04	3.74
682	417.5(a)(3)	Yes	0.42%	0.13%	5.87E-15	3.35

### 4.1.2 *Salmonella* in Intact Turkey

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 46 establishments with *Salmonella* testing data, of which 14 had 17 *Salmonella* positives and 32 did not have *Salmonella* positives. There were 1,422 total Intact Turkey *Salmonella* tests performed.

Table 4-3 presents the 3 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
1331	381.65(f)	No	2.97%	0.97%	7.58E-12	3.12
590	416.13(b)	No	4.03%	0.61%	3.52E-24	6.89
597	416.16(a)	Yes	1.17%	0.36%	1.53E-05	3.26

### 4.1.3 *Salmonella* in Ground Beef

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,244 establishments with *Salmonella* testing data, of which 138 had 212 *Salmonella* positives and 1,106 did not have *Salmonella* positives. There were 11,585 total Ground Beef *Salmonella* tests performed.

Table 4-4 presents the 3 regulations with more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
587	416.12(d)	Yes	1.92%	0.18%	5.78E-05	10.86
594	416.15(a)	Yes	7.16%	1.62%	8.61E-09	4.68
649	417.2(c)(4)	Yes	1.24%	0.29%	9.78E-49	4.32

#### 4.1.4 *Salmonella* in Intact Beef

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. FSIS tests beef trim and beef manufacturing trimmings as a surrogate for testing intact beef. There are 942 establishments with Intact Beef *Salmonella* testing data, of which 75 had 127 *Salmonella* positives and 867 did not have *Salmonella* positives. There were 4,565 total Intact Beef *Salmonella* tests performed.

Table 4-5 presents the 20 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability, as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
717	310.18(a)	Yes	4.14%	1.02%	2.11E-117	4.19
99	310.22(f)(2)	Yes	0.64%	0.14%	9.19E-03	4.72
152	316.6	No	2.44%	0.49%	3.26E-02	5.09
234	318.2(a)	Yes	1.06%	0.07%	8.87E-05	14.75

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
586	416.12(c)	Yes	1.52%	0.17%	6.74E-03	9.23
590	416.13(b)	No	0.48%	0.15%	1.90E-11	3.25
591	416.13(c)	No	4.80%	1.05%	1.47E-237	4.76
592	416.14	Yes	0.68%	0.23%	1.30E-13	3.01
594	416.15(a)	Yes	8.97%	1.65%	4.31E-09	5.87
595	416.15(b)	Yes	11.72%	1.72%	1.70E-08	7.57
597	416.16(a)	Yes	0.41%	0.13%	1.57E-13	3.07
630	416.3(b)	Yes	5.24%	0.70%	2.37E-07	7.81
631	416.3(c)	Yes	4.35%	0.86%	2.41E-05	5.24
636	416.4(d)	Yes	15.99%	4.92%	2.03E-87	3.68
640	416.5(c)	No	4.21%	0.05%	1.63E-06	91.09
645	417.2(a)(1)	No	10.67%	2.65%	7.70E-14	4.39
649	417.2(c)(4)	Yes	2.95%	0.34%	4.65E-145	8.83
657	417.3(a)(1)	Yes	11.84%	2.89%	5.57E-09	4.50
658	417.3(a)(2)	Yes	1.16%	0.37%	4.17E-05	3.14
659	417.3(a)(3)	Yes	15.20%	5.11%	3.76E-07	3.33

#### 4.1.5 *Salmonella* in Comminuted Chicken

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 141 establishments with Comminuted Chicken *Salmonella* testing data, of which 125 had 954 *Salmonella* positives and 16 did not have *Salmonella* positives. There were 1,896 total Comminuted Chicken *Salmonella* tests performed.

Table 4-6 presents the 5 regulations more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
1331	381.65(f)	No	1.14%	0.31%	9.59E-07	3.78
594	416.15(a)	Yes	8.72%	2.19%	2.26E-05	4.27
630	416.3(b)	Yes	11.35%	1.72%	6.93E-11	7.32
631	416.3(c)	Yes	6.99%	1.49%	1.04E-07	4.98
649	417.2(c)(4)	Yes	1.40%	0.30%	5.64E-27	4.74

#### 4.1.6 *Salmonella* in Comminuted Turkey

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. There are 59 establishments with Comminuted Turkey *Salmonella* testing data, of which 42 had 211 *Salmonella* positives and 17 did not have *Salmonella* positives. There were 1,173 total Comminuted Turkey *Salmonella* tests performed.

Table 4-7 presents the 6 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Comminuted Turkey *Salmonella* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Salmonella* positive in the period January 1, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
589	416.13(a)	No	1.65%	0.45%	1.96E-07	3.73
590	416.13(b)	No	0.63%	0.10%	1.25E-09	6.14
594	416.15(a)	Yes	4.50%	0.49%	1.38E-07	9.48
595	416.15(b)	Yes	6.47%	0.15%	9.28E-14	47.46

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
597	416.16(a)	Yes	0.39%	0.09%	1.12E-07	4.27
636	416.4(d)	Yes	13.71%	4.45%	1.92E-25	3.41

#### 4.1.7 *Salmonella* in Intact Pork

The noncompliance rate of each of the 149 candidate regulations in establishments three months before an Intact Pork *Salmonella* positive was compared with the average noncompliance rate of establishments that received Intact Pork *Salmonella* FSIS verification testing, but had no Intact Pork *Salmonella* positives in the period January 1, 2015 to December 31, 2015. There are 172 establishments with Intact Pork *Salmonella* testing data, of which 33 had 55 *Salmonella* positives and 139 did not have *Salmonella* positives. There were 411 total Intact Pork *Salmonella* tests performed.

Table 4-8 presents the 3 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Intact Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Intact Pork *Salmonella* positive in the period January 1, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
582	416.1	Yes	8.66%	2.34%	1.31E-35	3.96
591	416.13(c)	No	6.55%	2.07%	4.33E-80	3.32
631	416.3(c)	Yes	4.62%	0.68%	2.90E-06	7.10

#### 4.1.8 *Salmonella* in Ground Pork

The noncompliance rate of each of the 149 candidate regulations in establishments three months before a Ground Pork *Salmonella* positive was compared with the average noncompliance rate of establishments that received Ground Pork *Salmonella* FSIS verification testing, but had no Ground Pork *Salmonella* positives in the period January 1, 2015 to December 31, 2015. There are 296 establishments with Ground Pork *Salmonella* testing data, of which 87 had 145

*Salmonella* positives and 209 did not have *Salmonella* positives. There were 789 total Ground Pork *Salmonella* tests performed.

There are no regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that for which the noncompliance rate of the regulation in establishments three months before an Ground Pork *Salmonella* positive is higher than the average noncompliance rate for establishments with no Ground Pork *Salmonella* positive in the period January 1, 2015 to December 31, 2015.

#### 4.1.9 *Salmonella* in Chicken Parts

The noncompliance rate of each of the 149 candidate regulations in establishments three months before a Chicken Parts *Salmonella* positive was compared with the average noncompliance rate of establishments that received Chicken Parts *Salmonella* FSIS verification testing, but had no Chicken Parts *Salmonella* positives in the period January 1, 2015 to December 31, 2015. There are 406 establishments with Chicken Parts *Salmonella* testing data, of which 287 had 800 *Salmonella* positives and 119 did not have *Salmonella* positives. There were 3,470 total Chicken Parts *Salmonella* tests performed.

Table 4-9 presents the 9 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an Chicken Parts *Salmonella* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Salmonella* positive in the period January 1, 2015 to December 31, 2015.

**Table 4-9 Comparison of Noncompliance Rates 3 Months before a Chicken Parts *Salmonella* Positive with Those for Establishments with No Chicken Parts *Salmonella* Positive**

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Salmonella</i> Positive	Noncompliance Rate for Establishments with no <i>Salmonella</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
234	318.2(a)	Yes	1.26%	0.08%	1.59E-02	15.24
527	381.65(a)	Yes	3.14%	0.84%	1.20E-52	3.83
543	381.71(a)	Yes	13.63%	2.04%	1.73E-15	7.57
557	381.83	No	0.03%	0.00%	2.12E-02	6.83
564	381.91(a)	Yes	0.73%	0.10%	1.90E-05	7.42
565	381.91(b)	Yes	1.47%	0.42%	1.64E-10	3.53
631	416.3(c)	Yes	6.26%	1.87%	3.19E-18	3.50
658	417.3(a)(2)	Yes	0.59%	0.17%	5.03E-08	3.46
668	417.4(a)	Yes	11.26%	2.02%	3.25E-05	6.16

#### 4.1.10 *Salmonella* in Ready to Eat

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,007 establishments with *Salmonella* testing data, of which 6 had 6 *Salmonella* positives and 2,001 did not have *Salmonella* positives. There were 11,990 total Ready to Eat *Salmonella* tests performed.

There are no regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an 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, 2015 to December 31, 2015.

#### 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 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 1,281 establishments with *E. coli* O157:H7 testing data, of which 11 had 11 *E. coli* O157:H7 positives and 1,270 did not have *E. coli* O157:H7 positives. There were 15,454 total *E. coli* O157:H7 tests performed.

Table 4-10 presents the 4 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and there is an 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before an *E. coli* O157:H7 positive is higher than the average noncompliance rate for establishments with no *E. coli* O157:H7 positive in the period January 1, 2015 to December 31, 2015.

**Table 4-10 Comparison of Noncompliance Rates 3 Months before an *E. coli* O157:H7 Positive with Those for Establishments with No *E. coli* O157:H7 Positive**

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>E. coli</i> O157 Positive	Noncompliance Rate for Establishments with no <i>E. coli</i> O157 Positive	Two-Sided Fisher Exact p Value	Odds Ratio
99	310.22(f)(2)	Yes	2.78%	0.20%	1.10E-02	13.94
582	416.1	Yes	8.16%	2.26%	7.28E-13	3.84

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>E. coli</i> O157 Positive	Noncompliance Rate for Establishments with no <i>E. coli</i> O157 Positive	Two-Sided Fisher Exact p Value	Odds Ratio
636	416.4(d)	Yes	19.44%	5.15%	1.31E-13	4.45
682	417.5(a)(3)	Yes	1.13%	0.27%	8.37E-05	4.29

#### 4.2.2 Non-O157 STEC

The purpose of this section is to investigate the relationship between the candidate regulations and non- O157 Shiga toxin-producing *E. coli* (STEC) positives in MT55 (bench trim) and MT60 (beef or veal trim). FSIS has declared there are six non-O157 STEC adulterants in raw non-intact beef products and product components. On June 4, 2012, FSIS began testing for these six non-O157 STECs in beef manufacturing trimmings. The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 367 establishments with non-O157 STEC testing data, of which 23 had 59 non-O157 STEC positives and 344 did not have non-O157 STEC positives. There were 3,034 total non-O157 STEC tests performed.

Table 4-11 presents the 7 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is an 95% probability (as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

**Table 4-11 Comparison of Noncompliance Rates 3 Months before a Non-O157 STEC Positive with Those for Establishments with No Non-O157 STEC Positive**

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a Non-O157 STEC Positive	Noncompliance Rate for Establishments with no Non-O157 STEC Positive	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Yes	56.76%	2.30%	4.97E-24	55.79
586	416.12(c)	Yes	1.60%	0.11%	3.49E-03	14.79
587	416.12(d)	Yes	1.68%	0.13%	4.33E-03	12.84
631	416.3(c)	Yes	3.42%	0.95%	2.83E-02	3.71
633	416.4(a)	Yes	18.67%	6.60%	4.36E-24	3.25
636	416.4(d)	Yes	21.98%	8.35%	3.79E-22	3.09
660	417.3(a)(4)	Yes	2.29%	0.58%	1.47E-02	4.05

### 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 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 2,008 establishments with *Listeria monocytogenes* testing data, of which 43 had 46 *Listeria monocytogenes* positives and 1,965 did not have *Listeria monocytogenes* positives. There were 11,963 total *Listeria monocytogenes* tests performed.

Table 4-12 presents the 2 regulations that had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

**Table 4-12 Comparison of Noncompliance Rates 3 Months before a *Listeria monocytogenes* Positive with Those for Establishments with No *Listeria monocytogenes* Positive**

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Listeria monocytogenes</i> Positive	Noncompliance Rate for Establishments with no <i>Listeria monocytogenes</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
631	416.3(c)	Yes	8.33%	1.39%	1.37E-02	6.47
701	430.4(a)	Yes	0.37%	0.04%	1.14E-03	9.24

### 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 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 567 establishments with *Campylobacter* testing data, of which 264 had 854 *Campylobacter* positives and 303 did not have *Campylobacter* positives. There were 13,805 total *Campylobacter* tests performed.

Table 4-13 presents the 7 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
234	318.2(a)	Yes	2.91%	0.08%	4.67E-06	37.17
457	381.150(a)	No	8.06%	0.46%	2.34E-04	19.04
630	416.3(b)	Yes	4.79%	1.43%	4.17E-24	3.46
668	417.4(a)	Yes	11.28%	3.09%	3.36E-05	3.98
669	417.4(a)(1)	No	7.32%	1.94%	1.70E-02	4.00
675	417.4(b)	Yes	1.31%	0.40%	3.33E-03	3.34
701	430.4(a)	Yes	0.22%	0.03%	2.36E-02	7.00

#### 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 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 201 establishments with Intact Chicken *Campylobacter* testing data, of which 66 had 164 *Campylobacter* positives and 135 did not have *Campylobacter* positives. There were 6,129 total Intact Chicken *Campylobacter* tests performed.

Table 4-14 presents the 3 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
1349	381.76(b)(6)(ii)(A)	No	14.04%	0.49%	2.00E-09	33.36
648	417.2(c)	Yes	1.15%	0.27%	2.33E-02	4.38
682	417.5(a)(3)	Yes	0.80%	0.13%	1.51E-44	6.31

#### 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 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 46 establishments with *Campylobacter* testing data, of which 13 had 21 *Campylobacter* positives and 33 did not have *Campylobacter* positives. There were 1,323 total Intact Turkey *Campylobacter* tests performed.

Table 4-15 presents the 1 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in the three months before a *Campylobacter* positive is higher than the noncompliance rate for establishments with no *Campylobacter* positive in the period January 1, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
681	417.5(a)(2)	Yes	0.34%	0.11%	3.87E-02	3.03

#### 4.4.3 *Campylobacter* in Comminuted Chicken

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 141 establishments with Comminuted Chicken *Campylobacter* testing data, of which 40 had 161 *Campylobacter* positives and 101 did not have *Campylobacter* positives. There were 1,894 total Comminuted Chicken *Campylobacter* tests performed.

Table 4-16 presents the 7 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 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, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
550	381.76(a)*	Yes	2.99%	0.42%	3.20E-08	7.25
565	381.91(b)	Yes	2.11%	0.63%	1.75E-03	3.43
594	416.15(a)	Yes	9.79%	3.20%	2.64E-12	3.29
630	416.3(b)	Yes	17.39%	3.90%	1.52E-19	5.19
648	417.2(c)	Yes	1.31%	0.22%	4.70E-03	6.08
659	417.3(a)(3)	Yes	34.17%	3.84%	9.80E-27	13.01
675	417.4(b)	Yes	2.69%	0.55%	4.68E-03	5.05

#### 4.4.4 *Campylobacter* in Comminuted Turkey

The noncompliance rate of each of the 149 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 59 establishments with Comminuted Turkey *Campylobacter* testing data, of which 4 had 5 *Campylobacter* positives and 55 did not have *Campylobacter* positives. There were 1,171 total Comminuted Turkey *Campylobacter* tests performed.

There are no regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in establishments three months before a Comminuted Turkey *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Comminuted Turkey *Campylobacter* positive in the period January 1, 2015 to December 31, 2015.

#### 4.4.5 *Campylobacter* in Chicken Parts

The noncompliance rate of each of the 149 candidate regulations in establishments three months before a Chicken Parts *Campylobacter* positive was compared with the average noncompliance rate of establishments that received Chicken Parts *Campylobacter* FSIS verification testing, but had no Chicken Parts *Campylobacter* positives in the period January 1, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 405 establishments with Chicken Parts *Campylobacter* testing data, of which 207 had 503 *Campylobacter* positives and 198 did not have *Campylobacter* positives. There were 3,288 total Chicken Parts *Campylobacter* tests performed.

Table 4-17 presents the 3 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is a 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 a Chicken Parts *Campylobacter* positive is higher than the average noncompliance rate for establishments with no Chicken Parts *Campylobacter* positive in the period January 1, 2015 to December 31, 2015.

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

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before a <i>Campylobacter</i> Positive	Noncompliance Rate for Establishments with no <i>Campylobacter</i> Positive	Two-Sided Fisher Exact p Value	Odds Ratio
234	318.2(a)	Yes	1.53%	0.12%	3.06E-02	12.45
669	417.4(a)(1)	No	11.90%	2.88%	2.25E-02	4.55
675	417.4(b)	Yes	0.99%	0.25%	2.67E-02	3.98

#### 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 149 candidate regulations used to select all other FY2017 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, 2015 to December 31, 2015. The dataset used in the analysis consists of candidate PHR noncompliance rates for the 5,337 active meat and poultry establishments, of which 138 had 161 public health related NOIEs or suspensions and 5,199 did not have any public health related NOIEs or suspensions.

Table 4-18 presents the 24 regulations which had more than 30 verifications in a year, an odds ratio of 3.0 or greater, and for which there is 95% probability (as determined by a two-sided Fisher Exact p value of less than 0.05) that the noncompliance rate of the regulation in the three months before an enforcement action is higher than the noncompliance rate for establishments with no enforcement action in the period January 1, 2015 to December 31, 2015.

**Table 4-18 Comparison of Noncompliance Rates 3 Months before an Enforcement Action with Those for Establishments with No Enforcement Action**

Reg ID	Regulation Verified	On FY2016 PHR List	Noncompliance Rate in 3 Months before an Enforcement Action	Noncompliance Rate for Establishments with no Enforcement Action	Two-Sided Fisher Exact p Value	Odds Ratio
88	310.22(e)(1)	Yes	5.91%	1.71%	5.17E-04	3.62
90	310.22(e)(3)	Yes	4.46%	1.28%	1.68E-02	3.61
92	310.22(e)(4)(i)	Yes	1.11%	0.19%	3.32E-04	5.76
107	310.25(a)	Yes	3.83%	0.69%	2.14E-05	5.77
228	318.17(a)(1)(2)	No	2.90%	0.32%	2.52E-02	9.43
530	381.65(e)*	Yes	4.59%	1.04%	1.16E-18	4.56
1331	381.65(f)	No	5.49%	1.28%	2.62E-23	4.49
587	416.12(d)	Yes	1.25%	0.23%	7.26E-03	5.47
593	416.15 Corrective Actions	No	6.45%	0.54%	3.15E-02	12.69
594	416.15(a)	Yes	7.37%	2.13%	7.13E-05	3.65
597	416.16(a)	Yes	0.57%	0.16%	2.20E-20	3.46
630	416.3(b)	Yes	4.63%	1.11%	2.31E-05	4.30
631	416.3(c)	Yes	4.73%	1.50%	2.03E-04	3.26

<b>Reg ID</b>	<b>Regulation Verified</b>	<b>On FY2016 PHR List</b>	<b>Noncompliance Rate in 3 Months before an Enforcement Action</b>	<b>Noncompliance Rate for Establishments with no Enforcement Action</b>	<b>Two-Sided Fisher Exact p Value</b>	<b>Odds Ratio</b>
645	417.2(a)(1)	No	12.32%	2.08%	4.62E-35	6.60
649	417.2(c)(4)	Yes	2.15%	0.68%	4.49E-32	3.19
657	417.3(a)(1)	Yes	27.85%	2.33%	9.45E-18	16.17
659	417.3(a)(3)	Yes	25.61%	3.15%	1.08E-13	10.58
664	417.3(b)(3)	Yes	7.14%	0.76%	4.28E-03	10.00
665	417.3(b)(4)	Yes	9.40%	0.83%	6.42E-09	12.46
680	417.5(a)(1)	Yes	1.81%	0.33%	1.80E-52	5.62
681	417.5(a)(2)	Yes	0.90%	0.13%	3.44E-29	6.81
682	417.5(a)(3)	Yes	1.75%	0.29%	1.63E-62	6.21
701	430.4(a)	Yes	0.33%	0.05%	4.17E-04	6.59
704	430.4(b)(3)	Yes	5.92%	1.33%	2.45E-04	4.66

## 5.0 LIST OF FY2017 PHRS

Since many establishments produce multiple products and were included in multiple analyses in Chapter 4, a consolidated list of regulations applied to all establishments was selected to combine the above lists of pathogen-specific and enforcement PHRs into a single FY2017 PHR list. Table 5-1 presents the list of 54 FY2017 PHRs. These 53 PHRs were selected since they were verified more than 30 times in a year, had an odds ratio of 3.0 or greater, and had higher noncompliance rates in establishments three months before *Salmonella*, *E. coli* O157:H7, Non-O157 STEC, *Lm*, *Campylobacter* positives or enforcement actions than in establishments with no positives or enforcement actions.

The 54 FY2017 PHRs are composed of 7 regulations and 47 provisions of regulations. The 47 provisions fall under 22 different regulations. Thus, the 54 FY2017 PHRs represent 29 regulations, with the majority of FY2017 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 FY2017 PHRs**

Reg ID	List of FY2017 PHRs	Description	On FY2016 PHR List	NC Rate in 3 Months before a Pathogen Positive	NC Rate for Establishments with no Pathogen Positive	Two-Sided Fisher Exact p Value	Odds Ratio
29	301.2_Adulterated	Adulterated	Yes	56.76%	2.30%	4.97E-24	55.790
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes	4.14%	1.02%	2.11E-117	4.189
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes	5.91%	1.71%	5.17E-04	3.62
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes	4.46%	1.28%	1.68E-02	3.61
92	310.22(e)(4)(i)	Maintain daily records	Yes	1.11%	0.19%	3.32E-04	5.758
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes	0.64%	0.14%	9.19E-03	4.716

<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>	<b>NC Rate in 3 Months before a Pathogen Positive</b>	<b>NC Rate for Establishments with no Pathogen Positive</b>	<b>Two-Sided Fisher Exact p Value</b>	<b>Odds Ratio</b>
107	310.25(a)	Verification criteria for E. coli testing meat	Yes	3.83%	0.69%	2.14E-05	5.765
152	316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No	2.44%	0.49%	3.26E-02	5.086
228	318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No	2.90%	0.32%	2.52E-02	9.433
234	318.2(a)	All products subject to reinspection by program employees	Yes	2.91%	0.08%	4.67E-06	37.170
406	381.1_Adulterated	Adulterated	Yes	4.03%	0.78%	1.60E-03	5.328
457	381.150(a)	Lethality and Stabilization requirements for cooked poultry	No	8.06%	0.46%	2.34E-04	19.035
527	381.65(a)	Clean and sanitary practices; products not adulterated	Yes	3.14%	0.84%	1.20E-52	3.83
530	381.65(e)*	Zero-tolerance for visible fecal material entering chiller	Yes	4.59%	1.04%	1.16E-18	4.563
1331	381.65(f)	Procedures for controlling visible fecal contamination	No	5.49%	1.28%	2.62E-23	4.485
543	381.71(a)	Condemnation on ante mortem inspection	Yes	13.20%	1.10%	6.60E-20	13.719
550	381.76(a)*	Post-mortem inspection, when required, extant.	Yes	2.99%	0.42%	3.20E-08	7.251
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	No	14.04%	0.49%	2.00E-09	33.358
557	381.83	(HIMP ONLY) Septicemia or toxemia	No	0.03%	0.00%	2.12E-02	6.833

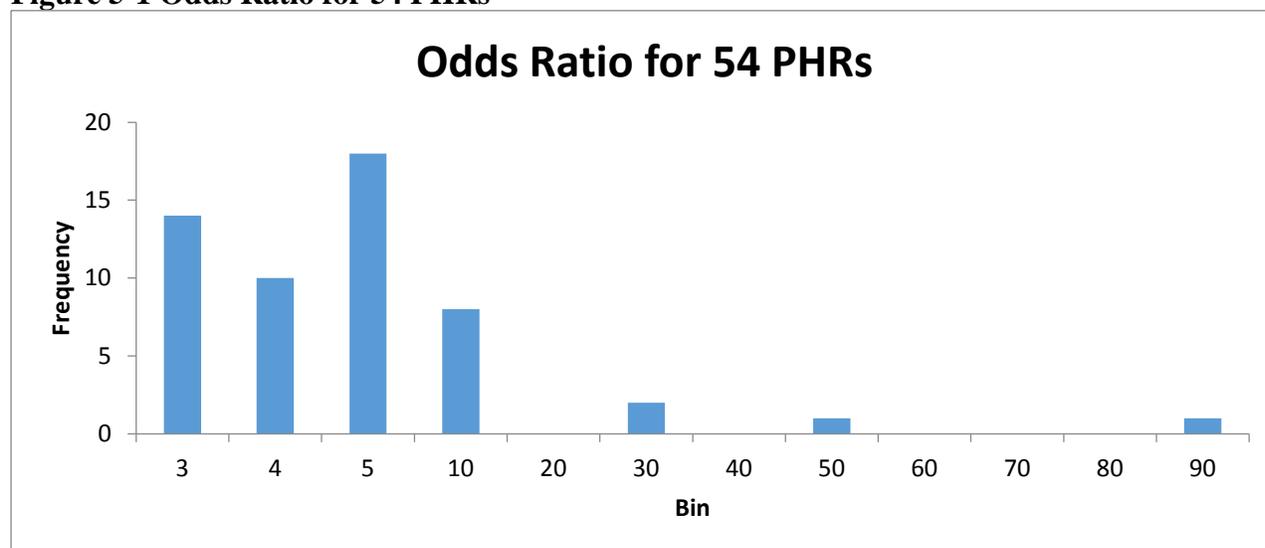
<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>	<b>NC Rate in 3 Months before a Pathogen Positive</b>	<b>NC Rate for Establishments with no Pathogen Positive</b>	<b>Two-Sided Fisher Exact p Value</b>	<b>Odds Ratio</b>
564	381.91(a)	Certain contaminated carcasses to be condemned	Yes	0.73%	0.10%	1.90E-05	7.421
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes	1.47%	0.42%	1.64E-10	3.53
582	416.1	Operate in a manner to prevent insanitary conditions	Yes	8.66%	2.34%	1.31E-35	3.96
586	416.12(c)	plan identifies procedures for pre-op	Yes	1.60%	0.11%	3.49E-03	14.792
587	416.12(d)	plan list frequency for each procedure & responsible individual	Yes	1.92%	0.18%	5.78E-05	10.860
589	416.13(a)	conduct pre-op procedures	No	3.74%	0.78%	0.00E+00	4.969
590	416.13(b)	conduct other procedures listed in the plan	No	0.58%	0.16%	5.62E-193	3.67
591	416.13(c)	plant monitors implementation of SSOP procedures	No	5.67%	1.34%	0.00E+00	4.441
592	416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes	0.71%	0.23%	4.55E-172	3.18
593	416.15 Corrective Actions	Corrective Actions	No	6.45%	0.54%	3.15E-02	12.690
594	416.15(a)	Appropriate corrective actions	Yes	5.87%	2.03%	9.86E-61	3.00
595	416.15(b)	Corrective action, procedures for	Yes	13.82%	2.55%	1.56E-192	6.135
597	416.16(a)	daily records required, responsible individual, initialed and dated	Yes	0.43%	0.14%	8.30E-177	3.08
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes	4.48%	0.88%	1.01E-84	5.318

<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>	<b>NC Rate in 3 Months before a Pathogen Positive</b>	<b>NC Rate for Establishments with no Pathogen Positive</b>	<b>Two-Sided Fisher Exact p Value</b>	<b>Odds Ratio</b>
631	416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes	5.20%	0.98%	2.37E-115	5.529
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes	19.86%	6.15%	0.00E+00	3.78
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes	23.02%	6.61%	0.00E+00	4.222
640	416.5(c)	Employees who appears to have any abnormal source of microbial contamination	No	4.21%	0.05%	1.63E-06	91.092
645	417.2(a)(1)	Hazard analysis	No	12.32%	2.08%	4.62E-35	6.604
648	417.2(c)	Contents of HACCP Plan	Yes	1.31%	0.22%	4.70E-03	6.075
649	417.2(c)(4)	List of procedures & frequency	Yes	1.66%	0.38%	0.00E+00	4.398
657	417.3(a)(1)	Identify and eliminate the cause	Yes	27.85%	2.33%	9.45E-18	16.165
658	417.3(a)(2)	CCP is under control	Yes	0.59%	0.17%	5.03E-08	3.46
659	417.3(a)(3)	Establish measures to prevent recurrence	Yes	34.17%	3.84%	9.80E-27	13.013
660	417.3(a)(4)	No adulterated product enters commerce.	Yes	2.29%	0.58%	1.47E-02	4.053
664	417.3(b)(3)	No adulterated product enters commerce	Yes	1.95%	0.53%	5.34E-04	3.74
665	417.3(b)(4)	Reassessment	Yes	9.40%	0.83%	6.42E-09	12.464
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes	11.26%	2.02%	3.25E-05	6.162
669	417.4(a)(1)	Initial validation	No	7.32%	1.94%	1.70E-02	4.00

<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>	<b>NC Rate in 3 Months before a Pathogen Positive</b>	<b>NC Rate for Establishments with no Pathogen Positive</b>	<b>Two-Sided Fisher Exact p Value</b>	<b>Odds Ratio</b>
675	417.4(b)	Reassessment of hazard analysis	Yes	1.31%	0.40%	3.33E-03	3.34
680	417.5(a)(1)	Written hazard analysis	Yes	1.81%	0.33%	1.80E-52	5.618
681	417.5(a)(2)	Written HACCP plan	Yes	0.90%	0.13%	3.44E-29	6.814
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes	1.75%	0.29%	1.63E-62	6.206
701	430.4(a)	Lm, post-lethality exposed RTE	Yes	0.33%	0.05%	4.17E-04	6.588
704	430.4(b)(3)	Alternative 3	Yes	5.92%	1.33%	2.45E-04	4.663

Figure 5-1 presents a histogram of the ratios (odds ratios) for each of the 54 PHRs between the odds of a non-compliance 3 months before a pathogen positive versus the odds of a non-compliance of the regulations for establishments with no pathogen positive. The average odds ratio is 9.97. That is, for a given PHR, the ratio of non-compliances to compliances for that regulation in establishments 3 months before a positive pathogen or enforcement action is on average 9.97 times higher than the ratio of non-compliances to compliances for that regulation in establishments with no pathogen positive or enforcement action.

**Figure 5-1 Odds Ratio for 54 PHRs**



Forty one of the previous 54 FY2016 PHRs are mapped into these 54 FY2017 PHRs. Approximately 76% of the FY2016 PHRs are included in the FY2017 PHRs. There are 13 additional regulations that were on the FY2016 PHR list and are not in the FY2017 PHR list (See Appendix E).

Table 5-2 lists the number of regulations triggered by different events for inclusion in the FY2017 PHR list. Most regulations were triggered by multiple events.

**Table 5-2 Events That Triggered Inclusion of a Regulation in the FY2017 PHR list**

Product	Number of Regulations	Percent
Campylobacter	7	5.56%
Campylobacter Ground Chicken	7	5.56%
Campylobacter Ground Turkey	0	0.00%
Campylobacter Intact Chicken	3	2.38%
Campylobacter Intact Turkey	1	0.79%
Campylobacter Chicken Parts	3	2.38%
Enforcement Actions	24	19.05%
NonO157 STEC	7	5.56%

<b>Product</b>	<b>Number of Regulations</b>	<b>Percent</b>
O157	4	3.17%
Listeria	2	1.59%
Salmonella	15	11.90%
Salmonella Ground Beef	3	2.38%
Salmonella Ground Chicken	5	3.97%
Salmonella Ground Turkey	6	4.76%
Salmonella Intact Beef	20	15.87%
Salmonella Intact Chicken	4	3.17%
Salmonella Intact Turkey	3	2.38%
Salmonella RTE	0	0.00%
Salmonella Intact Pork	3	2.38%
Salmonella Ground Pork	0	0.00%
Salmonella Chicken Parts	9	7.14%
Total	126	100.00%

## 6.0 CUT POINTS FOR FY2017 PHRS

The FY2017 PHRs are one of the original criteria from 2008 and additional criteria that FSIS has identified that are used in prioritizing Public Health Risk Evaluation (PHRE). These decision criteria are described in detail in FSIS' Directive 5100.4, "Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology" (FSIS 2015). 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 FY2017 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 FY2017 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 rate is approximately normally distributed. Only establishments with greater than or equal to 20 verifications and at least two non-compliances were considered when developing cut points.

To determine a set of annual FY2017 cut points, the mean and standard deviation of the natural log transformed non-zero FY2017 PHR rate (for establishments having more than 20 verifications in the past 90 days and at least two non-compliances) for each of four quarters and each of the two types of establishment operation is computed (the log transform of the non-zero FY2017 PHR rates is taken to obtain an approximately normal distribution, see Appendix F). These results are given in Table 6-1. 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 FY2017 PHR Rate**

Mean	Mean of Natural Log FY2017 PHR Rate		Standard Deviation of FY2017 PHR Rate	
	Combination	Processing	Combination	Processing
Jan-Mar 2015	-4.37	-4.74	0.95	0.85
Apr-Jun 2015	-4.15	-4.52	0.90	0.78
July-Sep 2015	-4.30	-4.77	1.03	0.87
Oct-Dec 2015	-4.39	-4.81	1.01	0.85
Average	-4.30	-4.71	0.97	0.84

The mean and standard deviation are averaged over the four quarters and the annual upper cut point is defined as the mean plus two standard deviations. Establishments that have PHR

noncompliance rates higher than the upper cut point for similar establishments are classified as Tier 1 and are candidates to receive a PHRE. For example, the upper cut point for the log transformed data for Processing establishments is  $-4.71 + 2*0.84 = -4.71 + 1.67 = -3.03$ . The cut point of the original, non-transformed PHR non-compliance data is the antilog of -3.03 or  $\text{Exp}(-3.03) = 4.81\%$ . Tables 6-2 and 6-3 present the FY2017 PHR Tier 1 and Tier 2 cut points for each of the two establishment operation types. Anything below the Tier 2 cut points would be in Tier 3. The FY2016 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 2017.

**Table 6-2 FY2017 PHR Tier 1 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	4.81%	4.80%
Combination	9.46%	9.25%

**Table 6- 3 FY2017 PHR Tier 2 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	3.16%	2.97%
Combination	5.82%	5.32%

Table 6-4 presents the number of establishments in each Tier based solely on the FY2017 PHR criterion and the cut points in Table 6-2. When applying the cut points to establishments with less than 20 verifications, establishments that qualify for Tier 1 but only have one non-compliance are moved to Tier 2. The other six decision criteria used in determining establishment Tiers were not used. Based solely on noncompliance rate with FY2017 PHRs, 60 establishments are in Tier 1 and candidates to receive PHREs. Table 6-3 is based on regulatory non-compliances for the period January 1 –March 31, 2016.

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

Classification	Number of Establishments
Tier 1	60
Tier 2	75
Tier 3	4,936
Total	5,071

Table 6-5 presents the number of establishments in each Tier based establishment operation type and only the PHR criterion. The other six decision criteria used in determining an establishment's Tier classification were not used. For example for processing establishments, based solely on non-compliances with the FY2017 PHRs, 47 processing establishments are Tier 1 and are candidates to receive PHREs. In total, 60 establishments are in Tier 1 based solely on non-compliances with the FY2017 PHRs. Table 6-4 is based on regulatory non-compliances during January 1 –March 31, 2016

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

<b>Classification</b>	<b>Processing</b>	<b>Combination</b>
Tier 1	47	13
Tier 2	52	23
Tier 3	3,937	999
Total	4,036	1,035

Table 6-6 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 January 1 –March 31, 2016

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

<b>Classification</b>	<b>Processing</b>	<b>Combination</b>	<b>Total</b>
Tier 1	83	18	101
Tier 2	191	147	338
Tier 3	3,793	870	4,663
Total	4,067	1,035	5,102

In using the decision tree methodology and the seven decision criteria to schedule PHREs, a new FSA is not automatically scheduled if the establishment has received an FSA in the past six months. Instead, the District is notified that the establishment has received a Tier 1 classification and it is up to the District to determine if the establishment should receive an additional PHRE and possible FSA. Table 6-7 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 January 1 –March 31, 2016. Seventy two establishments are candidate to receive a PHRE based on this data. The district may schedule additional PHREs at additional establishments based on other considerations. “For cause” FSAs are performed when the District Office determines that one is appropriate based on its analysis of the Public Health Risk Evaluation (PHRE), described in FSIS Directive 5100.4.

**Table 6-7 Tier Classification of Establishments without an FSA in Past Six Months Based on the all Seven Decision Criteria**

<b>Classification</b>	<b>Processing</b>	<b>Combination</b>	<b>Total</b>
Tier 1	58	14	72
Tier 2	155	110	265
Tier 3	3,240	713	3,953
Total	3,453	837	4,290

## 7.0 CONCLUSION

The purpose of this report is to develop a transparent and data-driven approach for selecting FY2017 PHR regulations used to prioritize certain Fy2017 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 FY2017 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. About seventy six percent of the regulations on the FY2016 PHR list are also on the FY2017 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 PHRE. FSAs are performed when the District Office determines that one is appropriate based on its analysis of the Public Health Risk Evaluation (PHRE), described in FSIS Directive 5100.4.

Tables 7-1 and 7-2 present the FY2017 PHR Tier 1 and Tier 2 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). Anything that falls below the Tier 2 cut point would be in Tier 3. The FY2016 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 FY2017 PHR Tier 1 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	4.81%	4.80%
Combination	9.46%	9.25%

**Table 7- 2 FY2017 PHR Tier 2 Cut Points**

Operation Type	FY2017 PHR Cut Points	FY2016 PHR Cut Points
Processing	3.16%	2.97%
Combination	5.82%	5.32%

## 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/wps/wcm/connect/fcaeabab-b89e-4bd4-b990-c697f34a797f/2010\\_Public\\_Health\\_Decision\\_Criteria\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990-c697f34a797f/2010_Public_Health_Decision_Criteria_Report.pdf?MOD=AJPERES))
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](http://www.fsis.usda.gov/wps/wcm/connect/9ee42a72-a1fc-4045-982b-b4dfe7e7a43f/NACMPI_Transcript_Subcmt2_011613.pdf?MOD=AJPERES)
5. Food Safety and Inspection Service (FSIS) 2015, Directive 5100.4, Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. <http://www.fsis.usda.gov/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES>

## APPENDIX A: FY2017 PHR REGULATIONS

Table A-1 presents the list of fifty four FY2017 Public Health Regulations (PHRs). On average, these PHR regulations have noncompliance rates three months before a pathogen positive or enforcement action 6.4 times higher than the PHR noncompliance rates for establishments with no pathogen positive or enforcement action.

**Table A-1 List of FY2017 PHRs**

<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>
29	301.2_Adulterated	Adulterated
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs
92	310.22(e)(4)(i)	Maintain daily records
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs
107	310.25(a)	Verification criteria for E. coli testing meat
152	316.6	Products not to be removed from official establishments unless marked in accordance with the regulations
228	318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef
234	318.2(a)	All products subject to reinspection by program employees
406	381.1_Adulterated	Adulterated
457	381.150(a)	Lethality and Stabilization requirements for cooked poultry
527	381.65(a)	Clean and sanitary practices; products not adulterated
530	381.65(e)*	Zero-tolerance for visible fecal material entering chiller
1331	381.65(f)	Procedures for controlling visible fecal contamination
543	381.71(a)	Condemnation on ante mortem inspection
550	381.76(a)*	Post-mortem inspection, when required, extent.
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
557	381.83	(HIMP ONLY) Septicemia or toxemia
564	381.91(a)	Certain contaminated carcasses to be condemned
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.
582	416.1	Operate in a manner to prevent insanitary conditions
586	416.12(c)	plan identifies procedures for pre-op
587	416.12(d)	plan list frequency for each procedure & responsible individual
589	416.13(a)	conduct pre-op procedures
590	416.13(b)	conduct other procedures listed in the plan
591	416.13(c)	plant monitors implementation of SSOP procedures
592	416.14	Evaluate effectiveness of SSOP's & maintain plan

<b>Reg ID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>
593	416.15 Corrective Actions	Corrective Actions
594	416.15(a)	Appropriate corrective actions
595	416.15(b)	Corrective action, procedures for
597	416.16(a)	daily records required, responsible individual, initialed and dated
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection
631	416.3(c)	Receptacles for storing inedible material must identify permitted use
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
640	416.5(c)	Employees who appears to have any abnormal source of microbial contamination
645	417.2(a)(1)	Hazard analysis
648	417.2(c)	Contents of HACCP Plan
649	417.2(c)(4)	List of procedures & frequency
657	417.3(a)(1)	Identify and eliminate the cause
658	417.3(a)(2)	CCP is under control
659	417.3(a)(3)	Establish measures to prevent recurrence
660	417.3(a)(4)	No adulterated product enters commerce.
664	417.3(b)(3)	No adulterated product enters commerce
665	417.3(b)(4)	Reassessment
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards
669	417.4(a)(1)	Initial validation
675	417.4(b)	Reassessment of hazard analysis
680	417.5(a)(1)	Written hazard analysis
681	417.5(a)(2)	Written HACCP plan
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
701	430.4(a)	Lm, post-lethality exposed RTE
704	430.4(b)(3)	Alternative 3

## **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 FY2017 PHRs is presented in Appendix A. The list of FY2016 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:

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

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

## APPENDIX C: FY2017 CANDIDATE REGULATIONS

Table C-1 presents the list of 149 candidate regulations. The noncompliance rates in Table C-1 are based on PHIS data for January 1, 2015 through December 31, 2015.

**Table C-1 FY2017 Candidate Regulations**

Reg ID	FY2017 Candidate Regulation	FY2016 PHR	Mandatory Regulation	Total FSIS Verifications	Total NCs <sup>1</sup>	NC <sup>1</sup> Rate
29	301.2_Adulterated	Yes	No	10,650	237	2.23%
43	304.3(a)	No	No	1,113	5	0.45%
45	304.3(c)	No	No	1,298	18	1.39%
53	309.2(a)	No	No	1,145	10	0.87%
54	309.3	No	No	158	1	0.63%
55	309.4	No	No	129	-	0.00%
56	309.5	No	No	7	-	0.00%
57	309.9	No	No	11	-	0.00%
69	310.18	Yes	No	480	9	1.88%
77	310.22(b)	No	No	6,684	21	0.31%
78	310.22(c)	Yes	Yes	56,316	161	0.29%
84	310.22(d)(2)	No	No	178	-	0.00%
88	310.22(e)(1)	Yes	No	13,869	188	1.36%
89	310.22(e)(2)	No	No	8,793	48	0.55%
90	310.22(e)(3)	Yes	No	9,007	97	1.08%
92	310.22(e)(4)(i)	Yes	No	101,722	305	0.30%
99	310.22(f)(2)	Yes	No	19,542	28	0.14%
101	310.22(g)(1)	No	No	2,624	6	0.23%
104	310.22(g)(4)	No	No	4,478	16	0.36%
107	310.25(a)	Yes	No	30,197	290	0.96%
108	310.25(b)	No	No	268	1	0.37%
109	310.25(b)(3)(ii)	No	No	357	1	0.28%
110	310.3	No	No	4,164	173	4.15%
114	311.16	No	No	126	14	11.11%
115	311.17	No	No	139	-	0.00%
116	311.24	No	No	9	-	0.00%
138	315.2	No	No	128	-	0.00%
152	316.6	No	No	11,401	71	0.62%
178	317.24(a)	No	No	4,779	11	0.23%
207	318.1(b)	No	No	93,593	15	0.02%
215	318.10(b)	Yes	No	3,099	11	0.35%
217	318.10(c)(1)	No	No	3,406	6	0.18%
218	318.10(c)(2)	No	No	739	1	0.14%
219	318.10(c)(3)	No	No	545	3	0.55%
221	318.14(a)	No	No	350	-	0.00%

<b>Reg ID</b>	<b>FY2017 Candidate Regulation</b>	<b>FY2016 PHR</b>	<b>Mandatory Regulation</b>	<b>Total FSIS Verifications</b>	<b>Total NCs<sup>1</sup></b>	<b>NC<sup>1</sup> Rate</b>
222	318.14(b)	No	No	919	-	0.00%
223	318.14(c)	No	No	37	-	0.00%
226	318.16(b)	No	No	392	1	0.26%
228	318.17(a)(1)(2)	No	No	3,999	16	0.40%
229	318.17(b)	No	No	970	1	0.10%
230	318.17(c)	No	No	37	-	0.00%
234	318.2(a)	Yes	No	53,702	101	0.19%
235	318.2(d)	No	No	9,679	45	0.46%
239	318.23(b)(1)	No	No	377	10	2.65%
241	318.23(b)(3)	No	No	23	3	13.04%
242	318.23(c)(1)	No	No	95	2	2.11%
243	318.23(c)(2)	No	No	19	1	5.26%
245	318.23(c)(4)	No	No	40	-	0.00%
246	318.23(c)(5)	No	No	19	-	0.00%
247	318.24	No	No	2,128	11	0.52%
251	318.303	No	Yes	7,991	10	0.13%
256	318.308	No	Yes	4,790	4	0.08%
268	318.6(b)(1)	No	No	3,548	1	0.03%
273	318.6(b)(4)	No	No	9,780	-	0.00%
274	318.6(b)(6)	No	No	13,707	2	0.01%
275	318.6(b)(8)	No	No	534	-	0.00%
329	319.5(b)	No	No	78	-	0.00%
406	381.1_Adulterated	Yes	No	11,522	136	1.18%
450	381.144(a)	No	No	2,046	3	0.15%
457	381.150(a)	No	No	2,167	18	0.83%
459	381.150(c)	No	No	89	2	2.25%
460	381.150(d)	No	No	7	2	28.57%
462	381.151(a)	No	No	43	-	0.00%
490	381.22(a)	No	No	422	-	0.00%
491	381.22(b)	No	No	1,485	6	0.40%
492	381.22(c)	No	No	320	3	0.94%
503	381.310	No	Yes	5,033	-	0.00%
504	381.311	No	Yes	4,860	-	0.00%
506	381.37(a)	No	No	2,251	17	0.76%
527	381.65(a)	Yes	No	89,697	1,204	1.34%
530	381.65(e)*	Yes	Yes	228,381	2,491	1.09%
543	381.71(a)	Yes	No	4,135	297	7.18%
545	381.72(a)	No	No	202	-	0.00%
546	381.72(b)	No	No	3	-	0.00%
550	381.76(a)*	Yes	No	24,242	526	2.17%

<b>Reg ID</b>	<b>FY2017 Candidate Regulation</b>	<b>FY2016 PHR</b>	<b>Mandatory Regulation</b>	<b>Total FSIS Verifications</b>	<b>Total NCs<sup>1</sup></b>	<b>NC<sup>1</sup> Rate</b>
557	381.83	No	No	196,857	64	0.03%
559	381.85	No	No	163	-	0.00%
564	381.91(a)	Yes	No	16,101	44	0.27%
565	381.91(b)	Yes	No	32,530	344	1.06%
571	381.94(a)*	Yes	No	1,566	8	0.51%
572	381.94(b)	No	No	345	2	0.58%
573	381.94(b)(3)(ii)	No	No	13	-	0.00%
582	416.1	Yes	Yes	655,740	19,009	2.90%
586	416.12(c)	Yes	No	47,789	101	0.21%
587	416.12(d)	Yes	No	62,535	155	0.25%
588	416.13 Implementation of SOP's	Yes	No	7,819	29	0.37%
589	416.13(a)	No	Yes	744,222	7,119	0.96%
590	416.13(b)	No	Yes	1,766,074	4,044	0.23%
591	416.13(c)	No	Yes	2,619,909	41,042	1.57%
592	416.14	Yes	Yes	1,584,124	4,385	0.28%
593	416.15 Corrective Actions	No	No	668	4	0.60%
594	416.15(a)	Yes	No	56,504	1,213	2.15%
595	416.15(b)	Yes	No	38,809	1,240	3.20%
597	416.16(a)	Yes	Yes	2,818,201	4,965	0.18%
630	416.3(b)	Yes	No	75,232	745	0.99%
631	416.3(c)	Yes	No	72,079	1,011	1.40%
633	416.4(a)	Yes	No	317,368	24,105	7.60%
636	416.4(d)	Yes	No	300,089	25,046	8.35%
640	416.5(c)	No	No	37,490	22	0.06%
641	416.6	No	No	2,964	176	5.94%
645	417.2(a)(1)	No	No	107,849	2,430	2.25%
648	417.2(c)	Yes	No	34,568	136	0.39%
649	417.2(c)(4)	Yes	Yes	1,380,050	8,436	0.61%
655	417.3 Corrective actions	No	No	446	1	0.22%
656	417.3(a)	No	No	1,553	3	0.19%
657	417.3(a)(1)	Yes	No	28,069	688	2.45%
658	417.3(a)(2)	Yes	No	149,843	740	0.49%
659	417.3(a)(3)	Yes	No	23,796	784	3.29%
660	417.3(a)(4)	Yes	No	43,298	423	0.98%
662	417.3(b)(1)	Yes	No	4,588	149	3.25%
663	417.3(b)(2)	Yes	No	4,025	134	3.33%
664	417.3(b)(3)	Yes	No	18,183	133	0.73%
665	417.3(b)(4)	Yes	Yes	27,372	232	0.85%

<b>Reg ID</b>	<b>FY2017 Candidate Regulation</b>	<b>FY2016 PHR</b>	<b>Mandatory Regulation</b>	<b>Total FSIS Verifications</b>	<b>Total NCs<sup>1</sup></b>	<b>NC<sup>1</sup> Rate</b>
666	417.3(c)	Yes	No	5,514	322	5.84%
668	417.4(a)	Yes	No	6,725	280	4.16%
669	417.4(a)(1)	No	No	4,425	130	2.94%
675	417.4(b)	Yes	Yes	30,040	118	0.39%
680	417.5(a)(1)	Yes	Yes	1,321,191	4,493	0.34%
681	417.5(a)(2)	Yes	Yes	1,194,926	1,853	0.16%
682	417.5(a)(3)	Yes	Yes	1,431,597	4,667	0.33%
689	417.5(f)	Yes	No	88,157	146	0.17%
690	417.6	No	No	553	127	22.97%
701	430.4(a)	Yes	Yes	293,714	193	0.07%
702	430.4(b)(1)	No	No	1,529	7	0.46%
703	430.4(b)(2)	Yes	No	12,992	127	0.98%
704	430.4(b)(3)	Yes	No	26,476	388	1.47%
705	430.4(c)(2)	Yes	Yes	282,447	224	0.08%
706	430.4(c)(3)	Yes	Yes	296,209	171	0.06%
707	430.4(c)(4)	No	No	2,794	20	0.72%
708	430.4(c)(5)	No	No	6,066	31	0.51%
709	430.4(c)(6)	No	No	6,700	110	1.64%
717	310.18(a)	Yes	Yes	312,671	3,194	1.02%
718	310.18(b)	No	No	21,050	4	0.02%
1241	354.242(b)	No	No	122	1	0.82%
1247	354.242(h)	No	No	80	-	0.00%
1250	354.243(a)	No	No	63	1	1.59%
1292	381.193(a)	Yes	No	126	9	7.14%
1331	381.65(f)	No	No	484,633	6,221	1.28%
1346	381.65(h)	No	No	3,514	-	0.00%
1348	381.69	No	No	309	5	1.62%
1349	381.76(b)(6)(ii)(A)	No	No	6,319	31	0.49%
1350	381.76(b)(6)(ii)(D)	No	No	367	42	11.44%
1351	381.76(b)(6)(ii)(C)	No	No	68,370	23	0.03%
1352	381.76(b)(6)(ii)(B)	No	No	566	14	2.47%

1. NC = Noncompliance

Table C-2 shows the 14 new regulations that were added to the candidate list for the FY2017 analysis.

**Table C-2 New Candidate Regulations Added**

<b>Reg ID</b>	<b>Regulation</b>	<b>Description</b>
589	416.13(a)	conduct pre-op procedures
590	416.13(b)	conduct other procedures listed in the plan
591	416.13(c)	plant monitors implementation of SSOP procedures
645	417.2(a)(1)	Hazard analysis
1344	381.65(f)	Procedures for controlling visible fecal contamination
1345	381.65(g)	Procedures for controlling contamination throughout the slaughter and dressing operation
1346	381.65(h)	Recordkeeping requirements
1347	381.66(b)	Chilling performance standards, except for ratites
1348	381.69	Maximum line speed rates under the New Poultry Inspection System
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing
1350	381.76(b)(6)(ii)(D)	Ready-to-Cook verification in NPIS
1351	381.76(b)(6)(ii)(C)	NPIS septicemia/toxemia
1352	381.76(b)(6)(ii)(B)	NPIS reprocessing and salvage
1444	311.14	Abrasions, bruises, abscesses, pus, etc.

## 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, 2014 to December 31, 2015.
2. Develop the list of establishments with at least one *Salmonella* positive in the four month period January 1, 2015 to December 31, 2015.
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 odds ratio is 3.0 or greater.
9. The final list of FY2017 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 FY2017 PHR LIST WITH FY2016 PHR LIST

Table E-1 presents a comparison of the FY2017 PHR list with the FY2016 PHR list (See FSIS (2014) for the FY2016 PHR list). Seventy six percent of the regulations on the FY2016 PHR list are also on the FY2017 PHR.

**Table E-1 Comparison of FY2017 Public Health Regulations with FY2016 PHR List**

RegID	List of FY2017 PHRs	Description	On FY2016 PHR List
29	301.2_Adulterated	Adulterated	Yes
717	310.18(a)	Carcasses, organs, and other parts handled in a sanitary manner	Yes
88	310.22(e)(1)	Written procedures for removal, segregation, and disposition of SRMs	Yes
90	310.22(e)(3)	Evaluate effectiveness of procedures for removal, segregation, and disposition of SRMs	Yes
92	310.22(e)(4)(i)	Maintain daily records	Yes
99	310.22(f)(2)	Use of routine operational sanitation procedures on equipment used to cut through SRMs	Yes
107	310.25(a)	Verification criteria for E. coli testing meat	Yes
152	316.6	Products not to be removed from official establishments unless marked in accordance with the regulations	No
228	318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef	No
234	318.2(a)	All products subject to reinspection by program employees	Yes
406	381.1_Adulterated	Adulterated	Yes
457	381.150(a)	Lethality and Stabilization requirements for cooked poultry	No
527	381.65(a)	Clean and sanitary practices; products not adulterated	Yes
530	381.65(e)*	Zero-tolerance for visible fecal material entering chiller	Yes
1331	381.65(f)	Procedures for controlling visible fecal contamination	No
543	381.71(a)	Condemnation on ante mortem inspection	Yes
550	381.76(a)*	Post-mortem inspection, when required, extent.	Yes
1349	381.76(b)(6)(ii)(A)	NPIS Sorting, Trimming, and Reprocessing	No
557	381.83	(HIMP ONLY) Septicemia or toxemia	No
564	381.91(a)	Certain contaminated carcasses to be condemned	Yes

<b>RegID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>
565	381.91(b)	Reprocessing of carcasses accidentally contaminated with digestive tract contents.	Yes
582	416.1	Operate in a manner to prevent insanitary conditions	Yes
586	416.12(c)	plan identifies procedures for pre-op	Yes
587	416.12(d)	plan list frequency for each procedure & responsible individual	Yes
589	416.13(a)	conduct pre-op procedures	No
590	416.13(b)	conduct other procedures listed in the plan	No
591	416.13(c)	plant monitors implementation of SSOP procedures	No
592	416.14	Evaluate effectiveness of SSOP's & maintain plan	Yes
593	416.15 Corrective Actions	Corrective Actions	No
594	416.15(a)	Appropriate corrective actions	Yes
595	416.15(b)	Corrective action, procedures for	Yes
597	416.16(a)	daily records required, responsible individual, initialed and dated	Yes
630	416.3(b)	Constructed, located & operated in a manner that does not deter inspection	Yes
631	416.3(c)	Receptacles for storing inedible material must identify permitted use	Yes
633	416.4(a)	Food contact surface, cleaning & sanitizing as frequency	Yes
636	416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected	Yes
640	416.5(c)	Employees who appears to have any abnormal source of microbial contamination	No
645	417.2(a)(1)	Hazard analysis	No
648	417.2(c)	Contents of HACCP Plan	Yes
649	417.2(c)(4)	List of procedures & frequency	Yes
657	417.3(a)(1)	Identify and eliminate the cause	Yes
658	417.3(a)(2)	CCP is under control	Yes
659	417.3(a)(3)	Establish measures to prevent recurrence	Yes
660	417.3(a)(4)	No adulterated product enters commerce.	Yes
664	417.3(b)(3)	No adulterated product enters commerce	Yes
665	417.3(b)(4)	Reassessment	Yes
668	417.4(a)	Adequacy of HACCP in controlling food safety hazards	Yes
669	417.4(a)(1)	Initial validation	No
675	417.4(b)	Reassessment of hazard analysis	Yes

<b>RegID</b>	<b>List of FY2017 PHRs</b>	<b>Description</b>	<b>On FY2016 PHR List</b>
680	417.5(a)(1)	Written hazard analysis	Yes
681	417.5(a)(2)	Written HACCP plan	Yes
682	417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits	Yes
701	430.4(a)	Lm, post-lethality exposed RTE	Yes
704	430.4(b)(3)	Alternative 3	Yes

There are thirteen regulations from the FY2016 PHR list that no longer appear in the FY2017 PHR list. These thirteen regulations are shown in Table E-2.

**Table E-2 Regulation from the FY2016 PHR list no longer on the FY2017 PHR list**

<b>Reg ID</b>	<b>List of FY2016 PHRs</b>	<b>Description</b>
69	310.18	Contamination of carcasses, organs, or other parts
78	310.22(c)	Disposal of SRM
215	318.10(b)	Products requiring treatment to destroy trichinae
571	381.94(a)*	Verification criteria for E. coli testing poultry
588	416.13 Implementation of SOP's	Implementation of SSOP
662	417.3(b)(1)	Segregate and hold the affected product
663	417.3(b)(2)	Determine the acceptability of the affected product
666	417.3(c)	Document corrective actions
689	417.5(f)	Official Review
703	430.4(b)(2)	Alternative 2
705	430.4(c)(2)	Lm, documentation that supports decision in hazard analysis
706	430.4(c)(3)	Lm, maintain sanitation in post-lethality processing environment
1292	381.193(a)	Poultry not intended for human food in commerce

## 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.

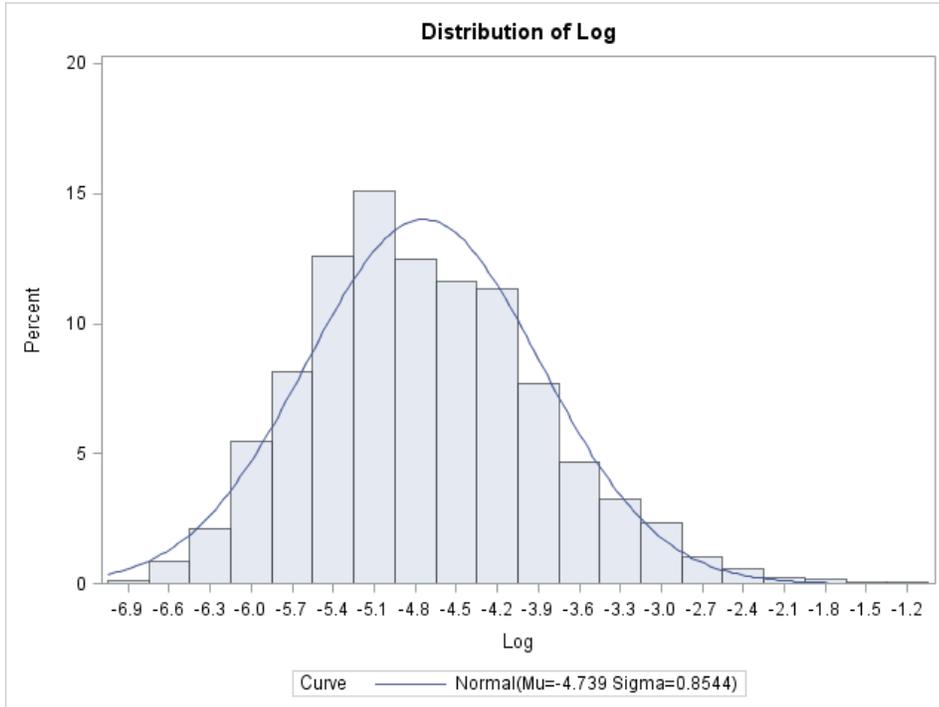
The PHR noncompliance rate is calculated by the following formula using the most recent three months of establishment verification inspection data:

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

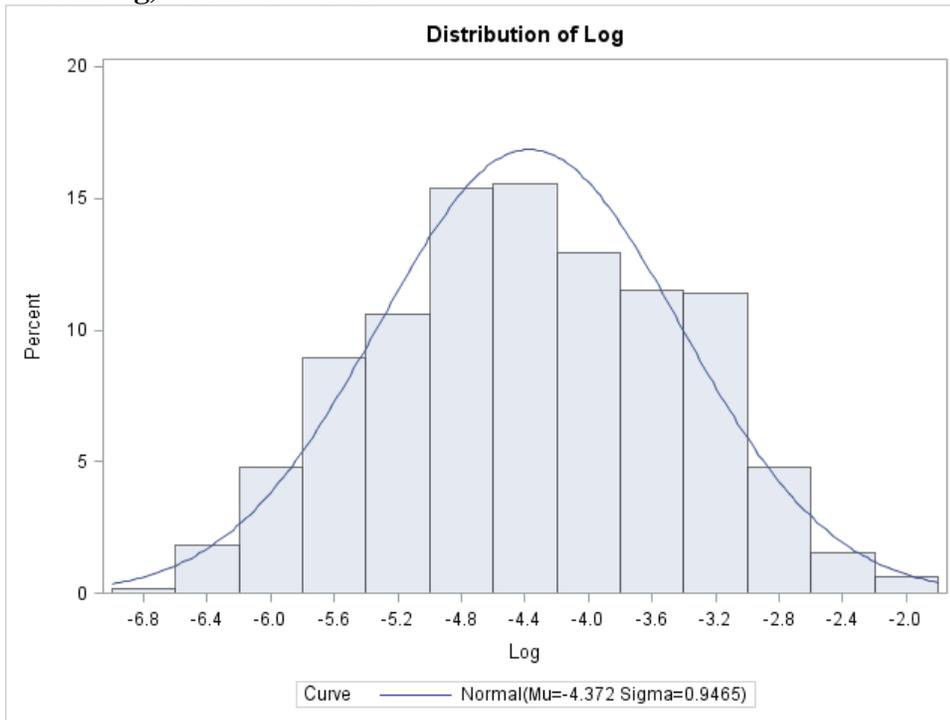
Establishments are categorized into one of two plant types (Processing Only and Slaughter/Processing; named Processing, and Combination in the main body of the report). The plant type is determined from the type of HACCP Inspection Task Codes performed at each establishment. If an establishment has only 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 20 verifications and at least two non-compliances are considered.

**Figure F-1 Log Transformed Non-zero Non-Compliance Rates of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Processing Establishments**



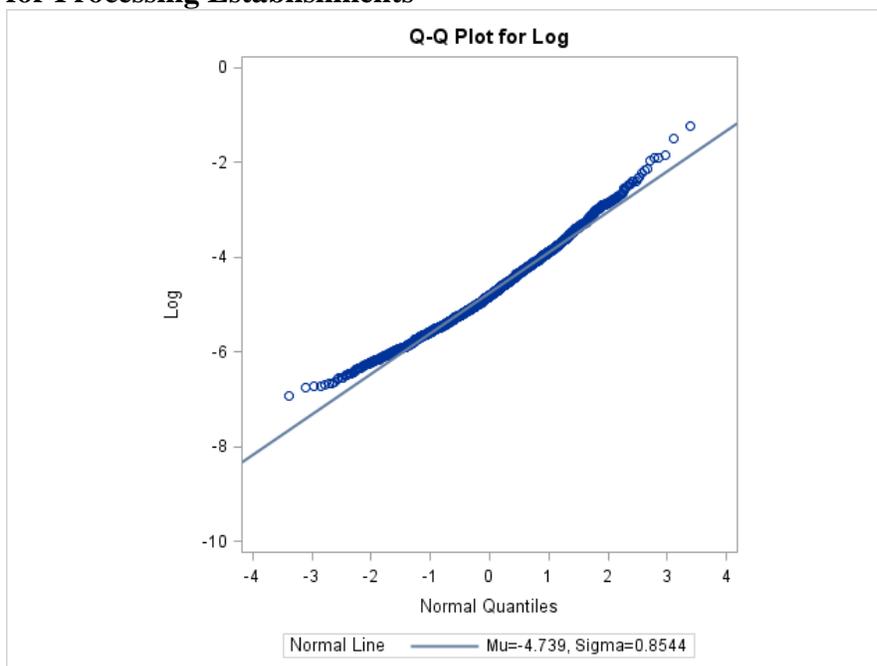
**Figure F-2 Regulatory Non-Compliance Rate of PHRs with 20 or More Verifications 3 Months before a Pathogen Positive or Enforcement Action for Both (Slaughter and Processing) Establishments**



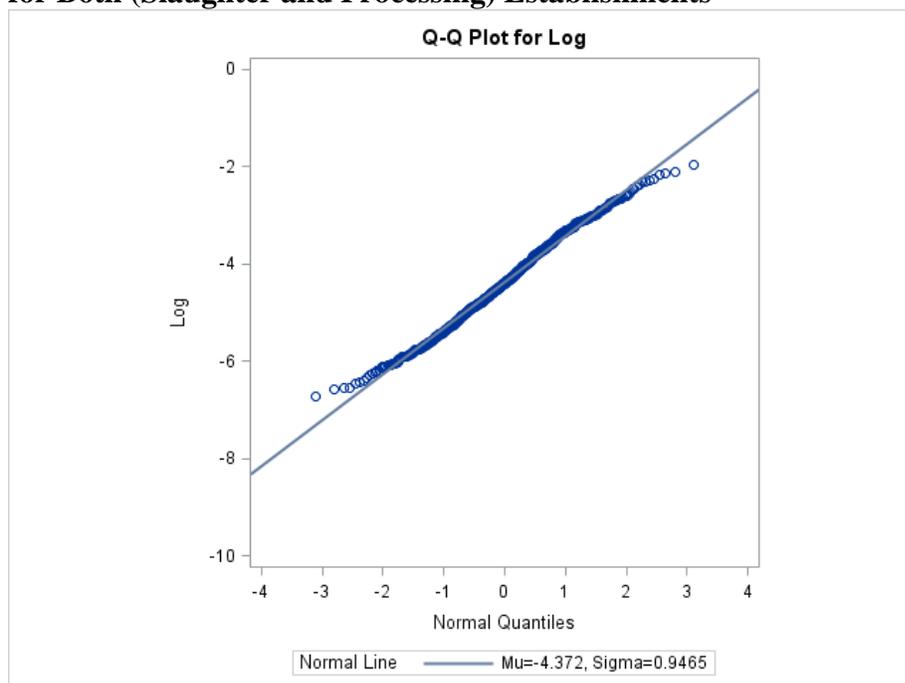
These distributions are approximately normally distributed. The Shapiro-Wilk test for normality  $W$  statistics for the two distributions are 0.988 and 0.993, respectively, which indicates near-normality (The test statistic  $W$  takes values between 0 and 1, with values close to 1 indicating near-normality).

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  $45^\circ$  line.

**Figure F-3 Q-Q Plot of the Log Transformed Non-Zero Non-Compliance Rates of PHRs with 20 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 20 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 20 or more PHR verification inspections and at least two non-compliances.

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 68 Tier 1 establishments per month based solely on the PHR criteria. The subset of the 72 establishments that have not had an FSA in the past 6 months will receive a PHRE.

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

	Number of Establishments	Mean	Standard Deviation			Tier Distribution (Number of Establishments)
<b>Q1CY2015</b>						Tier 1 77
Both	1,030	-4.37	0.95			Tier 2 105
Processing	3,994	-4.74	0.85			Tier 3 4,842
<b>Q2CY2015</b>						Tier 1 57
Both	1,038	-4.15	0.90			Tier 2 81
Processing	4,041	-4.52	0.78			Tier 3 4,941
<b>Q3CY2015</b>						Tier 1 66
Both	1,038	-4.30	1.03			Tier 2 101
Processing	4,024	-4.77	0.87			Tier 3 4,895
<b>Q4CY2015</b>						Tier 1 73
Both	1,039	-4.39	1.01			Tier 2 106
Processing	4,032	-4.81	0.85			Tier 3 4,892

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 60 PHREs in the March 2016 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	-4.30	-4.71
Standard Deviation	0.97	0.84

**Table F-3 March 2016 Tier Distribution Based on the PHR Criteria Only**

Classification	Plants
Tier 1	60
Tier 2	75
Tier 3	4,936
Total	5,071

## F-2 Scheduling FSAs Using Seven Criteria

Table F-4 presents the Tier distribution of establishments when using all seven decision criteria, including the FY2017 PHR regulations and the cut points defined from Table F-2. The table is derived from data for the three month period January 1 –March 31, 2016. 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 March 2016 Using All Seven Decision Criteria**

	<b>Number Plants in Each Tier Using all 7 Decision Criteria</b>	<b>Number Plants in Each Tier without FSA in Past 6 Months</b>
Tier 1	101	72
Tier 2	338	265
Tier 3	4,663	3,953
Total	5,102	4,290

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**

<b>Plant Type</b>	<b>Number Plants</b>	<b>Percent Plants</b>	<b>Number Tier 1 Plants</b>	<b>Percent Tier 1 Plants</b>	<b>Statistical Difference with Representation Among All Plants</b>
Processing	4,067	79.71%	83	82.18%	No
Combination	1,035	20.29%	18	17.82%	No
Totals	5,102	100.00%	92	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 not 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 except for Ground Beef, Pork Slaughter, Ground Pork and RTE.

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**

<b>Product Type</b>	<b>Number Plants Producing Product Type</b>	<b>Percent of all Plants</b>	<b>Number Tier 1 Plants</b>	<b>Percent Tier 1 Plants</b>	<b>Statistical Difference</b>
Chicken Slaughter	193	3.81%	4	6.67%	No
Turkey Slaughter	46	0.91%	-	0.00%	No
Beef Slaughter	639	12.60%	7	11.67%	No
Pork Slaughter	596	11.75%	1	1.67%	Yes
Ground Beef	1,622	31.99%	9	15.00%	Yes
Ground Chicken	808	15.93%	9	15.00%	No
Ground Turkey	315	6.21%	2	3.33%	No
Ground Pork	1,799	35.48%	9	15.00%	Yes
RTE	2,030	40.03%	33	55.00%	Yes
Poultry Combination	390	7.69%	5	8.33%	No
Total Number of Establishments	5,071		60		