

Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs

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SUMMARY

The objective of this report is to evaluate Food Safety and Inspection Service (FSIS) inspection findings in market hog slaughter establishments participating in the Hazard Analysis and Critical Control Point (HACCP) Inspection Models Project (HIMP) and determine whether the HIMP inspection system is performing as well as the existing inspection system in terms of safety and wholesomeness of hog slaughter and overall consumer protection. The evaluation is based on two time periods: the years CY2006 - CY2010 and the years CY2012 - CY2013. (The year CY2011 was a transition year for FSIS information systems and will not be considered). The evaluation compares the 5 HIMP market hog establishments with a set of 21 non-HIMP market hog slaughter establishments selected to be comparable with HIMP market hog establishments with respect to production volume, line speed, and days of slaughter operation. The FSIS inspection findings are assessed across three interrelated inspection activities:

1. Verification, by off-line inspectors, of the establishment's execution of its HIMP slaughter Process Control Plan (PCP), under which establishment employees sort out unacceptable carcasses and parts.
2. Verification by off-line inspectors of the establishment executing its Sanitation Standard Operating Procedures (Sanitation SOP) and its HACCP plans under 9 CFR Parts 416 and 417.
3. Verification of the outcomes of the establishment HACCP and process control plans, both organoleptic and microbiologic

A summary of results follows:

- 1. Verification, by off-line inspectors, of the establishment's execution of its HIMP slaughter Process Control Plan (PCP), under which establishment employees sort out unacceptable carcasses and parts.**

Under HIMP, employees of slaughter establishments sort animals at ante- and post-mortem prior to FSIS inspection. The rate of ante- and post-mortem sorting by HIMP establishment employees and condemnation by FSIS inspectors at non-HIMP market hog establishments are comparable (3.0 per 1,000 hogs versus 2.7 per 1,000 hogs, respectively). FSIS inspectors perform off-line inspection procedures in HIMP market hog establishments to verify that the establishments are executing their HIMP slaughter PCP. FSIS inspectors performed an average of 2,061 off-line verification inspections per HIMP market hog establishment in CY2010 versus an average of 1,482 off-line verification inspections per non-HIMP establishment. Overall, FSIS inspectors perform 1.4 times more off-line verification inspection procedures in HIMP market hog establishments than in non-HIMP market hog establishments and 1.5 times more Sanitation SOP and HACCP verification inspection procedures. This increased level of inspection provides increased assurance that HIMP market hog establishments are satisfying HACCP regulations and producing a wholesome and safe product.

2. Verification by off-line inspectors of the establishment executing its Sanitation Standard Operating Procedures (Sanitation SOP) and its HACCP plans under 9 CFR Parts 416 and 417

FSIS inspectors conduct off-line inspection procedures in HIMP market hog establishments to verify that they are complying with Sanitation SOP and HACCP regulations and designated performance standards for Food Safety (FS), Other Consumer Protection (OCP) defects, and pathogen levels. FSIS inspectors ensure that each establishment is complying with federal regulations and is operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. This report finds that under HIMP, market hog establishments are receiving an increased level of Sanitation SOP and HACCP inspections. The assumption is made that the number of inspection tasks performed per establishment is correlated with production of a safe product. The FSIS risk assessments on poultry slaughter (FSIS 2008, 2012, 2014) found that more off-line procedures were associated with lower *Salmonella* and *Campylobacter* prevalence and an increase in public illnesses avoided.

SSOP and HACCP Off-line Inspections

- In CY2010, FSIS inspectors performed 1.5 times more off-line Sanitation SOP and HACCP inspection verifications of public health-related regulations (W3NRs) in HIMP than non-HIMP market hog establishments.
- In CY2012 and CY2013, FSIS inspectors performed 1.1 times more off-line Sanitation SOP and HACCP inspection verifications of public health-related regulations (PHRs) in HIMP than non-HIMP market hog establishments.
- Although there are more 9 CFR 416 verifications and fewer 9 CFR 417 verifications in HIMP, both verifications are considered to address food safety issues and carry the same regulatory weight when enforcement actions are initiated.

SSOP and HACCP Regulatory Noncompliances

- In CY2006-CY2010, public health-related (W3NR) noncompliance rates of Sanitation SOP and HACCP regulations were 1.2 times higher in HIMP than non-HIMP market hog establishments. This difference is statistically significant.
- In CY2010 and CY2013, public health-related (PHR) noncompliance rates of Sanitation SOP and HACCP regulations were 1.1 times higher in non-HIMP than HIMP market hog establishments. Both differences are statistically significant.

3. Verification of the outcomes of the establishment HACCP and process control plans, both organoleptic and microbiologic

Before beginning HIMP, FSIS developed Food Safety (FS) and Other Consumer Protection (OCP) performance standards that market hog establishments must meet (FSIS

2000, Cates et al 2001¹). To ensure that HIMP market hog establishments are complying with FS and OCP performance standards, FSIS has increased the number of daily off-line verifications of market hog carcasses from 11 per line in non-HIMP market hog establishments to 24 per line in HIMP market hog establishments. For this report, FSIS requested that the District Offices provide the paper records stored at individual facilities that inspectors keep on FS and OCP for in-plant inspections for the two periods CY2009-CY2010 and CY2012-CY2013. The request was limited to these two time periods so as to limit the impact on field personnel and because it is believed that two years of data from before PHIS are sufficient to develop conclusions on FS and OCP.

HIMP Food Safety Performance

- Food safety conditions for systemic diseases in carcasses such as toxemia or septicemia (FS-1 defects) in HIMP market hog establishments, which were below 1 per 10 thousand carcasses in CY2009-CY2010, are below 3 in 100 thousand in CY2012-CY2013.
- Carcass contamination with fecal material, ingesta, and milk (FS-2 defects) in HIMP market hog establishments, was below 6 per 10 thousand carcasses in CY2009-CY2010. For CY2012-CY2013, fecal material, ingesta, and milk defects are below 5 per 10 thousand carcasses.
- Food safety conditions from systemic disease in live animals such as neurologic conditions (FS-3), found at ante-mortem were zero in CY2009-CY2010 and are less than 1 in 10 thousand for CY2012-CY2013.

HIMP Other Consumer Protection Performance

- Other Consumer Protection Conditions due to localized disease in carcasses such as arthritis (OCP-1 defects), cystic kidneys (OCP-2 defects), and bruise (OCP-3 defects) found at postmortem in HIMP market hog establishments are all less than one-half their OCP performance standards on average.

***Salmonella* Testing Results**

In July 2011, FSIS discontinued collecting *Salmonella* verification samples of carcasses in calves/bulls, steers/heifers and market hog slaughter classes. For the years CY2006 – CY2009, the *Salmonella* positive rates in HIMP market hog establishments were lower than those in non-HIMP comparison establishments but were higher in CY2010. The differences are not statistically significant for any of the years.

FSIS conducted a *Salmonella* baseline study on hog slaughter establishments during the thirteen month period August 2010 to August 2011. The program was designed to estimate the national prevalence of *Salmonella* in market hogs. The final sampling frame included 253 establishments that contribute approximately 99.9% of hogs slaughtered in the U.S. From this sampling frame, 152 random establishments were sampled. The *Salmonella* post-chill rates were:

¹ RTI began collecting baseline organoleptic and microbiological data in August 1998, before HIMP program began.

- 5 HIMP market hog establishments –0.69%
- 21 non-HIMP market hog comparison establishments -1.35%
- All 147 non-HIMP hog slaughter establishments in baseline study – 3.05%

The difference in *Salmonella* testing results between the 5 HIMP and the 21 non-HIMP comparison establishments is not statistically significant (Two Sided Exact Fisher $p = 0.55$). This is probably the result of the small sample size relative to the low *Salmonella* positive rate. The difference between HIMP market hog establishments and all 147 non-HIMP market hog establishments in the baseline study (includes the 21 non-HIMP comparison establishments) (0.69% versus 3.05%) is highly statistically significant (Two Sided Exact Fisher $p < 0.00001$).

Chemical Residues

FSIS conducts tests for residues of chemical use—including antibiotics, sulfonamides, and various other drugs, pesticides and environmental chemicals—in meat, poultry and egg products destined for human consumption. To ensure that the level of chemical residues remains low, FSIS conducts random residue sampling scheduled by headquarters and inspector-generated targeted sampling originating from the field. The number of annual chemical residue samples per market hog establishment is about the same in HIMP and non-HIMP comparison establishments (26 versus 27). The number of inspector generated chemical residue samples per market hog establishment is 1.7 times higher in HIMP market hog establishments than non-HIMP (619 versus 358).

- Over the period, CY2006-CY2010, HIMP market hog establishments had zero violative levels of chemical residues versus six in the non-HIMP comparison establishments. This difference is not statistically significant (Two-Sided Exact Fisher $p = 0.067$).
- For the period CY2012-CY2013, HIMP market hog establishments had 9 violative levels (0.15% of samples) versus 115 (0.76% of samples) in the non-HIMP market hog establishments. This is a statistically significant difference (Two-Sided Exact Fisher $p < 0.0001$).

Conclusion

FSIS's evaluation found that market hog slaughter establishments participating in HIMP are performing as well as comparable large non-HIMP market hog establishments and meeting FSIS expectations for the overall HIMP project. On this basis, FSIS sees no reason to discontinue HIMP in market hog establishments.

1.0 INTRODUCTION

In October 1999, FSIS initiated the Hazard Analysis and Critical Control Point (HACCP) Inspection Models Project (HIMP) project in volunteer slaughter establishments to determine whether new government slaughter inspection procedures, along with new plant responsibilities, could promote innovation and provide increased or equivalent food safety and consumer protection. Under HIMP, employees of slaughter establishments sort animals at both ante- and

post-mortem prior to FSIS inspection, making an initial determination whether they are diseased or unacceptable. Like the traditional inspection model, FSIS inspectors in HIMP market hog slaughter establishments inspect each head, viscera, and carcass after sorting by establishment employees. FSIS inspectors ensure that the establishment's ante-mortem and post-mortem process controls meet regulatory standards through online carcass-by-carcass inspection and additional off-line verification activities. This approach is consistent with HACCP principles where industry personnel rather than federal inspectors are responsible for identifying the steps in the slaughter process where food safety hazards are most likely to occur. They are also responsible for establishing controls that prevent or reduce these hazards prior to inspection. Currently, there are 20 young chicken, 5 young turkey, and 5 market hog slaughter establishments participating in HIMP. This report focuses on the 5 market hog slaughter establishments participating in the HIMP project.

Before beginning HIMP, Research Triangle Institute (RTI), a third-party consulting organization, conducted baseline organoleptic and microbiological data collection in 3 large traditional market hog slaughter establishments that volunteered to participate in the HIMP program (Cates et al. 2001²). The baseline data document the status of pre-HIMP market hog slaughter-line inspection systems thus providing a benchmark for comparing the performance of establishments operating under the HIMP inspection system with those operating under traditional (non-HIMP) inspection systems. In March 2000, FSIS held a public meeting to present the HIMP baseline results and receive comments on proposed HIMP performance standards developed from the baseline RTI data. In November 2000, FSIS published the final HIMP market hog performance standards for three Food Safety (FS) and three Other Consumer Protection (OCP) carcass conditions of concern (FSIS 2000). Prior to operating under HIMP, market hog establishments were expected to revise their HACCP systems to meet food safety standards and to develop slaughter process control plans to meet or exceed OCP standards. Establishments are responsible for identifying and removing carcasses and parts that do not meet applicable regulatory requirements and HIMP performance standards. FSIS inspectors are responsible for verifying that plants are continuously achieving the required outcomes and inspecting the results.

The objective of the present analysis is to evaluate the performance of HIMP market hog establishments and to determine whether the HIMP market hog inspection system meets Food Safety (FS) and Other Consumer Protection (OCP) standards and is performing as well as the existing inspection system in terms of safety and wholesomeness of hog slaughter and overall consumer protection. To accomplish this, HIMP market hog establishments are evaluated across a variety of operational parameters:

- Inspections
- Regulation verifications and noncompliances
- Public Health Related (W3NR and PHR) regulations
- Microbiological and chemical testing results
- Food Safety and OCP performance standards

² RTI began collecting baseline organoleptic and microbiological data in August 1998, before HIMP program began.

The evaluation is based on data for the years CY2006 through CY2010 and CY2012 through CY2013. The year CY2011 was a transition year for FSIS information systems and will not be considered.

Establishment performance results from CY2006 to CY2010 are based on data from the PBIS (Performance Based Inspection System) database and results from CY2012 to CY2013 are based on data from the PHIS (Public Health Inspection System) database. FSIS began transitioning establishments from the PBIS, which was in effect during the period of CY2006 to CY2010, to the PHIS in April 2011. The period April 2011 to December 2011 was a transitional period during which the inspection results for some establishments were recorded under PBIS, while others were recorded under PHIS. The data under the two systems are not completely compatible as discussed in Appendix A. For this reason, the transitional period CY2011 is not included in this update of the HIMP market hog report, and the analysis of CY2006-CY2010 data is separate from the CY2012-CY2013 data.

Throughout this document, results are first presented for CY2006 to CY2010 (these results are based on PBIS data) and then for CY2012 and CY2013 (these results are based on PHIS data). The evaluation compares the 5 large HIMP market hog establishments with a comparison set of 21 large non-HIMP market hog establishments selected to be comparable with HIMP market hog establishments with respect to production volume, line speed, and days of operation.

The FSIS inspection findings are assessed across three interrelated inspection activities:

1. Verification, by off-line inspectors, of the establishment's execution of its HIMP slaughter PCP, under which establishment employees sort unacceptable carcasses and parts.
2. Verification of the establishment executing its Sanitation SOP and HACCP food safety systems.
3. Verification of the outcomes of the establishment HACCP and process control plans, both organoleptic and microbiologic

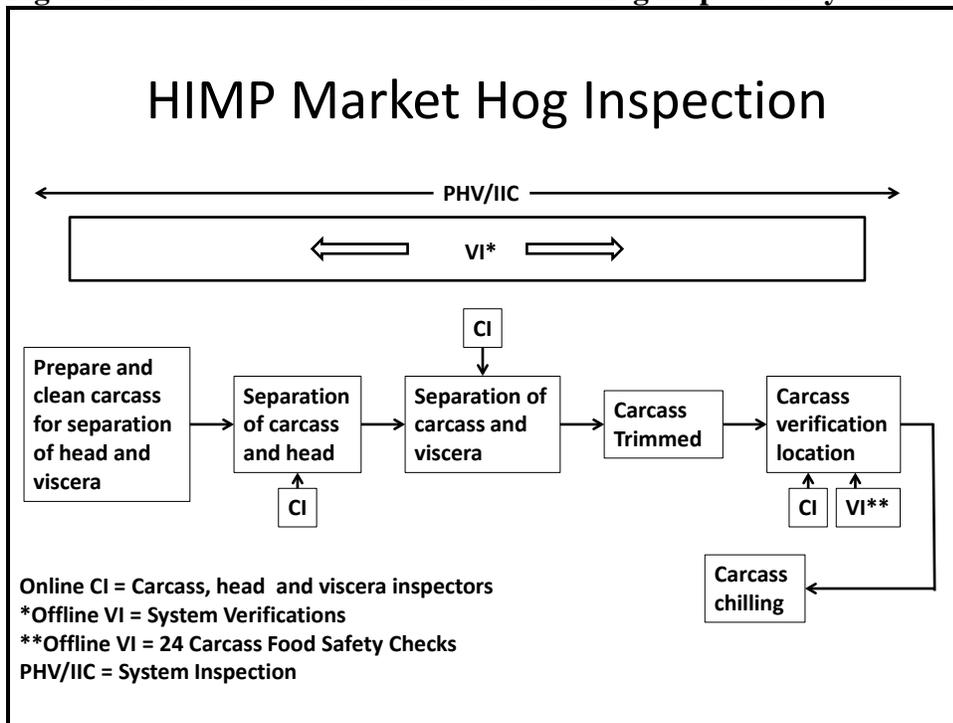
2.0 DESCRIPTION OF HIMP AND NON-HIMP MARKET HOG ESTABLISHMENTS

A description of HIMP and non-HIMP market hog inspection systems follows.

2.1 Inspection in HIMP and Non-HIMP Market Hog Establishments

The HIMP market hog inspection system has one ante-mortem inspector, two or three online carcass inspectors (CI), and one off-line verification inspector (VI) assigned to each line. The online CIs inspect every head, viscera, and carcass at the corresponding fixed locations on the slaughter line (See Figures 2-1) to ensure that market hog products receiving the USDA mark of inspection are not adulterated. The off-line VI performs system verifications and the 24 carcass food safety check. The major difference between HIMP and non-HIMP inspection is that the HIMP VI performs 24 food safety carcass checks versus 11 carcass food safety checks at non-HIMP market hog slaughter establishments. Market hog carcass inspection is conducted more efficiently under HIMP than under the non-HIMP inspection systems because establishment personnel have already sorted and removed diseased animals at ante-mortem and identified and removed unacceptable carcasses and parts at post-mortem just prior to FSIS inspection.

Figure 2-1 Flowchart of the HIMP Market Hog Inspection Systems



2.2 Line Speed Estimation

HIMP slaughter establishments are permitted to operate at higher evisceration line speeds than traditional slaughter establishments operating under current inspection systems as long as they maintain process control and meet or exceed Food Safety and OCP performance standards. To evaluate the impact of line speed on HIMP establishment performance, it is necessary to know line speeds in HIMP and comparison non-HIMP market hog establishments.

To clarify line speeds, the annual average line speed at a market hog slaughter establishment was calculated based on the establishment's annual slaughter volume, hours of operation, and the number of shifts and slaughter lines.

In CY2013, the estimated line speeds at the 5 HIMP market hog establishments varied from 885 to 1,295 head per hour (hph), with an estimated average line speed of 1,099 hph. The 21 non-HIMP comparison establishments had line estimated speeds of 571 to 1,149 hph, with an estimated average line speed of 977 heads per hour.³

³ Line speed estimates are calculated based on data provided by FSIS personnel on operating hours, donning and doffing times, and average overtime. Responses included ranges, averages, and estimates, so estimated line speeds likely vary from the actual line speeds. This results in estimated line speeds that may be above the actual operating line speeds and above the allowed maximum for non-HIMP establishments.

3.0 RESULTS

This section presents a summary of FSIS inspection findings in HIMP market hog establishments and compares them to inspection findings in 21 traditional non-HIMP market hog establishments of comparable size or with FSIS HIMP market hog performance standards derived from the RTI study of pre-HIMP market hog establishments as appropriate. The findings are organized around the following three interrelated FSIS inspection activities:

1. Verification, by off-line inspectors, of the establishment's execution of its HIMP slaughter process control plans, under which establishment employees sort acceptable and unacceptable carcasses and parts.
2. Verification of the establishment's execution of its Sanitation Standard Operating Procedures (Sanitation SOP) and its Hazard Analysis and Critical Control Point (HACCP) system under 9 CFR Parts 416 and 417.
3. Verification of the outcomes of the establishment's HACCP and process control plans, both organoleptic and microbiologic

3.1 Verification that the Establishment is Executing its HIMP Slaughter Process Control Plan (PCP) whereby Establishment Employees Sort Acceptable and Unacceptable Carcasses and Parts

Under HIMP, employees of slaughter establishments sort live animals at ante-mortem and carcasses at post-mortem, in both cases just prior to inspection by FSIS inspectors. The sorted carcasses are expected to meet or exceed Food Safety (FS) and Other Consumer Protection (OCP) performance standards. FSIS online inspectors inspect each head, viscera, and carcass as required by the Federal Meat Inspection Act (FMIA) and conduct off-line carcass verification sampling to verify that the establishment's finished product meets or exceeds the required outcome. The off-line inspectors also conduct other verification sampling of the establishment's processes and products to ensure compliance with Sanitation SOP, HACCP, and other FSIS regulatory requirements. This section describes the FSIS off-line verification activities of establishments executing their HIMP PCP and complying with food safety regulatory requirements.

3.1.1 Number of Off-line FSIS Verification Inspection Procedures per Establishment Under PBIS

FSIS inspectors conduct off-line verification inspection procedures in HIMP market hog establishments to verify that the establishment complies with established standards for food safety and OCP defects, pathogen levels, other applicable sanitation and HACCP federal regulations, and established HIMP performance standards.

Table 3-1 presents the ratio of the number of off-line inspection procedures per establishment in HIMP and non-HIMP market hog establishments for CY2010 (data for CY2006-CY2009 are presented in Appendix E). For CY2010, FSIS inspectors performed 1.4 times more total off-line verification inspection procedures and 1.5 more SSOP and HACCP inspection procedures in HIMP market hog establishments than in non-HIMP market hog establishments. This is primarily the result of the increased number of 03J01 verifications under HIMP. This

observation supports the determination that FSIS inspectors were ensuring that HIMP market hog establishments were complying with all federal regulations.

Table 3- 1 Number of Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS in CY2010

Procedure code ¹	Number of Inspection Procedures Per Establishment Per Calendar Year		HIMP/Non-HIMP Ratio
	5 HIMP Market Hog Establishments	21 Non-HIMP Market Hog Comparison Establishments	
01A01 ²	3.8	2.5	1.5
01B01	167.4	152.7	1.1
01B02	156.6	136.5	1.1
01C01	234.4	270.0	0.9
01C02	330.0	303.0	1.1
03A01	3.4	2.5	1.4
03J01	621.4	131.0	4.7
03J02	175.2	154.6	1.1
04C03	226.2	175.60	1.3
05A01	1.4	0.9	1.5
06D01	141.0	152.2	0.9
CY2010 Total for Procedures	2060.8	1482.2	1.4
CY2010 Total for SSOP and HACCP Procedures³	1692.2	1152.8	1.5

1. See Appendix B for description of inspection procedure codes
2. The 01A01 procedure is performed annually and anytime there are major changes to the establishment's existing SSOP
3. See Appendix A for description of sanitation SOP and HACCP procedures

3.1.2 Number of Off-line FSIS Verification Inspection Procedures for HACCP and Sanitation SOP per Establishment Under PHIS

For the years CY2012 and CY2013, comparisons of the ratios of the number of off-line inspection procedures per establishment in HIMP and non-HIMP market hog establishments were made on the basis of mandatory verifications and public health related (PHR) regulations. Mandatory verifications are the minimal subset of regulations that inspectors should verify every time they perform an inspection task. (Additional regulations listed under an inspection task are verified on a random basis and as appropriate). There are 31 mandatory verifications associated

with the 8 FSIS off-line mandatory verification inspection procedures that apply to all market hog slaughter establishments. Mandatory verifications are described in Appendix C.

Table 3-2 presents the ratio of number of off-line inspection verification of mandatory regulations for CY2012. For CY2012, FSIS inspectors performed 1.4 times more of the off-line inspection mandatory verifications in HIMP than in non-HIMP market hog establishments and 1.5 times more SSOP and HACCP mandatory verification regulations. This is due largely to the increased verification of 9 CFR 310.18 regulations and to a lesser extent increased verification of 9 CFR 416 regulation verifications. This is offset partially by reduced verifications of the 9 CFR 417 regulations.

Table 3- 2 Number of Mandatory Regulation Verifications per Establishment in HIMP and Non-HIMP Market Hog Establishments for CY2012

Mandatory Regulation Verified	Number of Mandatory Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
310.18 ¹	10,324.80	4,871.95	2.12
416.1	190.40	249.95	0.76
416.12(a)	561.40	524.38	1.07
416.13(a)	371.00	241.67	1.54
416.13(b)	610.40	595.90	1.02
416.13(c)	963.20	830.43	1.16
416.14	576.20	499.62	1.15
416.16(a)	1,027.00	884.24	1.16
416.16(b)	52.20	128.29	0.41
416.16(c)	410.80	352.38	1.17
417.2(c)(4)	288.00	334.48	0.86
417.2(c)(5)	235.00	302.57	0.78
417.2(c)(6)	254.80	319.19	0.80
417.2(c)(7)	260.80	340.00	0.77
417.3(a)(1)	80.60	116.24	0.69
417.3(a)(2)	211.00	307.05	0.69
417.3(a)(3)	82.40	114.10	0.72
417.3(a)(4)	47.80	94.38	0.51
417.3(b)(1)	28.80	49.86	0.58
417.3(b)(2)	28.60	53.86	0.53
417.3(b)(3)	39.60	82.81	0.48
417.3(b)(4)	23.60	42.67	0.55
417.3(c)	34.00	56.57	0.60
417.4(a)(2)(i)	216.40	269.33	0.80
417.4(a)(2)(ii)	327.20	332.05	0.99
417.4(a)(2)(iii)	344.20	347.29	0.99

Mandatory Regulation Verified	Number of Mandatory Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
417.5(a)(1)	226.60	292.19	0.78
417.5(a)(2)	276.00	331.00	0.83
417.5(a)(3)	437.60	440.48	0.99
417.5(b)	325.20	349.52	0.93
417.5(c)	324.20	344.52	0.94
CY2012 Total Mandatory² Regulations	19,180	14,099	1.36
CY2012 Total SSOP and HACCP Mandatory Regulations³	16,493	11,111	1.48

¹ Adjusted to reflect the 24 market hogs per 310.18 verification for HIMP market hog establishments versus 11 hogs per verification for non-HIMP market hog establishments

² See Appendix C for description of mandatory regulations

³ See Appendix A for description of sanitation SOP and HACCP procedures

Table 3-3 presents the ratio of number of off-line inspection verification of mandatory regulations for CY2013. In CY2013, FSIS inspectors performed 1.4 times more of the off-line inspection verifications of mandatory regulations in HIMP market hog establishments than in non-HIMP market hog establishments and 1.6 times more SSOP and HACCP mandatory verification regulations.

Table 3- 3 Number of Mandatory Regulation Verifications per Establishment in HIMP and Non-HIMP Market Hog Establishments for CY2013

Mandatory Regulation Verified	Number of Mandatory Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
310.18 ¹	10,804.80	4,850.48	2.23
416.1	273.80	323.52	0.85
416.12(a)	550.20	522.71	1.05
416.13(a)	344.80	201.19	1.71
416.13(b)	568.40	600.67	0.95
416.13(c)	1,036.40	881.95	1.18
416.14	574.80	513.90	1.12
416.16(a)	999.80	808.67	1.24
416.16(b)	60.80	129.00	0.47
416.16(c)	503.00	365.57	1.38

Mandatory Regulation Verified	Number of Mandatory Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
417.2(c)(4)	312.80	395.43	0.79
417.2(c)(5)	226.80	283.33	0.80
417.2(c)(6)	239.00	297.57	0.80
417.2(c)(7)	237.60	324.33	0.73
417.3(a)(1)	29.00	51.43	0.56
417.3(a)(2)	99.00	174.24	0.57
417.3(a)(3)	29.80	47.57	0.63
417.3(a)(4)	17.60	51.67	0.34
417.3(b)(1)	11.80	26.24	0.45
417.3(b)(2)	11.80	26.62	0.44
417.3(b)(3)	13.20	46.05	0.29
417.3(b)(4)	12.20	19.10	0.64
417.3(c)	21.40	35.19	0.61
417.4(a)(2)(i)	187.80	247.05	0.76
417.4(a)(2)(ii)	298.60	301.05	0.99
417.4(a)(2)(iii)	296.00	323.52	0.91
417.5(a)(1)	194.20	259.29	0.75
417.5(a)(2)	225.20	291.38	0.77
417.5(a)(3)	400.00	420.81	0.95
417.5(b)	311.00	320.10	0.97
417.5(c)	293.40	321.19	0.91
CY2013 Total Mandatory² Regulations	19,185.0	13,460.8	1.43
CY2013 Total SSOP and HACCP Mandatory Regulations³	16,825	10,767	1.56

¹ Adjusted to reflect the 24 market hogs per 310.18 verification for HIMP market hog establishments versus 11 hogs per verification for non-HIMP market hog establishments

² See Appendix C for description of mandatory regulations

³ See Appendix A for description of sanitation SOP and HACCP procedures

Table 3-4 presents the ratio of number of off-line inspection verification of public health regulations for CY2012. In CY2012, FSIS inspectors performed an equivalent number of total off-line inspection verifications of PHR regulations in HIMP market hog establishments as in non-HIMP market hog establishments and 1.1 times more SSOP and HACCP PHR verification regulations.

Table 3- 4 Number of Public Health-Related Regulations Verified per Establishment in HIMP and Non-HIMP Market Hog Establishments for CY2012

Public Health Regulations ¹ Verified	PHR Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
301.2_Adulterated	26.00	15.48	1.68
381.144(a) ²	0.00	0.05	0.00
381.65(a) ²	1.80	4.05	0.44
381.91(a) ²	0.20	0.52	0.38
381.91(b) ²	0.40	0.33	1.20
416.1	190.40	249.95	0.76
416.14	576.20	499.62	1.15
416.15(a)	241.80	168.95	1.43
416.15(b)	122.20	68.76	1.78
416.16(a)	1027.00	884.24	1.16
416.3(b)	37.20	15.33	2.43
416.4(d)	223.20	174.38	1.28
416.6	0.60	2.19	0.27
417.2(c)(4)	288.00	334.48	0.86
417.3(a)(1)	80.60	116.24	0.69
417.3(a)(2)	211.00	307.05	0.69
417.3(a)(3)	82.40	114.10	0.72
417.3(a)(4)	47.80	94.38	0.51
417.3(b)(1)	28.80	49.86	0.58
417.3(b)(3)	39.60	82.81	0.48
417.3(c)	34.00	56.57	0.60
417.4(a)	0.80	3.00	0.27
417.4(a)(1)	0.40	1.38	0.29
417.4(a)(3)	1.20	3.38	0.35
417.4(b)	0.40	1.10	0.37
417.5(a)(1)	226.60	292.19	0.78
417.5(a)(3)	437.60	440.48	0.99
CY2012 Total PHR Regulations¹	3,926	3,981	0.99
CY2012 Total SSOP and HACCP PHR Regulations	3,023	2,823	1.07

¹ See Appendix C for description of public health regulations

² Regulations from 9 CFR 381 apply only to poultry establishments, but on rare occasions have been inappropriately marked as verified at hog establishments. These regulations are included for completeness since they are part of the FSIS set of Public Health Regulations that were cited

which apply to all establishments. Due to their very low frequency of being cited, their inclusion or non-inclusion does not impact any of the findings or conclusions of this report.

Table 3-5 presents the ratio of number of off-line inspection public health regulation verifications for CY2013. In CY2013, FSIS inspectors performed an equivalent number of total off-line inspection verifications of HACCP public health-related (PHR) regulations in HIMP market hog establishments as in non-HIMP market hog establishments and 1.1 times more SSOP and PHR regulation verifications.

Table 3- 5 Public Health-Related Regulations Verified per Establishment in HIMP and Non-HIMP Market Hog Establishments for CY2013

Public Health Regulations ¹ Verified	PHR Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
	5 HIMP Hog Establishments	21 Non-HIMP Hog Establishments	
301.2_Adulterated	6.20	9.05	0.69
381.144(a) ²	0.00	0.19	0.00
381.65(a) ²	2.00	2.86	0.70
381.83 ²	0.20	0.10	2.10
381.91(a) ²	0.00	0.29	0.00
381.91(b) ²	0.20	0.33	0.60
416.1	273.80	323.52	0.85
416.14	574.80	513.90	1.12
416.15(a)	106.00	80.24	1.32
416.15(b)	57.60	39.62	1.45
416.16(a)	999.80	808.67	1.24
416.3(b)	57.00	16.38	3.48
416.4(d)	205.00	201.90	1.02
416.6	0.20	1.86	0.11
417.2(c)(4)	312.80	395.43	0.79
417.3(a)(1)	29.00	51.43	0.56
417.3(a)(2)	99.00	174.24	0.57
417.3(a)(3)	29.80	47.57	0.63
417.3(a)(4)	17.60	51.67	0.34
417.3(b)(1)	11.80	26.24	0.45
417.3(b)(3)	13.20	46.05	0.29
417.3(c)	21.40	35.19	0.61
417.4(a)	0.20	0.86	0.23
417.4(a)(1)	0.20	0.38	0.53
417.4(b)	0.60	0.71	0.84
417.5(a)(1)	194.20	259.29	0.75
417.5(a)(3)	400.00	420.81	0.95

Public Health Regulations¹	PHR Regulation Verifications per Establishment per calendar year		HIMP/Non-HIMP Ratio
CY2013 Total PHR Regulations¹	3,413	3,509	0.97
CY2013 Total SSOP and HACCP PHR Regulations	2,666	2,539	1.05

¹ See Appendix C for description of public health regulations.

² Regulations from 9 CFR 381 apply only to poultry establishments, but on rare occasions have been inappropriately marked as verified at hog establishments. These regulations are included for completeness since they are part of the FSIS set of Public Health Regulations that were cited which apply to all establishments. Due to their very low frequency of being cited, their inclusion or non-inclusion does not impact any of the findings or conclusions of this report.

From the CY2010 – CY2013 data, we can conclude that HIMP market hog establishments receive an equivalent number of verification inspections as non-HIMP market hog establishments, which ensures an equivalent scrutiny of compliance with sanitary dressing and process controls. Although there are more 9 CFR 416 verifications and fewer 9 CFR 417 verifications in HIMP, both verifications are considered to address food safety issues and carry the same regulatory weight when enforcement actions are initiated.

3.1.3 FSIS Condemnation Rates and HIMP Establishment Sorting Disposition Rates

Under HIMP, establishment sorters assume responsibility for identifying, sorting and disposing of noncompliant carcasses and all their associated parts just prior to and in the presence of FSIS carcass inspectors positioned at two or three locations on the slaughter line. FSIS inspectors inspect each carcass to verify that there has been proper sorting by plant sorters, and that only compliant products receive the USDA mark of inspection. Sorting rates are determined by the number of carcasses disposed by establishment sorters divided by the total number of market hogs slaughtered.

In non-HIMP hog establishments, FSIS inspectors have the responsibility for identifying, sorting, and verifying disposition of each carcass to ensure that only compliant products receive the USDA mark of inspection. FSIS condemnation rates are the number of carcasses condemned by FSIS Public Health Veterinarians (PHVs) divided by the total number of market hog slaughtered. This slaughter information was recorded in the FSIS electronic Animal Disease Reporting System (eADRS) until 2012 and now is recorded in PHIS. Under the current non-HIMP inspection system, FSIS has control of the carcass once it is presented for inspection until final inspection is completed. Establishment employees may dispose of carcasses only under FSIS supervision or as directed by the PHV.

In PBIS, FSIS employees recorded both ante-mortem and post-mortem condemnations. In PHIS, only the post-mortem carcass dispositions made by the PHV (carcasses railed out to the PHV)

are entered into PHIS. Thus, FSIS condemnation rates under PBIS and PHIS are not directly comparable (see Appendix A).

Table 3-6 presents a summary of the postmortem sorting rates for HIMP market hog establishments and condemnation rates for the comparison set of non-HIMP market hog establishments for the years CY2006 to CY2010. Sorting rates in HIMP are determined by the number of carcasses disposed by establishment sorters divided by the total number of market hogs slaughtered. Condemnation rates in non-HIMP are computed as the ratio of carcasses condemned by FSIS inspectors divided by the total number of market swine slaughtered.

Table 3- 6 Sorting and Condemnation Rates for HIMP and Non-HIMP Market Hog Establishments for CY2006 to CY2010

	2006	2007	2008	2009	2010
Sorting Rates in 5 HIMP Market Hog Establishments	0.11%	0.10%	0.10%	0.09%	0.11%
Condemnation Rates in 21 Non-HIMP Market Hog Establishments	0.07%	0.07%	0.06%	0.06%	0.06%

Table 3-7 presents a summary of the sorting rates (ante-mortem plus postmortem) for HIMP market hog establishments and condemnation rates (ante-mortem plus postmortem) for the comparison set of non-HIMP market hog establishments for the years CY2012 to CY2013. The sorting rates in HIMP market hog establishments by establishment sorters are statistically significantly higher than condemnation rates in non-HIMP market hog establishments for both years. This result suggests that employees of market hog slaughter establishments are effective in executing their responsibility to produce safe and wholesome products by sorting and disposing of noncompliant carcasses before they reach FSIS inspectors.

Table 3- 7 Sorting and Condemnation Rates for HIMP and Non-HIMP Market Hog Establishments for CY2012 and CY2013

	2012	2013
Sorting Rates in 5 HIMP Hog Establishments	0.29%	0.31%
Condemnation Rates in 21 Non-HIMP Market Hog Establishments	0.26%	0.28%

3.2 Verification of the Establishment Executing its Sanitation SOPs and its HACCP System

This section addresses FSIS verification inspection activities related to verification that the HIMP market hog establishment is executing its sanitation standard operating procedures (Sanitation SOP) and its hazard analysis and critical control point (HACCP) system under 9 CFR Parts 416 and 417.

3.2.1 Off-line Inspection Procedures Performed

The sanitation SOP regulations in 9 CFR Part 416 and the HACCP regulations in 9 CFR Part 417 are among the regulations most strongly related to public health. Sanitation standard operating procedures are written procedures that an establishment develops to maintain sanitary conditions

and prevent contamination of product. The establishment must maintain daily records sufficient to document implementation and monitoring of sanitation SOPs and any corrective actions taken. There are eight inspection procedures in PBIS associated with activities that FSIS inspectors perform to verify compliance with the sanitation SOP and HACCP regulations. In PBIS, there are seven sanitation SOP and HACCP inspection procedures that apply to all market hog slaughter establishments. These are 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, and 03J02. In PHIS, these are 01B01, 01B02, 01C01, 01C02, 03J02 and 03J03. (see Appendix A for explanation of differences between PBIS and PHIS).

In CY2010, FSIS inspectors in HIMP market hog establishments performed approximately 1.5 times more off-line procedures to verify compliance with sanitation SOP and HACCP regulatory requirements than in non-HIMP market hog establishments (see Table 3-1 above). In CY2012 and CY2013, FSIS inspectors in HIMP market hog establishments performed approximately 1.5 and 1.6 times more, respectively, off-line inspections of mandatory regulations to verify compliance with sanitation SOP and HACCP regulatory requirements than in non-HIMP market hog establishments (see Tables 3-2 and 3-3). Thus, there is more frequent verification of compliance with sanitation SOP and HACCP regulation in market hog HIMP market hog establishments, which ensures that any noncompliance with sanitary dressing and process controls will be more likely to be identified at HIMP establishments than at non-HIMP establishments.

3.2.2 Public Health Noncompliance Rates

FSIS inspection program personnel (IPP) perform inspection procedures in federally-inspected establishments each day to verify that the establishments are executing their SSOP and HACCP system under 9 CFR Parts 416 and 417. If IPP observe a noncompliance with a regulatory requirement, they are to document the finding on a noncompliance record (NR) to the establishment. Establishments are to respond to the NRs by describing their corrective and preventive actions to comply with the applicable regulation.

PBIS and PHIS use different lists of the most serious health-related regulations. PBIS used the list of W3NRs which was selected by a group of FSIS experts, while PHIS uses an updated list of Public Health Regulations (PHRs) derived through a more transparent and data-driven approach that identifies regulations with which there is an elevated rate of noncompliance during the three months before a *Salmonella*, *E. coli* O157: H7, or *Listeria monocytogenes* (Lm) positive.

Eleven inspection procedures in PBIS are used by FSIS inspectors in all market hog slaughter establishments. They are 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, 03J02, 04C03, 05A01 and 06D01. See Appendix B for a description of these inspection procedures. The number of inspection procedures performed and the number of health-related NRs issued were determined for each procedure code for each of the years CY2006 to CY2010 for each HIMP and control set of non-HIMP establishment.

Table 3-8 presents a summary of the W3NR noncompliance rates by procedure code for the 5 years of combined CY2006 to CY2010 data. Health-related noncompliance rates at HIMP market hog establishments for individual procedure codes are statistically higher for the three

inspection task codes marked with stars and are not statistically significantly different for remaining eight procedure codes. The W3NR rate for total sanitation SOP and HACCP health related procedures are statistically significantly higher in HIMP market hog establishments than in non-HIMP market hog establishments. These are computed as the sum of W3NR noncompliances in 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, and 03J02 divided by the number of inspections of these procedure codes.

Table 3- 8 Average CY2006-CY2010 W3NR Noncompliance Rates for HIMP and Non-HIMP Market Hog Establishments

Procedure Code ¹	HIMP Market Hog Establishments			Non-HIMP Comparison Market Hog Establishments		
	NCs	Total Procedures	Market Hog NC Rates	NCs	Total Procedures	Comparison Market Hog NC Rates
01A01	-	80	0.00%	-	3	0.00%
01B01	11	4,757	0.23%*	7	16,305	0.04%
01B02	61	3,914	1.56%	189	14,237	1.33%
01C01	21	6,070	0.35%	95	28,551	0.33%
01C02	187	8,544	2.19%	689	32,544	2.12%
03A01	-	72	0.00%	2	271	0.74%
03J01	187	15,246	1.23%*	84	13,300	0.63%
04C03	17	4,004	0.42%*	7	12,591	0.06%
03J02	28	4,614	0.61%	71	16,070	0.44%
05A01	-	21	0.00%	-	95	0.00%
06D01	-	4,282	0.00%	-	15,412	0.00%
SSOP and HACCP Health-Related NC Rates	495	43,297	1.14%*	1,137	121,281	0.94%

* indicates a statistically significant difference at the 0.05 level.

1. See Appendix B for description of procedure codes

The six inspection tasks in PHIS associated with activities that FSIS inspectors perform to verify compliance with the sanitation SOP and HACCP regulations are 01B01, 01B02, 01C01, 01C02, 03J02, and 03J03. See Appendix B for a description of these procedures. Table 3-9 and Table 3-10 present a summary of the Public Health Regulation (PHR) noncompliance rates for these seven inspection tasks by regulation for CY2012 and CY2013, respectively. For CY2012, PHR noncompliance rates at HIMP market hog establishments are statistically significantly higher for four regulations, statistically significantly lower for five regulations, and not statistically significantly different for eighteen regulations. Overall, the CY2012 PHR noncompliance rate for SSOP and HACCP regulations in HIMP market hog establishments is statistically significantly lower than that for the 21 comparison non-HIMP market hog establishments. For CY2013, PHR noncompliance rates at HIMP market hog establishments are statistically significantly higher for three regulations, statistically significantly lower for five regulations, and

not statistically significantly different for nineteen regulations. Overall, the PHR noncompliance rate in CY2013 for SSOP and HACCP regulations in HIMP market hog establishments is statistically significantly lower than that for the 21 comparison non-HIMP market hog establishments.

Table 3- 9 SSOP and HACCP Public Health (PHR) Noncompliance Rates for HIMP and Non-HIMP Market Hog Establishments for CY2012

Regulation Verified	HIMP Market Hog Establishments			Non-HIMP Comparison Market Hog Establishments		
	NC	Times Verified	Non-Compliance Rate	NC	Times Verified	Non-Compliance Rate
301.2_ Adulterated	12	130	9.23%*	51	296	17.23%
381.144(a) ¹	-	-		-	1	0.00%
381.65(a) ¹	-	-		-	10	0.00%
381.91(a) ¹	-	-		-	1	0.00%
381.91(b) ¹	-	-		-	1	0.00%
416.1	45	93	48.39%*	300	892	33.63%
416.14	5	2,881	0.17%*	149	10,492	1.42%
416.15(a)	19	1,209	1.57%*	164	3,548	4.62%
416.15(b)	13	611	2.13%*	102	1,444	7.06%
416.16(a)	71	5,135	1.38%*	90	18,569	0.48%
416.3(b)	2	118	1.69%	10	232	4.31%
416.4(d)	184	927	19.85%*	966	2,883	33.51%
417.2(c)(4)	23	909	2.53%*	59	4,501	1.31%
417.3(a)(1)	3	252	1.19%	10	1,502	0.67%
417.3(a)(2)	47	780	6.03%*	22	4,189	0.53%
417.3(a)(3)	3	266	1.13%	13	1,460	0.89%
417.3(a)(4)	3	91	3.30%	4	578	0.69%
417.3(b)(1)	1	10	10.00%	3	215	1.40%
417.3(b)(3)	2	55	3.64%	3	347	0.86%
417.3(c)	2	28	7.14%	4	246	1.63%
417.4(a)	1	2	50.00%	3	17	17.65%
417.4(a)(1)	-	1	0.00%	-	6	0.00%
417.4(a)(3)	-	4	0.00%	-	24	0.00%
417.4(b)	-	1	0.00%	-	12	0.00%
417.5(a)(1)	3	427	0.70%	11	2,734	0.40%
417.5(a)(3)	5	1,186	0.42%	17	5,076	0.33%
SSOP and HACCP Health-Related NC	444	15,116	2.94%*	1,981	59,276	3.34%

Rates						
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* indicates a statistically significant difference at the 0.05 level.

¹ Regulations from 9 CFR 381 apply only to poultry establishments, but on rare occasions have been inappropriately marked as verified at hog establishments. These regulations are included for completeness since they are part of the FSIS set of Public Health Regulations that were cited which apply to all establishments. Due to their very low frequency of being cited, their inclusion or non-inclusion does not impact any of the findings or conclusions of this report.

Table 3- 10 SSOP and HACCP PHR Noncompliance Rates for HIMP and Non-HIMP Market Hog Establishments for CY2013

Regulation Verified	HIMP Market Hog Establishments			Non-HIMP Comparison Market Hog Establishments		
	NCs	Times Verified	Non-Compliance Rate	NCs	Times Verified	Non-Compliance Rate
301.2_ Adulterated	-	31	0.00%*	89	180	49.44%
381.144(a) ¹	-	-		-	2	0.00%
381.65(a) ¹	-	1	0.00%	-	6	0.00%
381.83 ¹	1	1	100.00%	-	2	0.00%
381.91(a) ¹	-	-		-	2	0.00%
381.91(b) ¹	-	-		-	4	0.00%
416.1	117	465	25.16%	611	2,166	28.21%
416.14	5	2,874	0.17%*	102	10,792	0.95%
416.15(a)	11	530	2.08%*	93	1,685	5.52%
416.15(b)	4	288	1.39%*	72	832	8.65%
416.16(a)	59	4,999	1.18%*	70	16,982	0.41%
416.3(b)	11	211	5.21%	22	261	8.43%
416.4(d)	157	874	17.96%*	1,021	3,283	31.10%
417.2(c)(4)	56	860	6.51%*	96	4,559	2.11%
417.3(a)(1)	-	87	0.00%	7	680	1.03%
417.3(a)(2)	11	392	2.81%*	25	2,760	0.91%
417.3(a)(3)	1	91	1.10%	9	601	1.50%
417.3(a)(4)	-	30	0.00%	6	503	1.19%
417.3(b)(1)	-	2	0.00%	1	187	0.53%
417.3(b)(3)	-	8	0.00%	1	396	0.25%
417.3(c)	-	21	0.00%	9	146	6.16%
417.4(a)	-	1	0.00%	-	8	0.00%
417.4(a)(1)	-	1	0.00%	1	5	20.00%
417.4(b)	-	2	0.00%	-	6	0.00%
417.5(a)(1)	1	425	0.24%	4	2,441	0.16%
417.5(a)(3)	6	1,138	0.53%	23	4,829	0.48%

Regulation Verified	HIMP Market Hog Establishments			Non-HIMP Comparison Market Hog Establishments		
	NCs	Times Verified	Non-Compliance Rate	NCs	Times Verified	Non-Compliance Rate
Total SSOP and HACCP Health-Related NC Rates	440	13,332	3.30%*	2,262	53,318	4.24%

* indicates a statistically significant difference at the 0.05 level.

¹ Regulations from 9 CFR 381 apply only to poultry establishments, but on rare occasions have been inappropriately marked as verified at hog establishments. These regulations are included for completeness since they are part of the FSIS set of Public Health Regulations that were cited which apply to all establishments. Due to their very low frequency of being cited, their inclusion or non-inclusion does not impact any of the findings or conclusions of this report.

3.2.3 Postmortem Food Safety Disease Conditions (FS-1)

Table 3-11 presents rates of NRs issued at HIMP market hog establishments to document inspectors findings of food safety disease FS-1 conditions such as septicemia, pyemia, and toxemia as provided in 9 CFR 311.17. In PBIS, the NR rate is computed as the number of NRs citing 9 CFR 311.17 divided by the sum of the number of 03J01 and 03J02 procedures performed. No NRs are written for these disease conditions in non-HIMP market hog establishments since on line FSIS inspectors are responsible for sorting in non-HIMP market hog establishments.

A corresponding table for CY2012 and CY2013 is not presented since regulation 9 CFR 311.17 is not mandatory in PHIS. Thus, under PHIS task assignments, inspectors only verify the regulation randomly and are not required to record verifications unless they detect a noncompliance. Thus, noncompliance records for 9CFR 311.17 in PHIS are not uniform. Inspectors do perform FS-1 inspections on a daily basis as part of the food safety performance standard assessment, but performance of the inspection is not recorded in PHIS. (Monthly records of these verifications and noncompliances are kept at the facility. They were retrieved and are reported later in the report.)

Table 3- 11 Noncompliance Rates for Food Safety Disease Conditions (FS-1) at HIMP Market Hog Establishments for CY2006 to CY2010

Year	HIMP
2006	0.11%
2007	0.12%
2008	0.20%
2009	0.08%
2010	0.18%

3.2.4 Fecal Material, Ingesta, and Milk Contamination (FS-2)

Table 3-12 presents the HIMP and non-HIMP noncompliance rates for fecal material, ingesta, and milk contamination (FS-2) on market hog carcasses (9 CFR 310.18) for the years CY2006 to CY2010. The noncompliance rate is computed as the number of noncompliances citing 9 CFR 310.18 divided by the sum of the number of 03J01 and 03J02 procedures performed. The fecal material, ingesta, and milk contamination noncompliance rates at HIMP market hog establishments are not statistically significantly different from those in the control set of non-HIMP market hog establishments.

Table 3- 12 Noncompliance Rates for Fecal Material, Ingesta, and Milk Conditions at HIMP and Non-HIMP Comparison Establishments

Year	HIMP	Non-HIMP Comparison Establishments
2006	1.27%	0.85%
2007	0.89%	0.88%
2008	0.91%	0.56%
2009	0.97%	0.96%
2010	0.95%	0.93%

A corresponding table for CY2012 and CY2013 is presented since 9 CFR 310.18 is a mandatory in PHIS, and inspectors are required to enter FS-2 verifications into PHIS. (Monthly records of the FS-2 verifications and noncompliances are also kept at the facility. They were retrieved and are reported later in the report.)

Table 3-13 presents the HIMP and non-HIMP noncompliance rates for fecal material, ingesta, and milk contamination on market hog carcasses (9 CFR 310.18) for the years CY2012 and CY2013. The noncompliance rate is computed as the number of noncompliances citing 9 CFR 310.18 divided by the number of 9 CFR 310.18 verifications performed. The fecal material, ingesta, and milk contamination noncompliance rates at HIMP market hog establishments are not statistically significantly different from those in the control set of non-HIMP market hog establishments for CY2012 but are statistically significantly lower in CY2013 (Two- Sided Exact Fisher $p = 0.023$).

Table 3- 13 Noncompliance Rates for Fecal Material, Ingesta, and Milk Conditions at HIMP and Non-HIMP Market Hog Establishments for CY2012 and CY2013

Year	HIMP	Non-HIMP Comparison Establishments
2012	0.18%	0.21%
2013	0.15%	0.21%

3.2.5 Ante-Mortem Inspection (FS-3)

FSIS inspectors at HIMP and non-HIMP market hog establishments conduct ante-mortem inspections of the live animals presented for inspection before the slaughter process begins. At HIMP market hog establishments, establishment employees sort hogs for FS-3 conditions prior to crossing their designated CCP and FSIS ante-mortem inspection. Table 3-13 presents rate of NRs issued at HIMP market hog establishments to document FSIS inspectors' findings of food safety disease conditions at ante-mortem as provided in 9 CFR Part 309. This procedure is not applicable in non-HIMP market hog establishments. The noncompliance rate is computed as the number of 9 CFR Part 309-related NRs divided by the sum of the number of 03J01 and 03J02 procedures performed for the years CY2006-CY2010.

A corresponding table for CY2012 and CY2013 is not presented since 9 CFR Part 309 is not mandatory in PHIS, and inspectors are not required to enter FS-3 verifications into PHIS unless there is a noncompliance. (Monthly records of the verifications and noncompliances are kept at the facility. They were retrieved and are reported later in the report.)

Table 3- 14 Ante-Mortem 9 CFR Part 309 Noncompliance Rates at HIMP Market Hog Establishments

Year	HIMP
2006	0.06%
2007	0.25%
2008	0.22%
2009	0.13%
2010	0.05%

3.3 Verification of the Outcomes of the Establishment Slaughter HACCP and Process Control Plans, Both Organoleptic and Microbiologic

This section addresses FSIS inspection activities related to verification of the establishment's slaughter HACCP and process control plans (PCP) concerning the organoleptic detection of FS (food safety) and OCP (other consumer protection) defects. The establishment HACCP plan addresses the FS defects, while the process control plan addresses OCP concerns.

3.3.1 Food Safety Performance Standards

FSIS has a zero tolerance policy for food safety conditions (e.g. septicemia, toxemia, pyemia) identified as FS-1 conditions; fecal material, ingesta and milk contamination identified as FS-2 conditions; and certain conditions identified at ante-mortem (e.g. moribund, severe lameness, pyretic, and neurologic conditions) identified as FS-3 conditions. Under HACCP, FSIS detection of any food safety disease condition past the CCP represents a noncompliance and deviation of a critical limit. FSIS's performance standards (FS-1, FS-2 and FS-3) for these food safety conditions are zero (FSIS 2000). A comparison of market hog HIMP establishment performance with food safety performance standards is presented in Table 3-15. The analysis in Table 3-15

for CY2009 to CY2010 is based on FSIS food safety inspection findings for the approximately 2 year period April 1, 2009 through April 15, 2011. The food safety performance rates for FS-1 and FS-2 are computed as the number of food safety-related defects found during all 24 carcass verifications divided by the total number of verification checks performed. The food safety performance rate for FS-3 is computed as the number of ante-mortem related deficiencies divided by the total number of annual shifts.

The level of food safety defects is exceedingly small. Four of the five HIMP market hog establishments had zero FS-1 deficiencies in the two year period CY2012-CY2013 with the fifth having 3. This is an overall FS-1 deficiency rate of 3 per 100 thousand market hogs slaughtered. The defect rate for FS-2 in CY2012-CY2013 is 5 in ten thousand, which has decreased from 6 in ten thousand in CY2009-CY2010 and for both time periods is less than the 75% performance level of 2.6 per 100.

Table 3- 15 Achievement of Food Safety Performance Standards at HIMP Market Hog Establishments

	Performance Standards Based on Non-HIMP Inspection (% of carcasses)	CY2009-CY2010¹ HIMP Establishment Performance During FSIS Inspector Verification Checks (% of carcasses)	CY2012-CY2013² HIMP Establishment Performance During FSIS Inspector Verification Checks (% of carcasses)
FS-1 Infectious (e.g. septicemia, toxemia, cysticercus)	0.0%*	0.01%	0.00003%
FS-2 Digestive Content/Milk (e.g., fecal material, ingesta, milk)fecal contamination of viscera)	0.0%**	0.06%	0.05%
FS-3 Ante-Mortem Suspect	0.0%	0.00%	0.01%

*FSIS has a zero tolerance policy for Food Safety. Baseline result was 0.0% at 75th percentile.

** FSIS has a zero tolerance policy for Food Safety. Baseline result was 2.6% at 75th percentile.

1 Period of data collection: April 1, 2009 through April 15, 2011

2 Period of data collection: CY2012 – CY2013

3.3.2 Other Consumer Protection Performance Standards

Other Consumer Protection (OCP) standards are non-food safety standards concerned primarily with diseases of no public health significance and carcass processing defects. Using RTI data, FSIS developed OCP performance standards for HIMP market hog establishments and monitors

HIMP establishment performance to verify that OCP performance standards are being met. A comparison of HIMP market hog establishment performance with OCP performance standards is given in Table 3-16. The analysis is based on FSIS food safety inspection findings for the two year period CY2009 - CY2010 and the two year period CY2012 – CY2013. The HIMP OCP performance rates are computed as the number of OCP defects found by inspectors divided by the number of OCP verification checks performed. All HIMP market hog establishments were meeting OCP performance standards.

Table 3- 16 Achievement of OCP Performance Standards at HIMP Market Hog Establishments for CY2009 - CY2010 and CY2012 – CY2013

	Performance Standards Based on Non-HIMP Inspection (% of carcasses)	CY2009-CY2010¹ HIMP Establishment Performance During FSIS Inspector Verification Checks (% of carcasses)	CY2012-CY2013² HIMP Establishment Performance During FSIS Inspector Verification Checks (% of carcasses)
OCP 1 Carcass Pathology (e.g., arthritis, emaciation, erysipelas)	4.1%	1.2%	1.7% Range 0.05%-2.6%
OCP 2 Visceral Pathology (e.g., cystic kidneys, enteritis/gastritis, fecal contamination of viscera)	7.2%	2.3%	3.1% Range 0.4%-4.4%
OCP 3 Miscellaneous (e.g., anemia, bile, bruise, edema)	20.5%	8.3%	10.7% Range 3.1%-15.6%

1 Period of data collection: April 1, 2009 through April 15, 2011

2 Period of data collection CY2012 – CY2013

3.3.3 *Salmonella* Positive Rates

FSIS uses data from its *Salmonella* verification testing programs to verify that establishments are meeting their regulatory obligation of complying with *Salmonella* performance standards in 9 CFR 310.25(b). The Agency believes that the higher the percent positive rate, the greater the potential for the public to consume a product that may cause foodborne illness.

Table 3-17 presents a summary of the *Salmonella* percent positive rates for market hog HIMP and the control set of 21 non-HIMP market hog establishments for the years CY2006 to CY2010. The *Salmonella* positive rates in HIMP market hog establishments are lower than those in non-

HIMP comparison establishments for the years CY2006 to CY2009 but higher in CY2010. However, the differences are not statistically significant for any of the years. Thus, there is no statistically significant difference in the *Salmonella* verification testing results between market hog HIMP and non-HIMP market hog establishments for the years CY2006 to CY2010.

Table 3- 17 Salmonella Percent Positive Rates for HIMP and Non-HIMP Market Hog Establishments

	2006	2007	2008	2009	2010
5 HIMP Market Hog Establishments	1.06%	0.66%	0.00%	0.00%	2.29% ¹
21 Non-HIMP Comparison Establishments	1.39%	1.44%	1.51%	1.48%	0.69%

¹ Two establishments had 2 positives, one had 1 positive.

FSIS discontinued collecting *Salmonella* verification samples for carcasses in calves/bulls, steers/heifers and market hog slaughter classes in July 2011.

In addition to the *Salmonella* verification testing program, for the thirteen months from August 2010 to August 2011, FSIS conducted a *Salmonella* baseline study on market hog establishments. The program was designed to estimate the percent positive and level of microbiological pathogens and indicator bacteria on market hog carcasses, as well as to estimate the national prevalence of *Salmonella* in market hogs. The program collected 3,920 sponge samples from market hog carcasses (1,960 at Pre-Evisceration and 1,960 at Post-Chill from 2 separate shifts when available) at 152 establishments that slaughtered market hogs under Federal Inspection.

Table 3-18 presents the *Salmonella* percent positive for HIMP and non-HIMP market hog establishments at pre-evisceration and post-chill. The difference between HIMP and the 21 non-HIMP comparison establishments is not statistically significant (Two Sided Exact Fisher $p = 0.55$). This result is probably attributable to the small sample size relative to the low *Salmonella* positive rate. The difference between 5 HIMP market hog establishments and all 147 non-HIMP market hog establishments in the baseline study (includes the 21 non-HIMP comparison establishments) (0.65% versus 3.05%) is highly statistically significant (Two Sided Exact Fisher $p < 0.00001$).

Table 3- 18 Salmonella Positive Rate from Market Hog Baseline Study (August 2010-August 2011)

Plant Type	Pre-evisceration			Post-chill		
	Number of Positives	Number of Samples	Salmonella Percent Positive	Number of Positives	Number of Samples	Salmonella Percent Positive
5 HIMP Plants	176	288	61.11%	2	288	0.69%
21 Non-HIMP Comparison Plants	915	1,189	76.96%	16	1,189	1.35%
All 147 Non-HIMP Plants in Baseline Study	1189	1672	71.11%	51	1672	3.05%

3.3.4 Chemical Residue Sampling

FSIS conducts tests for chemicals—including antibiotics, sulfonamides, and various other drugs, pesticides and environmental chemicals—in meat, poultry and egg products destined for human consumption. Directed chemical residue testing consists of sampling tissue from randomly selected food animals. Directed sampling tasks are generated from FSIS Headquarters for the National Residue Program. Table 3-19 presents the number of directed chemical residue samples per market hog establishment. As can be expected under random sampling, the number of scheduled directed chemical residue samples per market hog establishment is about the same in HIMP and non-HIMP market hog establishments.

Table 3- 19 Directed Residue Samples at HIMP and Non-HIMP Market Hog Establishments

Year	Directed Residue Samples					
	HIMP			Non-HIMP		
	Number of Plants	Number of Samples	Samples per Plant	Number of Plants	Number of Samples	Samples per Plant
2006	4	13	3.25	20	99	4.95
2007	5	55	11.00	21	226	10.76
2008	5	52	10.40	21	311	14.81
2009	5	68	13.60	21	271	12.90
2010	5	126	25.20	21	553	26.33
2012	5	116	23.20	21	545	25.95
2013	5	128	25.60	21	568	27.05

Inspector generated chemical residue sampling is a targeted sample as it occurs when the in-plant Public Health Veterinarians (PHVs) suspect that an animal may have a violative level of a chemical residue. When a chemical residue sample is collected, the carcass is held pending the results of laboratory testing, and if a carcass is found to contain violative levels of residues, the carcass is condemned.

Table 3-20 presents the number of inspector generated chemical residue samples in HIMP and non-HIMP market hog establishments for the years CY2009 - CY2010 and CY2012 – CY2013. On average inspectors at HIMP market hog establishments collected 2.7 times more chemical residue samples than inspectors at non-HIMP market hog establishments for CY2009 – CY2010 and 1.7 times more for CY2012 – CY2013.

Table 3- 20 Inspector Generated Sampling at HIMP and Non-HIMP Market Hog Establishments CY2009 - CY2013

Year	HIMP			Non-HIMP		
	Number of Plants	Number of Samples	Samples per Plant	Number of Plants	Number of Samples	Samples per Plant
2009	5	1,858	371.60	18	2,861	158.94
2010	4	2,515	628.75	19	3,945	207.63
2012	5	2,916	583.20	21	7,561	360.05
2013	5	3,094	618.80	21	7,509	357.57

Over the period CY2006-CY2010, there were 6 violative levels of chemical residues in the 21 traditional non-HIMP market hog establishments and none in the 5 HIMP market hog establishments. (0 violations per plant per year in HIMP versus 0.057 in non-HIMP) This difference is not statistically significant (Two-Sided Exact Fisher $p = 0.067$).

Over the period CY2012-CY2013, there were 9 violative levels out of 6,010 chemical residue samples (0.15%) in the 5 HIMP market swine establishments and 115 violative levels out of 15,070 samples (0.76%) in the 21 non-HIMP market swine establishments (1.5 violate chemical residue samples per billion HIMP pounds slaughtered versus 4 per billion non-HIMP pounds slaughtered). This difference is statistically significant (Two-Sided Exact Fisher $p < 0.0001$). This finding suggests that HIMP market hog establishments are exercising active control of potential chemical residue hazards in their products. This approach may result from better control over contract grower relationships by HIMP market hog establishments.

4.0 CONCLUSION

The objective of this report is to evaluate Food Safety and Inspection Service (FSIS) inspection findings in market hog slaughter establishments participating in the Hazard Analysis and Critical Control Point (HACCP) Inspection Models Project (HIMP) and to determine whether the HIMP inspection system is performing as well as the existing inspection system in terms of safety and wholesomeness of the products produced and of overall consumer protection. The evaluation is based on two time periods: the years CY2006 - CY2010 and the years CY2012 - CY2013. The evaluation compares the 5 HIMP market hog establishments with a comparison set of 21 non-HIMP market hog slaughter establishments selected to be comparable with HIMP market hog establishments with respect to production volume, line speed, and days of slaughter operation.

This report finds that HIMP market hog establishments are receiving more off-line food safety related inspection verification checks than the traditional non-HIMP market hog establishments. HIMP market hog establishments have higher compliance with Sanitation SOP and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella* verification testing positive rates than traditional non-HIMP market hog establishments, and lower levels of violative chemical residues. This report finds that under HIMP, market hog establishments are receiving an increased level of Sanitation SOP and HACCP inspection. The assumption is made that the number of inspection tasks performed per establishment is correlated with production of a safe product. The FSIS risk assessments on poultry slaughter (FSIS 2008, 2012, 2014) found that more off-line procedures were associated with lower *Salmonella* and *Campylobacter* prevalence and an increase in public illnesses avoided. Moreover, it is certainly the case that the more inspection tasks are performed, the more likely it is that any food safety defects will be identified by inspection personnel and then dealt with by the establishment.

Before beginning HIMP, FSIS developed Food Safety (FS) and Other Consumer Protection (OCP) performance standards that HIMP market hog establishments should meet (FSIS 2000, Cates et al 2001⁴). To enhance the likelihood that HIMP market hog establishments are complying with food safety and OCP performance standards, FSIS has increased the number of daily off-line verifications of market hog carcasses from 11 per line in non-HIMP market hog establishments to 24 per line in HIMP. For this report, FSIS requested that the District Offices provide the paper records stored at individual facilities that inspectors keep on FS and OCP for in-plant inspections for the two periods CY2009-CY2010 and CY2012-CY2013. The request was limited to these two time periods so as to limit the impact on field personnel. The year CY2011 was not included since it is not included in the rest of this evaluation.

A summary of results follows:

- Food safety conditions (FS-1) due to carcasses affected by systemic disease conditions such as toxemia and septicemia in HIMP market hog slaughter establishments are below 1 per 10 thousand carcasses in CY2009-CY2010 and are less than 3 in 100 thousand in CY2012 and CY2013. Food safety conditions (FS-2), carcass contamination with fecal material, ingesta, and milk, were below 6 per 10 thousand carcasses in CY2009-CY2010 and are below 5 per 10 thousand carcasses in CY2012-CY2013.

⁴ RTI began collecting baseline organoleptic and microbiological data in August 1998, before HIMP program began.

- Food safety conditions (FS-3), systemic disease in live animals such as neurologic conditions found at ante-mortem, were zero in CY2009-CY2010 and are less than 1 in 10 thousand for CY2012-CY2013.
- OCP conditions, localized disease conditions such as arthritis (OCP-1 defects), cystic kidneys (OCP-2 defects), and bruises (OCP-3 defects), in HIMP market hog establishments average about one-half the corresponding OCP performance standards.
- In CY2006-CY2010, the W3NR noncompliance rates for standard SOP and HACCP were about 1.2 times higher in HIMP market hog establishments than in non-HIMP market hog establishments. In CY2012 and CY2013 the health-related (PHR) noncompliance rates for SSOP and HACCP were 1.1 times lower in HIMP market hog establishments than in non-HIMP market hog establishments.
- The *Salmonella* positive rates in HIMP market hog establishments are lower than those in non-HIMP comparison establishments for the years CY2006 to CY2009 but higher in CY2010. However, the differences are not statistically significant for any year individually.
- In the thirteen month (August 2010 to August 2011) *Salmonella* baseline study on market hog establishments, the *Salmonella* positive rate post-chill for HIMP market hog establishments is 0.5 times lower (0.69% versus 1.35%) than in the 21 comparison non-HIMP market hog establishments. This difference is not statistically significant, probably because of the large sample sizes required to show significant difference between low *Salmonella* rates. The difference between HIMP market hog establishments and all other establishments in the baseline study (0.65% versus 3.05%) is highly statistically significant (Two Sided Exact Fisher $p < 0.00001$).
- On average inspectors at HIMP market hog establishments collected 2.7 times more chemical residue samples than inspectors at non-HIMP market hog establishments. Over the period CY2006-CY2010, there were 6 incidences of violative levels of chemical residues in the 21 traditional non-HIMP market hog establishments and none in the 5 HIMP market hog establishments.
- In the period CY2012 to CY2013, there were 9 violative levels out of 6,010 chemical residue samples (0.15%) in the 5 HIMP market hog establishments and 115 violative levels out of 15,070 samples (0.76%) in the 21 non-HIMP market hog establishments (1.5 violate chemical residue samples per billion HIMP pounds slaughtered versus 4 per billion non-HIMP pounds slaughtered). This result suggests that HIMP market hog establishments are exercising active control of potential chemical hazards in their products.

FSIS's evaluation found that market hog slaughter establishments participating in HIMP are performing as well as comparable large non-HIMP market hog establishments and meeting FSIS expectations for the overall HIMP project. On this basis, FSIS sees no reason to discontinue HIMP in market hog establishments.

5.0 REFERENCES

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6.0 APPENDIX

Appendix A-Differences Between PBIS and PHIS Information Systems

Differences between PBIS and PHIS include the following:

- Inspection verifications in PBIS and PHIS are recorded differently. In PBIS, verifications were recorded under the proper inspection task code, but the exact regulation verified was recorded only if the establishment was noncompliant. Thus, with PBIS data, it was possible to determine how many times a particular inspection task was performed, and how many times an establishment was noncompliant with a particular regulation, but not how many times a particular regulation was verified. In PHIS, the regulation number of each verification is recorded along with whether it was compliant or not. Thus, in PHIS, it is known how many times a particular inspection task was performed, how many times particular regulation was verified, and how many times an establishment was noncompliant with a particular regulation.
- Some inspection task codes changed during the transition from PBIS to PHIS. For example, the inspection task codes 01A01, 03A01, 03J01, 05A01, and 06D01 that were used in PBIS are not used in PHIS (See Appendix B for a description of the procedure codes.). The verifications performed under these PBIS procedure codes are now performed under different PHIS procedure codes. In addition, some new inspection task codes were added to PHIS and are not in PBIS.
- Noncompliances rates are computed differently for data from PBIS than from PHIS. For PBIS data, noncompliance rates are computed as the total noncompliances for a given regulation divided by the total number of inspections for all regulations (This is because PBIS only records that an inspection was performed, but not the regulation verified, not unless the establishment was noncompliant with the regulation.) In PHIS, noncompliance rates are computed as the total noncompliances for a given regulation divided by the total number of inspection verifications for that regulation (this is because in PHIS the regulation number is recorded for each verification.) The result of this difference is that the noncompliance rates for the same regulation under PBIS and PHIS are not directly comparable.
- PBIS and PHIS use different lists of the most serious health-related regulations. PBIS used the list of W3NRs which was selected by a group of FSIS experts, while PHIS uses an updated list of Public Health Regulations (PHRs) that was derived through a more transparent and data-driven approach that identifies regulations that have statistically significantly higher noncompliance rates in the three months before *Salmonella*, *Escherichia coli* O157: H7, or *Listeria monocytogenes* (Lm) positives.

In the PBIS dataset (CY2006 to CY2010) there are 11 FSIS off-line verification inspection procedures that apply to all market hog slaughter establishments. Each inspection procedure has an associated code and the procedures determine the type of inspection activities that FSIS personnel perform to verify compliance with specific regulatory requirements. The 11 verification inspection procedures considered in this HIMP study for CY2006 to CY2010 are:

- Verify an establishment's compliance with the sanitation SOP regulations in 9 CFR Sections 416.11 through 416.16 (procedure codes 01A01, 01B01, 01B02, 01C01, 01C02);
- Verify compliance with the HACCP regulations in 9 CFR Part 417 (procedure codes 03A01, 03J01, and 03J02);
- Verify compliance with livestock product examination (procedure code 04C03);
- Verify compliance with generic *E. coli* testing requirements under 9 CFR 310.25 (procedure code 05A01); and
- Verify compliance with the Sanitation Performance Standards regulations in 9 CFR 416.1-416.6 (procedure code 06D01).

Under the PHIS dataset (CY2012 to CY2013) there are 9 FSIS off-line verification inspection procedures that apply to all market hog slaughter establishments. The 9 verification inspection procedures considered in this HIMP study for CY2012 to CY2013 are:

- Verify an establishment's compliance with the sanitation SOP regulations in 9 CFR 416.11-416.16 (procedure codes 01B01, 01B02, 01C01, 01C02);
- Verify compliance with the HACCP regulations in 9 CFR Part 417 (procedure codes 03C02, 03J02);
- Verify livestock zero tolerance verification 9 CFR 310.18 (procedure code 03J03);
- Verify compliance with generic *E. coli* testing requirements under 9 CFR 310.25 (procedure code 01E01); and
- Verify compliance with the Sanitation Performance Standards regulations in 9 CFR 416.1-416.6 (procedure code 01D01) and

There are eight inspection procedures in PBIS associated with activities that FSIS inspectors perform to verify compliance with the sanitation SOP and HACCP regulations. These are 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, and 03J02.

There are six inspection procedures in PHIS associated with activities that FSIS inspectors perform to verify compliance with the sanitation SOP and HACCP regulations. These are 01B01, 01B02, 01C01, 01C02, 03J02, and 03J03.

Appendix B- Description of PBIS Inspection Task Codes

FSIS inspectors perform inspection verification procedures to verify that establishments are executing their sanitation standard operating procedures (SSOP) and hazard analysis and critical control point (HACCP) system as specified under federal regulations 9 CFR 416 and 9 CFR 417. Table B-1 presents a summary of the 11 PBIS procedure codes considered in this study.

Table B- 1 PBIS Procedure Codes And Procedure Code Descriptions

Procedure Code	Description
01A01	Verify that establishment has met regulations for development or maintenance of sanitation standard operating procedures (SSOP)
01B01	Pre-operational review of establishment’s SSOP records to verify daily documentation of implementation and monitoring of SSOP procedures and required corrective actions.
01B02	Pre-operational review and observation of SSOP including implementation and monitoring, maintenance, corrective actions, and recordkeeping. Observe sanitation conditions; check one or more areas to ensure establishment is clean.
01C01	Review establishment’s operational SSOP records to verify that the regulatory requirements for operational sanitation are met. Ensure monitoring activities are conducted at required frequency, that the corrective actions are initiated to prevent direct contamination, and that records are being authenticated.
01C02	The 01C02 procedure is for operational SSOP verification. It is the same as the 01B02 procedure except that it is conducted during operations. It inspects one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product, observes the establishment perform the monitoring procedures, and compares finding to what the establishment has documented.
03A01	Determine establishment met regulation requirements for development and implementation of hazard analysis critical control point (HACCP) Plan(s)
03J01	Verify one or more HACCP requirements for monitoring, verification, and recordkeeping at a slaughter establishment. The 03J01 procedure is designed to provide a “snapshot” of the HACCP system. A 03J01 noncompliance necessitates performing a 03J02 procedure. FSIS Directive 5000.1
03J02	Verify all HACCP requirements at all critical control points in the HACCP establishment for a specific production. Verify that the pre-shipment review requirements for that specific production have been met. FSIS Directive 5000.1
04C04	Verify that poultry slaughter establishments comply with the relevant regulations for poultry finished product standards and good commercial practices for poultry slaughter
05A01	Review establishment E. Coli records to determine maintained accuracy in accord with regulation—verifies compliance with the basic regulatory requirements for <i>E. coli</i> testing in slaughter establishments.

Procedure Code	Description
06D01	Verify compliance with Sanitation Performance Standards requirements -- addresses the manner in which establishments must be operated and maintained to prevent the creation of insanitary conditions, thereby ensuring that insanitary conditions are not created, and that product is not adulterated.

Table B-2 presents a summary of the 9 PHIS procedure codes considered in this study.

Table B- 2 PHIS Inspection Task Code Description

Inspection Task Code	Guidance
01B01	Pre-operational Sanitation SOP verification by review of establishment records
01B02	Review the establishment's SSOP and become familiar with the procedures
01C01	Verify operational SSOP records
01C02	Verification of the establishment's operational SSOP
01D01	Verification of the sanitation performance standards
01E01	Generic <i>E. coli</i> Verification
03C02	Verify all 5 HACCP regulatory requirements at all CCPs for specific production
03J02	Verification of all 5 HACCP regulatory requirements through the review/observation and recordkeeping components.
03J03	Verification of zero tolerance for feces, milk, ingesta on livestock carcasses

Appendix C: Regulations Descriptions for Market Hog Establishments

Table C-1 provides a list of the 31 mandatory federal regulations that apply to market hog establishments.

Table C- 1 Mandatory Regulations for Market Hog Establishments

Regulation	Regulation Description
310.18	Contamination of carcasses, organs, or other parts
416.1	Operate in a manner to prevent insanitary conditions
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.12(a)	develop written procedures
416.13(a)	conduct pre-op procedures
416.13(b)	conduct other procedures listed in the plan
416.13(c)	plant monitors implementation of SSOP procedures
416.16(a)	daily records required, responsible individual, initialed and dated
416.16(b)	records OK on computers
416.16(c)	location and retention of records maintained
417.2(c)(4)	List of procedures & frequency
417.2(c)(5)	contents of HACCP plan/corrective action
417.2(c)(6)	Record keeping system
417.2(c)(7)	List of verification procedures/frequency
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(a)(4)	No adulterated product enters commerce.
417.3(b)(1)	Segregate and hold the affected product
417.3(b)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions
417.4(a)(2)(i)	Calibrate process-monitoring instruments
417.4(a)(2)(ii)	Direct observations
417.4(a)(2)(iii)	Records Review
417.5(a)(1)	Written hazard analysis
417.5(a)(2)	Written HACCP plan
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits
417.5(b)	Annotated at time of event
417.5(c)	Review prior to shipment

PBIS and PHIS use different lists of the most serious health-related regulations. PBIS used the list of W3NRs which was selected by a group of FSIS experts, while PHIS uses an updated list of Public Health Regulations (PHRs) that was derived through a more transparent and data-driven approach that identifies regulations that have higher noncompliance rates in the three months before *Salmonella*, *E. coli* O157: H7, or *Listeria monocytogenes* (Lm) positives. There are 33 PHRs, but only 28 PHRs apply to market hog establishments. Table C-2 provides a list of the 28 PHRs that apply to market hog establishments.

Table C- 2 Public Health Regulations (PHRs) for Market Hog Establishments

Regulation	Regulation Description
381.83	Septicemia or toxemia
416.1	Operate in a manner to prevent insanitary conditions to ensure product is not adulterated
416.14	Evaluate effectiveness of SSOP's & maintain plan
416.6	Any room, compartment, equipment or utensil found insanitary or could create adulterated product must be marked with a US Rejected tag and cannot be used until made acceptable. Only FSIS program employee may remove "U.S. Rejected" tag
301.2_Adulterated	The term adulterated applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance
381.65(a)	Operations must adhere strictly to clean and sanitary practices; products must not be adulterated
381.91(a)	Certain contaminated carcasses to be condemned
381.91(b)	Reprocessing of carcasses contaminated with digestive tract contents must be under the supervision of an inspector and thereafter found not to be adulterated.
416.15(a)	Appropriate corrective actions
416.15(b)	Corrective action, procedures for
416.16(a)	Maintain daily records documenting the implementation and monitoring of SSOP and corrective actions taken
416.3(b)	Constructed, located & operated in a manner that does not deter inspection to determine sanitary condition
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
417.2(c)(4)	List of procedures & frequency must be in the HACCP plan
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	CCP is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(a)(4)	No adulterated product enters commerce.
417.3(b)(1)	Segregate and hold the affected product following unforeseen event
417.3(b)(3)	No adulterated product enters commerce following unforeseen event

Regulation	Regulation Description
417.3(c)	Document corrective actions
417.4(a)	Adequacy of HACCP in controlling food safety hazards
417.4(a)(1)	Initial validation
417.4(a)(3)	Reassessment, at least annually or when necessary
417.4(b)	Reassessment of hazard analysis
417.5(a)(1)	Establishment shall maintain a written hazard analysis
417.5(a)(3)	Records documentation and monitoring of CCP's and Critical Limits as prescribed in the HACCP plan

Appendix D: HIMP Market Hog Performance Standards

The appendix presents the performance standard categories and performance standards for HIMP market hog slaughter establishments.

Table D- 1 Market Hog Performance Standards for HIMP Market Hog Establishments

Performance Standard Categories	Plant Performance Standards
FS-1—Condition – Infectious (for example: septicemia/toxemia, pyemia, cysticercus)	Zero
FS-2 – Condition – Digestive Content/Milk (for example: fecal material, ingesta, milk)	Zero
FS-3 – Ante-mortem Suspect (for example: neurologic conditions, moribund, pyrexia, severe lameness)	Zero
OCP-1 – Carcass- Pathology* (for example: arthritis, emaciation, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)	4.1%
OCP-2 – Visceral Pathology* (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites – other than Cysticercus, peritonitis)	7.2%
OCP-3 – Miscellaneous (for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)	20.5%

Appendix E: Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS CY2006 through CY2009

The appendix presents the inspection procedures performed per establishment in HIMP and Non-HIMP market hog slaughter establishments for the individual years CY2006 through CY2009.

Table E- 1 Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS in CY2006

Procedure Code	5 HIMP Market Hog Establishments (Procedures/ Establishment)	21 Non-HIMP Market Hog Comparison Establishments (Procedures/ Establishments)	HIMP/Non-HIMP Ratio
01A01	3.2	3.8	0.8
01B01	224.8	150.0	1.5
01B02	159.0	134.2	1.2
01C01	258.6	261.2	1.0
01C02	358.4	312.8	1.1
03A01	1.2	1.9	0.6
03J01	549.6	124.4	4.4
03J02	188.6	148.9	1.3
04C03	0.0	0.0	0.0
04C04	0.0	0.0	0.0
05A01	0.4	1.2	0.3
06D01	205.8	143.2	1.4
CY2006 Total for Procedures	1949.6	1281.7	1.5
CY2006 Total for SSOP and HACCP Procedures	1743.4	1137.2	1.5

Table E- 2 Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS in CY2007

Procedure Code	5 HIMP Market Hog Establishments (Procedures/ Establishment)	21 Non-HIMP Market Hog Comparison Establishments (Procedures/ Establishments)	HIMP/Non HIMP Ratio
01A01	4.2	3.0	1.4
01B01	199.8	161.6	1.2
01B02	161.0	133.6	1.2
01C01	245.8	275.6	0.9
01C02	347.8	314.4	1.1
03A01	2.2	2.0	1.1
03J01	621.2	127.6	4.9
03J02	187.8	149.0	1.3
04C03	160.0	106.9	1.5
04C04	0.0	2.1	0.0
05A01	1.2	1.0	1.2
06D01	174.8	145.0	1.2
CY2007 Total for Procedures	2105.8	1421.8	1.5
CY2007 Total for SSOP and HACCP Procedures	1769.8	1166.8	1.5

Table E- 3 Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS in CY2008

Procedure Code	5 HIMP Market Hog Establishments (Procedures/ Establishment)	21 NonHIMP Market Hog Comparison Establishments (Procedures/ Establishments)	HIMP/Non HIMP Ratio
01A01	2.8	3.1	0.9
01B01	186.4	158.3	1.2
01B02	151.4	136.8	1.1
01C01	239.0	277.8	0.9
01C02	341.6	313.5	1.1
03A01	5.6	3.4	1.6
03J01	630.2	122.3	5.2
03J02	192.4	157.9	1.2
04C03	204.0	152.6	1.3
04C04	0.0	4.7	0.0
05A01	0.6	0.6	1.1
06D01	170.0	149.2	1.1
CY2008 Total for Procedures	2124.0	1480.2	1.4
CY2008 Total for SSOP and HACCP Procedures	1749.4	1173.1	1.5

Table E- 4 Inspection Procedures Performed per Establishment in HIMP and Non-HIMP Market Hog Establishments Under PBIS in CY2009

Procedure Code	5 HIMP Market Hog Establishments (Procedures/ Establishment)	21 NonHIMP Market Hog Comparison Establishments (Procedures/ Establishments)	HIMP/Non HIMP Ratio
01A01	2.0	2.5	0.8
01B01	173.0	153.8	1.1
01B02	154.8	136.8	1.1
01C01	236.2	275.0	0.9
01C02	331.0	306.0	1.1
03A01	2.0	3.1	0.6
03J01	626.8	128.0	4.9
03J02	178.8	154.9	1.2
04C03	210.6	164.5	1.3
04C04	0.0	5.1	0.0
05A01	0.6	0.8	0.7
06D01	164.8	144.2	1.1
CY2009 Total for Procedures	2080.6	1474.9	1.4
CY2009 Total for SSOP and HACCP Procedures	1704.6	1160.2	1.5