

Evaluation of HACCP Inspection Models Project (HIMP)

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SUMMARY

The objective of this report is to evaluate Food Safety and Inspection Service (FSIS) inspection findings in young chicken slaughter establishments participating in the HACCP Inspection Models Project (HIMP) program and, as appropriate, compare them with established HIMP performance standards or with a comparison set of 64 non-HIMP establishments comparable with HIMP establishments with respect to production volume, lines speed, and geographical distribution. The FSIS inspection findings are assessed across four interrelated inspection activities:

1. Inspection of each carcass by on line FSIS inspectors to determine whether the carcass is not adulterated and therefore eligible to bear the mark of inspection
2. Verification, by off line inspectors, of the establishment's execution of its HIMP process control plan, under which establishment employees sort acceptable and unacceptable carcasses and parts
3. Verification of the establishment 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.
4. Verification of the outcomes of the establishment HIMP process control plan, both organoleptic and microbiologic

A summary of results follows:

- **Inspection of each carcass by on line FSIS inspectors to determine whether the carcass is not adulterated and therefore eligible to bear the mark of inspection**

The data show that as a result of industry practices, such as carcass sorting activities, very few adulterated poultry carcasses are presented to inspectors stationed at the end of the slaughter line in HIMP establishments. The number of carcasses with septicemia, toxemia, or fecal material that arrive at the online carcass inspector location is very low (less than 8 carcasses with infectious conditions per million carcasses processed and less than 0.8 carcasses with fecal contamination per 1,000 carcasses). These levels are less than those found in the baseline non-HIMP plants after carcasses have passed FSIS carcass inspection. The carcass inspector (CI) in HIMP establishments further reduces the number of carcasses with septicemia/toxemia or visible fecal contamination.

For septicemia/toxemia, the CI detected affected carcasses at a rate of 0.000004% or 4 per 100 million carcasses slaughtered. For visible fecal contamination, the CI detected affected carcasses at a rate of 0.0009% or 9 per million carcasses slaughtered. These data demonstrate that CIs in HIMP establishments detect and condemn carcasses affected with septicemia and toxemia, as well as carcasses with visible fecal contamination, before such carcasses enter the chiller.

These findings support that the online inspectors in HIMP establishments are performing in a manner that enables them to properly inspect each carcass and, therefore, make the necessary appraisals to adequately identify adulterated carcasses.

- **Verification, by off line inspectors, of the establishment's execution of its HIMP process control plan, under which establishment employees sort acceptable and unacceptable carcasses and parts**

FSIS inspectors perform offline inspection procedures in HIMP establishments to verify that the establishments are executing their HIMP process control plan. Because fewer inspectors are required to conduct online carcass inspection in HIMP establishments, FSIS is able to conduct more offline food safety related inspection activities. FSIS inspectors performed an average of 14,136 offline verification inspections per HIMP establishment in CY2010 versus an average of 8,724 offline verification inspections per non-HIMP establishment. Overall, FSIS inspectors perform 1.6 times more offline verification inspection procedures in HIMP establishments than in non-HIMP establishments and 3.2 times more HACCP verification inspection procedures. This increased level of inspection insures that HIMP establishments continuously satisfy food safety performance standards and HACCP regulations and are maintaining OCP- and food safety defects at levels that are less than in non-HIMP establishments and thereby producing a safer product.

- **Verification of the establishment executing its sanitation standard operating procedures (SSOP) and its hazard analysis and critical control point (HACCP) system under Code of Federal Regulations 9 CFR 416 and 417**

FSIS inspectors conduct offline inspection procedures in HIMP establishments to monitor for food safety and OCP defects, pathogen levels, and for compliance with federal sanitation and HACCP regulations. In CY2010 FSIS inspectors performed about 2.8 times more SSOP and HIMP inspection procedures in HIMP establishments than in non-HIMP establishments and find that over a 5 year period the health-related non-compliance rates for SSOP and HACCP are about 1.4 times lower in HIMP establishments than in non-HIMP establishments.

In CY2010, FSIS inspectors in HIMP establishments performed 3.4 more 03J01 procedures than inspectors in non-HIMP establishments. The inspection activities under the 03J01 procedures include among other things, verification of food safety standards and all slaughter HACCP requirements. The majority of these activities involve verifying an establishment's compliance with FSIS's zero tolerance for visible fecal contamination. The rate of 03J01 health-related non-compliances over a 5 year period is about 1.6 times lower in HIMP establishments than in non-HIMP establishments

The rate of visible fecal material contamination in HIMP establishments is about half that in non-HIMP establishments. Since fecal contamination of carcasses is the primary avenue for contamination by pathogens in slaughter establishments, HIMP establishments should have lower public health impacts than non-HIMP establishments.

- **Verification of the outcomes of the establishment process control plan, both organoleptic and microbiologic**

Toxemia and septicemia food safety conditions in HIMP establishments are below 8 per million carcasses, which is 125 times less than HIMP performance standards.

Salmonella positive rates in HIMP establishments average about 80% those in non-HIMP establishments. FSIS believes that lower *Salmonella* positive rates result in fewer public health impacts (FSIS 2011). *Salmonella* positive rates at HIMP establishments were not found to be related to line speed.

Fecal contamination levels are below 8 per ten thousand carcasses, which is about 19 times less than HIMP performance standards. FSIS believes that lower fecal contamination levels and *Salmonella* positive rates result in fewer public health impacts.

These data indicate that compared to inspection on non-HIMP establishments, HIMP has improved the safety of poultry products and increased overall consumer protection.

FSIS concludes that an inspection system based on the HIMP system in which establishments are responsible for sorting and identifying unacceptable carcasses and parts before an online FSIS inspector performs a visual carcass-by-carcass inspection will ensure an equivalent, if not better, level of food safety and other consumer protection than that provided by the existing poultry slaughter inspection systems.

Given the low numbers of adulterated poultry carcasses presented to the inspector in HIMP establishments, the stability of line speeds in the HIMP pilot project, and the ability of the carcass inspector to personally inspect each and every carcass leaving the slaughter line sufficiently to identify adulterated carcasses, FSIS has determined that the addition of a second carcass inspector to each line would not further HIMP project objectives and is not necessary to meet statutory mandates.

1.0 INTRODUCTION

In October 1999, FSIS initiated the HIMP project in volunteer slaughter establishments to determine whether new government slaughter inspection procedures, along with new plant responsibilities, could improve food safety and increase consumer protection. Under HIMP employees of slaughter establishments sort carcasses on the slaughter line before they reach FSIS on-line inspectors, making an initial determination whether they are unacceptable, allowing the on-line inspector to focus on any remaining food-safety issues. This approach is consistent with HACCP where industry rather than federal inspectors is responsible for identifying steps in food production where food safety hazards are most likely to occur and for establishing controls that prevent or reduce them. Currently, there are 20 young chicken; 5 young turkey, and 5 market hog slaughter establishments participating in HIMP. This report focuses on the 20 young chicken slaughter establishments in HIMP.

FSIS inspectors perform post-mortem inspection on a bird-by-bird basis of every chicken eviscerated at a HIMP establishment that enters commerce. The purpose of post-mortem inspection is to insure that any carcasses or parts that are unwholesome or adulterated, and thereby unfit for human food, do not enter commerce. A short history of HIMP is given in Appendix A.

Prior to beginning HIMP, Research Triangle Institute (RTI) conducted baseline organoleptic and microbiological data collection in 16 young chicken slaughter plants that volunteered to participate in the HIMP program. The baseline data documents the accomplishments of pre-HIMP slaughter-line inspection systems and provide a measure for comparing performance of establishments operating under the new HIMP inspection system with those operating under traditional inspection systems. In March 2000, FSIS held a public meeting to present the HIMP baseline results and receive comments on proposed HIMP performance standards (FSIS 2000a). In November, 2000 FSIS published the final HIMP performance standards for two food safety and five Other Consumer Protection (OCP) concerns. HIMP establishments are expected to revise their HACCP systems to achieve the food safety standards and to develop process control plans to achieve OCP standards. Plants are responsible for identifying and removing carcasses that do not meet these standards. FSIS inspectors are responsible for verifying that plants are continuously achieving the required outcomes. The National Alliance for Food Safety determined that food safety performance standards provide a scientifically valid measure by which performance of HIMP establishments can be evaluated (Hargis et al. 2002).

Following entry of the 16 young chicken slaughter plants into the HIMP program, data was again collected in order to evaluate the achievements of the new inspection system. RTI conducted an initial evaluation of the performance of HIMP chicken slaughter establishments in 2001 that suggested inspection under HIMP was equivalent or superior to that of traditional inspection (Cates et al. 2001). Subsequent data collection over the time periods Sep 18, 2000 – April 30, 2001, Sep 18, 2000 - Sep 30, 2002 and July 14, 2003 - December 31, 2004 confirmed that HIMP plants were meeting or exceeding HIMP performance standards (FSIS 2001, 2002b, 2008a). Organoleptic and microbiological data compared to the performance standards were

- Food safety measures

- Septicemia/Toxemia rates
- Visible fecal contamination rates
- Other Consumer Protection measures
 - OCP1 (Animal Diseases, e.g., airsacculitis)
 - OCP2 (Miscellaneous Conditions, e.g., bruises, sores, and other processing defects)
 - OCP3 (Digestive Content, e.g., ingesta)
 - OCP4 (Dressing Defects- Other, e.g., feathers)
 - OCP5 Dressing Defects- Digestive Tract Tissue, e.g., bursa, cloaca)

These studies demonstrated that HIMP young chicken slaughter establishments were performing as well or better than young chicken slaughter establishments under traditional (non-HIMP) inspection systems.

The objective of the present analysis is to update these previous evaluations of HIMP performance and to determine whether the HIMP inspection system results in improved safety of poultry products and increased overall consumer protection, while ensuring carcass-by-carcass inspection of each eviscerated carcass. The current evaluation is based on data for the years CY2006 through CY2010, with exceptions where only more recent data are available. The evaluation compares the 20 HIMP young chicken establishments with established HIMP performance standards or with a comparison set of 64 non-HIMP establishments selected to be comparable with HIMP establishments with respect to production volume, lines speed, and geographical distribution. The FSIS inspection findings are assessed across four interrelated inspection activities:

1. Inspection of each carcass by on line FSIS inspectors to determine whether the carcass is not adulterated and therefore eligible to bear the mark of inspection
2. Verification, by off line inspectors, of the establishment's execution of its HIMP process control plan, under which establishment employees sort acceptable and unacceptable carcasses and parts
3. Verification of the outcomes of the establishment process control plan, both organoleptic and microbiologic
4. Verification of the establishment executing its SSOP and HACCP systems under Code of Federal Regulations 9 CFR 416 and 417.

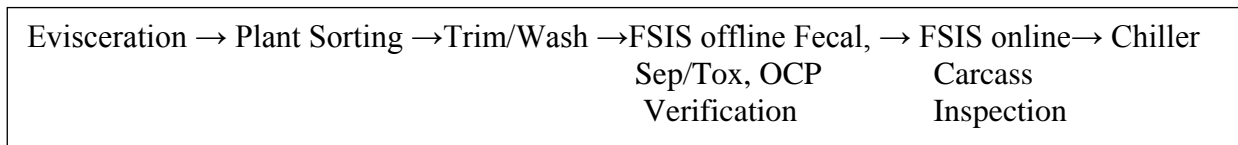
2.0 DESCRIPTION OF HIMP AND NON-HIMP ESTABLISHMENTS

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

2.1 Inspection in HIMP and Non-HIMP Establishments

Under the HIMP inspection system, one online carcass inspector (CI) and one offline verification inspector (VI) are assigned to each line. The online CI visually inspects every carcass at a fixed location on the evisceration line immediately prior to the chiller (See Figure 2-1), to insure that poultry products do not injure human health in any way because they “consist in whole or part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthy, unwholesome, or otherwise unfit for human food; Poultry Products Inspection Act (PPIA) Sec. 453(g)(3)” or “has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious of human health; PPIA Sec. 453(g)(4).” Carcass inspection is conducted much more efficiently under HIMP than under the non-HIMP inspection systems because establishment personnel have already sorted (i.e., removed from the evisceration line), trimmed, and reprocessed the carcasses, thereby removing most visible defects, before the online carcass inspector appraises them. More detail on the activities of the online and offline inspectors under HIMP is given in Appendix A.

Figure 2- 1 Flowchart for HIMP Inspection System

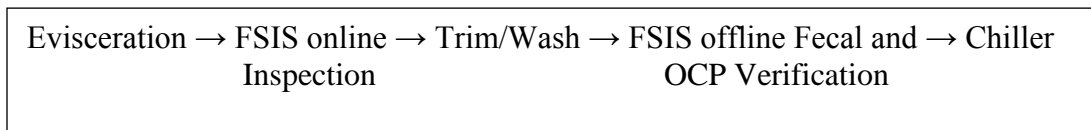


Establishment controls for food safety hazards reasonably likely to occur, for example critical control points (CCP) for Infectious Conditions (FS-1) or Fecal Material Contamination (FS-2), can be located either before or after the FSIS carcass inspection. Sixty percent (12 establishments) of the young chicken HIMP establishments have the CCP for FS-1 (Sep/Tox) before the CI and all 20 of the young chicken establishments have the CCP for FS-2 (fecal material) located after the CI. CIs do not create noncompliance records for visible fecal material when the CCP for fecal material is located after the CI.

Under the current (non-HIMP) inspection, online food inspectors visually inspect every carcass, with its corresponding viscera, at a fixed location on the evisceration line immediately following separation of the viscera from the interior of the carcass (see Figure 2-2). Carcasses have not been sorted prior to the online inspection. The number of online inspectors is dependent on the type of inspection system (see 9 CFR 381.67 and 381.76). The FSIS offline inspectors collect 10 bird samples at the end of the line prior to the chiller to reinspect carcasses that have passed FSIS online inspection and have been trimmed and washed by the establishment. Reinspection verifies

Finished Product Standards program described in 9 CFR 381.76 (other consumer protections). The off line inspector also selects 10 bird samples to verify that the food safety standard (zero tolerance) for fecal contamination is being met.

Figure 2- 2 Flowchart for Traditional (Non-HIMP) Inspection Systems



2.2 Line Speed Estimation

HIMP slaughter establishments are permitted to operate at higher line speeds than slaughter establishments operating under current inspection systems. To evaluate the impact of line speed on HIMP establishment performance, it is necessary to know line speeds in HIMP establishments.

In 2010, FSIS through a contractor collected profile data on official establishments in order to populate the establishment profile data set in the Public Health Information System (PHIS) (Dynamac 2010). This profile data contains, among other things, information on the number of lines, line speeds, and the inspection system used by FSIS inspectors at establishments. In 2011 FSIS conducted another survey on line speeds at poultry slaughter establishments. Line speeds in these two data sets agree in all but a few cases. However, many line speeds obtained from the survey are maximum permitted line speeds rather than average operating line speeds.

To clarify line speeds, the annual average line speed at a young chicken slaughter establishment was calculated based on the establishment’s annual slaughter volume, hours of operation, and the number of evisceration lines. Appendix B presents a description of the methodology.

The average line speeds at the 20 young chicken HIMP establishments vary from 88 to 180 birds per minute (bpm), with an average line speed of 131 bpm. The 64 non-HIMP comparison establishments have an average line speed of 115 birds per minute.

2.3 Selection of Non-HIMP Comparison Establishments

Two sets of non-HIMP establishments were selected for comparison with the 20 HIMP establishments. The first was a subset of non-HIMP establishments selected to be similar to HIMP establishments with respect to total slaughter volume, line speeds, and geographic distribution. This set is selected to minimize confounding effects of volume, line speeds, and geographical distribution on comparisons of operating performance between HIMP establishments and traditionally inspected establishments. The second comparison set of 176 establishments consists of all non-HIMP establishments that slaughtered young chickens in all 5 years considered in the current study. A description of the selection process follows:

- Control Set of 64 Non-HIMP Establishments
 - A set of all non-HIMP establishments with similar operating characteristics as HIMP establishments were selected. These are all non-HIMP establishments that operated in all 5 years of the study, had CY2010 production volumes greater than 40 million head per year, had average lines speeds greater than 80 bpm, and operated in the same 7 districts as HIMP establishments. Note that the average lines speeds of the 64 non-HIMP comparison set do not completely overlap with those of HIMP establishments since line speeds in non-HIMP establishments are limited to 140 bpm, while HIMP establishments have line speeds up to 180 bpm.
- Comparison Set of 176 All Non-HIMP Establishments
 - All non-HIMP slaughter establishments that slaughtered young chickens at some time in each of the years CY2006 to CY2010 were selected for the all non-HIMP comparison set. There are 176 establishments in the all non-HIMP comparison set.

Table 2-1 presents a summary of the HIMP and two sets of comparison non-HIMP establishments. HIMP establishments have an average line speed of 131 birds per minute while the 64 non-HIMP comparison establishments have an average line speed of 115 birds per minute.

Table 2- 1 Characteristics of Comparison Young Chicken Slaughter Establishments

	Description	Number of Establishments	CY2010 Production Volumes	CY2010 Line Speeds
HIMP	All HIMP establishments	20	38to 115million birds	88 to 180 bpm
Non-HIMP	Non-HIMP establishments with operating characteristics similar to HIMP establishments	64	40 to 110 million birds	81 to 140 bpm
All Non-HIMP	All non-HIMP establishments that operated during the 5 years of the study	176	400 birds to 130 million birds	1 to 140 bpm

Table 2-2 presents a summary of the geographical distribution of the establishments. For both HIMP and comparison non-HIMP establishments, approximately 70% operate in the Southeast (Alabama, Arkansas, Georgia, North Carolina, South Carolina, Mississippi, Tennessee, and West Virginia) and about 30% operate in the Southwest (Missouri, Oklahoma, and Texas).

Table 2- 2 Geographical Distribution of HIMP and Comparison Non-HIMP Establishments

District	Lawrence	Springdale	Dallas	Beltsville	Raleigh	Atlanta	Jackson
Number of HIMP	1	4	2	2	3	2	6
Number of Comparison Non-HIMP	4	12	6	4	11	13	15

3.0 RESULTS

This section presents a summary of FSIS inspection findings in HIMP establishments and compares them to inspection findings in a comparison set of 64 non-HIMP establishments or with FSIS HIMP performance standards, as appropriate. The findings are organized around the following four interrelated inspection activities:

1. Inspection of each carcass by on line FSIS inspectors to determine whether the carcass is not adulterated and therefore eligible to bear the mark of inspection
2. Verification, by off line inspectors, of the establishment's execution of its HIMP process control plan, under which establishment employees sort acceptable and unacceptable carcasses and parts
3. Verification of the establishment 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.
4. Verification of the outcomes of the establishment process control plan, both organoleptic and microbiologic

3.1 Inspection of Each Carcass by Online FSIS Inspectors to Determine Whether the Carcass is Not Adulterated and therefore Eligible to Bear the Mark of Inspection

An important issue that this HIMP report addresses is whether FSIS inspectors in young chicken slaughter establishments operating under HIMP are able to make a determination as to whether each carcass is not adulterated and therefore eligible to bear the mark of inspection. To address this issue, the HIMP report evaluates the ability of the FSIS online carcass inspector (CI) to detect carcasses affected with septicemia/toxemia and visible fecal contamination before the chiller.

Data collected from April 1, 2009, to March 31, 2011, show that the CI in HIMP establishments found 125 carcasses affected with Septicemia/Toxemia and 26,815 carcasses with visible fecal contamination (see Tables 3-1 and 3-2). This data demonstrates that the CI in HIMP establishments is able to identify carcasses affected with Septicemia/Toxemia and visible fecal contamination.

The findings of FSIS off-line verification inspector (VI) checks show that fewer than 8 per 1 million carcasses (0.0008%) processed in HIMP establishments have septicemia/toxemia and that fewer than 8 per ten thousand carcasses (0.08%) processed in HIMP establishments have visible fecal contamination (Tables 3-1 and 3-2). These rates are lower than in the RTI baseline non-HIMP establishments. As the data above show, the CI in HIMP establishments further reduces the number of carcasses with septicemia/toxemia or visible fecal contamination. These data demonstrate the HIMP inspection system improves young chicken product food safety.

Table 3-1 below compares the rate at which CIs and VIs in HIMP establishments detect carcasses affected with Septicemia/Toxemia conditions. Table 3-2 compares the rate at which CIs and VIs detected carcasses with visible fecal contamination.

Table 3- 1 Comparison of Sep/Tox Detection Rates for Carcass and Verification Inspectors

	Number Sep/tox findings detected CY2009-CY2010	Carcasses Inspected	Sep/tox detection rate
Carcasses Inspectors	125	2.97E+09	0.000004%
Verification Inspectors	32	3.82E+06	0.0008%

Table 3- 2 Comparison of Fecal Detection Rates for Carcass and Verification Inspectors

	Number fecal contaminations detected CY2009-CY2010	Carcasses Inspected	Fecal detection rate
Carcasses Inspectors	26,815	2.97E+09	0.0009%
Verification Inspectors	2,994	3.822E+06	0.08%

These data demonstrate that, although CIs in HIMP establishments are presented with an extremely low rate of adulterated carcasses, they do detect and condemn carcasses affected with septicemia and toxemia, as well as carcasses with visible fecal contamination, before such carcasses enter the chiller, thereby reducing food safety defects to levels lower than found in the RTI baseline non-HIMP establishments.

3.2 Verification by Offline Inspectors of the Establishment Executing its HIMP Process Control Plan under which Establishment Employees Sort Acceptable and Unacceptable Carcasses and Parts

Under HIMP, employees of slaughter establishments sort carcasses on the slaughter line before they reach FSIS on-line inspectors. The sorted carcasses are expected to meet food safety and OCP performance standards. FSIS inspectors verify that plants are continuously achieving the required outcomes. This section address inspection activities in HIMP establishments related to verification by offline inspectors of the establishment executing its HIMP process control plan under which establishment employees sort acceptable and unacceptable carcasses and parts to achieve performance standards.

3.2.1 Offline Inspection Procedures per Establishment

FSIS inspectors conduct offline inspection procedures in HIMP establishments to monitor for food safety and OCP defects, pathogen levels, and for compliance with federal sanitation and HACCP regulations. It is expected that the number of offline inspection procedures will be higher in HIMP than non-HIMP establishments and that the noncompliance rates will be lower. This will increase the confidence that HIMP establishments are complying with all federal regulations and are producing a safe and wholesome product.

This study focuses on 11 FSIS offline inspection procedures that apply to all poultry 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 inspection procedures considered in this HIMP study are:

- Verify an establishment’s compliance with the sanitation SOP regulations in 9 CFR 416.11-416.16 (procedure codes 01A01, 01B01, 01B02, 01C01, 01C02);
- Verify compliance the HACCP regulations in 9 CFR part 417 (procedure codes 03A01, 03J01, 03J02);
- Verify compliance with relevant regulations for finished product standards (FPS) or OCPs and good commercial practices (procedure code 04C04);
- Verify compliance with generic E. coli testing requirements under 9 CFR 381.91 (procedure code 05A01); and
- Verify compliance with the Sanitation Performance Standards regulations in 9 CFR 416.1-416.6 (procedure code 06D01).

These procedures, which are further described in Appendix C, reflect FSIS verification activities related to, among other things, the establishment’s sanitary practices and HACCP implementation.

Because fewer inspectors are required to conduct online carcass inspection in HIMP establishments, FSIS is able to conduct more offline food safety related inspection activities. Table 3-3 presents for CY2010 the ratio of the number of offline inspection procedures per establishment in HIMP and non-HIMP establishments for the 11 inspection procedures considered in this study. Overall, FSIS inspectors perform 1.6 times more of the 11 offline verification inspection procedures in HIMP establishments than in non-HIMP establishments. This increased level of inspection insures that HIMP establishments are maintaining OCP- and food safety defects at levels that are less than in non-HIMP establishments and thereby producing a safer product.

The number of 04C04 inspections in HIMP establishments in Table 3-3 appears to be less than in non-HIMP establishments. However, the number of 04C04 inspection procedures in HIMP and non-HIMP establishments is not directly comparable since they are counted differently. In HIMP plants, a minimum of 2 OCP 10 bird sample sets are conducted in a single shift and are counted as a single 04C04 inspection procedure. In non-HIMP plants, each 10 bird sample set is counted as a separate 04C04 inspection procedure.

Table 3- 3 Ratios of Inspection Procedures per Establishment in HIMP to Non-HIMP for CY2010

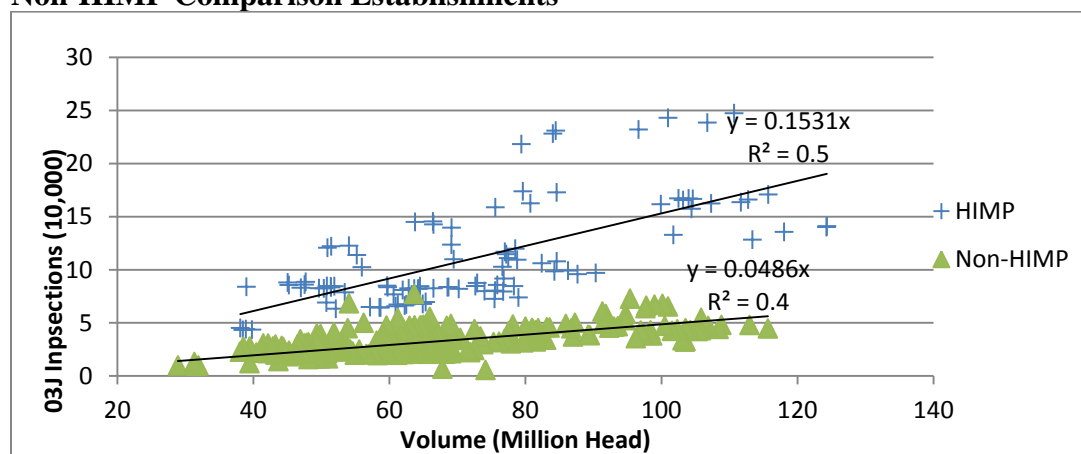
Procedure Code¹	20 HIMP Establishments (Procedures/Establishment)	64 Non-HIMP Comparison Establishments (Procedures/Establishment)	HIMP/Non-HIMP Ratio
01A01	3.4	3.7	0.9
01B01	140.3	148.7	0.9

01B02	98.0	110.9	0.9
01C01	259.2	272.5	1.0
01C02	294.8	299.0	1.0
03A01	2.5	1.9	1.3
03J01	10296.1	3027.5	3.4
03J02	287.0	259.4	1.1
04C04	2612.3	4447.4	0.6
05A01	0.2	1.3	0.2
06D01	142.2	151.5	0.9
Total for all 11 Procedures	14135.9	8723.7	1.6
Total for 8 SSOP and HACCP Procedures	60,112.10	20,140.88	3.0

1. See Appendix C for description of inspection procedure codes

Figure 3-1 presents the annual number of 03J inspections (03J01 plus 03J02) per establishment for HIMP and non-HIMP establishments for CY2006-CF2010. The inspection activities under the 03J01 and 03J02 procedures include among other things, verification of food safety standards and all slaughter HACCP requirements. The majority of these activities involve verifying an establishment's compliance with FSIS's zero tolerance for visible fecal contamination. Figure 3-1 indicates that HIMP establishments receive more 03J inspections than non-HIMP establishments and that the number of 03J inspections increases with establishment volume.

Figure 3- 1 Annual Number of 03J Inspections as a Function of Volume for HIMP and Non-HIMP Comparison Establishments



3.2.2 FSIS Condemnation Rates and HIMP Establishment Sorting Rates

In non-HIMP establishments, FSIS condemnation rates are the number of carcasses condemned by FSIS on-line inspectors divided by the total number of young chickens slaughtered. This information is reported in the FSIS electronic Animal Disease Reporting System (eADRS). In

the current non-HIMP inspection system, establishment employees are not allowed to proactively dispose of adulterated carcasses, since FSIS assumed this activity when federal inspection was first provided to the poultry industry.

Under HIMP, employees of slaughter establishments assume their responsibility to produce safe and wholesome products by sorting and disposing of non-complying carcasses before they reach the FSIS online carcass inspector positioned at the end of line to inspect each carcass. HIMP establishment employees dispose of non-complying carcasses at many locations both prior to and after the establishment sorting station. The number of carcasses disposed of at the sorting station is reported in the eADRS. However, carcasses disposed at other locations are not recorded. Table 3-4 presents a summary of the sorting rates for HIMP establishments and condemnation rates for the control set of non-HIMP establishments for the years CY2006 to CY2010. Sorting rates are determined by the number of carcasses disposed by establishment sorters divided by the total head slaughtered. Condemnation rates are computed as the ratio of heads condemned by FSIS inspectors divided by total production volume in heads. Appendix H presents more detailed information on sorting and condemnation rates for young chicken slaughter establishments for the years CY2006 to CY2010.

The data show that sorting rates in HIMP establishments are less than condemnation rates in non-HIMP establishments. This is to be expected since reported sorting rates by HIMP employees do not provide a complete record of all birds removed. HIMP establishment employees are only required to report the number of birds sorted at sorting stations at the end of the evisceration line. Birds removed prior to the evisceration line or at locations other than sorting stations are not consistently recorded by industry and provided to FSIS for recording in eADRS. Despite the fact that sorting and condemnation rates are not directly comparable, these rates are included in this report for completeness. However, they cannot be used to compare the effectiveness of sorting by HIMP establishments; instead FSIS verification inspection to determine compliance with HIMP performance standards for food safety and OCPs measures are used to determine the effectiveness of establishment sorting activities. The verification checks are performed randomly through a shift with approximately one ten-bird check per hour providing reliable data that sorting is effective.

Table 3- 4 Sorting and Condemnation Rates for HIMP and Non-HIMP Broiler Establishments

	2006	2007	2008	2009	2010
Sorting Rates in 20 HIMP Establishments	0.27%	0.27%	0.45%	0.27%	0.23%
Condemnation Rates in 64 Non-HIMP Establishments	0.42%	0.39%	0.39%	0.34%	0.30%
Condemnation Rates in 176 All Non-HIMP Establishments	0.45%	0.42%	0.40%	0.34%	0.30%

3.3 Verification of the Establishment Executing its Sanitation SOPs and its HACCP System under 9 CFR parts 416 and 417

This section addresses FSIS inspection activities related to verification that the HIMP establishment is executing its sanitation standard operating procedures (SSOP) and its hazard analysis and critical control point (HACCP) system under Code of Federal Regulations 9 CFR 416 and 417.

3.3.1 Offline Inspection Procedures Performed

The sanitation SOP regulations in 9 CFR 416 and the HACCP regulation in 9 CFR 417 are among the regulations most strongly related to public health. Sanitation standard operating procedures are written procedures that an establishment develops to prevent contamination or direct 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 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. In CY2010, FSIS inspectors performed approximately 2.8 more offline procedures to verify compliance with sanitation SOP and HACCP regulatory requirements in HIMP than in non-HIMP establishments. FSIS inspectors also performed 3.4 more 03J01 procedures in CT2010 in HIMP than in non-HIMP establishments (see Table 3-3 above). 03J01 procedures verify food safety standards and HACCP requirements in slaughter establishments.

Thus, FSIS verification inspectors are performing more verification of slaughter HACCP requirements including food safety (infectious and fecal) verification checks in HIMP than in non-HIMP establishments. This insures that HIMP establishments continuously meet food safety performance standards and HACCP regulations. Under HIMP, FSIS inspectors are able to spend more time on HACCP prevention-oriented inspections and better protect the public from foodborne diseases.

3.3.2 Public Health Non-Compliance Rates

FSIS inspection program personnel perform inspection procedures in federally-inspected establishments each day to verify that the establishments are executing their SSOP and HACCP system under 9 CFR 416 and 417. A noncompliance record (NR) is a written record that documents noncompliance with FSIS regulations. It is expected that noncompliance rates will be lower in HIMP than non-HIMP establishments since establishments assume more responsibility for their production processes. This will increase the confidence that HIMP establishments are complying with all federal regulations and are producing a safe and wholesome product.

In 2007 FSIS categorized its regulations according to potential public health significance and identified 61 out of 565 possible regulations most strongly related to public health (FSIS 2007). NRs documenting noncompliance with these regulations are referred to as health-related or “W3NRs.” For purposes of this report, the terminology “health-related” will be used. The rate at which an establishment fails to meet these health-related requirements and receives a health-related noncompliance is considered by FSIS to be an indication of the establishment’s inability to control its production process and risk.

Eleven inspection procedures are utilized by FSIS inspectors in all poultry slaughter establishments. They are 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, 03J02, 04C04, 05A01 and 06D01. See Appendix C for a description of these inspection procedures and associated codes. 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 sets of non-HIMP establishments.

Table 3-5 presents a summary of the health-related noncompliance rates for these establishments. The health-related noncompliance rate for an inspection procedure code is calculated by dividing the total number of health-related NRs associated with that procedure code by the total number of inspection procedures performed under that procedure code. There is no statistical difference between HIMP establishments and non-HIMP establishments for the majority of the procedure codes. Health-related noncompliance rates for HIMP establishments were statistically lower or were not statistically different for 47 HIMP/non-HIMP comparisons in Table 3-5 and the rates were statistically higher for 3 comparisons. These data demonstrate that HIMP establishments are meeting all food safety and HACCP sanitation and process control regulations designed to insure that establishments are producing safe and wholesome products. Appendix C presents further detail on the health-related noncompliance analysis.

Table 3- 5 Health-Related Noncompliance Rates for HIMP and Non-HIMP Broiler Establishments

Proc Code ¹	2006		2007		2008		2009		2010	
	HIMP Broiler Estab.	Non-HIMP Comparison Broiler Estab.	HIMP Broiler Estab.	Non-HIMP Comparison Broiler Estab.	HIMP Broiler Estab.	Non-HIMP Comparison Broiler Estab.	HIMP Broiler Estab.	Non-HIMP Comparison Broiler Estab.	HIMP Broiler Estab.	Non-HIMP Comparison Broiler Estab.
01A01	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.42%
01B01	0.47%	0.57%	0.17%	0.24%	0.31%	0.52%	0.00%	0.04%	0.07%	0.02%
01B02	1.67%	1.97%	1.60%	1.82%	2.71%*	1.30%	0.52%*	1.36%	0.05%	0.10%
01C01	0.74%*	0.40%	0.27%*	0.44%	0.40%	0.50%	0.17%	0.27%	0.29%	0.33%
01C02	2.08%*	1.47%	1.64%	1.61%	1.25%*	1.74%	1.12%	1.11%	0.25%	0.37%
03A01	0.00%	1.72%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%
03J01	1.01%*	1.26%	0.79%*	1.35%	0.96%*	1.43%	0.98%*	1.40%	0.78%*	1.62%
03J02	0.80%	0.95%	0.61%	0.61%	0.67%	0.87%	0.89%	0.77%	0.33%*	0.55%
05A01	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
06D01	0.07%	0.13%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

* indicates a statistically significant difference at the 0.05 level.

1. See Appendix C for description of procedure code

Table 3-6 presents a summary of the health-related noncompliance rates by process code for the 5 years of combined CY2006 to CY2010 data. Health-related noncompliance rates at HIMP establishments are not statistically different or are statistically lower for all procedure codes. These data again demonstrate that HIMP establishments are satisfying all food safety and HACCP sanitation and process control regulations designed to insure that establishments are producing safe and wholesome products.

Table 3- 6 Five Year Average Health-Related NR Rates for HIMP and Non-HIMP Broiler Establishments

Procedure Code ¹	HIMP Broiler Establishments	Non-HIMP Comparison Broiler Establishments
01A01	0.00%	0.09%
01B01	0.21%	0.28%
01B02	1.33%	1.33%
01C01	0.38%	0.39%
01C02	1.27%	1.27%
03A01	0.00%	0.39%
03J01	0.90%*	1.41%
03J02	0.67%	0.75%
05A01	0.00%	0.00%
06D01	0.02%	0.03%

* indicates a statistically significant difference at the 0.05 level.

1. See Appendix C for description of procedure codes

3.3.3 Fecal Contamination

Under the HIMP system, FSIS inspectors conduct off-line verification checks for fecal contamination 8 times per day per line, which is four times more frequently than under traditional inspection. FSIS inspectors also inspect each carcass at the end of the slaughter line for fecal contamination and have affected carcasses removed and condemned.

The current report analyzes fecal contamination rates for HIMP and non-HIMP comparison establishments for the years CY06 to CY10. The fecal NR rate was computed as the number of fecal contamination NRs divided by the sum of the number of 03J01 and 03J02 procedures performed. The fecal NR rates at HIMP establishments are statistically lower than those in both the control set of non-HIMP establishments and the all non-HIMP comparison set for all the years considered (Table 3-7). The rate of visible fecal material contamination on carcasses in HIMP establishments is about half that in non-HIMP establishments. Since in slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens, it is expected that that pathogen rates (e.g. *Salmonella* positive rates) should be lower in HIMP establishments.

Table 3- 7 Fecal NR Rates at HIMP and Non-HIMP Comparison Establishments

	HIMP	Non-HIMP Comparison Establishments	All Non-HIMP Establishments
2006	0.70%	1.10%	1.07%
2007	0.59%	1.21%	1.17%
2008	0.67%	1.25%	1.26%
2009	0.65%	1.25%	1.20%
2010	0.73%	1.49%	1.40%

To further analyze the fecal NR rates in HIMP and non-HIMP establishments, the number of fecal NRs was regressed against the HIMP dummy variable (denoting whether an establishment is HIMP or control non-HIMP), production volume and the number of 03J procedures. The purpose of the analysis is to determine the influence of production volume and number of 03J procedures on the number of fecal NRs and fecal NR rates. The analysis shows that (a) there is not a statistically significant difference between HIMP and non-HIMP with respect to the number of fecal NRs after adjusting for number of 03J01 and 03J02 procedures performed, (b) fecal NR rates are statistically significantly lower in HIMP establishments than non-HIMP establishments after adjusting for production volume, and (c) production volume is not a statistically significant predictor of fecal NR rates. Appendix D presents the details of the negative binomial regression for fecal NR rates.

It is expected that the rate of visible fecal contamination on carcasses in HIMP establishments will not depend on line speeds. To evaluate the effect of line speeds on fecal NR rates, a negative binomial regression was performed using CY2010 data since that is the only year for which line speeds are available. There is no statistical difference in fecal NR rates between establishments with different line speeds. Appendix E presents the details of the negative binomial regression for fecal NR rates and line speeds. The analysis indicates that increased line speeds in HIMP establishments are not having a negative impact on visible fecal contamination rates.

3.4 Verification of the Outcomes of the Establishment Process Control Plan, both Organoleptic and Microbiologic

This section addresses FSIS inspection activities related to verification of the organoleptic and microbiologic outcomes of the establishment process control plan.

3.4.1 Food Safety Performance Standards

FSIS has a zero tolerance policy for food safety conditions involving infectious conditions (e.g., Septicemia/Toxemia) and fecal material contamination. FSIS developed food safety performance standards (FS-1 and FS-2) for these conditions set at the 75th percentile of what was achieved under the Research Triangle Institute (RTI) baseline study (see Appendix A for discussion of performance standards). A comparison of young chicken HIMP establishment performance with HIMP food safety performance standards is given in Table 3-8. The analysis is based on FSIS food safety inspection findings for the 2 year period April 1, 2009 to March 31, 2011. Performance standards for HIMP establishments provide a scientifically valid measure by which changes in food safety data can be assessed (Hargis et al. 2002).

Septicemia/Toxemia food safety conditions in HIMP establishments are below 8 per million carcasses, which is 125 times less than the HIMP performance standard (Table 3-8). Fecal material contamination levels are below 8 per ten thousand carcasses, which is about 19 times less than HIMP performance standards.

Table 3- 8 HIMP Achievement of Food Safety Performance Standards at Young Chicken Establishments

Defect Categories	Performance Standards Based on Traditional Inspection (% of carcasses)	HIMP Establishment Performance During FSIS Offline Inspector Verification Checks (% of carcasses)
Food Safety 1 Condition- Infectious (e.g., Septicemia, toxemia)	0.1% *	0.0008% ± 0.002% Range 0.0 – 0.008%
Food Safety 2 Contamination- Digestive Content (e.g., fecal material)	1.5% *	0.08% ± 0.05% Range 0.008 – 0.17%

* FSIS has a zero tolerance policy for Food Safety 1 & 2
 Period of data collection: April 1, 2009 through March 31, 2011

Despite the low rate of food safety defects in HIMP establishments, it is expected that FSIS carcass inspectors will detect and remove remaining food safety defects, thereby lowering the rate of food safety defects even further. In the HIMP system, the FSIS online CI is positioned at the end of the production process just before the chiller, making the inspector well positioned to find adulterated carcasses. Evaluation of the FSIS online CI findings over the past 2 years (April 1, 2009 to March 31, 2011) show that the CI can inspect sufficiently to detect adulterated carcasses, both FS-1 and FS-2, in young chicken HIMP establishments. At the carcass inspection station, the CI found 125 carcasses affected with infectious conditions and 26,815 carcasses affected with visible fecal material (Tables 3-9 and 3-10).

The CI detection rates for Sep/tox and for fecal findings are calculated by dividing the number of affected carcasses by slaughter volume minus the number of condemned carcasses or the total number of carcasses sampled; respectively. For Sep/tox, the CI detected affected carcasses at a rate of 0.000004% (or 4 per 100 million carcasses inspected). For fecal contamination the CI detected affected carcasses at a rate of 0.0009% (or 9 per million carcasses inspected). Although these rates are low, they provide evidence that the carcass inspector can inspect sufficiently to detect adulterated carcasses.

The FSIS offline VI detection rates for Sep/tox and for fecal findings are calculated by dividing the number of affected carcasses by number of verification inspections (80 per line per shift per days of production), which is 4 times greater in HIMP than in non-HIMP establishments. For the 2 year period considered, the VIs found 32 carcasses affected with Sep/tox and 2,994 carcasses affected with visible fecal material (Tables 3-9 and 3-10). For Sep/tox, the VIs detected affected carcasses at a rate of 0.0008% (or 8 per million carcasses slaughtered). For fecal material, the VIs detected affected carcasses at a rate of 0.08% (or 8 per ten thousand carcasses inspected). It is important to note that the VI removes their sampled carcasses from the evisceration line for inspection, and conducts an examination and inspection of each bird for up to one minute each which allows for possibly greater identification of food defects than CIs.

Table 3- 9 Comparison of Sep/Tox Detection Rates for Carcass and Verification Inspectors

	Number Sep/tox findings detected CY2009-CY2010	Carcasses Inspected	Sep/tox detection rate
Carcasses Inspectors	125	2.97E+09	0.000004%
Verification Inspectors	32	3.82E+06	0.0008%

Table 3- 10 Comparison of Fecal Detection Rates for Carcass and Verification Inspectors

	Number fecal contaminations detected CY2009-CY2010	Carcasses Inspected	Fecal detection rate
Carcasses Inspectors	26,815	2.97E+09	0.0009%
Verification Inspectors	2,994	3.822E+06	0.08%

The data demonstrate that while fewer adulterated poultry carcasses are presented to the inspector in HIMP establishments, FSIS carcasses inspectors can inspect sufficiently to detect adulterated carcasses.

3.4.2 Other Consumer Protection Performance Standards

Other consumer protection (OCP) standards are non-food safety standards concerned primarily with carcass appearance. FSIS developed OCP performance standards for HIMP establishments and monitors HIMP establishment performance to verify that OCP performance standards are being met. It is expected that HIMP establishments maintain OCP defects at levels below the OCP performance standards. OCP performance standards provide a scientifically valid measure by which changes in food safety and other consumer protection data can be assessed (Hargis et al. 2002).

A comparison of young chicken HIMP establishment performance with OCP HIMP performance standards is given in Table 3-11 (see Appendix A for discussion of HIMP performance standards). The analysis is based on FSIS food safety inspection findings for the 2 year period January 1, 2009 through December 31, 2010.

For the two year period CY2009 through CY2010, FSIS verification data show that OCP defect levels average about half the corresponding OCP performance standards. It is emphasized that FSIS verification of OCP defect levels occurs before the CI is presented with the carcass. It is expected that FSIS carcass inspection will result in further reductions in OCP levels.

Table 3- 11 HIMP Achievement of OCP Performance Standards at Young Chicken Establishments

	Performance Standards	HIMP Establishment

	Based on Non-HIMP Inspection (% of carcasses)	Performance During FSIS Inspector Verification Checks (% of carcasses \pm one standard deviation)
OCP 1 Condition-Animal Diseases (e.g., airsacculitis)	1.7%	0.38% \pm 0.36% Range 0.0-1.25%
OCP 2 Condition- Miscellaneous (e.g., bruises, sores, and other processing defects)	52.5%	34.1% \pm 9.3% Range 18.2- 49.9%
OCP 3 Contamination-Digestive Content (e.g., ingesta)	18.6%	6.3% \pm 4.3% Range 0.25 – 15.2%
OCP 4 Dressing Defects- Other (e.g., feathers)	80.0%	66.4% \pm 10.4% Range 41.2 – 80.2%
OCP 5 Dressing Defects- Digestive Tract Tissue (e.g., bursa, cloaca)	20.8%	9.8% \pm 4.0% Range 3.2 – 15.8%

Period of data collection: CY2009 through CY2010

It is expected that the increased line speeds in HIMP establishments will not result in an increase rate of OCP defects on carcasses. Poisson and negative binomial regressions were evaluated for utility in analyzing OCP rates versus line speeds. It was decided to use negative binomial regression. The analysis shows that there is no statistically significant difference in OCP2 – OCP5 rates between HIMP establishments with different line speeds. OCP1 rates do show a positive correlation with line speeds, but the model with line speed does not fit significantly better than random chance (i.e., the null model without line speeds). The analysis suggests that increased line speeds in HIMP establishments are not having a negative impact of OCP defect levels.

One OCP condition that is difficult for online carcass inspectors to identify is avian leukosis, a viral disease that affects chickens. Avian leukosis is not transmissible to humans and does not present a human health concern. However, it may render poultry carcasses and viscera unwholesome (as do other OCPs). Therefore, it is important to identify its presence in poultry intended to receive the USDA official inspection legend. Avian visceral leukosis cannot be identified through a carcass inspection alone, but rather is detected by observing the viscera. Accordingly, in the young chicken HIMP establishments a FSIS offline inspector observes the carcass and corresponding viscera of the first 300 birds slaughtered of each flock to evaluate the leukosis status of the flock.

It is common commercial practice to vaccinate each flock of chickens for viral leukosis. On rare occasions, the vaccine is not effective. If it is not, visceral leukosis is present throughout the

entire flock. In the young chicken HIMP establishments, the first 300 birds slaughtered of each flock are observed to evaluate the leukosis status of the flock. Based on this analysis, the Inspector in Charge (IIC) or Supervisory Public Health Veterinarian (SPHV) decides whether a flock is designated as positive for leukosis and may expand the sample size, if necessary. If a flock is found to be positive, a FSIS offline inspector inspects each viscera for visceral leukosis only at a location where it can be identified with the carcass until all carcasses in the flock have been slaughtered. It is FSIS experience that when a flock has avian visceral leukosis, 10 to 15 percent of the birds in the flock have detectable leukosis lesions. For a flock in which 10% of the birds have detectable avian leukosis, a 300 bird sample provides a greater than 95% probability of detecting 22 or greater birds with visible leukosis lesions. Thus a 300 bird sample is adequate to detect avian leukosis in a flock.

3.4.3 *Salmonella* Positive Rates

FSIS uses data from its *Salmonella* verification testing programs to verify that establishments are meeting their regulatory obligations. 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 3-12 presents a summary of the *Salmonella* percent positive rates for HIMP and the control set of 64 non-HIMP establishments for the years CY2006 to CY2010. In CY2006-CY2008, the *Salmonella* positive rate in HIMP establishments was statistically significantly lower than in the non-HIMP comparison set and there was no statistically significant difference in the years CY2009 and CY2010. The *Salmonella* positive rate in HIMP establishments was statistically significantly lower than in the all non-HIMP comparison set for CY2006 to CY2009. There was no statistically significant difference in CY2010. Appendix F presents further detail on the *Salmonella* verification testing results for young chicken slaughter establishments for the years CY2006 to CY2010.

Table 3- 12 Salmonella Percent Positive Rates for HIMP and Non-HIMP Broiler Establishments

	2006	2007	2008	2009	2010
20 HIMP Broiler Establishments	9.0%	5.8%	4.2%	4.9%	4.7%
64 Non-HIMP Comparison Establishments	10.8%	8.5%	7.3%	4.3%	4.0%
176 All Non-HIMP Establishments	11.1%	8.1%	7.6%	6.8%	4.7%

It is expected that the increased line speeds in HIMP establishments will not result in increased *Salmonella* positive rates. To evaluate the effect of line speeds on *Salmonella* positive rates, a negative binomial regression was performed on *Salmonella* positive rates versus line speed. The analysis shows that there is no statistical difference in the *Salmonella* positive rate between establishments with different line speeds. This analysis is based on the 10 HIMP establishments with *Salmonella* testing during CY2010. The line speeds for these 10 establishments ranged from 98 to 162 bpm. Appendix E presents the details of the negative binomial regression for *Salmonella* and line speed. The analysis indicates that increased line speeds in HIMP establishments are not having a negative impact on *Salmonella* positive rates.

4.0 DISCUSSION

In October 1999, FSIS began the HIMP project to determine whether new government slaughter inspection procedures, in conjunction with new plant responsibilities, could improve food safety in slaughter establishments. Under HIMP, employees of slaughter establishments sort carcasses before they reach FSIS on-line inspectors, making an initial determination whether they are unacceptable, allowing the on-line inspector to focus on fewer food-safety issues. This approach is consistent with HACCP where industry rather than federal inspectors is responsible for identifying steps in food production where food safety hazards are most likely to occur and for establishing controls that prevent or reduce them. Currently, there are 20 young chicken; 5 young turkey, and 5 market hog slaughter establishments participating in HIMP. This report focuses on the 20 young chicken slaughter establishments in HIMP.

4.1 Previous Evaluations of HIMP Performance

Prior to implementing the HIMP program, Research Triangle Institute (RTI) established a baseline level of performance in traditional (non-HIMP) young chicken slaughter establishments. RTI collected thousands of samples from 16 young chicken slaughter establishments operating under existing inspection systems. The sampled birds had already passed FSIS online inspection, undergone trimming by establishment personnel to remove visible defects, and been determined by FSIS offline inspectors to be in compliance with FSIS Finished Product Standards. Based on this baseline level of performance, FSIS developed HIMP performance standards for two food safety and five Other Consumer Protection (OCP) non-food safety defects.

The HIMP performance standards were set at the 75th percentile of what the 16 young chicken slaughter establishments were achieving under traditional inspection before they entered the HIMP program. To meet the HIMP performance standards, food safety and OCP defects at HIMP establishments, after establishment employee sorting, will have to be 25 percent lower before FSIS carcass inspection than the corresponding levels in non-HIMP establishments after FSIS carcass inspection.

To meet HIMP performance standards, HIMP establishments must reduce food safety (Septicemia/Toxemia and fecal) and OCP defects in carcasses to levels less than found in the RTI baseline non-HIMP plants after carcasses have passed FSIS carcass inspection. And these lower levels of carcass defects must be achieved before the FSIS carcass inspector in HIMP establishments inspects the carcasses. To verify that FSIS carcass inspectors are being presented with carcasses satisfying the HIMP performance standards, FSIS verification inspectors check 80 birds per line per shift for food safety defects and between 20 and 50 birds per line per shift for OCP defects each day.

RTI conducted an initial evaluation of the performance of HIMP chicken slaughter establishments in 2001 (Cates et al. 2002). That evaluation found that young chicken slaughter establishments under HIMP performed as well as or better than they did before beginning the HIMP program. Subsequent verifications over the time periods Sep 18, 2000 – April 30, 2001,

Sep 18, 2000 - Sep 30, 2002 and July 14, 2003 - December 31, 2004 confirmed that HIMP plants were meeting HIMP performance standards (FSIS 2001, 2002, 2008a). These studies demonstrated that HIMP young chicken slaughter establishments were performing as well or better than young chicken slaughter establishments under traditional inspection systems.

The present study updates these studies based on data for the years CY2006 through CY2010, with exceptions where earlier data are not available. The evaluation compares the 20 HIMP young chicken establishments with established HIMP performance standards or with a comparison set of 64 non-HIMP establishments selected to be comparable with HIMP establishments with respect to production volume, lines speed, and geographical distribution. Performance metrics used in the comparison of HIMP and non-HIMP establishments are presented in Table 4-1. This table presents the data used in comparing HIMP and non-HIMP establishments and why it was selected. It is expected that HIMP establishments will perform at least as well or better than non-HIMP plants with respect to these performance metrics.

Table 4- 1 Performance Metrics for Comparing HIMP and Non-HIMP Establishments

Performance Metrics for Comparing HIMP and Non-HIMP Establishments	Justification for Metric
Food Safety Metrics <ul style="list-style-type: none"> • Septicemia and toxemia rates • Visible Fecal contamination rates 	FSIS has zero tolerance for food safety defects Component of FSIS performance standards for HIMP plants Food safety metrics provide a scientifically valid measure by which performance of HIMP establishments can be evaluated (Hargis et al. 2002)
Other Consumer Protection Metrics	Component of FSIS performance standards for HIMP plants OCP defects at high levels can render carcasses unwholesome OCPs provide a scientifically valid measure by which performance of HIMP establishments can be evaluated (Hargis et al. 2002)
Offline Inspection Procedures <ul style="list-style-type: none"> • Number of offline inspection procedures • Rate of health-related regulatory non-compliances 	Offline inspections verify sanitation and HACCP process control plans and whether the plant is meeting relevant carcass performance standards Regulatory non-compliances are indicators of process control Increasing offline inspection procedures results in lower <i>Salmonella</i> positive rates (FSIS 2008b)
<i>Salmonella</i> Positive Rates	<i>Salmonella</i> on carcasses poses a potential risk to consumers

4.2 Food Safety Performance Standards

Food safety performance standards are an accepted means of evaluating the food safety performance of HIMP establishments (Hargis et al. 2002). FSIS has a zero tolerance policy for food safety conditions involving infectious conditions (e.g., Septicemia/ Toxemia) and fecal material contamination. However, for the purpose of comparison of performance between HIMP and non-HIMP establishments, FSIS developed food safety performance standards (FS-1 and FS-2) for these conditions set at the 75th percentile of what was achieved under the RTI baseline study.

The FSIS offline inspectors check 80 birds per day for each line and each shift for Septicemia/Toxemia and for fecal findings. The National Alliance for Food Safety determined that food safety performance standards provide a scientifically valid measure by which performance of HIMP establishments can be evaluated (Hargis et al. 2002).

Since the inception of HIMP in 1999, HIMP plants have consistently maintained food safety defects at levels less than the FSIS food safety performance standards. For the period CY2009 through CY2010, toxemia and septicemia food safety conditions in HIMP establishments are below 8 per million carcasses, which is 125 times less than HIMP performance standards. Fecal contamination levels are below 8 per ten thousand carcasses, which is about 19 times less than HIMP performance standards.

This means that level of food safety (infectious and fecal) carcass defects achieved in HIMP establishments before the FSIS carcass inspector in HIMP establishments inspects the carcasses is at least 19 times lower than levels found in the RTI baseline non-HIMP plants after carcasses have passed FSIS carcass inspection.

Table 4- 2 HIMP Achievement of Food Safety Performance Standards

	Food Safety Performance Standards (% of carcasses)	HIMP Plant Performance 9/00-4/01 ¹	HIMP Plant Performance 9/00-9/02 ²	HIMP Plant Performance 2009-2010
FS-1 Infectious Conditions (e.g., Septicemia, toxemia)	0.1%*	0.001%	0.003%	0.008%
FS-2 Digestive Content Contamination (e.g., fecal material)	1.5%*	0.1%	0.1%	0.08%

* FSIS has a zero tolerance policy for Food Safety 1 & 2

1. Fourteen young chicken HIMP establishments post redesign (see FSIS 2001)

2. Twenty one young chicken HIMP establishments post redesign (see FSIS 2002b)

Table 4-2 compares Septicemia/Toxemia rates in HIMP establishments with food safety performance measures. Another comparison that can be made is to compare 2009-2010 Septicemia/Toxemia rates in HIMP establishments with Septicemia/Toxemia rates in non-HIMP

establishments in the same time period. Table 4-3 presents Septicemia/Toxemia rates in non-HIMP plants for the years 2006 to 2010. While Septicemia/Toxemia detection rates in non-HIMP establishments have declined over time, they are still higher than the performance standards for Septicemia/Toxemia in HIMP establishments (see Table 4-2). The rate at which FSIS offline verification inspectors detect Septicemia/Toxemia defects in HIMP establishments is about 14 times less than FSIS inspectors detect Septicemia/Toxemia in non-HIMP establishments.

Assuming that the incoming rate of Septicemia/Toxemia defects on birds is about the same in both HIMP and non-HIMP establishments, this indicates that HIMP establishment employees are effective at removing (sorting) birds with Septicemia/Toxemia defects before they are presented to FSIS carcass and offline inspectors.

Table 4- 3 Septicemia/Toxemia Rates in HIMP and Non-HIMP Establishments

	2006	2007	2008	2009	2010
20 HIMP Broiler Establishments				0.008%	
64 Non-HIMP Comparison Broiler Establishments	0.17%	0.14%	0.13%	0.12%	0.11%
167 All Non-HIMP Broiler Establishments	0.19%	0.17%	0.15%	0.13%	0.12%

In addition to comparing fecal contamination rates in HIMP establishments with performance standards, fecal noncompliances in HIMP establishments can be compared with those in non-HIMP establishments. In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Therefore, FSIS enforces a “zero tolerance” standard for visible fecal material on poultry carcasses.

Over the time period CY06 to CY10, the rates of visible fecal contamination on young chicken carcasses at HIMP establishments average about 50 percent lower than those in both the control set of non-HIMP establishments and the all non-HIMP comparison set (Table 3-7).

This analysis confirms that HIMP establishments are meeting all food safety performance standards and have statistically significantly less visible fecal contamination on carcasses than do non-HIMP establishments.

4.3 Other Consumer Protection (OCP) Standards

FSIS established five performance standards for OCP non-food safety concerns in HIMP establishments. Non-compliance with OCP concerns does not constitute a food safety issue, but it may result in unwholesome product. The National Alliance for Food Safety determined that OCP performance standards provide a scientifically valid measure by which performance of HIMP establishments could be evaluated (Hargis et al. 2002).

Since the inception of HIMP, HIMP plants have consistently maintained OCP defect levels less than FSIS OCP performance standards. For the two year period CY2009 through CY2010,

HIMP plants have maintained OCP defect levels that average about half the corresponding OCP performance standards (Table 4-4).

Table 4- 4 HIMP Achievement of OCP Performance Standards

	Performance Standards Based on Non-HIMP Inspection (% of carcasses)	HIMP Establishment Performance 2000-2001 ¹	HIMP Establishment Performance 2000-2002 ²	HIMP Establishment Performance 2009-2010 (% of carcasses ± one standard deviation)
OCP 1 Condition-Animal Diseases (e.g., airsacculitis)	1.7%	1.0%	1.1%	0.38% ± 0.36% Range 0.0-1.25%
OCP 2 Condition-Miscellaneous (e.g., bruises, sores, and other processing defects)	52.5%	26.3%	26.9%	34.1% ± 9.3% Range 18.2-49.9%
OCP 3 Contamination-Digestive Content (e.g., ingesta)	18.6%	9.6%	10.0%	6.3% ± 4.3% Range 0.25 – 15.2%
OCP 4 Dressing Defects-Other (e.g., feathers)	80.0%	54.4%	60.8%	66.4% ± 10.4% Range 41.2 – 80.2%
OCP 5 Dressing Defects-Digestive Tract Tissue (e.g., bursa, cloaca)	20.8%	7.0%	8.1%	9.8% ± 4.0% Range 3.2 – 15.8%

1. See FSIS (2001)
2. See FSIS (2002b)

This analysis confirms that HIMP establishments are meeting all OCP performance standards. This means that the level of OCP carcass defects achieved in HIMP establishments before the FSIS carcass inspector in HIMP establishments inspects the carcasses is lower than levels found in the RTI baseline non-HIMP plants after carcasses have passed FSIS carcass inspection.

4.4 Offline Inspection Procedures

FSIS inspectors conduct offline inspection procedures in HIMP establishments to ensure compliance with mandatory food safety standards and federal regulations. These inspection procedures include monitoring for food safety and OCP defects, pathogen levels, and for compliance with federal sanitation and HACCP regulations. It is expected that the number of offline inspection procedures will be higher in HIMP than non-HIMP establishments and that the noncompliance rates will be lower. This will increase the confidence that HIMP establishments are complying with all federal regulations and are producing a safe and wholesome product.

The FSIS risk assessment on poultry slaughter inspection (FSIS 2008b) found that increasing the number of offline inspection procedures, especially sanitation, HACCP, and sampling procedures, should reduce *Salmonella* positive levels in establishments. Because fewer inspectors are required to conduct online carcass inspection under HIMP, FSIS is able to conduct more offline inspection activities.

Overall, FSIS inspectors perform 1.6 times more total offline verification inspection procedures and 3 times more sanitation and HACCP inspection procedures in HIMP establishments than in non-HIMP establishments (see Table 3-3). These procedures include verifying compliance with both OCP- and food safety-related regulations.

Since FSIS inspectors perform more offline verification inspection procedures in HIMP plants, the FSIS poultry slaughter risk assessment predicts that *Salmonella* positive rates should be lower in HIMP plants. The data indicate that *Salmonella* positive rates in HIMP establishments average about 80% those in non-HIMP establishments (see below and Table 3-12).

Health-related non-compliance rates provide an indication of the effectiveness of establishment process control. When considered over CY2006 to CY2010, health-related non-compliance rates at HIMP plants are not statistically different or are statistically lower for all comparable procedure codes.

This analysis confirms that HIMP establishments are complying with federal regulations as well or better than non-HIMP establishments. Since the majority of offline inspection procedures in young chicken slaughter establishments involve verifying sanitation and HACCP regulations, HIMP plants are complying with federal sanitation and HACCP regulations as well as or better than non-HIMP plants.

4.5 Salmonella Positive Rates

Salmonella in raw product is not an adulterant, but however does pose a potential health risk to consumers. FSIS estimates that *Salmonella* on young chicken carcasses causes about 170,000 illnesses each year (FSIS 2011). The principal effect of verifying *Salmonella* levels on young chicken carcasses is to encourage industry to produce a safer product.

Salmonella positive rates in HIMP establishments average about 80% those in non-HIMP establishments. *Salmonella* positive rates at HIMP establishments were not found to be related to

line speed. FSIS believes that lower *Salmonella* positive rates result in fewer public health impacts (FSIS 2011).

This analysis confirms that HIMP establishments have equal or lower *Salmonella* positive rates than non-HIMP establishments.

4.6 Carcass-By-Carcass Inspection

A key issue that this report addresses is whether FSIS inspectors in young chicken slaughter establishments operating under the HIMP inspection system are able to make a determination as to whether each carcass is not adulterated and therefore eligible to bear the mark of inspection.

The data show that as a result of industry practices, such as carcass sorting activities, very few adulterated poultry carcasses are presented to inspectors stationed at the end of the slaughter line in HIMP establishments (see Tables 4-2 and 4-4). The number of carcasses with septicemia or toxemia that arrive at the online carcass inspector location is very low (less than 8 carcasses with infectious conditions per million carcasses processed), as is the number of carcasses with visible fecal contamination (less than 8 carcasses with fecal contamination per 10,000 carcasses). The low rate at which adulterated carcasses are presented for inspection under HIMP allows FSIS inspectors to inspect sufficiently to determine whether each carcass is not adulterated.

If the frequency of defects exceeds the carcass inspector's ability to inspect each carcass, he or she can request the Inspector in Charge to perform additional food safety verification checks and or reduce the line speed. Under traditional (non-HIMP) carcass inspection, the inspector visually inspects each carcass, its corresponding viscera, and physically touches each carcass to look inside. HIMP establishment carcass inspection is a visual carcass inspection of the carcass of each bird that eliminates the time required for the hand motion associated with touching the carcass. Carcass inspection under HIMP takes less time than under traditional inspection.

Evaluation of carcass inspector food safety findings for the most recent 2 year period (April 2009 to April 2011) shows that HIMP carcass inspectors can inspect sufficiently to detect both infectious conditions (FS-1) and visible fecal material (FS-2) adulterated carcasses in young chicken HIMP establishments. Although defect levels presented to the carcass inspector are low (125 and 19 times less than HIMP performance standards for sep/tox and fecal contamination, respectively), the HIMP carcass inspector detects carcasses with infectious conditions at a rate of 4 per 100 million carcasses slaughtered and visible fecal contamination at a rate of 9 per million carcasses slaughtered. The FSIS carcass inspectors can inspect sufficiently to detect adulterated carcasses.

Because under the HIMP system, the online inspector is positioned at the end of the slaughter line and just before the immersion chiller, he or she is well-positioned to prevent carcasses with fecal contamination from entering the chiller and to protect consumers from adulterated products. They see birds after the establishment's interventions have been applied to verify that the carcasses are free of food safety defects.

Before implementing the HIMP program, FSIS established food safety and non-food safety performance standards as a means for measuring the performance of slaughter establishments operating under the new HIMP inspection procedures (see Appendix A). Performance standards provide a scientifically valid measure by which changes in food safety and OCP data can be assessed (Hargis et al. 2002). HIMP establishments have consistently maintained food safety defect levels at least a factor of 10 less than the performance standards and OCP finding levels that average about half the corresponding OCP performance standards.

Under the HIMP system, FSIS inspectors conduct off-line verification checks for fecal contamination four times more frequently than under traditional inspection. FSIS online inspectors also inspect each carcass at the end of the slaughter line for fecal contamination and have affected carcasses removed and condemned. Evaluation of carcass inspector food safety findings data from April 2009 to April 2011 shows that the HIMP FSIS inspectors find and remove carcasses with visible fecal material. In addition, fecal positive rates in HIMP establishments average about half those in non-HIMP establishments.

As part of a Government Accountability Office (GAO) review of the HIMP models project (GAO 2001), 210 USDA inspectors and veterinarians were surveyed as to whether product safety was the same or better under HIMP system as compared to the traditional system. Seventy one percent of USDA inspectors and veterinarians surveyed indicated that product safety was the same or better under HIMP system as compared to the traditional system, and 57% indicated that product quality was the same or improved. The National Alliance for Food Safety review (Hargis et al. 2002) agreed that the data indicated that the safety and quality of young chickens inspected under the HIMP system is either the same or improved as compared to the traditional system. The CY2009 to CY2010 data analyzed in the current report show that all HIMP establishments are meeting the food safety and OCP performance standards for HIMP.

In aggregate, these findings support that the on line inspectors in HIMP establishments are performing in a manner that enables them to properly inspect each carcass and, therefore, make the inspection to identify adulterated carcasses. The data demonstrate that while fewer adulterated poultry carcasses are presented to the inspector in HIMP establishments, FSIS carcasses inspectors can inspect sufficiently to find adulterated carcasses.

5.0 CONCLUSION

This final report contains an evaluation of FSIS inspection findings in HIMP establishments and, as appropriate, compares those with established HIMP performance standards or with a comparison set of 64 non-HIMP establishments selected to be comparable with HIMP establishments with respect to production volume, lines speed, and geographical distribution.

The evaluation confirms, in agreement with previous evaluations, that HIMP establishments are meeting all food safety and OCP HIMP performance standards. The HIMP performance standards are a stringent metric. To meet HIMP performance standards, HIMP establishments must reduce food safety (infectious and fecal) and OCP defects in carcasses to levels less than found in the RTI baseline non-HIMP plants after carcasses have passed FSIS carcass inspection. And these lower levels of carcass defects must be achieved before the FSIS carcass inspector in HIMP establishments inspects the carcasses. Compliance with HIMP performance standard means that HIMP establishments are reducing food safety and OCP defects in carcasses to levels less than or equal to levels in non-HIMP establishments.

Fecal contamination rates and *Salmonella* positive rates are lower in HIMP than in non-HIMP establishments. FSIS believes that lower *Salmonella* positive rates result in fewer public health impacts (FSIS 2011).

Because fewer inspectors are required to conduct online carcass inspection in HIMP establishments, FSIS is able to conduct more offline food safety related inspection activities. HIMP establishments have higher compliance with SSOP and HACCP prevention practice regulations and lower levels of non-food safety defects, fecal defect rates, and *Salmonella* verification testing positive rates than non-HIMP establishments. These data indicate that HIMP inspection provides improvements in food safety and other consumer protections.

A summary of results follows:

- Toxemia/septicemia food safety conditions in HIMP establishments are below 8 per million carcasses, which is 125 times less than HIMP performance standards.
- Toxemia/septicemia defect rates are about 14 times lower in HIMP than non-HIMP establishments.
- Fecal contamination levels are below 8 per ten thousand carcasses, which is about 19 times less than HIMP performance standards.
- OCP conditions in HIMP establishments average about half the corresponding OCP performance standards.
- SSOP and HACCP systems in HIMP establishments function statistically better or not statistically different than comparison non-HIMP establishments for all comparable slaughter-related procedure codes. The rate of HACCP 03J01 health-related noncompliances in HIMP establishments is 1.6 times lower than in non-HIMP establishments.
- The fecal NR rates at HIMP establishments are about half than those in non-HIMP establishments. Fecal NR rates are not found to be related to line speed.

- *Salmonella* positive rates in HIMP establishments average about 80% those in non-HIMP establishments. *Salmonella* positive rates at HIMP establishments were not found to be related to line speed.

In aggregate, the findings support that the online inspectors in HIMP establishments are performing in a manner that enables them to properly inspect each carcass and, therefore, make the appraisals sufficient to identify adulterated carcasses. The data demonstrate that fewer adulterated poultry carcasses are presented to the inspector in HIMP establishments and that the FSIS carcasses inspector can perform in a manner that that enables them to properly inspect each carcass.

Given the low numbers of adulterated poultry carcasses presented to the inspector in HIMP establishments, the stability of line speeds in the HIMP pilot project, and the ability of the carcass inspector to personally inspect each and every carcass leaving the slaughter line, FSIS has determined that the addition of a second carcass inspector to each line would not further HIMP project objectives and is not necessary to meet statutory mandates.

6.0 REFERENCES

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7.0 APPENDICES

Appendix A - History of HIMP

HIMP was developed by FSIS to test inspection models that produce a more flexible and efficient inspection system. A key element of HIMP is that establishment personnel are required to conduct carcass sorting activities before FSIS conducts online carcass inspection so that only carcasses that the establishment deems likely to pass inspection are presented to the carcass inspector. HIMP allows FSIS carcass inspectors to perform a carcass-by carcass inspection more efficiently and in less time than is the case where establishments have not sorted and trimmed carcasses before they are inspected. As a result, under HIMP, a single online carcass inspector is able to conduct an effective carcass-by-carcass inspection at higher line speeds, subject to the establishment's ability to maintain continuous process control. Because fewer inspectors are required to conduct online carcass inspection, FSIS is able to conduct more offline food safety related inspection activities.

A-1 HIMP Inspection activities

Every HIMP establishment has an online CI and an offline VI. The online carcass inspector conducts a carcass-by-carcass appraisal before the carcasses enter the chiller. If the online carcass inspector observes any food safety hazards on any of the carcasses, such as the presence of septicemic or toxemic animal disease or fecal material, he or she stops the line to prevent the contaminated carcass from entering the chiller.

In addition to the online carcass inspector, one offline verification inspector is assigned for each evisceration line in HIMP establishments. The HIMP offline inspectors focus their attention on food safety related inspection activities, such as conducting HACCP and sanitation verification procedures and collecting samples for pathogen testing. The offline VI also verifies and evaluates the HACCP and OCP process control plans and determines whether the establishment is meeting relevant regulatory requirements and performance standards.

The duties of the CI include:

- Visually inspects each carcass on the line including the exterior of the carcasses as they are presented to see if they are adulterated
- Identifies FS-1 or FS-2 affected carcasses defects
 - If the CI is before the CCPs for Sep/Tox and fecal contamination and the CI identifies an FS-1 or FS-2 defect, he or she stops the evisceration line and has the carcass removed and documents each finding on a tally sheet, but does not write a NR.
 - If the CI is after the CCPs for Sep/Tox and fecal contamination and the CI identifies an FS-1 or FS-2 defect, he or she stops the evisceration line and has the carcass removed, and writes an NR.
- Condemns carcasses with OCP defects that clearly exhibit condemnable conditions

The duties of the VI include:

- Conduct scheduled and unscheduled sampling by examining carcasses, selected in 10 bird sets before the CI position, to determine if the establishment is complying with relevant performance standards.
- Conduct eight 10-bird-sample sets per line for shift for FS-1 and FS-2 defects. If the VI finds a food safety defect (FS-1 or FS-2), he or she will document the noncompliance on a NR.
- Conduct OCP verification activities. The minimum number of OCP sample sets per line is two sets (20 birds) and the minimum number of birds per shift is 50. The VI writes an NR to document the failure of OCP-1 maximum limits.
- Issue an NR, if at any point within the 25-day period the 25-day limit for OCP performance is exceeded for any OCP category.
- Assess the overall design and execution of all the establishment processes under its HACCP and process control procedures.
- Verify HACCP and process control plans and whether the plant is meeting relevant carcass performance standards.

A-2 HIMP Performance Standards

Under HIMP, FSIS has established performance standards for food safety (FS) and non-food safety defects (also known as OCP) found in young chickens, hogs, and turkeys. The food safety performance standards are set at zero to protect consumers from conditions that may be harmful. The OCP performance standards are set at the 75th percentile of what was achieved under the Research Triangle Institute (RTI) baseline study; thus, 25 percent of the establishments entering HIMP have to improve upon their baseline results in order to meet the more stringent standards.

To develop the OCP performance standards, RTI collected thousands of samples from 16 young chicken slaughter establishments operating under the existing inspection systems. The sampled birds had already passed FSIS online inspection, undergone trimming by establishment personnel to remove visible defects, and been determined by FSIS offline inspectors to be in compliance with FSIS Finished Product Standards (FPS). Then, FSIS ranked the 16 establishments based on their performance under each of the five OCP categories. The performance standard for each OCP category was then established based on the performance level of the establishment representing the 75th percentile for that category (i.e., the performance level of the fourth-best performing establishment of each category). Thus, the OCP performance standards represent a reduction from the highest prevalence of defects found in product that had passed the FPS. Participating establishments must revise their HACCP systems to meet these food safety performance standards and establish process control systems to address the OCP concerns.

No food safety or non-food safety defects are acceptable to FSIS. HIMP is an effort to reduce and eliminate defects that pass through traditional inspection. Under HIMP inspection, FSIS inspectors check for fecal contamination and other organoleptic food safety defects four times more frequently than under the traditional system to ensure that performance standards are met.

A-3 HIMP Pilot Project Litigation

In June 1997 FSIS sought public comment on the proposed HIMP inspection model project. Under the HIMP inspection system proposed at that time, FSIS did not plan to have fixed FSIS inspection stations on slaughter lines. Instead, FSIS inspectors would provide oversight at the slaughter lines and verification that establishments were properly implementing HACCP, among other things.

In April 1998, the FSIS inspectors' union filed suit in the United States District Court to enjoin the USDA from proceeding with the pilot project, on the grounds that it violated the Federal Meat Inspection Act, 21 U.S.C. section 604, and the Poultry Products Inspection Act, 21 U.S.C. section 455, by not requiring federal government officials to perform carcass-by-carcass postmortem inspections.

In September 1999, U.S. District Court ruled the proposed HIMP pilot project did not violate the requirements of the federal meat and poultry inspection statutes. In June 2000, the United States Court of Appeals for the District of Columbia Circuit ruled that delegating the task of inspecting carcasses to establishment employees violated the acts because both statutes require that federal inspectors, rather than private employees, determine whether a product is adulterated.

As a result of this ruling, in September 2000, FSIS redesigned the pilot project and placed at least one FSIS inspector back at a fixed location on each slaughter line to inspect each carcass and determine whether it is adulterated. In January 2001, the United States Court of Appeals ruled that the redesigned HIMP pilot project satisfied the requirements of the federal meat and poultry inspection statutes.

A-4 Research Triangle Institute Study

The purpose of the HIMP pilot study was to determine if HIMP establishments could provide a level of safety and quality equal to or better than traditionally inspected slaughter establishments. To obtain data with which to evaluate the performance of HIMP establishments, FSIS contracted with Research Triangle Institute (RTI) to gather baseline data on the performance of traditional young chicken slaughter establishments. Between 1998 and 2000 and prior to young chicken slaughter establishments beginning to operate under HIMP, RTI conducted a study of 16 young chicken establishments to establish baseline organoleptic and microbial levels at traditional young chicken slaughter establishments. Based on baseline information, FSIS developed and published performance standards on November 2, 2000 that allow for evaluation of HIMP establishment food safety and other consumer protection performance relative to traditional inspection systems.

After the HIMP program began and during the period September of 2000 to December of 2001, RTI collected microbial and organoleptic data in the 16 young chicken establishments in the HIMP pilot study to determine their performance relative to the performance standards established in November 2000. HIMP establishment performance for FS-1 or FS-2 was less than 0.003% and 0.1% for carcasses with defects for FS-1 and FS-2, respectively, compared to the performance standards of 0.1% and 1.5%, respectively, which are based on performance at non-HIMP establishments. HIMP establishment OCP performance was also consistently below OCP performance standards.

The RTI study concluded that inspection under the new models is equivalent and in some ways superior to that of traditional inspection (Cates et al. 2001). The pilot project suggested that the HIMP inspection system can maintain or improve food safety and other consumer protection conditions relative to traditional hands-on inspection methods.

A-5 National Alliance for Food Safety Review

In 2002 a technical review team selected by the National Alliance for Food Safety under contract with FSIS reviewed results of the RTI study. The review team consisted of nationally and internationally recognized experts in the area of poultry microbiology, food safety, poultry health, poultry processing, and statistical evaluation. The results of the National Alliance for Food Safety review were published in Hargis et.al. (2002). The review team determined that the overall design and methodology of the RTI study were generally appropriate, and were perhaps the best available options to allow for comparison of organoleptic data between the traditional and HIMP systems. The Hargis et al. (2002) report found that the RTI data showed marked improvement in the organoleptic defect scores of carcasses processed under the HIMP model system as compared to the baseline data collected under the traditional system.

Appendix B - Line Speed Methodology

It is possible to calculate annual average line speed at young chicken slaughter establishments from an establishment's annual slaughter volume, hours of operation, and the number of evisceration lines as follows:

- The annual slaughter volume and total annual hours of operation for each shift and weekday of operation are obtained from the electronic Animal Disease Reporting System (eADRS). For each shift and weekday of operation, the total heads slaughtered per minute can be calculated by dividing the annual heads slaughtered by the annual duration of operation in minutes.
- Average heads slaughtered per minute is calculated by averaging the above, usually 10, numbers (5 days and 2 shifts). Saturdays and Sundays are excluded since they generally have smaller volumes.
- An average line speed is computed by dividing the heads slaughtered per minute by the number of lines obtained from the PHIS establishment profile dataset (Dynamac 2010).
- The calculated line speed is compared with lines speeds from the 2011 line speed survey and the PHIS establishment profile to provide a reality check.

The data presented in Table B-1 can be used to illustrate the process (This is data for a single establishment). The table gives the annual heads slaughtered as a function of the day of the week (2= Monday and 7= Saturday) and shift. The table also gives the start and end time of each weekday of operation, from which the duration of slaughter operations can be calculated. In most cases, slaughter establishments work an 8.5 hour shift that includes two 15 minute breaks. Thus, most slaughter establishments actually slaughter 8 hours per shift. The 8 hours of slaughter time is converted to 480 minutes. Sometimes the night shift operates on slightly different hours. The actual hours of operation for each establishment are used in the calculation of slaughter rates for that establishment.

To obtain the slaughter rate for a given shift and day of the week, the annual heads slaughtered for each shift/day of the week combination is divided by the days per year of slaughter operations to yield heads slaughtered per shift per day. This is then divided by the slaughter time in minutes (480 in example Table A-1) for that shift/day of the week to obtain the heads slaughtered per minute for a given shift/day of the week. The slaughter rates on Saturdays are not calculated because of the lack of data on hours of operation and the low slaughter volumes on Saturdays. The 10 slaughter rates for each of the 2 shifts and 5 days of the week are then averaged to obtain an average slaughter rate in heads per minute.

Table B- 1 Example Data Used to Compute Slaughter Rates

shift	Day of week	Start Time of Shift	Stop Time of Shift	Slaughter time in min	Heads Slaughtered	Days per year of Slaughter	Slaughter rate (bpm)
1	2	600	1430	480	7812867	48	319.153
1	3	600	1430	480	8443243	51	324.615
1	4	600	1430	480	8224615	50	322.534
1	5	600	1430	480	8344310	51	320.812
1	6	600	1430	480	8130976	50	318.862
1	7			.	1990439	13	.
2	2	1500	2330	480	7761714	48	317.063
2	3	1500	2330	480	8199549	51	315.246
2	4	1500	2330	480	8097335	50	317.543
2	5	1500	2330	480	8140068	50	319.218
2	6	1500	2330	480	7968529	50	312.491
2	7			.	1398501	10	.

To convert average heads slaughtered per minute into an average line speed it is necessary to know the number of evisceration lines in operation at each establishment. The number of lines is obtained from the establishment profile dataset (Dynamac 2010). The calculated line speeds are then compared with line speeds from the 2011 survey and the establishment profile dataset and an estimate made of the most likely number of lines at each establishment. Based on the most likely number of lines, the most likely line speed is estimated. Table B-2 presents a summary of the line speeds for the HIMP and non-HIMP establishments.

Table B-2 Summary of Line Speeds for HIMP and Non-HIMP Establishments

	Number of Establishments	CY2010 Production Volumes	CY2010 Number of Lines	CY2010 Line Speeds
HIMP	20	38.8 to 115.7 million birds	1 to 5	88 to 180 bpm
Non-HIMP	64	41.2 to 108.4 million birds	2 to 6	81 to 140 bpm

Appendix C- W3NR Non-Compliance Rates

C-1—Procedures 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 C-1 presents a summary of the 11 procedure codes considered in this study along with the associated health-related (W3NR) federal regulation numbers.

Table C- 1 Procedure Code Description

Procedure Code	Description	Associated RegNbrs
01A01	Verify that establishment has met regulations for development or maintenance of sanitation standard operating procedures (SSOP)	416.15(a), 416.15(b)
01B01	Pre-operational review of establishment's SSOP records to verify daily documentation of implementation and monitoring of SSOP procedures and required corrective actions.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3)
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.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 416.4(d), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3)
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.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 416.4(d), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3),
03A01	Determine establishment met regulation requirements for development and implementation of hazard analysis critical	381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1),

	control point (HACCP) Plan(s)	417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a), 417.6
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	301.2(1)_Adulterated, 301.2(1)_E.coli_O157:H7, 301.2(1)_L.monocytogenes, 301.2(1)_Salmonella, 301.2(2)_Adulterated, 301.2(3)_Adulterated, 301.2(4)_Adulterated, 301.2(4)_Foreign_Material, 301.2(6)_Adulterated, 301.2(9)_Adulterated, 309.3, 309.4, 309.9, 310.22(b), 310.22(d)(2), 310.25(a), 310.25(b), 311.16, 311.17, 318.14(a), 381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.144(a), 381.151(a), 381.65(e), 381.83, 381.91(a), 381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1), 417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a), 417.6
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	301.2(1)_Adulterated, 301.2(1)_E.coli_O157:H7, 301.2(1)_L.monocytogenes, 301.2(1)_Salmonella, 301.2(2)_Adulterated, 301.2(3)_Adulterated, 301.2(4)_Adulterated, 301.2(4)_Foreign_Material, 301.2(6)_Adulterated, 301.2(9)_Adulterated, 309.3, 309.4, 309.9, 310.22(b), 310.22(d)(2), 310.25(b),

		311.16, 311.17, 318.14(a), 381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.144(a), 381.151(a), 381.65(e), 381.83, 381.91(a), 381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1), 417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a), 417.6
04C04	Verify that poultry slaughter establishments comply with the relevant regulations for poultry finished product standards and good commercial practices for poultry slaughter	381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.78, 381.91(a)
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.	310.25(a), 310.25(b), 381.91(a)
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.	310.22(b), 310.22(d)(2), 416.1, 416.4(d)

C-2—W3NR Rate Year by Year Analysis

This appendix presents the W3NR rates for eleven (11) procedure codes and the fecal contamination regulation 381.65(e) W3NR rate for young chicken slaughter establishments for each of the years CY2006 to CY2010. There is no statistical difference between HIMP establishments and Non-HIMP establishments for the majority of the process codes. W3NR rates

for HIMP establishments were statistically lower or were not statistically different for 49 entries in Table C-2 and the rates were statistically higher for 6 entries.

Table C- 2 W3NR Rates for Each Procedure Code by Year

	CY2006 HIMP	Non-HIMP Comparison Establishment s	All Non- HIMP Establishment s	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176		
01A01Number W3NRs	-	-	-	No difference	No Difference
01A01Number Procedures	77	263	528		
01A01 W3NR Rate	0.00%	0.00%	0.00%		
01B01Number W3NRs	14	55	97	No difference	No Difference
01B01Number Procedures	2,952	9,577	25,234		
01B01W3NR Rate	0.47%	0.57%	0.38%		
01B02 Number W3NRs	35	149	264	No difference	No difference
01B02 Number Procedures	2,102	7,572	20,365		
01B02 W3NR Rate	1.67%	1.97%	1.30%		
01C01 Number W3NRs	40	73	209	HIMP Greater pvalue=0.0014	HIMP Greater pvalue=0.0374
01C01Number Procedures	5,405	18,309	40,330		
01C01 W3NR Rate	0.74%	0.40%	0.52%		
01C02 Number W3NRs	123	308	513	HIMP greater pvalue=0.0009	HIMP greater pvalue<0.0001
01C02Number Procedures	5,913	21,022	45,076		
01C02 W3NR Rate	2.08%	1.47%	1.14%		
03A01 Number W3NRs	-	1	2	No difference	No difference
03A01Number Procedures	41	58	118		
03A01 W3NR Rate	0.00%	1.72%	0.016949153		
03J01Number W3NRs	2,360	2,257	4,105	HIMP less pvalue<0.0001	HIMP less pvalue<0.0001
03J01Number Procedures	233,595	179,342	333,996		
03J01 W3NR Rate	1.01%	1.26%	1.23%		
03J02 Number W3NRs	60	160	290	No difference	No difference
03J02 Number Procedures	7,544	16,919	34,983		
03J02 W3NR Rate	0.80%	0.95%	0.83%		
05A01Number W3NRs	-	-	-	No difference	No difference
05A01Number Procedures	22	93	238		
05A01 W3NR Rate	0.00%	0.00%	0.00%		
06D01 Number W3NRs	3	15	25	No difference	No difference
06D01Number Procedures	4,441	11,279	25,572		
06D01 W3NR Rate	0.07%	0.13%	0.10%		

	CY2007 HIMP	Non-HIMP Comparison Establishment s	All Non- HIMP Establishment s	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176		
01A01Number W3NRs	-	-	1	No difference	No difference
01A01Number Procedures	63	240	542		
01A01 W3NR Rate	0.00%	0.00%	0.18%		
01B01Number W3NRs	5	22	51	No difference	No difference
01B01Number Procedures	2,866	9,326	24,590		
01B01W3NR Rate	0.17%	0.24%	0.21%		
01B02 Number W3NRs	34	139	209	No difference	HIMP greater pvalue=0.0101
01B02 Number Procedures	2,130	7,625	20,931		
01B02 W3NR Rate	1.60%	1.82%	1.00%		
01C01 Number W3NRs	14	80	183	No difference	No difference
01C01Number Procedures	5,209	18,019	40,265		
01C01 W3NR Rate	0.27%	0.44%	0.45%		
01C02 Number W3NRs	95	330	509	No difference	HIMP greater pvalue=0.0008
01C02Number Procedures	5,790	20,500	45,005		
01C02 W3NR Rate	1.64%	1.61%	1.13%		
03A01 Number W3NRs	-	-	1	No difference	No difference
03A01Number Procedures	62	82	224		
03A01 W3NR Rate	0.00%	0	0.45%		
03J01Number W3NRs	1,764	2,510	4,594	HIMP less pvalue<0.0001	HIMP less pvalue<0.0001
03J01Number Procedures	224,564	185,311	346,569		
03J01 W3NR Rate	0.79%	1.35%	1.33%		
03J02 Number W3NRs	34	103	221	No difference	No difference
03J02 Number Procedures	5,530	16,947	36,055		
03J02 W3NR Rate	0.61%	0.61%	0.61%		
05A01Number W3NRs	-	-	-	No difference	No difference
05A01Number Procedures	1	36	88		
05A01 W3NR Rate	0.00%	0.00%	0.00%		
06D01 Number W3NRs	-	-	-	No difference	No difference
06D01Number Procedures	2,913	11,014	24,864		
06D01 W3NR Rate	0	0.00%	0.00%		

	CY2008 HIMP	Non-HIMP Comparison Establishment s	All Non- HIMP Establishment s	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176		
01A01Number W3NRs	-	-	-	No difference	No difference
01A01Number Procedures	70	228	411		
01A01 W3NR Rate	0.00%	0.00%	0.00%		
01B01Number W3NRs	9	47	58	No difference	No difference
01B01Number Procedures	2,865	8,970	23,637		
01B01W3NR Rate	0.31%	0.52%	0.25%		
01B02 Number W3NRs	55	102	143	HIMP higher pvalue<0.0001	HIMP higher pvalue<0.0001
01B02 Number Procedures	2,029	7,870	20,950		
01B02 W3NR Rate	2.71%	1.30%	0.68%		
01C01 Number W3NRs	21	88	158	No difference	No difference
01C01Number Procedures	5,281	17,442	39,969		
01C01 W3NR Rate	0.40%	0.50%	0.40%		
01C02 Number W3NRs	68	335	467	HIMP less pvalue=0.0126	No difference
01C02Number Procedures	5,432	19,286	43,799		
01C02 W3NR Rate	1.25%	1.74%	1.07%		
03A01 Number W3NRs	-	-	5	No difference	No difference
03A01Number Procedures	74	161	411		
03A01 W3NR Rate	0.00%	0.00%	1.22%		
03J01Number W3NRs	2,087	2,673	4,977	HIMP less pvalue<0.0001	HIMP less pvalue<0.0001
03J01Number Procedures	218,315	186,981	347,703		
03J01 W3NR Rate	0.96%	1.43%	1.43%		
03J02 Number W3NRs	38	140	194	No difference	No difference
03J02 Number Procedures	5,661	16,166	35,352		
03J02 W3NR Rate	0.67%	0.87%	0.55%		
05A01Number W3NRs	-	-	-	No difference	No difference
05A01Number Procedures	4	36	109		
05A01 W3NR Rate	0.00%	0.00%	0.00%		
06D01 Number W3NRs	-	-	-	No difference	No difference
06D01Number Procedures	2,596	10,363	23,482		
06D01 W3NR Rate	0	0.00%	0.00%		

	CY2009 HIMP	Non-HIMP Comparison Establishment s	All Non- HIMP Establishment s	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176		
01A01Number W3NRs	-	-	-	No difference	No difference
01A01Number Procedures	49	203	377		
01A01 W3NR Rate	0.00%	0.00%	0.00%		
01B01Number W3NRs	-	4	10	No difference	No difference
01B01Number Procedures	2,631	9,144	23,831		
01B01W3NR Rate	-	0.04%	0.04%		
01B02 Number W3NRs	10	107	127	HIMP less pvalue=0.0024	No difference
01B02 Number Procedures	1,915	7,853	20,365		
01B02 W3NR Rate	0.52%	1.36%	0.62%		
01C01 Number W3NRs	9	48	87	No difference	No difference
01C01Number Procedures	5,293	17,563	39,643		
01C01 W3NR Rate	0.17%	0.27%	0.22%		
01C02 Number W3NRs	62	211	322	No difference	HIMP greater pvalue=0.0026
01C02Number Procedures	5,522	18,963	43,331		
01C02 W3NR Rate	1.12%	1.11%	0.74%		
03A01 Number W3NRs	-	-	-	No difference	No difference
03A01Number Procedures	63	99	262		
03A01 W3NR Rate	0.00%	0	0		
03J01Number W3NRs	2,050	2,614	4,663	HIMP less pvalue<0.0001	HIMP less pvalue<0.0001
03J01Number Procedures	210,170	186,883	344,353		
03J01 W3NR Rate	0.98%	1.40%	1.35%		
03J02 Number W3NRs	48	125	203	No difference	HIMP greater pvalue=0.0077
03J02 Number Procedures	5,405	16,186	34,901		
03J02 W3NR Rate	0.89%	0.77%	0.58%		
05A01Number W3NRs	-	-	-	No difference	No difference
05A01Number Procedures	6	51	111		
05A01 W3NR Rate	0.00%	0.00%	0.00%		
06D01 Number W3NRs	-	-	-	No difference	No difference
06D01Number Procedures	2,675	10,335	23,316		
06D01 W3NR Rate	0	0.00%	0.00%		

	CY2010 HIMP	Non-HIMP Comparison Establishment s	All Non- HIMP Establishment s	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176		
01A01Number W3NRs	-	1	1	No difference	No difference
01A01Number Procedures	67	237	489		
01A01 W3NR Rate	0.00%	0.42%	0.20%		
01B01Number W3NRs	2	2	6	No difference	No difference
01B01Number Procedures	2,806	9,514	24,511		
01B01W3NR Rate	0.07%	0.02%	0.02%		
01B02 Number W3NRs	1	7	11	No difference	No difference
01B02 Number Procedures	1,960	7,095	19,190		
01B02 W3NR Rate	0.05%	0.10%	0.06%		
01C01 Number W3NRs	15	58	79	No difference	No difference
01C01Number Procedures	5,184	17,440	40,089		
01C01 W3NR Rate	0.29%	0.33%	0.20%		
01C02 Number W3NRs	15	71	104	No difference	No difference
01C02Number Procedures	5,896	19,137	44,300		
01C02 W3NR Rate	0.25%	0.37%	0.23%		
03A01 Number W3NRs	-	1	2	No difference	No difference
03A01Number Procedures	49	119	320		
03A01 W3NR Rate	0.00%	0.01	0.63%		
03J01Number W3NRs	1,613	3,133	5,442	HIMP less pvalue<0.0001	HIMP less pvalue<0.0001
03J01Number Procedures	205,922	193,763	353,900		
03J01 W3NR Rate	0.78%	1.62%	1.54%		
03J02 Number W3NRs	19	92	140	HIMP less pvalue=0.0382	No difference
03J02 Number Procedures	5,740	16,601	35,646		
03J02 W3NR Rate	0.33%	0.55%	0.39%		
05A01Number W3NRs	-	-	-	No difference	No difference
05A01Number Procedures	4	85	146		
05A01 W3NR Rate	0.00%	0.00%	0.00%		
06D01 Number W3NRs	-	-	-	No difference	No difference
06D01Number Procedures	2,844	9,696	22,401		
06D01 W3NR Rate	0	0.00%	0.00%		

**C-3-- W3NR Rates by Procedure Code for the 5 years of combined CY2006 to CY2010
Data**

Table C-3 present the W3NR rate for each procedure code based on 5 years of CY2006 to CY2010 combined data. Thus, the number of W3NRs and inspection procedures for each code represents the total number over 5 years of inspection results.

Table C- 3 W3NR Rates by Procedure Code for the 5 years of Combined CY2006 to CY2010

	Chicken Only HIMP	Non-HIMP Comparison Establishments	All Non-HIMP Establishments	Chi Square p value
Number of Establishments	100	320	880	
01A01Number W3NRs	0	1	2	
01A01Number Procedures	326	1,171	2,347	1.00*
01A01 W3NR Rate	0.00%	0.09%	0.09%	
01B01Number W3NRs	30	130	222	
01B01Number Procedures	14,120	46,531	121,803	0.17
01B01W3NR Rate	0.21%	0.28%	0.18%	
01B02 Number W3NRs	135	504	754	
01B02 Number Procedures	10,136	38,015	101,801	0.96
01B02 W3NR Rate	1.33%	1.33%	0.74%	
01C01 Number W3NRs	99	347	716	
01C01Number Procedures	26,372	88,773	200,296	0.72
01C01 W3NR Rate	0.38%	0.39%	0.36%	
01C02 Number W3NRs	363	1,255	1,915	
01C02Number Procedures	28,553	98,908	221,511	0.97
01C02 W3NR Rate	1.27%	1.27%	0.86%	
03A01 Number W3NRs	0	2	10	
03A01Number Procedures	289	519	1,335	0.54*
03A01 W3NR Rate	0.00%	0.39%	0.75%	
03J01Number W3NRs	9,874	13,187	23,781	
03J01Number Procedures	1,092,566	932,280	1,726,521	<0.0001
03J01 W3NR Rate	0.90%	1.41%	1.38%	
03J02 Number W3NRs	199	620	1,048	
03J02 Number Procedures	29,880	82,819	176,937	0.15
03J02 W3NR Rate	0.67%	0.75%	0.59%	
05A01Number W3NRs	0	0	0	
05A01Number Procedures	37	301	692	
05A01 W3NR Rate	0.00%	0.00%	0.00%	
06D01 Number W3NRs	3	15	25	

06D01Number Procedures	15,469	52,687	119,635	0.78*
06D01 W3NR Rate	0.02%	0.03%	0.02%	

* indicates p value is computed using Fisher Exact test

C-4—Negative Binomial Regression Statistics for W3NRs Rates by Procedure Code for 5 Years of Combined Data

To normalize for the slaughter volumes and the number of process code procedures, a negative binomial regression analysis was performed for each procedure code using 5 years of data. The number of W3NRs was regressed against a dummy variable denoting whether a establishment was HIMP or control non-HIMP and the production volume for the 5 years of combined data for CY2006 to CY2010. The number of 03J inspections was used as an offset variable.

The results are shown in Table C-4. W3NR rates at HIMP establishments are not statistically different or are statistically lower for all procedure codes except 04C04. The procedure code 04C04 verifies non-food safety consumer protection regulatory requirements and is performed at different rates in HIMP and non-HIMP establishments.

Table C- 4 Regression Statistics for Number of W3NRs by Process Code for 5 Years of Combined Data

Process Code	Variable	Estimate	Standard Error	Chi Square	P value
01A01	Intercept	1.5677	12.9933	0.01	0.9040
	HIMPDummy	-27.6234	15869.30	0.00	0.9986
	Production Volume	-0.0333	0.2054	0.03	0.8713
	Dispersion	804.0334	925.8368		
01B01	Intercept	-0.1591	0.7794	0.04	0.8382
	HIMPDummy	-0.6642	0.4645	2.04	0.1527
	Production Volume	0.0193	0.0120	2.59	0.1075
	Dispersion	9.2756	1.7328		
01B02	Intercept	3.1925	0.6741	22.43	<.0001
	HIMPDummy	-0.0120	0.3747	0.00	0.9744
	Production Volume	-0.0070	0.0101	0.48	0.4886
	Dispersion	9.2316	1.1098		
01C01	Intercept	0.4194	0.3470	1.46	0.2269
	HIMPDummy	-0.3401	0.2539	1.79	0.1805
	Production Volume	0.0145	0.0052	7.93	0.0049
	Dispersion	3.1293	0.3983		
01C02	Intercept	2.3099	0.3607	41.01	<.0001
	HIMPDummy	-0.1834	0.2585	0.50	0.4779
	Production Volume	0.0047	0.0056	0.71	0.4010
	Dispersion	3.4362	0.2976		
03A01	Intercept	4.1981	10.3933	0.16	0.6863
	HIMPDummy	-27.2746	9131.202	0.00	0.9976

	Production Volume	-0.0543	0.1643	0.11	0.7408
	Dispersion	816.8107	634.6140		
03J01	Intercept	2.7731	0.1369	410.60	<.0001
	HIMPDummy	-0.3793	0.0913	17.28	<.0001
	Production Volume	-0.0012	0.0020	0.33	0.5657
	Dispersion	0.5750	0.0388		
03J02	Intercept	2.6808	0.3613	55.06	<.0001
	HIMPDummy	0.1647	0.2350	0.49	0.4833
	Production Volume	-0.0106	0.0053	4.00	0.0456
	Dispersion	3.5151	0.3672		
05A01	Intercept	19.7704	0.0000		
	Intercept	-12.2725	0.0000		
	HIMPDummy	-0.0499	0.0000		
	Production Volume	1.144E12	0.0000		
06D01	Intercept	-1.7397	1.0185	2.92	0.0876
	HIMPDummy	-0.4317	0.7379	0.34	0.5585
	Production Volume	0.0079	0.0145	0.30	0.5868
	Dispersion	5.3516	4.4165		

Appendix D - Fecal NR Rate Regression

A Negative Binomial regression on the fecal counts using the GENMOD Procedure was performed. The model specification information is as follows:

Distribution	Negative Binomial
Link Function	Log
Dependent Variable	Number of Fecal NRs

A clustered analysis was performed on 420 data points from CY2006 to CY2010 (20 HIMP and 64 non-HIMP establishments for 5 years each). Production volumes were divided by 1 million and 03J counts were divided by 1,000.

D-1 Negative Binomial Three Parameter Model for Fecal Counts

The first model developed was a negative binomial regression with three input variables (HIMP, Production Volume, and Total 03J01/02 Procedures) and a response variable of fecal counts. The model is regressed on 420 data points (100 HIMP data points and 320 non-HIMP data points).

The results are

Empirical Standard Error Estimates

Parameter	Estimate	Standard Error	95% Confidence Limits		Z	Pr > Z
Intercept	3.0348	0.2490	2.5467	3.5229	12.19	<.0001
HIMPDummy	-0.1800	0.2339	-0.6385	0.2785	-0.77	0.4415
ProductionVolume	0.0049	0.0041	-0.0031	0.0129	1.20	0.2287
_03J01J02	0.0970	0.0269	0.0443	0.1496	3.61	0.0003

Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	416	457.1109	1.0988
Scaled Deviance	416	457.1109	1.0988
Pearson Chi-Square	416	431.6861	1.0377
Scaled Pearson X2	416	431.6861	1.0377
Log Likelihood		63773.9134	
Full Log Likelihood		-1972.7961	
AIC (smaller is better)		3955.5923	
AICC (smaller is better)		3955.7372	
BIC (smaller is better)		3975.7936	

After adjusting for production volume and 03J procedures, there is no statistical difference between HIMP and non-HIMP in the number of fecal NRs.

D-2 Negative Binomial Two Parameter Model for Fecal Counts

A negative binomial regression was performed with two input variables (HIMP and Production Volume).

The results are

Empirical Standard Error Estimates

Parameter	Estimate	Standard Error	95% Confidence Limits		Z	Pr > Z
Intercept	2.9302	0.2463	2.4475	3.4130	11.90	<.0001
HIMPDummy	0.4801	0.1295	0.2263	0.7338	3.71	0.0002
ProductionVolume	0.0114	0.0035	0.0046	0.0182	3.28	0.0010

Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	417	457.2437	1.0965
Scaled Deviance	417	457.2437	1.0965
Pearson Chi-Square	417	437.4870	1.0491
Scaled Pearson X2	417	437.4870	1.0491
Log Likelihood		63772.8977	
Full Log Likelihood		-1973.8118	
AIC (smaller is better)		3955.6236	
AICC (smaller is better)		3955.7200	
BIC (smaller is better)		3971.7846	

The two parameter model does not fit the data significantly better than the three parameter model (since the log likelihoods are nearly identical resulting in a p value of 0.15)

A negative binomial regression was performed with two input variables (HIMP and Total 03J Inspections).

The results are

Empirical Standard Error Estimates

Parameter	Estimate	Standard Error	95% Confidence Limits		Z	Pr > Z
Intercept	3.2810	0.0998	3.0855	3.4766	32.88	<.0001
HIMPDummy	-0.3026	0.2316	-0.7565	0.1512	-1.31	0.1912
_03J01J02	0.1203	0.0242	0.0729	0.1678	4.97	<.0001

Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	417	457.6650	1.0975
Scaled Deviance	417	457.6650	1.0975
Pearson Chi-Square	417	407.9347	0.9783
Scaled Pearson X2	417	407.9347	0.9783
Log Likelihood		63760.4740	
Full Log Likelihood		-1986.2356	
AIC (smaller is better)		3980.4711	
AICC (smaller is better)		3980.5675	
BIC (smaller is better)		3996.6321	

This two parameter model fits the data significantly better than the three parameter model (p value <0.0001). It does not show a statistically significant difference between HIMP and non-

HIMP with respect to the number of fecal NRs after adjusting for number of 03J inspections.

D-3 Negative Binomial Two Parameter Model for Fecal Counts with Offset for Number of 03J Procedures

To determine the impact of production volume on the fecal NR rate, a negative binomial regression on fecal counts using the GENMOD Procedure with an offset for the number of 03J procedures was performed. The use of the offset for the number of 03J01 procedures is equivalent to regressing fecal NR rate on production volume. The model specification information is as follows:

Distribution	Negative Binomial
Link Function	Log
Dependent Variable	Number of Fecal NRs
Offset Variable	Log_03J01J02

Empirical Standard Error Estimates

Parameter	Estimate	Standard Error	95% Confidence Limits		Z	Pr > Z
Intercept	2.6390	0.2714	2.1071	3.1709	9.72	<.0001
HIMPDummy	-0.5989	0.1341	-0.8617	-0.3360	-4.47	<.0001
ProductionVolume	-0.0011	0.0038	-0.0086	0.0063	-0.30	0.7620

Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	417	456.6893	1.0952
Scaled Deviance	417	456.6893	1.0952
Pearson Chi-Square	417	417.5443	1.0013
Scaled Pearson X2	417	417.5443	1.0013
Log Likelihood		63770.2476	
Full Log Likelihood		-1976.4619	
AIC (smaller is better)		3960.9239	
AICC (smaller is better)		3961.0203	
BIC (smaller is better)		3977.0849	

Production volume is not a statistically significant predictor of fecal NR rates. After adjusting for production volume, the rate of fecal NRs in HIMP establishments is statistically less than in non-HIMP establishments.

Appendix E - Line Speed Analysis

Two different negative binomial regression analyses are presented in this Appendix: the first for fecal NRs and the second for *Salmonella* positives.

E-1 Fecal NR Analysis

A negative binomial regression on the fecal NR counts and line speeds using the GENMOD Procedure was performed. The model specification is as follows:

Distribution	Negative Binomial
Link Function	Log
Dependent Variable	Fecal NRs
Offset Variable	log Total 03J01J02 Procedures

The analysis is restricted to CY2010 since that is the only year for which line speeds are available.

E-1.1 Negative Binomial Three Parameter Fecal Model with Offset for Log Number of 03J Procedures Performed

A negative binomial regression with three input variables (HIMP, production volume, and line speed) and a response variable of fecal NRs was performed with an offset for Log number of 03Jprocedures performed.

Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq
Intercept	1	2.2992	0.4290	1.4585	3.1400	28.73	<.0001
HIMPdummy	1	-0.7688	0.1878	-1.1369	-0.4007	16.76	<.0001
ProductionVolume	1	-0.0020	0.0041	-0.0100	0.0060	0.24	0.6235
LineSpeed	1	0.0048	0.0038	-0.0027	0.0123	1.58	0.2089
Dispersion	1	0.4372	0.0669	0.3239	0.5900		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	80	89.4566	1.1182
Scaled Deviance	80	89.4566	1.1182
Pearson Chi-Square	80	82.6261	1.0328
Scaled Pearson X2	80	82.6261	1.0328
Log Likelihood		15346.6840	
Full Log Likelihood		-405.1567	
AIC (smaller is better)		820.3133	
AICC (smaller is better)		821.0825	
BIC (smaller is better)		832.4674	

After adjusting for HIMP status and production volume there is no statistical difference in the fecal NR rates between establishments with different line speeds.

E-1.2 Negative Binomial Two Parameter Fecal Model with Offset for Log Number of 03J Procedures Performed

A negative binomial regression with two input variables (HIMP and line speed) and a response variable of fecal NRs was performed with an offset for Log number of 03J procedures performed.

Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq
Intercept	1	2.2473	0.4151	1.4337	3.0608	29.31	<.0001
HIMPDummy	1	-0.7820	0.1865	-1.1475	-0.4165	17.59	<.0001
LineSpeed	1	0.0041	0.0036	-0.0029	0.0111	1.34	0.2478
Dispersion	1	0.4382	0.0670	0.3247	0.5914		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	81	89.4935	1.1049
Scaled Deviance	81	89.4935	1.1049
Pearson Chi-Square	81	83.7916	1.0345
Scaled Pearson X2	81	83.7916	1.0345
Log Likelihood		15346.5648	
Full Log Likelihood		-405.2758	
AIC (smaller is better)		818.5515	
AICC (smaller is better)		819.0579	
BIC (smaller is better)		828.2748	

Line speed is not a statistically significant predictor of fecal NR rates.

E-2.0 *Salmonella* Positives Analysis

A negative binomial regression on the *Salmonella* positives and line speeds using the GENMOD Procedure was performed. The model specification is as follows:

Distribution	Negative Binomial
Link Function	Log
Dependent Variable	<i>Salmonella</i> positives
Offset Variable	log Total 03J01J02 Procedures

The analysis is restricted to CY2010 since that is the only year for which lines speeds are available.

E-2.1 Negative Binomial Three Parameter *Salmonella* Model with Offset for Log Number of *Salmonella* Tests Performed

A negative binomial regression with three input variables (HIMP, production volume, and line speed) and a response variable of *Salmonella* positives was performed with an offset for Log number of *Salmonella* verification tests performed.

Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.9002	1.1402	-5.1349	-0.6655	6.47	0.0110
HIMPDummy	1	0.1677	0.4726	-0.7586	1.0941	0.13	0.7226
ProductionVolume	1	-0.0000	0.0000	-0.0000	0.0000	1.65	0.1990
LineSpeed	1	0.0050	0.0095	-0.0136	0.0235	0.27	0.6008
Dispersion	1	0.8292	0.4082	0.3160	2.1762		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	39	45.4653	1.1658
Scaled Deviance	39	45.4653	1.1658
Pearson Chi-Square	39	34.6058	0.8873
Scaled Pearson X2	39	34.6058	0.8873
Log Likelihood		-5.7467	
Full Log Likelihood		-70.8680	
AIC (smaller is better)		151.7359	
AICC (smaller is better)		153.3575	
BIC (smaller is better)		160.5419	

Line speed is not a statistically significant predictor of *Salmonella* positive rates between establishments.

E-2.2 Negative Binomial Two Parameter *Salmonella* Model with Offset for Log Number of *Salmonella* Tests Performed

A negative binomial regression with two input variables (HIMP and line speed) and a response variable of *Salmonella* positives was performed with an offset for Log number of *Salmonella* verification tests performed.

Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq
Intercept	1	-3.4638	1.0921	-5.6044	-1.3233	10.06	0.0015
HIMPDummy	1	0.0379	0.4723	-0.8878	0.9637	0.01	0.9360
LineSpeed	1	0.0017	0.0094	-0.0167	0.0201	0.03	0.8573
Dispersion	1	0.9584	0.4345	0.3941	2.3306		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	40	44.3942	1.1099
Scaled Deviance	40	44.3942	1.1099
Pearson Chi-Square	40	33.4443	0.8361
Scaled Pearson X2	40	33.4443	0.8361
Log Likelihood		-6.5582	
Full Log Likelihood		-71.6794	
AIC (smaller is better)		151.3588	
AICC (smaller is better)		152.4114	
BIC (smaller is better)		158.4036	

Line speed is not a statistically significant predictor of *Salmonella* positive rates between establishments.

Appendix F - Salmonella Positive Rates

This Appendix presents *Salmonella* verification testing results for young chicken slaughter establishments for the years CY2006 to CY2010. The *Salmonella* positive rates in HIMP establishments were statistically significantly less than in the comparison non-HIMP establishments for the 3 years CY2006 through CY2008. There is no statistical difference between the *Salmonella* positive rates in HIMP and the Non-HIMP comparison establishments for the years CY2009 and CY2010.

CY2006	HIMP Salmonella	Non-HIMP Comparison Salmonella	All Non-HIMP Broiler Salmonella	HIMP/ Non-HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176	HIMP less pvalue=0.0496	HIMP less pvalue=0.0189
Positives	92	424	989		
Total Tests	1,026	3,935	8,898		
Salmonella Rate	8.97%	10.78%	11.11%		

CY2007	HIMP Salmonella	Non-HIMP Comparison Salmonella	All Non-HIMP Broiler Salmonella	HIMP/ Non-HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176	HIMP less pvalue=0.0028	HIMP less pvalue=0.0067
Positives	56	297	650		
Total Tests	963	3,479	8,056		
Salmonella Rate	5.82%	8.54%	8.07%		

CY2008	HIMP Salmonella	Non-HIMP Comparison Salmonella	All Non-HIMP Broiler Salmonella	HIMP/ Non-HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176	HIMP less pvalue=0.0008	HIMP less pvalue=0.0002
Positives	33	203	434		
Total Tests	787	2,780	5,712		
Salmonella Rate	4.19%	7.30%	7.60%		

CY2009	HIMP Salmonella	Non-HIMP Comparison Salmonella	All Non-HIMP Broiler Salmonella	HIMP/ Non-HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176	No difference	HIMP less pvalue=0.0195

Positives	38	104	387		
Total Tests	780	2,401	5,651		
Salmonella Rate	4.87%	4.33%	6.85%		

CY2010	HIMP Salmonella	Non-HIMP Comparison Salmonella	All Non- HIMP Broiler Salmonella	HIMP/ Non- HIMP Comparison	HIMP/ All Non-HIMP
Number of Establishments	20	64	176	No difference	No difference
Positives	20	56	146		
Total Tests	427	1,390	3,115		
Salmonella Rate	4.68%	4.03%	4.69%		

Appendix G – Sorting and Condemnation Rates For HIMP and Non-HIMP

Table G- 1 Sorting and Condemnation Rates for HIMP and All Non-HIMP Establishments in CY2010

	Production Volume (Heads)	Sorted or Condemned (Heads)	% Sorted or Condemned
20 Young chicken HIMP Establishments	1,486,323,399	3,369,458	0.23
64 Young chicken NonHIMP Comparison Establishments	4,229,139,755	12,831,408	0.30
176 Traditional Young Chicken Establishments	7,067,147,697	21,507,692	0.30

Table G- 2 Sorting and Condemnation Rates for HIMP and All Non-HIMP Establishments in CY2009

	Production Volume (Heads)	Sorted or Condemned (Heads)	% Sorted or Condemned
20 Young chicken HIMP Establishments	1,446,334,828	3,968,132	0.27
64 Young chicken NonHIMP Comparison Establishments	4,094,877,048	13,734,416	0.34
176 Traditional Young Chicken Establishments	6,877,930,806	23,466,502	0.34

Table G- 3 Sorting and Condemnation Rates for HIMP and All Non-HIMP Establishments in CY2008

	Production Volume (Heads)	Sorted or Condemned (Heads)	% Sorted or Condemned
20 Young chicken HIMP Establishments	1,465,425,094	6,565,999	0.45
64 Young chicken NonHIMP Comparison Establishments	4,128,546,087	16,054,300	0.39
176 Traditional Young Chicken Establishments	7,067,955,141	28,511,869	0.40

Table G- 4 Sorting and Condemnation Rates for HIMP and All Non-HIMP Establishments in CY2007

	Production Volume (Heads)	Sorted or Condemned (Heads)	% Sorted or Condemned
20 Young chicken HIMP Establishments	1,450,583,852	3,850,234	0.27
64 Young chicken NonHIMP Comparison Establishments	4,123,286,110	16,053,200	0.39
176 Traditional Young Chicken Establishments	7,047,631,288	29,522,408	0.42

Table G- 5 Sorting and Condemnation Rates for HIMP and All Non-HIMP Establishments in CY2006

	Production Volume (Heads)	Sorted or Condemned (Heads)	% Sorted or Condemned
20 Young chicken HIMP Establishments	1,467,047,880	3,978,092	0.27
64 Young chicken NonHIMP Comparison Establishments	4,075,325,331	16,958,281	0.42
176 Traditional Young Chicken Establishments	6,919,393,008	30,783,786	0.45

LIST OF ACRONYMS

BPM – Birds per minute
CCP – Critical Control Points
CI – Carcass Inspector
FS-1 – Food Safety 1 Infectious Conditions
FS-2 – Food Safety 2 Fecal Material Contamination
FSIS – Food Safety and Inspection Service
GAO – Government Accountability Office
HACCP – Hazard Analysis Critical Control Point
HIMP – HACCP Inspection Models Project
NR – Non-compliance Record
OCP – Other Consumer Protections
PHIS – Public Health Information System
RTI – Research Triangle Institute
SSOP – Sanitation Standard Operation Procedures
USDA – United States Department of Agriculture
VI – Verification Inspector
W3NR- W3 Non-compliance Record