Assessment of the Potential Change in Human Risk of *Salmonella* Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments

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List of Acronyms

ADP – Average Daily Production Volume
AER – Absolute Error Rate
AIC – Akaike Information Criterion
ANOVA – Analysis of Variance
AUC – Area Under Curve
CDC – U.S. Centers for Disease Control and Prevention
CI – Confidence Interval
FN – False Negative
FP – False Positive
FR – Federal Register
FSIS – Food Safety and Inspection Service
HACCP – Hazard Analysis and Critical Control Point
HIMP – HACCP-based Inspection Models Project
IPP – Inspection Program Personnel
ISP – Inspection System Procedure
MPN – Most Probable Number
NR – Noncompliance Record Inspection Procedure Variable
NPIS – New Poultry Inspection System
NSIS – New Swine Inspection System
P – Post-Simulation Prevalence
P_0 – Baseline or Initial Prevalence
PBIS – Performance-Based Inspection System
PHIS – Public Health Information System
PR HACCP – Pathogen Reduction Hazard Analysis and Critical Control Point
ROC – Receiver Operating Curve
SNP – Scheduled but Not Performed Inspection Procedure Decision Variable
SP – Scheduled and Performed Inspection Procedure Decision Variable
TC – Total Correct
U – Scheduled Inspection Procedure Decision Variable
USDA – United States Department of Agriculture
VIF – Variance Inflation Factor
W3NR – Health Related Noncompliance Record

SUMMARY

Background

FSIS is the food safety agency of the United States Department of Agriculture (USDA). With its mission of promoting public health, FSIS has legal authority to regulate the slaughter and production processes of meat and related industries. FSIS is currently considering proposals to improve public health through the design of a modernized approach to swine inspection known as the New Swine Inspection System (NSIS). FSIS conducted this public health risk assessment to inform proposals for altering market hog slaughter establishment inspection under a NSIS.

Currently, FSIS Inspection Program Personnel (IPP, "inspectors") in market hog establishments perform a variety of online and offline duties. Online duties include examining carcasses and parts for food safety and non-food safety defects, while offline duties include verifying compliance with sanitation, Hazard Analysis and Critical Control Point (HACCP), and humane handling requirements. Many of the online inspection tasks currently carried out by FSIS inspectors are related to food quality and do not align with the FSIS mission of food safety. This risk assessment aims to estimate any potential change in illness or risks, measured as change in *Salmonella* prevalence, from modifying the allocation of FSIS inspectors in market hog slaughter establishments. To do so, this report considers multiple alternative scenarios that provide FSIS inspectors more time and flexibility to perform offline inspection tasks.

This report, which has undergone a formal peer review, is consistent with FSIS' focus on *Salmonella* outlined in the Agency's 1996 implementation of the HACCP inspection system. That focus was due to the following key characteristics of *Salmonella*: "…(1) it is the most common bacterial cause of foodborne illness; (2) FSIS baseline data show that *Salmonella* colonizes a variety of mammals and birds, and occurs at frequencies which permit changes to be detected and monitored; (3) current methodologies can recover *Salmonella* from a variety of meat and poultry products; and (4) intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should be effective against other pathogens" (FSIS, 1996). In addition, FSIS' exploratory sample recently confirmed that *Salmonella* is much more frequently detected in pork products (16.7%) than methicillin-resistant *Staphylococcus aureus* (4.5%)[1].

[1] Results of Phase I of FSIS' pork exploratory study can be found at: https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/special-sampling-projects/raw-pork-sampling.

In October 1997, FSIS initiated the voluntary HACCP-based Inspection Models Project (HIMP) in five market hog slaughter establishments that volunteered to participate in the project. With HIMP implementation, participating establishments streamlined their slaughter process so that their personnel are responsible for online examining and sorting, decreasing the number of FSIS inspectors needed to conduct many of those activities (FSIS, 2011a). This allowed for FSIS inspector reassignment to offline duties including humane handling verification and HACCP and sanitation inspection procedures and food safety-related tasks.

HIMP establishments have demonstrated the capacity for FSIS inspectors to conduct up to 50% more offline procedures than in non-HIMP establishments. One policy option FSIS is considering is to implement a voluntary inspection system, similar to HIMP, for market hog establishments under the NSIS. This change would relocate some FSIS inspectors from online to offline duties, performing public health-related and other assignments while still verifying that establishments consistently maintain sanitary operations.

Structure and Scope

The quantitative probabilistic food safety risk assessment detailed in this report aims to estimate potential changes in illness or risks from modifying the allocation of FSIS inspectors in market hog slaughter establishments. This assessment uses the historical relationship between variations in the numbers and completion status of *scheduled and unscheduled off line*[1] inspection activities recorded in FSIS-regulated market hog slaughter establishments and the prevalence of *Salmonella* on carcasses in these establishments. This relationship is then used to estimate changes in the number of domestic market hog-attributable human salmonellosis cases that would be expected to result from implementation of a HIMP-like inspection system in more establishments, according to the prevalence-based risk model.

The prevalence-based approach employed in this risk assessment—and applied to prevalence and inspection records from hog slaughter facilities—is the same approach used in the peer reviewed risk model used for the 2014 risk assessment supporting Modernization of Poultry Slaughter Inspection (79 FR 49565), namely a production-

[1] Performed procedures are recorded by FSIS inspectors at each establishment to determine noncompliance with USDA food safety regulations. For this assessment activities are categorized as ***scheduled and performed (SP)***; ***scheduled but not performed (SNP)***; ***unscheduled (U)***; or a ***noncompliance record (NR).*** These categories of procedure types and characteristics will be termed "inspection activities" throughout the remainder of the Executive Summary and in the body of the report.

weighted logistic regression of positive and negative *Salmonella* test results on illness risk variables including plant descriptors and FSIS inspection procedures using maximum likelihood estimates (MLE) for parameters with a multivariate normal (MVN) distribution employing Monte Carlo simulated errors that result in the uncertainty estimate for illnesses avoided.

This model uses the correlation between FSIS sampling prevalence data and foodborne illnesses, with attribution estimates published by the U.S. Centers for Disease Control and Prevention (CDC). By applying this linear relationship to the variety of novel inspection program scenarios, this risk assessment estimates the changes in annual human illnesses that could result depending on how FSIS modernizes its swine inspection system.

As with any formal risk assessment, data limitations mean that this assessment relies on assumptions. The model and analyses presented examine available data to describe the quantitative relationship between observed *Salmonella*-positive hog carcass samples and inspection activities taking place in market hog slaughter establishments. The relationship is modeled using a number of potential decision variables in individual- and combined-adjustment scenarios. It is assumed that the observed association of decision variable rates and percentage *Salmonella* positive samples, from 2010 to 2011 with 7,471 samples from 164 market hog establishments, is predictive of the underlying relationship in all plants that may adopt the new protocol. However, we could not fully quantify the uncertainty in this relationship due to the low prevalence of *Salmonella* positive samples on hogs[2].

It is further assumed that there is a proportional relationship between observed *Salmonella* positive samples in market hog slaughter establishments and market hog-attributable human salmonellosis. A great deal of the quantitative portion of this risk assessment focuses on these two relationships. The methods used here have been applied extensively in other peer reviewed published risk assessments (Bartholomew *et al*., 2005; Williams and Ebel 2012; Ebel *et al*., 2012; Withee *et al*., 2009).

An additional assumption includes that there is a relationship, similar to the relationship observed in poultry products, between market hog carcass contamination rates and

[2] As FSIS explained in the proposed rule (83 FR 4780, 4786), the Agency discontinued its *Salmonella* verification sampling program for market hogs in 2011 because the estimated prevalence of *Salmonella* on hog carcasses was low, and FSIS did not find enough pathogen positives to justify the resources needed (e.g., time and supplies) to conduct carcass swabbing.

contamination of downstream pork products (parts, ground pork) that are consumed. These assumptions are discussed in depth in the report. Further, although this risk assessment does not compare the 5 HIMP to the 35 non-HIMP establishments that FSIS anticipates would adopt a new inspection system, it does assume that the non-HIMP establishments would experience similar changes in the divisions of scheduled versus unscheduled, and performed versus unperformed inspection activities to that which was observed for the 5 HIMP establishments. It also assumes that other characteristics are similar between the two. Where data were available, this analysis controlled for these differences (see Appendix C).

Because the relationship between contamination prevalence and illnesses applied in this risk assessment is based on observed relationships, and because there is no evidence or reason to believe that modernizing FSIS' swine inspection system would systematically change consumer behavior, storage and transport characteristics, or the sources or likelihood of cross-contamination at retail, this model does not explicitly include those sources of uncertainty. The predictive value of contamination prevalence as opposed to contamination load in estimating human illnesses was also validated internally in the risk assessment, with an analysis of variance (ANOVA) test indicating that carcasses slaughtered in establishments with relatively low prevalence of *Salmonella* did not show significantly different contamination load (measured by enumeration of *Salmonella* colony-forming units per gram) when compared to establishments with relatively high prevalence of *Salmonella*. In other words, if the proportion of carcasses with no detectable *Salmonella* contamination increases with implementation of a NSIS, illnesses caused by consumers' exposure to these carcasses are expected to decrease proportionally.

The model is designed to account for multiple sources of uncertainty, thus producing illness reduction estimates as statistical expected values (averages) within robust uncertainty bounds. This is achieved by understanding the three multiplicative multicomponent sources of uncertainty that contribute to estimates of overall uncertainty. These sources are (1) U.S. annual non-typhoidal domestic market hog foodborne salmonellosis cases, (2) market hog pork product contamination characterized as prevalence, and (3) scenario uncertainty arising from model parameters and data variability.

The largest contributor to overall uncertainty in this risk assessment model is the estimate of human illnesses. To address the fact that no surveillance system can perfectly capture all foodborne illnesses and the items consumed to cause them, CDC analysts modeled average values for domestic foodborne *Salmonella* illnesses attributed to pork. They calculated Bayesian credibility intervals around these averages, constructed from a complex multiplicative model consisting of 15 uncertainty distributions. The underlying dataset is made up of laboratory confirmed human salmonellosis cases. This number is then sequentially multiplied by distributions that take into account illness severity, test sensitivity, under-diagnosis, underreporting, population density adjusted to 2006 U.S. census estimates, and the potential for *Salmonella* illnesses to have arisen from various sources other than domestically produced food (Scallan, 2011). Within this risk assessment of market hog slaughter inspection systems, illness estimates attributable to total pork consumption were adjusted by production volume to identify the fraction and number of illnesses attributable to market hog products.

Lesser but still significant contributors to the uncertainty around this risk assessment's final estimates of illnesses avoided include (1) model parameters accorded multivariate normal variability with Monte Carlo uncertainty, and (2) multiplicative scenario parameter and individual *Pert* distribution uncertainty which, when combined multiplicatively and propagated through all stages of the model, provide robust mean illness reduction estimates, as well as robust uncertainty bounds.

Within FSIS information systems, inspection activities are identified by inspection system procedure codes that differentiate groups of activities such as sanitation, HACCP, and sampling. Each code is further delineated into more precise procedures which are noted in the system as one of the following potential decision variables: activities ***scheduled and performed (SP)***; ***scheduled but not performed (SNP)***; ***unscheduled (U)***; or a ***noncompliance record (NR)*** for performed procedures recorded as an establishment's noncompliance with USDA food safety regulations. Noncompliance records were included in this assessment for theoretical evaluation only as a possible decision variable because they had been used in the New Poultry Slaughter Inspection (NPIS) risk assessment which used a similar overall approach. For this market hog slaughter risk assessment, the variables associated with these activities represent the sum of each type of category across the various inspection procedure codes in an establishment on each day that a *Salmonella* sample was collected. Unlike SP, SNP, and U, NR depends on noncompliance by establishments and is not used as an FSIS decision variable. Historic occurrences of establishment noncompliance may help explain variability in pathogen performance that already has been observed. However, because future NR rates mostly depend on the behavior of establishments, it is not feasible to assume that they can be varied (like SP, SNP, and U) solely by reallocating agency inspection resources. Therefore, implementation scenarios that simulate future changes in the NR variable are considered infeasible, but their theoretical examination potentially offers risk management insights.

There are two analytical stages in this risk assessment model. The model is divided into four submodels: samples taken at HIMP (five establishments) and non-HIMP (159 establishments) both at pre-evisceration and post-chill, focusing on the one submodel for non-HIMP establishments at post-chill. In Stage 1, the regression model uses historical data to characterize the relationship between the numbers of offline procedures in each potential decision variable category (SP, SNP, U, and NR) and the percentage of market hog carcass samples that are positive for *Salmonella.* The selection of decision variables was informed by previous experience with the Poultry Slaughter Risk Assessment model (FSIS, 2014). The relationships calculated in Stage 1 are used as input for Stage 2. Stage 2 uses these relationships to estimate how applying inspection procedure rates for decision variables from HIMP establishments to more non-HIMP establishments would impact the annual number of human salmonellosis cases by using the results only from the post-chill submodel for non-HIMP establishments.

For Stage 2, different scenarios that reflect expected changes in decision variable rate(s) when non-HIMP establishments are theoretically converted to a HIMP-like program are constructed and compared. The predicted changes in percentage of *Salmonella* positive samples that would result from these scenarios are used to calculate proportional changes in the number of market hog-attributable annual human salmonellosis cases. There are two implementation scenario types considered for adoption, indiscriminate (multiple decision variable dependent) and discriminate (single decision variable dependent). Under the indiscriminate scenarios, modifications in the rates of up to four decision variables (SP, SNP, U, and NR) are modeled in combination. Under the discriminate scenarios, each decision variable rate is modeled one at a time to increase or decrease independent of any other decision variable.

Of the various scenarios considered for adoption, only the indiscriminate scenario involving only the SP, SNP, and U decision variables was used for the final analysis. The risk model was built from the sampling data from 159 market hog slaughter establishments over the 2010-2011 time periods. A subsample of 35 establishments most probable to adopt the new inspection system was used to estimate the probable public health effect using the predictive model obtained from the full sample of establishments. Because the uncertainty from the subsample of 35 establishments was large due to the small sample size, additional inspection data from these establishments during the 2010-2011 time periods was used to assess uncertainty in public health effect. The uncertainty predictions assumed no change in the *Salmonella* prevalence and inspection rates which were held to the 2010-2011 time period level. All model predictions are related to the 2010 through 2011 time period, even though *Salmonella* sampling stopped for all pork establishments by 2012, and review of FSIS data through 2016 showed a production volume increase of nearly 10% and unchanged inspection rates in these establishments.

Risk Management Questions

This risk assessment addresses the following risk management questions to help inform FSIS on its decisions related to modernizing market hog slaughter inspection:

- *What predicted effects will various models for increasing the number of offline inspection tasks in non-HIMP establishments have on human salmonellosis rates?*

- *Where within a hog slaughter establishment can relocated inspectors have the most impact toward reducing Salmonella prevalence and corresponding human illness?*

- *What is the magnitude of uncertainty about the predicted prevalence and illness effects?*

Findings

What predicted effects will various models for increasing the number of offline inspection tasks in non-HIMP establishments have on human salmonellosis rates?

The expected number of salmonellosis cases attributed to market hog products annually (annual salmonellosis rate) is estimated to be 69,857 (calculations and references detailed in the Methods section of this report, Table 6). Overall results indicate that modifying non-HIMP establishments' inspection procedure rates in any of the model scenarios presented is most likely to decrease salmonellosis illnesses. The indiscriminate scenario model relies on changes in the rates-- treating up to four variables as potential decision variables and modifying them in combination. This type of scenario is most like HIMP establishments as it was designed to represent generalized HIMP-like procedure rates adjusted for plant characteristics.

Certain scenarios containing the NR decision variable were found to be infeasible. For example, NR procedure occurrence is positively correlated with prevalence, which is problematic in the long run when models rely on the assumption that NR rates are dependent on the numbers of inspection procedures performed.

When the feasible indiscriminate scenario (SP+SNP+U) is considered, the prevalence at post-chill is estimated to decrease on average 7.08% (4,944 illnesses) with full implementation (all 159 market hog establishments participate), and to decrease on average 3.63% (2,533 illnesses) if only the 35 large and small non-HIMP establishments adopt a NSIS. Under the infeasible indiscriminate scenario (SP+SNP+U+NR) *Salmonella* prevalence at post-chill is estimated to decrease on average 10.49% (7,327 illnesses) with full implementation, or to decrease on average 9.20% (6,426 illnesses) if only 35 establishments participate. There are potential tradeoffs to consider among the implementation scenarios evaluated under various models. If only a single discriminate scenario is considered, there is less than a 0.01% probability of an adverse effect—that is, an increase in illnesses in response to the inspection system change—under the SNP scenario, while the SNP+U and SP+SNP indiscriminate scenarios both have probabilities of an adverse effect of less than 5%. However, the illness reduction for any of these scenarios is less than half that of the preferred scenario.

Where within a hog slaughter establishment can relocated inspectors have the most impact toward reducing Salmonella prevalence and corresponding human illness?
Redistribution of inspectors to offline inspection activities in the inspection categories evaluated is estimated to produce a reduction in human salmonellosis cases. The model predicts that maximum reduction in the percentage of *Salmonella* positive samples and market hog-attributable salmonellosis cases occurs when the average numbers of offline inspection procedures performed (SP and U) increase 25% and the numbers of SNP and NR inspection procedures decrease 50% and 46.67%, respectively. Among the feasible implementation scenarios, the highest estimated mean reduction in illnesses is obtained by scenarios that reallocate inspectors to increasing both SP and U while decreasing SNP. As noted above, however, the results suggest a tradeoff between potential gains and the degree of confidence in doing no harm.

What is the magnitude of uncertainty about the predicted prevalence and illness effects?
The approach used in this assessment, which models the relationship between the frequency of inspection activities and pathogen prevalence, quantitatively explores some sources of uncertainty in the change in future inspection activities that would likely be observed, and the rates of human salmonellosis attributable to market hog-derived products. The data limitations and assumptions discussed above, including the low prevalence of contamination on hog carcasses and the assumptions regarding the similarity fidelity of the implementation in the plants that did and did not participate in HIMP, could not be quantitatively modeled, thus are limitations of the modeling performed in this report. However, we were able to quantitatively explore other aspects of the uncertainty in the modeling parameters using methods and data sources described in the Methods and Results sections of this assessment.

Under the feasible (SP+SNP+U) scenario with full participation, the model estimates an average reduction in prevalence of 7.08% with uncertainty bounds (10^{th} and 90^{th} percentiles, respectively) of 3.42% and 10.71% reduced prevalence. Analysis of the feasible (SP+SNP+U) scenario with all inspection data from 2010-2011 for the 35-establishment subset produced an estimate of average reduction in prevalence at 3.63%, with 10^{th} percentile uncertainty bound increase of 2.46% and a 90^{th} percentile uncertainty bound decrease of 9.57% reduced *Salmonella* contamination prevalence. Further analysis of the feasible (SP+SNP+U) scenario with all inspection data from 2010-2011 for the 35-establishment subset produced an estimate of average reduction in prevalence at 3.63%, with 10^{th} and 90^{th} percentile uncertainty bounds at 1.10% and 6.14% reduced *Salmonella* contamination prevalence.

As a result of these prevalence changes, under the feasible (SP+SNP+U) scenario with full participation, the model estimates an average change in illnesses of 4,944 with uncertainty bounds of 2,386 illnesses avoided (10^{th} percentile) and 7,481 illnesses avoided (at the 90^{th} percentile uncertainty bound). There is a 3.8% probability of any adverse effect (i.e., an increase in illnesses). Analysis of the feasible (SP+SNP+U) scenario with empirical inspection data from 2010-2011 for the 35-establishment subset gave uncertainties of average illness reduction of 2,533 illnesses with the 10^{th} and 90^{th} percentiles of an increase 1,719 in illnesses and 6,685 decrease in illnesses, respectively. Overall there is approximately 80% probability of a decrease in illnesses. Further analysis of the feasible (SP+SNP+U) scenario with all inspection data from 2010-2011 for the 35-establishment subset gave uncertainties of average illness reduction of 2,533 with the 10^{th} and 90^{th} percentiles of 768 and 4,287 respectively, and a 4.0% probability of any adverse effect, or 96% probability of a decrease in illnesses. The magnitude of the uncertainty is such that the mean of the estimated uncertainty distribution suggests a reduction in illnesses under all scenarios considered.

Under the infeasible (SP+SNP+U+NR) scenario with full participation, the model estimates an average prevalence reduction of 10.49% with uncertainty bounds (10^{th} and 90^{th} percentiles, respectively) of 6.55% and 14.83% reduced prevalence. If only the 35 large and small non-HIMP market hog establishments adopt a NSIS, under the infeasible indiscriminate scenario (SP+SNP+U+NR), the model estimates a reduction in prevalence at 9.20%, with 10^{th} and 90^{th} percentile uncertainty bounds at 6.49% and 12.19% reduced *Salmonella* contamination prevalence; with the 2,330 sample days: 9.20%, with 10^{th} and 90^{th} percentile uncertainty bounds at 2.48% and 16.67% reduced

Salmonella contamination prevalence.

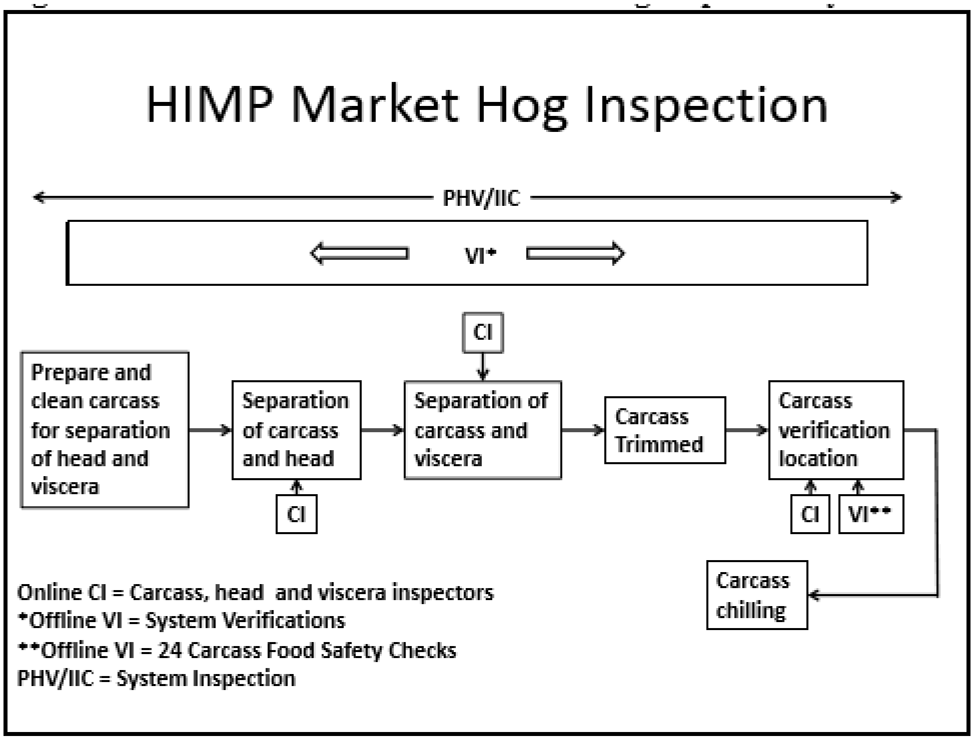
The model predicts, for the infeasible indiscriminate scenario (SP+SNP+U+NR) with full participation, an uncertainty distribution of change in illnesses with a 10th percentile decrease of 4,578 and 90th percentile decrease of 10,357 with an average decrease of 7,327 and a 1.4% probability of any adverse effect. If only the 35 large and small non-HIMP market hog establishments adopt a NSIS, under the infeasible indiscriminate scenario (SP+SNP+U+NR), the model predicts an uncertainty distribution of changes in illnesses with a 10th percentile decrease of 4,533 and a 90th percentile decrease of 8,514 with an average decrease of 6,426 and a > 98% probability of a decreasing illnesses. The corresponding estimates for the 2,330 sample days are a 10th percentile decrease of 1,732 and a 90th percentile decrease of 11,643 with an average decrease of 6,426 and approximately a 93% probability of a decreasing illnesses.

INTRODUCTION

FSIS is the food safety agency of the United States Department of Agriculture (USDA). With its mission of promoting public health, FSIS has legal authority to regulate the slaughter and production processes of meat and related industries. FSIS is considering modernizing its market hog slaughter inspection system by implementing a New Swine Slaughter Inspection System (NSIS). Key FSIS policy objectives in modernization are permitting flexibility for establishments to meet their specific quality and production standards, improving the efficiency with which the Agency can verify that slaughter establishments maintain safe production practices over time, and continuing to ensure that FSIS-regulated establishments produce safe products in accordance with FSIS statutory and regulatory requirements. Currently, FSIS inspectors in market hog establishments perform hands-on online inspection tasks, such as identifying bruises that do not necessarily contribute to food safety. The primary goal of this risk assessment is to understand the downstream public health effects of altering allocation of inspectors in more hog slaughter establishments. To this end, this report considers multiple scenarios that provide FSIS inspectors more time and flexibility to accomplish offline inspection tasks focused on establishment-specific public health risk factors.[2]

Overview of HACCP-based Inspection Models Project (HIMP)

FSIS initiated the voluntary HACCP-based Inspection Models Project (HIMP) in five market hog slaughter establishments in 1999. Under HIMP, FSIS inspectors are able to focus on offline inspection activities including humane handling and sanitation inspection procedures, HACCP verification, and other food safety-related tasks. Specifically, the HIMP market hog inspection system has one Public Health Veterinarian, two or three online carcass inspectors (CI), and up to two off-line verification inspectors (VIs) assigned to each line. The online CIs inspect every head, viscera, and carcass at fixed locations on the slaughter line (See Schematic 1) to ensure that market hog products receiving the USDA mark of inspection are not adulterated. The off-line VIs perform system verifications and the 24 carcass food safety check. Industry personnel conduct sorting activities for food safety and non-food safety defects before FSIS inspection. FSIS inspectors continue to ensure that the establishment's ante- and post-mortem process controls meet regulatory standards through online carcass-by-carcass inspection. The major difference between HIMP and non-HIMP inspection is that the FSIS offline inspectors (VI in Schematic 1 below) perform 24 food safety carcass checks versus 11 carcass food safety checks at non-HIMP market hog slaughter establishments. The number of checks is higher under HIMP to support increased verification that establishment personnel have properly sorted and removed diseased animals at ante-mortem and identified and removed unacceptable carcasses and parts at post-mortem just prior to FSIS inspection.



Schematic 1: Process Flow for HIMP Market Hog Inspection Systems
Source: Evaluation of HIMP for Market Hogs, FSIS 2014

Comparison of HIMP and non-HIMP inspection

FSIS, in a previous analysis, has compared the 5 HIMP market hog establishments with a comparison set of 21 non-HIMP market hog slaughter establishments selected to be comparable with HIMP market hog establishments with respect to production volume, line speed, and days of slaughter operation. (FSIS, 2014). Those analyses found no statistically significant difference in the prevalence of *Salmonella*-positive samples observed in HIMP establishments compared to non-HIMP establishments during the sampling period (CY 2006 to CY 2010). However, the limited number of samples collected per plant, the low prevalence of contamination, and the small number of HIMP establishments relative to non-HIMP establishments means that there is low statistical power to detect differences between inspection systems.

To address those concerns, this risk assessment is designed using weighted regression modeling and Monte Carlo simulation to address the following specific risk management questions:

Risk Management Questions

- *What predicted effects will various models for increasing the number of offline inspection tasks in non-HIMP establishments have on human salmonellosis rates?*
- *Where within a hog slaughter establishment can relocated inspectors have the most impact toward reducing Salmonella prevalence and corresponding human illness?*
- *What is the magnitude of uncertainty about the predicted prevalence and illness effects?*

The remainder of this document discusses the data and methods that were used in the risk assessment, the results of the analysis and discussion of those results. The main body is followed by nine appendices, which provide more details about the model used in the main body (Appendix A); data sets (Appendix B);a discussion of model selection (Appendix C); details about the inspection procedure decision variables (Appendix D); details about the structural variables (Appendix E); an analysis using data splitting (Appendix F); sensitivity analysis (Appendix G); additional discussions of alternative models, data transformation, power analysis and multicollinearity diagnostics (Appendix H); and a list of variables and coding used to denote data in the risk assessment model (Appendix I).

DATA

1. **FSIS Microbiological Data:** 7,471 sampling results from 5 HIMP and 159 non-HIMP (164 total) market hog slaughter establishments
   a. Market Hog Baseline study (August 2010 - August 2011) *Salmonella* sampling data from 148 establishments (including 5 HIMP). 3,846 samples: 1,925 collected at the pre-evisceration stages of the slaughter process and 1,921 collected at post-chill (following final interventions).
   b. PR/HACCP market hog carcass sampling data (August 2010 - December 2011) referred to as "routine sampling" from 20 establishments (including 5 HIMP). 3,625 post-chill samples from the *Salmonella* verification program results.

Table 1 and Table 2 summarize the microbiological data.

Table 1: Number of Establishments Sampled in Baseline Study and Routine Sampling

	Number of Market Hog Establishments Sampled			
	Baseline		**PR-HACCP**	**All**
	Pre-Evisceration	Post-Chill	Routine	Total
non-HIMP	142	143	16	159 (143+16)
HIMP	5	5	4	5
Total	**147**	**148**	**20**	**164**

Abbreviations: HIMP (HACCP-based Inspection Models Project); PR-HACCP (Pathogen Reduction; Hazard Analysis and Critical Control Point). HIMP establishments were included in both the Market Hog Baseline and PR-HACCP studies. Pre-evis and post-chill samples were taken from Baseline non-HIMP plants while PR-HACCP Routine samples were only from the post-chill stage of slaughter. Some plants are double-counted except in the "All / Total" column.

Table 2: Summary of Establishment Type-Specific Sample Location and Results

	Number of samples tested for *Salmonella*	Number of samples positive for *Salmonella*	% *Salmonella* Positive
All Non-HIMP Establishments			
Baseline Study, Pre-Evisceration	1,638	1,163	71.00
Baseline Study, Post-Chill	1,634	48	2.94
Routine (Post-Chill)	3,412	97	2.84
All HIMP Establishments			
Baseline Study, Pre-Evisceration	287	175	60.98
Baseline Study, Post-Chill	287	2	0.7
Routine (Post-Chill)	213	2	0.94
All Establishments (HIMP and Non-HIMP)			
Baseline Study, Pre-Evisceration	1,925	1,338	69.51
Baseline Study, Post-Chill	1,921	50	2.6
Routine (Post-Chill)	3,625	99	2.73
35 Large and Small non-HIMP Establishments			
Pre-Evisceration	1,278	984	77.00
Post-Chill	1,276	24	1.88
Routine (Post-Chill)	933	11	1.18

Abbreviations: HIMP (HACCP-based Inspection Models Project). Routine (post-chill) samples were only from the post-chill stage of slaughter from establishments in the PR-HACCP study.

2. **Inspection Procedures Data:**
Inspection procedure activities carried out at FSIS-regulated establishments are scheduled by FSIS headquarters and are performed by inspectors as time allows. For our model, the numbers of inspection procedure activities are classified under four potential decision variable categories: activities (1) scheduled and performed (SP), (2) scheduled but not performed (SNP), (3) unscheduled (U), and (4) noncompliance records (NR). ***Scheduled and Performed Procedures (SP)*** are the number of procedures that are scheduled at headquarters and that the inspector completes in the specified establishment within a given period of time. ***Scheduled and Not Performed Procedures (SNP)*** represents the number of procedures that are scheduled at headquarters but that the inspector does not complete in the specified establishment within a given period of time. ***Unscheduled Procedures (U)*** are procedures not on the scheduled list for each establishment but that may be performed in response to possible establishment noncompliance with regulations or simply as an expansion of routine inspection procedures when time and personnel are available. More unscheduled procedures are performed when establishments are fully staffed and offline inspectors are not required to fill line positions or are not required to perform

other duties. ***Noncompliance Records (NR)*** are written records that document noncompliance with FSIS regulations, capturing when an inspector finds that an establishment is not properly implementing its sanitation, HACCP, or other food safety procedures or processes, and/or other controls. A NR notifies the establishment of the noncompliance and that it should take action to remedy the situation and prevent its recurrence. NRs may be observed and recorded when performing scheduled and unscheduled procedures.

Procedure codes and results for inspection activities within these categories were recorded in the same 164 establishments and on the same days as the *Salmonella* sampling cultures described in parts (1.a) and (1.b) above (August 2010 - December 2011). The data set contained records of 165,506 offline inspection activities — 111,225 were SP, 9,088 were SNP, 40,686 were U, and 4,507 were entries documented as noncompliance records. Inspection data was retrieved from the FSIS Performance Based Inspection and Public Health Information Systems (PBIS and PHIS).

3. Human Illness Data:

Estimates for the annual number of human salmonellosis cases attributable to market hog consumption are based on values from Centers for Disease Control and Prevention (CDC) foodborne illness FoodNet surveillance and outbreak surveillance data) as reported by Scallan (CDC, 2011)[a] and Painter (2013)[b], as well as analysis of FSIS data (2010-2015). Distribution parameters and percentile estimates are detailed in the Methods section of this report.

[a] Scallan (2011) *Salmonella* surveillance data 2005-2008
[b] Painter (2013) *Salmonella* outbreak data 1998-2008 Technical Appendix 1 Table 5 where the distribution mode is 6.3%

ASSUMPTIONS

As with any complex risk assessment, this risk assessment relies on a number of assumptions. The major assumptions utilized in this risk assessment are described in Table 3. Additionally, the risk assessment relied on other assumptions that were not explicitly incorporated into the model.

- Relationship between HIMP for poultry slaughter and for hog slaughter
    - This risk assessment is independent of the poultry slaughter risk assessment and relies on data from hog slaughter establishments. However, FSIS assumes, for the purpose of this risk assessment, that the differences between the process of slaughtering hogs and slaughtering poultry do not alter the relationship between the presence of *Salmonella* contamination post-slaughter and human illness.

The use of a HIMP system for market hogs is substantially similar to the use of a HIMP system for poultry, with both having industry sort animals and carcasses to remove those with quality defects, and both leading to an increase in FSIS off-line inspection. In addition, the *Salmonella* data for both poultry and hog slaughter facilities come from samples at similar locations in the slaughter process. Additionally, hog slaughter establishment specialization has been facilitated by vertical integration within the industry, much like the poultry industry. (Muth *et al.,* 2007).

- Relationship between carcass contamination rates and downstream product (parts, ground) contamination rates
  - FSIS assumes, for the purpose of this risk assessment, that the relationship between *Salmonella* contamination of hog carcasses and downstream products such as pork parts (e.g., pork chops) and ground pork closely mirrors that of the established relationship between *Salmonella* contamination of poultry (e.g., chicken) carcasses and downstream products such as chicken parts and ground chicken. While FSIS did not conduct any specific analyses to examine this assumption, the Agency has conducted numerous peer-reviewed analyses of the relationship between *Salmonella* contamination frequency on chicken carcasses and chicken parts (Ebel, et al, 2019). These analyses indicate that the prevalence of *Salmonella* contamination on downstream products (e.g., parts) often exceeds that for the prevalence of *Salmonella* contamination in upstream products (e.g., carcasses) The higher prevalence is logical given that samples of downstream products contain primals from multiple carcasses, increasing the likelihood of a single sample being contaminated.

- Relationship between HIMP and non-HIMP establishments
  - It is important to note that this risk assessment is not a comparison of HIMP and non-HIMP establishments. As stated previously, this risk assessment sought to estimate changes in the number of domestic market hog-attributable human salmonellosis cases that would be expected to result from implementation of a HIMP-like inspection system in more establishments, according to the prevalence-based risk model. It is possible that other differences exist between HIMP and non-HIMP establishments that the risk assessment did not quantify. That said, in the 2014 Evaluation of HIMP for Market Hogs report, FSIS conducted numerous analyses to examine what differences, if any, exist between HIMP market hog establishments than in non-HIMP market hog establishments. This evaluation found that market hog slaughter establishments

participating in HIMP are performing as well as comparable large non-HIMP market hog establishments and meeting FSIS expectations for the overall HIMP project (FSIS, 2014).

In addition to the assumptions described above, this risk assessment is subject to additional model-based assumptions. Table 3 summarizes the data inputs, outputs, and these model assumptions.

Table 3: Available Information and Assumptions in the Risk Assessment

Information Required	Available Data	Assumptions
Stage 1: Estimate relationship between establishment variations in FSIS inspection activities and frequency of *Salmonella* proportion positive on market hog carcasses using a production volume-weighted logistic regression model.		
Inspection Data	FSIS establishment-level data on the number of specific inspection activities[a] conducted from August 2010 through December 2011, stored in PBIS.	Data are representative of market hog slaughter establishments.
Microbiological Data	• FSIS establishment-level pre-evisceration and post-chill *Salmonella* sampling data from market hogs baseline studies (August 2010 - August 2011). • Establishment-level FSIS PR/HACCP market hog carcass post-chill samples from the *Salmonella* verification program results (August 2010 - December 2011).	Data are representative of market hog slaughter establishments.
Production Volume Data	FSIS establishment-level production volume data.	
Stage 2: Explore the potential risk implications for increasing various offline inspection activities using a simulation model that combines the statistical relationship estimated in Stage 1 with relevant sources of uncertainty and the attribution of human illness to pork product *Salmonella* contamination.		
Estimated mean number of human *Salmonella* illnesses attributable to market hog product consumption	Independent FSIS analysis to estimate attributable shares (2013)[b]. The total annual number of *Salmonella* illnesses in the United States is estimated by CDC (Scallan *et al.*, 2011). Then attributable shares (FSIS, 2013)[b] is applied to credibility intervals calculated using Painter *et al.* (2013).	Human illnesses can be modeled as a Poisson process because in microbial food safety, sporadic exposure events are considered independent events and chronic exposures to pathogens are not considered.
Relationship between *Salmonella* on market hog carcasses and human *Salmonella* illnesses	The relationship between product contamination and human illnesses has been published previously.	The probability that exposure to a random contaminated serving would produce illness is constant regardless of changes in the frequency of exposure to the pathogen on a per-serving basis (that is, dose levels at consumption are independent of the frequency of contamination)[d].
Distribution of establishments	Use plant size data from FSIS' PBIS and PHIS databases.	The rate at which procedures would be performed is based on the distribution of the plant sizes.

Information Required	Available Data	Assumptions
Percentage of offline inspection procedures that would be conducted in each establishment under the proposed inspection system	No empirical data available. Therefore, different scenario types were developed on the basis of the increased percentage of offline procedures performed in establishments in the HIMP compared with non-HIMP establishments (FSIS, 2011a)[b]. Those scenarios are used to model the effect of increased offline procedures across all FSIS-regulated establishments and compared to the 'baseline' of current establishment activities. Assumptions specific to the two different scenario types are outlined below.	• There would be a shift of the majority of online inspectors to offline inspection duties while leaving one inspector online for final carcass inspection[e]. The proposed increase in offline inspectors is expected to increase scheduled, performed and unscheduled procedures[f]. Increased availability of offline inspectors should increase unscheduled procedures while reducing scheduled but not performed procedures[g]. • An estimate of the distribution for offline inspection activities performed upon implementation of the proposed inspection system would reflect the distribution for offline inspection activities observed in establishments currently operating under HIMP.
	Indiscriminate Scenarios No data available on how FSIS might emphasize or de-emphasize activities in proposed inspection system; all procedure categories are tested simultaneously.	Data from HIMP plants indicate: • SP and U procedures: assumed the most likely change is an increase of 30%, a minimum of no change and a maximum of a 50% increase. • SNP procedures: assumed the most likely change is a decrease of 50%, a minimum of no change and a maximum of 100% reduction. • Under the infeasible scenario, as a theoretical exercise NR procedures assumed most likely change is 10% increase, a maximum of a 20% increase, and a minimum of no change. Under the feasible scenario, NR is treated as a structural variable.
	Discriminate Scenarios No assumption that FSIS would emphasize any particular procedure. Therefore, each procedure category is tested one at a time for emphasis in the proposed inspection system.	• The SP, SNP, U, and NR procedures are, in turn, each changed according to each respective uncertainly distribution while the other three procedure categories are fixed to baseline levels. • The procedure distributions are modeled as above.

[a] The six groups of inspection activities and four specific 03 procedures analyzed are: sanitation (01), HACCP (03), wholesomeness/economic consumer protection (04), sampling (05), other inspection requirements (06), food defense procedures (08), sanitation performance standards (06D01), raw ground (03B), raw not ground (03C), and fecal checks (03J). Additionally, the subset of W3NR's also was evaluated establishment Sanitation SOP verification (01A01), pre-operational sanitation verification (01B01, 01B02), operational sanitation verification (01C01, 01C02), and HACCP plan verification (03A01), verify fecal check or other HACCP verification requirements (03J01, 03J02), verify E. coli standards (05A01), and verify sanitation standards (06D01).
[b] FSIS (2013). Potential Public Health Impact of *Salmonella* Performance Guidance for Market Hogs. Available at: http://www.allfoodlab.com/wp-content/uploads/2014/01/FSIS-Compliance-Guideline-on-Controlling-Salmonella-in-Market-Hogs-FSIS-2014-0002-00011.pdf
[c] Williams M.S., Ebel, E.D., Vose, D. 2011. Framework for Microbial Food-Safety Risk Assessments Amenable to Bayesian Modeling Risk Analysis. *Risk Analysis*, Vol. 31, no. 4, 548-565.
[d] This assumption is supported by empiric evidence. FSIS chicken carcass baseline results indicate that the average concentration of *Salmonella* per milliliter of rinsate had not changed from 1995 in 2007, but the prevalence of positive carcasses was different.
[e] This shift in inspectors is from the Preliminary Regulatory Impact Analysis (PRIA) of the proposed market hog slaughter rule.
[f] This assumption follows from the observation that there are fewer scheduled but not performed procedures and more unscheduled procedures performed when establishments are fully staffed and offline inspectors are not required to fill line positions
[g] Based on analysis of the Market Hog HACCP Inspection Models Project (HIMP) (FSIS, 2014).
Abbreviations: CDC, Centers for Disease Control and Prevention; FSIS, Food Safety and Inspection System; HIMP, HACCP-Based Inspection Models Project; NR, noncompliance records; PBIS, Performance-Based Inspection System; PHIS, Public Health Inspection System; SNP, scheduled and not performed procedures; SP, scheduled and performed procedures; U, unscheduled procedures.

METHODS

Figure 1 provides an overview of the two analytical stages conducted as part of this microbial risk assessment model. This model uses available FSIS inspection activity and pathogen testing data to assess the influence of those activities on the conditional likelihood of finding *Salmonella* positive samples at the pre-evisceration or post-chill stages of slaughter. Available human illness data is used to model the effect of changes in the likelihood of *Salmonella* positive samples on the numbers of human illnesses avoided.

In Stage 1, a binary logistic production log-volume weighted regression model uses historical data to characterize the relationship between structural variables and offline inspection procedures (SP, SNP, U, and NR) and the proportion of market hog carcasses that are positive for *Salmonella*. The regression model calculated in Stage 1 is used as input for Stage 2 which focuses on constructing and comparing different scenarios which reflect potential changes in decision variable rate(s) when converting non-HIMP establishments to a NSIS. The methods used here have been applied extensively in other peer reviewed risk assessment publications (Bartholomew et al., 2005; Williams and Ebel 2012; Ebel et al., 2012; Withee et al., 2009). A number of different models were explored for use in this risk assessment, as was the use of volume weighting without log transformation. None of those models performed substantively better than the unconditional fixed effects logistic regression used here. Furthermore, the estimated number of illnesses avoided using those models, or using the volume weighting without log transformation, was higher than the model and weighting chosen for the final analysis. Therefore, the model chosen provides a conservative estimate of illness reductions compared with possible models. Appendix H presents the results using different models and without log transforming the volume weighting.

In Stage 2, there are two implementation scenario types: indiscriminate and discriminate. For both types, inspection procedure rates for potential decision variables from HIMP establishments are applied to non-HIMP establishments. This means that the number of SP, SNP, U, and, under some scenarios, NR inspection procedures performed in the Monte Carlo simulation model is a function of the number of offline inspectors and inspection efficiency expected for the non-HIMP establishment converting to a NSIS. As another alternative scenario, the SP+U scenario is considered if SNP is eliminated from the feasible scenario. These scenarios are used to estimate how relocation of FSIS inspectors would change the percentage of market hog *Salmonella* positive samples.

These predicted changes in *Salmonella* positive sample percentages are then used to calculate proportional changes in market hog-attributable salmonellosis cases. Under the infeasible indiscriminate scenario, modifications in rate of four decision variables (SP, SNP, U, and NR) are all made at the same time, targeting the inspection procedure categories for maximum inspection activity. Under the feasible indiscriminate scenario, modifications in rate of three decision variables (SP, SNP, and U) are all made at the same time, and NR is treated as a fixed, structural variable. For the discriminate scenarios (Disc), the value of the decision variable for one or more of the inspection procedure categories is changed to the HIMP-like value while the values of the other three decision variables are kept at baseline levels. In addition, each of the seven implementation scenarios is evaluated under two different NSIS adoption scenarios: NSIS is adopted by all 164 non-HIMP market hog establishments or NSIS is adopted by the 35 large and small non-HIMP market hog establishments. In total, 30 total scenarios are examined: 9 implementation (SP, SNP, U, NR, SP+U, SNP+U, SP+U+NR, SP+SNP, SP+SNP+U, and SP+SNP+U+NR) X 3 adoption (159 establishments- 5,046 sample days, 35 establishments (Version 1)- 2,330 sample days, and 35 establishments (Version 2)- 22,621 inspection days).

FSIS Microbiological Data

- FSIS *Salmonella* data from the Market Hog Baseline pre-evisceration and post-chill samples (August 2010 - August 2011).
- FSIS PR/HACCP market hog carcass post-chill samples from the *Salmonella* verification program results (August 2010 - December 2011).

Inspection Procedure Data

- The number of specific inspection activities[a]:
  - Scheduled and performed procedures (SP)
  - Scheduled and not performed procedures (SNP)
  - Unscheduled procedures (U)
  - Instances of observed and reported noncompliance records (NR)
- From same establishments and dates as Microbiological Data.

Regression Model Inputs

Stage 1: Estimate the relationship between establishment variations in FSIS inspection activities and frequency of *Salmonella* positives on market hog carcasses.
Conduct a weighted logistic regression analysis to estimate the relationship between offline inspection procedures and contamination.

Regression Model Output

Coefficients (β) for the relationship between inspection activities and contamination.

Human Illness Data Application

Estimated mean number of human *Salmonella* illnesses attributable to market hog products consumption:

1. Total illnesses with swine attribution estimated by CDC (Painter *et al.*, 2013).
2. Independent FSIS analysis to estimate attributable shares for market hogs (2011).
3. Apply the shares attributable to credibility intervals calculated using Scallan *et al.* (2011).

Simulation Model Inputs

Stage 2: Explore the effect of increasing various offline inspection activities using a simulation model and the relationship estimated in Stage 1.
Predictions are made for scenarios with adjustments to the number of the four different inspection procedures (Indiscriminate, Disc(SP), Disc(SNP), Disc(U), Disc(NR), and Disc (SP+SNP+U)).

Application of Scenarios

1. Develop scenarios for the increased percentage of offline procedures based on the number of those procedures performed in establishments in the HACCP–based Inspection Models Project (HIMP) compared with non-HIMP establishments. Data on procedures in HIMP from FSIS (2011)[b].
2. Use these scenarios to model the effect of increases in various offline procedures across all FSIS-regulated establishments.

Prediction Output

Estimated Annual Number of Human Illnesses from *Salmonella*
($\lambda_{predicted} = \lambda_{ill} - \lambda_{avoided}$)

Figure 1: Overview of the Microbial Risk Assessment

This figure summarizes the two major stages of the risk assessment of alternative scenarios, and the inputs and outputs from those stages.

[a] The six groups of inspection activities and four specific 03 procedures analyzed are: sanitation (01), HACCP (03), wholesomeness/economic consumer protection (04), sampling (05), other inspection requirements (06), food defense procedures (08), sanitation performance standards (06D01), raw ground (03B), raw not ground (03C), and fecal checks (03J). Additionally, the subset of W3NR's also was evaluated establishment Sanitation SOP verification (01A01), pre-operational sanitation verification (01B01, 01B02), operational sanitation verification (01C01, 01C02), and HACCP plan verification (03A01), verify fecal check or other HACCP verification requirements (03J01, 03J02), verify *E. coli* standards (05A01), and verify sanitation standards (06D01).
[b] *Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs* (FSIS, 2014) is available at: http://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AJPERES.

The full regression model for this assessment characterizes four segmented subsets of the whole dataset (HIMP evisceration, HIMP post-chill, non-HIMP evisceration, and non- HIMP post-chill)[3]. The magnitude and direction of the regression coefficient estimates relating inspection procedure rate and *Salmonella* prevalence are drawn from the decision variable distributions observed in market hog HIMP and non-HIMP establishments from the full model. Each segmented subset result—that is, each estimate of percentage *Salmonella* positives—is calculated by changing the indices for establishment type and sample location. Though data from both pre-evisceration sampling and post-chill sampling were included in Stage 1, Stage 2 estimates are based on only the non-HIMP post-chill segment subset, reflecting the effect that applying HIMP-like procedure levels to non-HIMP establishments would have on post-chill *Salmonella* positive sample percentages only. This is referred to as the "post-chill model for non-HIMP establishments." The subsetted segment simulation model for non-HIMP establishments at post-chill applies the proportional expected increase in scheduled and unscheduled procedures and a decrease in scheduled but not performed procedures and noncompliance records (under some simulations). This subsetted segment model allows estimation of the probability inspectors at non-HIMP establishments change the frequency at which they perform a decision variable procedure at assumed changes in inspection rates.

The analysis does not *a priori* assume that any of the decision variables is more important than the others; instead, the analysis is designed to estimate the effect of changing variables or combinations of variables on the prevalence of human illness.

[3] Relevant code and scripts to run the model will be posted to FSIS' website.

Uncertainty

Table 4 summarizes key uncertainties in the risk assessment. The risk model incorporates the uncertainty of:

(I) The initial analyses and data used;

(II) The change in future inspection activities likely to be observed when converting non-HIMP establishments to a HIMP-like inspection configuration; and

(III) Current estimates of *Salmonella* human illness associated with market hog food products, and how the associated uncertainty affects the uncertainty in the assessment's predictions about the change in human illnesses estimated to occur as a result of implementation of the proposed inspection system.

Table 4: Summary of Key Uncertainties in the Microbial Risk Assessment

Contributors to Uncertainty	Symbol	Classification	Handling of Uncertainty in the Model	Relative Importance
Regression coefficients	$\boldsymbol{\beta}$	Statistical	Modeled as multivariate normal distributions.	Least influential uncertainty
Adjustment parameters to reflect the number of future offline inspection activities	$\mathbf{A_i}$	Modeling	Modeled as *Pert* uncertainty distributions.	Intermediate uncertainty
Baseline annual number of domestic foodborne *Salmonella* illnesses	$\boldsymbol{\lambda_{ill}}$	Modeling	Use the 95% confidence interval from Scallan *et al.* (2011), and use that interval in a putative lognormal distribution to reflect uncertainty about all *Salmonella* attributable illnesses	Most influential uncertainty because it includes the fractional uncertainties below as multipliers
Fraction of all domestic foodborne illnesses attributable to *Salmonella* in hogs	$\boldsymbol{f_{hog}}$	Modeling	Use the 90% credibility interval from Painter *et al.* (2013) with a *Pert* uncertainty distribution	
Fraction of *Salmonella* illnesses attributable to market hogs	$\boldsymbol{f_{market.hog}}$	Modeling	Use FSIS data from 2010-2015 with a *Pert* uncertainty distribution	

Uncertainty distributions describing the possible effects of changes in the four potential decision variables' inspection procedure categories were developed using HIMP and non-HIMP information provided in *Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs* (FSIS, 2014). The number of the different inspection activities modeled in each scenario was identified from the tabulated values of those activities conducted in HIMP market hog establishments which also were reported in the aforementioned FSIS HIMP report (FSIS, 2014).

Stage 1: Characterizing the Relationship between FSIS Inspection Activities and Product Contamination using a Regression Model

Data Sources and Structure

Two categories of FSIS-generated data from market hog establishments were used for Stage 1 of this assessment, microbiological data from samples collected from hog carcass contamination testing and records describing the non-sampling inspection activities carried out by Inspection Program Personnel (IPP, "inspectors"). To develop the regression model that comprises Stage 1 of this risk assessment, microbiological and inspection data collected from the Market Hog Baseline Study (August 2010 - August 2011), PR/HACCP verification program (August 2010 - December 2011), and inspection procedure data were extracted from FSIS databases. This data yielded a (7,471x25) initial model matrix in which each of the 7,471 rows represented a given plant's individual sample day. The 25 columns included a binary indicator of the presence or absence of *Salmonella* (0 – no growth from sample; 1 – some visible growth from sample), one column stating model intercept values, 20 columns describing the plant structural characteristics, and four columns describing the number of associated procedures in each of the potential decision variable categories (SP, SNP, U, and NR) for that establishment's sample day. Structural characteristics describe differences in plant design, inspection system, and demographic information.

FSIS uses computerized information systems to schedule inspection activities and capture the results of those activities. The Performance Based Inspection System (PBIS) was used before 2012. In January 2012, FSIS transitioned from PBIS to the Public Health Information System (PHIS) to collate and centralize data. This risk assessment contains both PBIS and PHIS data, but only records associated with inspection codes common to both systems were used. A data cleaning step which identifies data from overlapping categories between PBIS and PHIS was carried out in order to avoid introducing bias or confounding at this early phase of the model. Within PBIS and PHIS, inspection activities are identified by inspection procedure (ISP) codes that differentiate groups of activities, such as sanitation, HACCP, wholesomeness and economic consumer protection, sampling, sanitation performance standards, and food defense procedures. Each ISP code is further delineated into more specific activities. Each activity scheduled or conducted is noted in PBIS or PHIS as: scheduled and performed (SP); scheduled but not performed (SNP); unscheduled (U); or a noncompliance record (NR) for performed procedures recorded as an establishment noncompliance with USDA food safety regulations. In this risk assessment, the four possible decision variables represent the sum of each type of activity across the various ISP codes in each establishment each day that a *Salmonella* sample was collected as shown in Table 5.

Table 5: Detail of Total Inspection System Procedure Codes Evaluated Together and in Subsets in Stage 1 Decision Variable Categories

No.	Code Sum*	Activity	Detail Sum**	Elements	ISP Code	Procedures
1	sum01	sanitation	sum01A	Verification	01A01	sanitation SOP
2	sum01	sanitation	sum01B	Preoperational	01B01	m/v/r/ca/fu[4]
3	sum01	sanitation	sum01B	Preoperational	01B02	01B01 verification
4	sum01	sanitation	sum01C	Operational	01C01	m/v/r/ca/fu[4]
5	sum01	sanitation	sum01C	Operational	01C02	01C01 verification
6	sum03	HACCP	sum03A	Verification	03A01	HACCP plan
7	sum03	HACCP	sum03B	raw ground	03B01	m/v/r/ca/fu[4]
8	sum03	HACCP	sum03B	raw ground	03B02	03B01 verification
9	sum03	HACCP	sum03C	raw not ground	03C01	m/v/r/ca/fu[4]
10	sum03	HACCP	sum03C	raw not ground	03C02	03C01 verification
11	sum03	HACCP	sum03E	not heat treated-shelf stable	'03E01	m/v/r/ca/fu[4]
12	sum03	HACCP	sum03F	not heat treated-shelf stable	'03E02	03E01 verification
13	sum03	HACCP	sum03F	heat treated-shelf stable	03F01	m/v/r/ca/fu[4]
14	sum03	HACCP	sum03F	heat treated-shelf stable	03F02	03F01 verification
15	sum03	HACCP	sum03G	fully cooked-not shelf stable	03G01	m/v/r/ca/fu[4]
16	sum03	HACCP	sum03G	fully cooked-not shelf stable	03G02	03G01 verification
17	sum03	HACCP	sum03H	heat treated-not fully cooked	03H01	m/v/r/ca/fu[4]
18	sum03	HACCP	sum03H	heat treated-not fully cooked	03H02	03H01 verification
19	sum03	HACCP	sum03I	secondary inhibitors-not shelf stable	03I01	m/v/r/ca/fu[4]
20	sum03	HACCP	sum03I	secondary inhibitors-not shelf stable	03I02	03I01 verification
21	sum03	HACCP	sum03J	slaughter/fecal check	03J01	m/v/r/ca/fu[4]
22	sum03	HACCP	sum03J	slaughter/fecal check	03J02	03J01 verification
23	sum04	W/ECP[1]	sum04A01	yield/shrink	04A01	m/v/r/ca/fu[4]

No.	Code Sum*	Activity	Detail Sum**	Elements	ISP Code	Procedures
24	sum04	W/ECP[1]	sum04A02	product solution formulation	04A02	m/v/r/ca/fu[4]
25	sum04	W/ECP[1]	sum04A03	comminuted/mechanically separated	04A03	m/v/r/ca/fu[4]
26	sum04	W/ECP[1]	sum04A04	battered products	04A04	m/v/r/ca/fu[4]
27	sum04	W/ECP[1]	sum04B01	product meets standard	04B01	m/v/r/ca/fu[4]
28	sum04	W/ECP[1]	sum04B02	packaging/labeling standards	04B02	m/v/r/ca/fu[4]
29	sum04	W/ECP[1]	sum04B03	stated label net weight	04B03	m/v/r/ca/fu[4]
30	sum04	W/ECP[1]	sum04B04	product identification	04B04	m/v/r/ca/fu[4]
31	sum04	W/ECP[1]	sum04C02	humane slaughter requirements	04C02	m/v/r/ca/fu[4]
32	sum04	W/ECP[1]	sum04C03	non-food safety product req.	04C03	m/v/r/ca/fu[4]
33	sum04	W/ECP[1]	sum04C04	humane slaughter (economic)	04C04	m/v/r/ca/fu[4]
34	sum05	sampling	sum05A01	generic *E. coli* record plan	05A01	verification
35	sum05	sampling	sum05A02	generic *E. coli* record review	05A02	m/v/r/ca/fu[4]
36	sum05	sampling	sum05C01	random residue sample	05C01	sample collection
37	sum06	OIR/SPS[2]	sum06A01	export regulation compliance	06A01	m/v/r/ca/fu[4]
38	sum06	OIR/SPS[2]	sum06B01	custom exempt retail compliance	06B01	m/v/r/ca/fu[4]
39	sum06	OIR/SPS[2]	sum06D01	sanit. performance standards	06D01	m/v/r/ca/fu[4]
40	sum06	OIR/SPS[2]	sum06D02	facility sanitation compliance	06D02	m/v/r/ca/fu[4]
41	sum08	Food Defense[3]	sum08S14	water systems	08S14	unscheduled check
42	sum08	Food Defense[3]	sum08S15	processing/manufacture	08S15	unscheduled check
43	sum08	Food Defense[3]	sum08S16	storage areas	08S16	unscheduled check
44	sum08	Food Defense[3]	sum08S17	shipping/receiving	08S17	unscheduled check

* Contains all the Detail Sum elements for the ISP code category (01, 03, 04, 05, 06, 08
** Detail Sum refers to the procedure summed within given code summed ISP elements with their descriptions
[1]W/ECP = Wholesomeness/Economic Consumer Protection
[2] OIR/SPS = Other Inspection Requirements/Sanitation Performance Standards
[3] Food Defense procedures performed under Homeland Security requirements
[4] m/v/r/ca/fu = Indication that the procedure corresponds to one of the following action types: Monitoring, Verification, Records Checks, Corrective Action to Noncompliance, or Follow Up Reassessment to Corrective Action

Modeling Procedures

Stage 1 is a daily production volume-weighted logistic regression model with the regression coefficients estimated from the maximum quasi-likelihood equations of the Fisher scoring algorithm using SAS 9.4 software[2]. The regression analysis relates the binary variable for *Salmonella* contamination to the cumulative logistic distribution which gives the probability of having *Salmonella*-positive samples taken from market hog carcasses. The regression model treats observed detection or non-detection of *Salmonella* in a sample collected on a given market hog carcass as the dependent variable or output, with the variables for establishment profile and decision variables as independent variables or input. The regression model predicts the conditional likelihood of *Salmonella* positive samples given the input values. These independent variables consist of categorical and continuous structural variables, which describe differences in plant design, inspection system, numbers of inspectors, demographic characteristics, and the four possible decision variables (SP, U, SNP, and NR). Data describing establishments' line speeds were incomplete and not included in the model.

The four categories of possible decision variables are treated as statistically independent uncertainty distributions in the first stage of the model and are realistically likely to influence one another when changes to inspection systems, as in HIMP, are implemented. For example, a proposed increase in offline inspectors is expected to increase scheduled and performed and unscheduled procedures while reducing scheduled but not performed procedures, and the model treats these as weakly correlated events in the model's second stage, meaning that the correlations never reach significance given the data sample size. These assumptions follow from the observation that there are fewer scheduled but not performed procedures and more unscheduled procedures performed when establishments are fully-staffed and offline inspectors are not required to fill online positions. The sample correlation matrix was used to model these effects in the second stage. The model also expects that in the long-run, noncompliance records would decrease with an increase in the number of offline inspection tasks performed. Establishments under this inspection paradigm are expected to achieve greater process control through increases in offline procedures in addition to industry-wide commercial and technological innovation that will likely occur over time.

Regression Model Prevalence Output

The regression analysis produces regression coefficients that reflect the strength of the association between the inspection activities and *Salmonella* contamination. *Salmonella*

[2] Proc logistic SAS 9.4 Service Pack 1 Copyright © 2002-2003 by SAS Institute Inc., Cary, NC, USA

prevalence is estimated using these coefficients in log production volume weighted estimating equations incorporating the regression coefficients generated in Stage 1 as input for Stage 2 to develop distributions of potential illnesses avoided. For a more detailed description of the regression model and its results, as well as the effects of using alternate models, see Appendices A-H.

Stage 2: Model to Predict the Effect of Changes in the Numbers of Inspection Procedures

Stage 2 of the risk assessment incorporates human illness data and estimating equations from the Stage 1 regression model to estimate how the prevalence of *Salmonella* on market hogs, and ultimately annual number of human salmonellosis cases, might be expected to change in relation to up to four inspection procedures categories with weakly correlated uncertainty distributions. To identify the decision variable categories of offline inspection procedures that could have the greatest public health impact, multiple plausible scenarios were developed. In the indiscriminate scenarios (denoted InDisc), all relevant decision variable categories were modified to HIMP-like rates with up to four decision variables, while in four discriminate scenarios (denoted Disc), each of the four possible decision variable categories were modified to HIMP-like rates when holding each of the others constant at their means.

Data Sources

Estimates for the mean number of human *Salmonella* illnesses attributable to consumption of pork products are based on distribution parameters from the Centers for Disease Control and Prevention (CDC) total domestic foodborne illness and outbreak data (CDC, 2001-2007) as reported by Scallan *et al.* (CDC, 2011) and Painter *et al.* (2013)—see Table 6.

Baseline prevalence (denoted *Prev(baseline)* in equations listed later in this document) is estimated as the baseline percent positive *Salmonella* samples of those samples drawn from market hog carcasses at the post-chill stage of slaughter. These values, as well as the other parameters included in the model, are described in greater detail in the Modeling Procedures section, as well as in Appendix B.

Table 6: Attribution Breakdown for Market Hog-Attributable *Salmonella* Illnesses

Domestic Foodborne *Salmonella* Illness Category	Distribution	5th Percentile	Mean	95th Percentile
All Commodities[a]	*Log-Normal*[a]	644,786	1,085,707	1,679,667[d]
		Minimum	**Mean**	**Maximum**
Proportion of domestic foodborne *Salmonella* from Pork[b]	*Pert*	3.6%	6.7	11.4%
Proportion of Pork *Salmonella* from Market Hogs[c]	*Pert*	93.0%	96.0%	98.0%
		5th Percentile	**Mean**	**95th Percentile**
Salmonella illnesses from Market Hogs	Output	34,237	69,857	111,673[e]

[a] Scallan (2011) *Salmonella* surveillance data 2005-2008
[b] Painter (2013) *Salmonella* outbreak data 1998-2008 Technical Appendix 1 Table 5 where the distribution mean is 6.3%
[c] FSIS swine slaughter data (2010-2015) where the distribution mean is 96.033%
[d]Based on a standard deviation of 322,794
[e]Based on standard deviation of 24,435

Modeling Procedures

The multivariate normal estimating equations developed in the regression analysis are averaged across all data points and are solved for a minimum of 100,000 iterations until all further solutions produced fell within 0.01% or less of the cumulative mean. The resulting prevalence estimates were then used in the inspection rate adjustment model applied in Stage 2 to generate the distributions of illnesses avoided (see Table 7). Contaminated carcass population prevalence estimates are derived from the average annual production log-volume weighted average prevalence estimates for individual non-HIMP establishments.

The modeling framework in Stage 2 stems from the three primary determinants of adverse human health outcomes from foodborne pathogens: (1) the frequency of exposure to the pathogen, (2) the distribution of pathogens in a random exposure event on a per-serving basis, and (3) the probability that a random exposure event causes the adverse human health outcome (Cox, 2006; Haas, 1996). In microbial food safety, sporadic exposure events are considered independent events and chronic exposures to pathogens are typically not considered to contribute significantly to the burden of illness.

Table 7: Adjustment Distributions Applied to Procedure Rate Values in One Indiscriminate and Four Possible Discriminate Implementation Scenarios

Scenario	SP	SNP	U	NR
InDisc (SP+SNP+U+NR)	*Pert*(0.0, 1.25, 1.5)	*Pert*(0.0, 0.5, 1.0)	*Pert*(0.0, 1.25, 1.5)	*Pert*(0.0, 0.5, 1.2)
Disc(SP)	*Pert*(0.0, 1.25, 1.5)	$X_{SNPbaseline}$	$X_{Ubaseline}$	$X_{NRbaseline}$
Disc(SNP)	$X_{SPbaseline}$	*Pert*(0.0, 0.5, 1.0)	$X_{Ubaseline}$	$X_{NRbaseline}$
Disc(U)	$X_{SPbaseline}$	$X_{SNPbaseline}$	*Pert*(0.0, 1.25, 1.5)	$X_{NRbaseline}$
Disc(NR)	$X_{SPbaseline}$	$X_{SNPbaseline}$	$X_{Ubaseline}$	*Pert*(0.0, 0.5, 1.2)
InDisc(SP+SNP+U)	*Pert*(0.0, 1.25, 1.5)	*Pert*(0.0, 0.5, 1.0)	*Pert*(0.0, 1.25, 1.5)	$X_{NRbaseline}$

Note, only the SP+SNP+U discriminates are considered for the final model.
Abbreviations: SP, scheduled performed; SNP, scheduled not performed; U, unscheduled; NR, noncompliance record; NPR, no procedures recorded.

In this model, structural variables are treated as fixed as in the final model with the same random variation and, therefore, their means do not change in modeled scenarios. A prevalence-based model estimates changes in annual illness cases based on changes in the frequency of occurrence of the pathogen among food commodities (Williams *et al*., 2011). The basic model is:

$$P(ill) = P(ill \mid exp)P(exp)$$

where *P(ill)* is the probability of illness from a product-pathogen pairing across a population, *P(ill|exp)* is the probability that exposure to a random contaminated serving would produce illness[3], and *P(exp)* is the frequency of exposure to the pathogen on a per-serving basis[4]. This basic model enables a simple estimation of annual illnesses avoided ($\lambda_{avoided}$) resulting from an intervention that reduces prevalence.

The model used to predict the effect of the increased offline market hog inspection procedures is defined as follows:

$$\lambda_{avoided} = \left[1 - \frac{Prev(scenario)}{Prev(baseline)}\right] \lambda_{ill}$$

[3] *P(ill|exp)* is the solution to the integral where *R(D)* is the dose-response function and the exposure distribution of doses (*D* > 0 organisms) is the probability density *f(D)* (discussed in Williams *et al,* 2011).
[4] Exposure to a contaminated serving can be defined at any point in the farm-to-table continuum assuming that *P(exp)* is proportional to the percentage of positive units observed at some point prior to consumption (i.e., these measures of occurrence differ by a multiplicative constant). The best data available to FSIS for measuring frequency are from the point of commercial production (e.g., retail-ready raw chicken carcasses).

where $\lambda_{avoided}$ is the estimated annual rate of product-pathogen illnesses avoided following modeled alternative scenarios; λ_{ill} is the current annual rate of product-pathogen illnesses (i.e., illnesses at the baseline); *Prev(scenario)* is the non-HIMP establishments' post-chill prevalence of pathogen-contaminated market hog carcasses estimated from the regression model with FSIS non-HIMP data following implementation of a modeled scenario; and *Prev(baseline)* is the post-chill prevalence of pathogen-contaminated market hog carcasses estimated from the regression model with FSIS data prior to inspection changes[5].

The advantage of this modeling approach is that it avoids the need to estimate an exposure distribution or a dose-response relationship because these relationships are expected, based on previously published and peer-reviewed empirical relationships identified by FSIS risk analysts (Williams *et al*., 2011), not to change between the baseline and scenario pork production and consumption conditions. The prevalence-based risk model employed in this risk assessment applies the previously defined linear relationship to the variety of plausible novel inspection program scenarios to link estimates of changes to contamination prevalence with illness estimates. Effective use of FSIS' database of inspection procedures and sampling outcomes eliminates these components of traditional risk assessment that may be sources of error or broader uncertainty due to biased or inadequate dose-response or consumption data for relevant products and pathogens.

One critical assumption that underlies this model is that dose levels at consumption are independent of the frequency of contamination (in other words, the level of contamination is independent of pathogen prevalence). Put simply, the contamination distribution and the dose-response function drop out of the equation by becoming constant with this assumption. This assumption asserts that the probability of illness given a non-zero exposure to *Salmonella* through a market hog-derived product (*P(ill|exp)*) is constant regardless of changes in any modeled individual's probability of such exposure (*P(exp)*). The reliability of this assumption has been explored previously (Ebel and Williams, 2015). Although it is plausible that pathogen prevalence changes would not be reliable predictors of changes in the likelihood of exposure (for example, in cases where a product class was very heavily contaminated and low prevalence could still

[5] Note that $\lambda_{avoided}$ might be negative if scenario prevalence exceeds baseline prevalence. In such cases, the negative sign would reflect an increase in the number of illnesses.

lead to high cross-contamination rates), FSIS data on market hog contamination and consumption indicate that a prevalence-based model is appropriate. Despite large differences in prevalence between establishments in the baseline study, only small differences in microbial concentration were observed (see the third bullet below). As in the other calculations in this report, volume-weighted percent positive values are used here to approximate prevalence and the terms are used interchangeably.

To validate the assumption of independence between *Salmonella* prevalence and concentration, the following calculations were carried out:

- Data were pulled from the baseline study, which included multiple baseline samples from each establishment.
- For each positive sample, the most probable number (MPN) method for *Salmonella* concentration was applied.
- Out of the 149 establishments in the baseline, 89 had positive *Salmonella* samples and these were divided into high and low percent-positive groups based on whether sampling had been carried out at pre-evisceration (89 establishments) or post-chill (49 establishments) locations along the production line. The difference in concentration of contaminating *Salmonella* was not significant (3 MPN/cm^2 vs. 1 MPN/cm^2 on average; high-positive vs. low-positive establishments with sample collection via carcass sponge, $p = 0.15$). On the other hand, the difference in sample positive rates was significant (67% vs. 20% positive samples, on average; high-positive vs. low-positive establishments, $p < 0.0001$) (analysis of FSIS Market Hog Baseline Data, 2011). This is strong evidence for use of the proportional model.

A similar lack of correlation between contamination levels and contamination prevalence has been observed in other species, particularly notable in the 1995 and 2007 young chicken baseline surveys (FSIS, 1996; FSIS, 2009), as well as other product-pathogen pairs (Crouch *et al*., 2009; Withee *et al*., 2009).

The baseline prevalence is defined as:

$$Prev(baseline) = \sum_{j=1}^{n} w_j \times \frac{e^{\alpha + \beta_1 X_{1j} + \ldots + \beta_i X_{ij} + \ldots + \beta_{22} X_{22j}}}{1 + e^{\alpha + \beta_1 X_{1j} + \ldots + \beta_i X_{ij} + \ldots + \beta_{22} X_{22j}}}$$

where the variable values (X) are drawn from FSIS sampling data, coefficients (β) are estimated via the logistic regression models described above, values of *i* represent each independent predictor, values of *j* represent each individual instance of sampling included in the model, *n* represents the total number of *Salmonella* sampling occasions for the hog carcasses (i.e., n = 7,471 samples including pre-evisceration and post-chill at baseline), and w_j is a fractional weight given to each sampling occasion to reflect the base-10 logarithm of carcasses slaughtered per year as a time-weighted average for each sampled establishment. Because the logistic regression model predicts the probability of an individual sample being positive (given the X_{ij} values for that sample), this equation multiplied by its fractional weight is summed to calculate prevalence across the entire population of samples.

Weights are defined as the logarithm of average daily production volume for plant j (ADP_j) divided by the sum of all establishments' weighting factors, with the formula:

$$w_{ij} = \frac{average\ through\ all\ i\ for\ plant\ j\left(\frac{log10(\ ADP_{ij}}{N_j}\right)}{\sum_{i=1}^{7471}\left(\sum_{j=1}^{164}\left(average\ through\ all\ i\ for\ all\ plant\ j\left(\frac{log10(\ ADP_{ij}}{N_j}\right)\right)\right)}$$

The data set was comprised of daily sampling results from 164 establishments, with each establishment having recorded between two and 190 sampling results. The establishment weights reflect the differing number of days per year each establishment conducts market hog slaughter. Figure 2 depicts the variability production volume for these 164 establishments. The production volume grouping appears to roughly correspond to Very Small, Small, and Large HACCP establishment sizes: one cluster, at the far right of the graph, is comprised of HACCP-Large establishments, while the HACCP-Very Small plants cluster tightly near the x-axis and the HACCP-Small plants cluster parallel to the x-axis but around 50 sampling days (shown with ellipses on the graph).

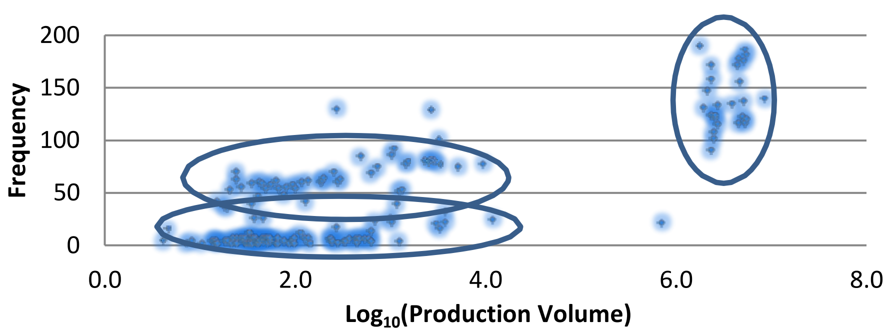


Figure 2: Scatter Plot of 164 Establishments' Daily Averaged Production Volume
Fuzziness of symbols indicates that these are averages and the production volume varies over time.

The modeled prevalence following implementation of a given scenario is:

$$Prev(scenario) = \sum_{j=1}^{164} w_j \times \frac{e^{\alpha+\beta_1 X_{1j}+\cdots+\beta_i X_{ij}+\cdots+\beta_{22}X_{22j}}}{1+e^{\alpha+\beta_1 X_{1j}+\cdots+\beta_i X_{ij}+\cdots+\beta_{22}X_{22j}}}$$

where one or more of the decision variables are adjusted by a factor A_i to account for the change that occurs with modeled scenario implementation. The A_i values are drawn from *Pert* distributions for adjusting each of the four possible decision variables; these distributions describe the expected changes in inspection procedure rates for non-HIMP establishments at post-chill when adopting the proposed new inspection system.

Baseline and scenario prevalence sums are calculated for non-HIMP establishments' post-chill locations, with the two sums differing only in that the scenario sum has each scenario-relevant decision variable multiplied by its respective *Pert* distribution function. In each discriminate scenario sum, the only procedure rate values (*X*) that will be adjusted (multiplied by a change distribution, *A*) will be the values from the decision variable category being modeled as the key predictor. All other *X* values will be set to their respective averages, thus being treated as fixed structural variables for that scenario.

To estimate post-chill prevalence in non-HIMP establishments, the regression model indices for categorical HIMP and sample location are set to "non-HIMP" and "post-chill" when estimating baseline prevalence (*Prev(baseline)*) or scenario prevalence (*Prev(scenario)*). All other independent variable values except the scenario's variable(s) of interest are set to the unadjusted procedure rate average value (*X*).

In this assessment, there are varying levels of uncertainty associated with the following inputs: current annual rate of *Salmonella* foodborne illness (λ_{ill}), baseline prevalence of *Salmonella* on market hog carcasses, scenario prevalence of *Salmonella* on market hogs, adjustment factor (A_i), the fraction of positive foodborne salmonellosis cases attributable to hog-derived products (f_{hog}), and the fraction of hogs that are market hogs ($f_{market\ hog}$). To assess the overall uncertainty about the scenarios' estimated annual rate of illness avoided ($\lambda_{avoided}$), a Monte Carlo model[6] was developed to propagate those sources of uncertainty

[6] All Monte Carlo simulations were performed using Palisade's @Risk 7.0 software add-on in Microsoft Excel. Each simulation comprises 100,000 iterations; this number of iterations produces outputs that change by <0.01% from one simulation to the next indicating the criterion for convergence was met. The advanced sensitivity analysis option in @Risk 7.0 was used for the sensitivity analysis.

onto the estimate. Such a simulation results in a probabilistic conclusion, as it produces a distribution of outcomes with varying likelihoods. The software used also allows for sensitivity analysis, to determine the critical factors and rank the input distribution functions in the model according to the impact they have on the outputs.

Uncertainty about regression coefficients is modeled as multivariate normal:

$$\mathbf{b_{ii}} \sim Normal\ (\boldsymbol{\mu}, \boldsymbol{\Sigma}),$$

where μ is a vector of mean regression coefficients (β), and Σ is the variance-covariance matrix generated from the regression analysis[7].

Uncertainty about the adjustment factor (A_i) is modeled:

$$A_i = Pert \text{ (minimum, most likely, maximum).}$$

Uncertainty about the current annual rate of illness for those consuming market hog products and contracting salmonellosis (λ_{ill}) is modeled as the product of three independent uncertainty distributions:

$$\lambda_{ill} = lognormal\ (\mathbf{m}, \mathbf{s})\ x\ f_{hog}\ x\ f_{market\ hog}$$

or,

$$\lambda_{ill} = lognormal\ (\mathbf{m}, \mathbf{s})\ x\ Pert(0.036, 0.063, 0.114)\ \text{x}\ Pert(0.930, 0.970, 0.980)$$

The values for the ***m*** and ***s*** are the mean and standard deviation taken from Table 6. The *Pert* distributions are written as in @Risk. Because $\lambda_{avoided}$ is a function of the scenario prevalence-to-baseline prevalence ratio and these values can be reasonably assumed to be correlated for each iteration, these simulations paired the estimates of the scenario and baseline prevalence values and as such were run in parallel. This way, both prevalence estimates contributing to a single ratio would be based on the regression coefficient plus the same margin of uncertainty. In other words, the same random error distributions were applied in generating the varying regression coefficients for each model iteration. This procedure ensures that each simulation is internally consistent, reflecting that scenario prevalence is not independent of baseline prevalence in reality.

Attribution

Attribution of foodborne illnesses to certain organisms and product types (Table 6) was carried out by combining information from multiple authoritative sources and FSIS analyses (Scallan *et al.,* 2011; Painter, *et al.*, 2013; FSIS Swine Slaughter Data, 2010-15).

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[7] Random values for this multivariate normal distribution are generated using the Cholesky decomposition method (Press *et al.* 2007).

For the purposes of this assessment, the proportion of salmonellosis cases attributed to market hogs is estimated by multiplying the estimated number of all domestic foodborne salmonellosis illnesses by the proportions of all *Salmonella* in pork illnesses, and the proportion of market hogs with respect to the total number of hogs slaughtered. The distribution of salmonellosis cases was assumed to be the same within the subpopulation of market hog-attributable cases as in the population of cases overall, though FSIS recognizes that illnesses attributable to contaminated roaster- or sow-derived pork meat cannot be distinguished from those attributable to market hog-derived pork meat through current outbreak investigation procedures.

Generating estimates of total non-typhoidal domestic foodborne salmonellosis illnesses from market hogs is a more complex process than multiplying three component estimates. These estimated values for mean and confidence interval are calculated using a complex Bayesian model composed of 15 multiplicative uncertainty distributions. The multiplicative chain begins with laboratory confirmed cases with known analysis sensitivity which are rescaled using individual *Pert* distributions (missing values estimated as missing at random) for individual illness severity, underdiagnoses, underreporting, medical care seeking, non-travel relatedness, stool sample uncertainty, and non-foodborne relatedness all adjusted for FoodNet surveillance capture adjusted to the 2006 US Census population estimates (Scallan, 2011; TechApp2, TechApp3).

CDC describes these values as conservative and robust estimates due to the multiplicative modeling. This model estimate of total illness uncertainty is believed to incorporate multiple unmeasured sources contributing to the overall mean and credibility interval cited by CDC such as consumer behavior, *Salmonella* death, growth, product cross contamination in transport and storage and other unmeasured variability in the risk model. Any uncertainty in the number of infectious *Salmonella* requiring a dose-response component is modeled as constant due to the observed lack of correlation between MPN counts and prevalence and the statistically insignificant difference in average MPN counts and prevalence.

Table 6 outlines the baseline numbers of human *Salmonella* illnesses due to market hog consumption. Further details about how these values and their parameters were calculated can be found in Appendix G.

Modeling Multiple Alternative Scenarios

One objective of this risk assessment is to understand the implications of various modernization scenarios designed to reduce market hog carcass *Salmonella* prevalence. Baseline prevalence values were calculated assuming that the data gathered from plants and used in the regression model is generally representative of large, small, and very small market hog slaughter plants operating under standard HACCP protocols. For the modernized scenarios, the values for each decision variable are expected to change as described below with implementation of the new inspection system.

FSIS inspection records in HIMP establishments are expected to closely resemble the inspection procedure records that would be generated with the proposed change to a modernized inspection approach adjusted for establishment size. As described in the Market Hog HIMP Report, 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 — noting that the HIMP establishment sizes were all large and were compared to only large non-HIMP establishments for this comparison. This translates to approximately 1.5 times as many offline verification procedures and 3.2 times as many HACCP verification procedures carried out in HIMP as in non-HIMP establishments. However, these five HIMP establishments are not perfect predictors of future performance once a similar modernization program is in place in additional establishments. Though we expect that implementation of a modernized inspection system in non-HIMP establishments would result in procedure rates and contamination rates similar to those observed in HIMP establishments adjusted for size during the 2010-11 study, this assessment can only make estimates that may vary due to unforeseen circumstances or industry-level changes. In order to have the best understanding of multiple possible outcomes following implementation, uncertainty analysis has been carried out and described in this report. These results are shown in Appendix G and form a basis for baseline and scenario analysis of non-HIMP post-chill performance (N= 661,457 observations).

To generate the parameters of the *Pert* distributions applied in each change scenario, the HIMP establishment observations were combined with some assumptions about extremes of inspection performance. Using this data and comparing with the poultry slaughter risk assessment data (FSIS 2014), it was assumed that a most likely value of a 25% increase in SP and U procedures should be applied in our modeled scenarios. This assumption also was employed in the FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection (2014) based on the possible increase in inspection procedures across all establishments based on in-plant inspector experience. Analysis of HIMP and non-HIMP establishments for the entire year of 2010 does not contradict this assumption (see Appendix B, Table B 11 for further detail).

Scheduled and performed (SP) and unscheduled procedures (U) in an establishment could increase, decrease, or stay the same once an establishment adopts the inspection system in the proposed change. By increasing availability of inspectors to perform offline tasks, the modernized system should produce similar changes in SP and U procedure rates, and so the same *Pert* distribution function will be applied for both SP and U decision variables. It is plausible that SP and U procedures may decrease in frequency below that observed in the current dataset of non-HIMP establishments, even though a substantial number of plants in this group already record zero procedures on many production days (Table 8).

The model for a modernized inspection system should include the possibility that more establishments may record zero SP or U procedures than do so under the HIMP system as currently implemented. Therefore, because unforeseen circumstances may increase the number of establishments recording zero procedures relative to the current observed baseline in the dataset available, a *Pert* distribution for both SP and U decision variables requires a lower limit of zero as a worst-case scenario minimum. The upper limit, increasing procedures by 50% in either category, seems plausible in the context of previous risk assessments evaluating slaughter inspection systems, as well as the HIMP plants observed maximum procedure rates. SP and U distributions were thus modeled:

Ai *(SP and U) = Pert (0.0, 1.25, 1.5).*

Table 8: Frequency of "No Procedures Recorded" in Decision Variable Categories (HIMP and non-HIMP Data; n = 29,884[a])

Criterion	SP	SNP	U	NR
Total Number "NPR"	39	4,747	253	6,014
non-HIMP Number "NPR"	37	4,342	253	5,506
non-HIMP Percent "NPR"	0.50	58.12	3.39	73.70
HIMP Number "NPR"	2	405	0	507
HIMP Percent "NPR"	0.03	5.42	0	6.79
Total Number not "NPR"	7,432	2,724	7,218	1,457
Total Percent "NPR"	0.52	63.54	3.39	80.50

[a] 7,471 total sample records x 4 decision variables per record = 29,884 cells interrogated for this table.
Abbreviations: SP, scheduled performed; SNP, scheduled not performed; U, unscheduled; NR, noncompliance record; NPR, no procedures recorded.

Scheduled but not performed procedures would most likely decline under the proposed inspection system, as SNP procedures are generally due to insufficient personnel availability to complete the assigned offline procedure. Because the proposed inspection system may result in a decrease in the number of SNP procedures due to inspectors' increased availability, the baseline value for SNP procedures is assumed to be the maximum expected rate. A 50% decrease was estimated as the most likely result of implementing a modernized inspection system, and the lower limit of possible observations was considered to be 0% or complete prevention of any SNP procedures. Therefore, the distribution for the SNP decision variable was modeled:

$$A_{SNP} = Pert\ (0.0,\ 0.5,\ 1.0).$$

Hypothetical scenarios for noncompliance records were evaluated but not considered to be useful in the final model analysis. These variables were considered as valuable establishment control variables in the final model. These scenarios were developed using data from the five HIMP establishments to model how noncompliance records might change in establishments under different inspection scenarios (FSIS, 2011a). On average, HIMP market hog establishments demonstrate 10% more reported PHR noncompliances than do non-HIMP market hog establishments. However, in the 2006-2010 timeframe, 20% more W3NR noncompliances were observed in HIMP as opposed to non-HIMP establishments. From 2012 through 2013, HIMP establishments demonstrated 1.44 times fewer PHR noncompliances than non-HIMP establishments. It remains possible that under the modeled scenario those noncompliance records (NRs) may be eliminated completely or may not change at all. For a conservative noncompliance estimate, a most-likely value for change in NR rates at HIMP establishments was defined as 50% of the rates observed in non-HIMP establishments. The NR uncertainty with a maximum was estimated to be 120% and the minimum, 0%. Thus, the NR decision variable was modeled:

$$A_{NR} = Pert\ (0.0,\ 0.5,\ 1.2).$$

Implementation Scenarios

To predict how annual human salmonellosis rates might change considering that HIMP establishment performance would not change following implementation of the proposed change, it is assumed that the four possible decision variables would all change in non-HIMP establishments adopting NSIS according to the assumptions outlined above. Those adjustment distributions were then applied to create six different implementation scenarios considered to be most informative—four in which the frequency of each grouping of inspection procedures was individually modified by each respective A_i, one in which three groupings were modified simultaneously by their respective A_i distributions, and one in which all four groupings were modified simultaneously using all the A_i distributions (Table 7). It should be noted that the model correlation submatrix was applied to the uncertainty distributions used for indiscriminate scenarios' decision variables allowing for them to have defined correlations. This correlation matrix was estimated from the observed frequencies of the input data.

Once these adjustment distributions have been applied to the non-HIMP establishment procedure rates, the post-chill *Salmonella* prevalence values predicted through that model were used to calculate a number of illnesses avoided. The percent reduction in prevalence, as a proportion, was multiplied by the total number of illnesses attributed to market hog-derived *Salmonella* exposure.

RESULTS

Regression Analysis Output

Table 9 presents the results of the regression analysis for the four potential decision variable categories of inspection activities (SP, SNP, U, and NR) for *Salmonella* positive market hog samples. This analysis evaluates the correlation between each of those inspection activities and product contamination. These results indicate that with each unit increase in SP and U procedures performed, *Salmonella* prevalence is estimated to decrease. In addition, each unit decrease in SNP and NR procedures is estimated to decrease the prevalence of *Salmonella* positive samples in that same plant. Note that the model predicts that increased prevalence is associated with increased NR rate. All coefficient estimates are significant, indicating that the associated variables are significant contributors to explaining the observed variance in prevalence, though the magnitude of each effect varies. All regression coefficients are significant at the 99.9% confidence level.

Table 9: Stage 1 Regression Analysis Results for Potential Decision Variable Estimates of Coefficients

Variable	DF	Coefficient Estimate (β)	Coeff Standard Error	Coeff Wald ChiSq	p-value	Standardized Coefficient	Variable Mean (X)	Variable Standard Deviation
SP	1	-0.0079	0.0035	5.1672	0.0230	-0.2131	4.3344	19.4329
SNP	1	0.0207	0.0102	4.0913	0.0431	0.0809	0.4101	2.932
U	1	-0.0110	0.0057	3.6384	0.0565	-0.1491	1.4386	9.882
NR	1	0.0978	0.0148	43.4050	<.0001	0.2676	0.1404	1.943

n = 7,471 sample results and independent variable records
Abbreviations: Coeff, Coefficient; DF, degrees of freedom; NR = observation and reporting by inspectors of a noncompliance record; SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.
Source: FSIS analysis of Agency-generated data

The SNP regression coefficient, representing the change in *Salmonella* prevalence expected from a change in the number of scheduled and not performed procedures, is positive and second greatest in magnitude than any of the other decision variables' regression coefficients ($\beta_{SNP} = 0.0207$, $p = 0.0017$, all results shown in Table 9). In contrast, the regression coefficients for the SP and U decision variables were negative and statistically significant, suggesting that increasing the number of any of these procedures performed also could decrease *Salmonella* prevalence in market hogs.

Increasing SP procedures is a logical consequence of decreasing SNP procedures, though not mathematically equivalent without holding the total number of procedures constant ($\beta_{SP} = -0.0079$, $p = 0.0004$). Increasing the number of U procedures also is logically connected with a decrease in *Salmonella* prevalence, as the knowledge that more unscheduled procedures will occur offline will likely motivate establishment operators to improve process control to avoid production slowdowns ($\beta_{U} = -0.0110$, $p = 0.0030$).

The NR variable has the largest regression coefficient which indicates that it has the strongest correlation with observed *Salmonella* prevalence. However, because controlling the NR rate in establishments simply by reallocating FSIS inspection resources to offline activities is not feasible, the NR variable is considered only as a theoretical examination. Unlike the other three categories of inspection activities, which are indications of inspector performance, NR captures the results of the inspection task; that is, whether the establishment is compliant or non-compliant with FSIS regulations. NRs are not only a function of how frequently FSIS conducts inspection tasks but also indicate the effectiveness of the establishment's food safety practices, as well as other characteristics such as inspector behavior. These other characteristics are idiosyncratic and not directly captured in the model, but likely contribute to the uncertainty around observed NR rates. Decreasing the number of NRs, according to the regression analysis, is associated with reduced *Salmonella* prevalence ($\beta_{NR} = 0.0978$, $p < 0.0001$) as a result of a higher number of inspections targeting food safety procedures.

Recommending a decrease in procedures that may result in NRs is not a practical solution to the problem of positive carcass sampling and may only occur when an establishment has achieved process control (it can be assumed that the sample data were mostly from establishments in process control). Such a decrease could be caused after increased inspector vigilance discovering decreased process control and resulting in initially more NRs followed by a decrease due to slaughter establishment's regaining process control indicated by fewer positive *Salmonella* samples. Also to be considered is the likelihood of the number of NRs increasing. This possibility was captured in the modeled *Pert* distribution that set its upper limit to 20% above baseline even though process control would be most likely with a 50% reduction from baseline. Half of the 100,000 iterations in this case were below the median of 0.52 and half were above.

While the regression coefficients indicate the strength and direction of the variable's relationship with *Salmonella* prevalence, the products of each decision variable regression coefficient times its mean indicates the estimated impact on the

Salmonella percent positives. These products are: SP (-0.03424); SNP (0.0085); U (-0.0158); NR (0.0137). The SP variable has the largest product of coefficient times its mean; therefore, it has more impact on the percent positive *Salmonella* expectation than the other variables for the same unit average effect. The order of importance for all decision variables is SP>U>NR>SNP according to the coefficient-mean product.

Estimated Annual Changes in Salmonella Prevalence in Market Hog Establishments and Concomitant Changes in Human Illness

The estimated changes in *Salmonella* prevalence are summarized in Table 10, and the estimated changes in procedure rates in market hog establishments are summarized in Table 11. Among the feasible implementation scenarios, the indiscriminate scenario (SP+SNP+U) —which was designed to represent HIMP-like inspection procedure rates – produced the greatest feasible estimates for prevalence reduction (a mean of 7.08% fewer *Salmonella* positives is estimated with implementation of this scenario for all market hog establishments and a mean of 3.63% for the 35 large and small market hog establishments). Table 12 and Table 13 summarize the estimated changes in human illnesses for the different scenarios assuming all market hog establishments or the 35 large and small market hog establishments participate, respectively. Table 14 summarizes the estimated change in human illness for the 35 establishment subsample using a larger sample size to better estimate the uncertainty distributions for each scenario. In Table 10, the estimated number of illnesses prevented was highest with the infeasible indiscriminate (SP+SNP+U+NR) scenario; 7,327 fewer market hog-associated salmonellosis cases would be estimated, based on the mean (expected value) of the simulated uncertainty distribution. Under the feasible indiscriminate (SP+SNP+ U) scenario for all market hog establishments, an estimated 4,944 fewer illness would be expected. The discriminate scenarios which have single variable means changing produced estimates of expected illness reductions ranging from 1,277 (U) to 2,383 (NR) illnesses prevented. If the 35 large and small market hog establishments participate, the infeasible indiscriminate scenario (SP+SNP+U+NR) estimates an expected decrease of 6,426 illnesses. Ninety percent (90%) credibility intervals are provided in the tables. If SP, SNP, and U are modified to be similar to HIMP establishments, an estimated mean 2,533 illness could be avoided; and the discriminate scenarios which have single variables changing produced mean estimates ranging from 506 (U) to 3,893 (NR) illnesses.

Table 10: Estimates of Average *Salmonella* Prevalence Change

Scenario	Salmonella Prevalence (%)	Reduction Cases	Change (%)	Reduction 5%ile	Reduction 95%ile	Reduction 10%ile	Reduction 90%ile
159 Large, Small, and Very Small Market Hog Establishments							
Baseline	2.0127	69,857	--	--	--	--	--
Disc(SP)	1.9651	1,651	2.3634	-1.407	5.4920	-0.3640	4.7870
Disc(SNP)	1.9546	2,016	2.8859	2.0710	4.0835	2.1842	3.7257
Disc(U)	1.9759	1,277	1.8280	-0.7900	4.0080	-0.0586	3.5150
Disc(NR)	1.9440	2,383	3.4113	2.1689	5.1973	2.3523	4.6687
SP+U	1.9283	2,928	4.1914	-1.0910	8.8590	0.3760	7.7480
SNP+U	1.9178	3,293	4.7139	1.9370	7.2070	2.6830	6.6270
SP+U+NR	1.8596	5,311	7.6027	2.4330	13.2470	3.6850	11.7420
SP+SNP+U	1.8702	4,944	7.0773	2.1200	11.9620	3.4160	10.7090
SP+SNP+U+NR	1.8016	7,327	10.4886	5.4450	16.4880	6.5540	14.8260
SP+SNP	1.9070	3,667	5.2493	1.771	8.628	2.671	7.778
35 Large and Small Market Hog Establishments (Version 1)							
Baseline	0.0094	69,857	--	--	--	--	--
Disc(SP)	0.0093	770	1.1023	-5.3770	6.3900	-3.4940	5.2070
Disc(SNP)	0.0092	1,257	1.7994	0.6581	3.4755	0.8211	2.9758
Disc(U)	0.0093	506	0.7243	-3.3790	4.1140	-2.2150	3.3640
Disc(NR)	0.0089	3,893	5.5728	2.8650	9.4400	3.2700	8.3020
SP+U	0.0092	1,276	1.8266	-6.9300	9.5050	-4.4860	7.6820
SNP+U	0.0092	1,763	2.5237	-1.3850	6.5560	-0.4220	5.4960
SP+U+NR	0.0087	5,169	7.4010	-1.2510	17.2870	0.7520	14.5670
SP+SNP+U	0.0091	2,533	3.6260	-4.6590	11.5970	-2.4610	9.5700
SP+SNP+U+NR	0.0085	6,426	9.1988	0.6940	19.6110	2.4800	16.6680
SP+SNP	0.0091	2,027	2.9016	-3.0730	8.5220	-1.4800	7.1160
35 Large and Small Market Hog Establishments (Version 2)							
Baseline	0.0094	69,857	--	--	--	--	--
Disc(SP)	0.0093	770	1.1023	-1.4850	3.2730	-0.7770	2.7820
Disc(SNP)	0.0092	1,257	1.7994	1.2644	2.5861	1.3384	2.3517
Disc(U)	0.0093	506	0.7243	-1.0790	2.2380	-0.5790	1.8950
Disc(NR)	0.0089	3,893	5.5728	4.7244	6.7934	4.8491	6.4312
SP+U	0.0092	1,276	1.8266	-1.8060	5.0610	-0.8020	4.2900
SNP+U	0.0092	1,763	2.5237	0.8000	4.3410	1.2180	3.8640
SP+U+NR	0.0087	5,169	7.3994	3.8450	11.3040	4.6990	10.2600
SP+SNP+U	0.0091	2,533	3.6260	0.2100	7.0020	1.0990	6.1360
SP+SNP+U+NR	0.0085	6,426	9.1988	5.7310	13.3260	6.4890	12.1880
SP+SNP	0.0091	2,027	2.9016	0.5120	5.2310	1.1240	4.6450

Abbreviations: NR, observation and reporting by inspectors of a noncompliance record; SNP, scheduled not performed procedures; SP, scheduled and performed procedures; U, unscheduled procedures performed.
Source: FSIS analysis of Agency generated data, post-chill sampling points. Summary statistics derived using Monte Carlo simulation for ten scenarios.

Table 11: Procedure Rates for Baseline and Estimates with Application of Scenarios

Scenarios	Total Procedures	Total Procedure Percentiles (5%, 95%)	Change from Baseline (%)	Change from Baseline Percentiles (5%, 95%)	Procedure No. at Baseline
Baseline	165,506	--	--	--	165,506
Disc(SP)	139,031	(124,941, 153,121)	25	(12.3, 37.7)	111,225
Disc(SNP)	4,544	(2,241, 6,846)	-50	(-75.3, -24.7)	9,088
Disc(U)	50,857	(45,703, 56.011)	25	(12.3, 37.7)	40,686
Disc(SP+SNP+U)	194,432	167283, 205,709	21	(6.5,57.0)	160,999
SP+SNP+U+NR	196,836	(124,440, 278,695)	18.93	(7.8, 30.1)	165,506

Abbreviations: NR = observation and reporting by inspectors of a noncompliance record; SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.
Source: FSIS analysis of Agency generated data, including pre-evisceration and post-chill sampling points.
Summary statistics derived using Monte Carlo simulations of the five scenarios.

Table 12: Estimated Illness Reduction Scenario Uncertainty - 159 Establishments (5,046 Sample Days)[a]

Statistic	SP	SNP	U	NR	SP+U	SNP+U	SP+U+NR	SP+SNP+U	SP+SNP+U+NR	SP+SNP
Mean	1,651	2,016	1,277	2,383	2,928	3,293	5,311	4,944	7,327	3,667
Standard Deviation	1,868	792	1,349	884	2,858	1,471	3,096	2,745	3,172	1,951
Mode	2,160	1,795	1,626	2,044	3,276	3,203	5,187	4,992	6,835	3,955
5th Percentile	-983	1,447	-552	1,515	-762	1,544	1,699	1,481	3,804	1,237
10 th Percentile	-254 (ok)	1,526	-41	1,643	-263	1,969	2,574	2,386	4,578	1,866
50 th Percentile	1,795	1,937	1,375	2,272	3,067	3,264	5,210	4,970	7,127	3,687
90 th Percentile	3,344	2,603	2,456	3,261	5,413	4,660	8,202	7,481	10,357	5,434
95 th Percentile	3,836	2,853	2,800	3,631	6,188	5,147	9,254	8,357	11,518	6,027
Probability of Increased Illnesses[b]	15.30%	<0.01%	13.30%	<0.01%	10.30%	3.60%	4.40%	3.80%	1.4%	3.00%

[a]This table describes human illness-avoided estimates ($\lambda_{avoided}$) resulting from scenario HIMP inspection procedure rates applied to non-HIMP market hog carcass *Salmonella* contamination rates at post-chill using a sample size of 6,684 for prediction.

[b]This percentage represents the probability that an increase in illness of any size, even one illness, will occur. In other words, it is the likelihood that the decrease in illnesses will be negative.

Abbreviations: NR = observation and reporting by inspectors of a noncompliance record; SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.

Source: FSIS analysis of Agency generated data (2010-2011).

Table 13: Estimated Illness Reduction Scenario Uncertainty - 35 Selected Establishments - Version 1 (2,330 Sample Days) [a]

Statistic	SP	SNP	U	NR	SP+U	SNP+U	SP+U+NR	SP+SNP+U	SP+SNP+U+NR	SP+SNP
Mean	770	1,257	506	3,893	1,276	1,763	5,169	2,533	6,426	2,027
Standard Deviation	3,945	1,032	2,511	2,572	6,330	3,037	7,121	3,801	7,308	4,435
Mode	1,430	896	1,971	3,125	1,630	1,830	5,043	3,801	5,358	2,186
5th Percentile	-3,757	460	-2,361	2,001	-4,842	-968	-875	-3,255	484	-2,147
10 th Percentile	-2,441	574	-1,547	2,284	-3,134	-295	525	-1,719	1,732	-1,034
50 th Percentile	1,030	1,147	661	3,654	1,518	1,737	4,911	2,607	6,038	2,108
90 th Percentile	3,637	2,079	2,350	5,799	5,366	3,839	10,176	6,685	11,643	4,971
95 th Percentile	4,464	2,428	2,873	6,594	6,640	4,580	12,075	8,102	13,699	5,954
Probability of Increased Illnesses[b]	36.80%	1.30%	34.70%	1.50%	33.50%	15.60%	9.30%	20.90%	6.20%	22.00%

[a]This table describes human illness-avoided estimates ($\lambda_{avoided}$) resulting from scenario HIMP inspection procedure rates applied to non-HIMP market hog carcass *Salmonella* contamination rates at post-chill using a sample size of 2,330 for prediction.

[b]This percentage represents the probability that an increase in illness of any size, even one illness, will occur. In other words, it is the likelihood that the decrease in illnesses will be negative.

Abbreviations: NR = observation and reporting by inspectors of a noncompliance record; SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.

(Version 1) Means that the model has been run in this case using 2,330 sample days

Source: FSIS analysis of Agency generated data (2010-2011).

Table 14: Estimated Illness Reduction Scenario Uncertainty-35 Selected Establishments - Version 2 (22,631 Sample Days)[a]

Statistic	SP	SNP	U	NR	SP+U	SNP+U	SP+U+NR	SP+SNP+U	SP+SNP+U+NR	SP+SNP
Mean	770	1,257	506	3,893	1,276	1,763	5,169	2,533	6,426	2,027
Standard Deviation	1,064	585	770	454	1,482	759	1,605	1,698	1,641	1,010
Mode	1,052	1,055	760	3,721	1,510	1,753	5,188	2,879	5,980	2,138
5th Percentile	-1,037	883	-754	3,300	-1,262	559	2,686	147	4,003	357
10 th Percentile	-543	935	-404	3,387	-560	851	3,283	768	4,533	785
50 th Percentile	864	1,205	571	3,818	1,366	1,745	5,096	2,549	6,288	2,040
90 th Percentile	1,944	1,643	1,324	4,493	2,997	2,700	7,168	4,287	8,514	3,245
95 th Percentile	2,286	1,807	1,563	4,746	3,535	3,032	7,897	4,892	9,309	3,654
Probability of Increased Illnesses[b]	19.5%	<0.01%	20.5%	<0.01%	16.8%	1.40%	2.90%	4.0%	1.8%	2.70%

[a]This table describes human illness-avoided estimates ($\lambda_{avoided}$) resulting from scenario HIMP inspection procedure rates applied to non-HIMP market hog carcass *Salmonella* contamination rates at post-chill using a sample size of 22,631 for prediction.

[b]This percentage represents the probability that an increase in illness of any size, even one illness, will occur. In other words, it is the likelihood that the decrease in illnesses will be negative.

Abbreviations: NR = observation and reporting by inspectors of a noncompliance record; SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.

(Version 2) means that the model has been run in this case using 23,631 sample days.

Source: FSIS analysis of Agency generated data (2010-2011).

With implementation of the indiscriminate scenario (SP+SNP+U+NR), FSIS inspectors in market hog establishments are predicted to carry out up to 196,836 inspection procedures per year, which is an increase of 18.93% over baseline. On average, total category-specific procedures were predicted to increase from a baseline of 111,225 to 139,031 with application of the scenario Disc(SP); increase from 40,686 to 50,857 with application of Disc(U); and decrease from 9,088 to 4,544 with application of Disc(SNP). The mean, 5th percentile, and 95th percentile values from the modeled distribution are provided in Table 11 for all estimates.

Table 12 and Table 13 show the estimated mean, standard deviation, mode, and the 5/10th and 90/95th percentile values for illnesses avoided, as well as the approximate likelihood of an increase in illnesses, with implementation of the six scenarios, where *Salmonella* percent positive reductions at post-chill would result in changes to the illness rate in consumers eating market hog products. Table 12 shows estimates assuming that all market hog establishments participate; Table 13 shows estimates produced from model Version 1, based on 2,330 sample days and assuming the 35 large and small market hog establishments participate. Table 14 also depicts a scenario in which 35 large and small market hog establishments participate, but incorporates inspection procedure data from days when no *Salmonella* samples were drawn—thus including data from 22,631 sample days. This method increases the amount of information about each establishment that is incorporated in the simulation; however, it does not account for all the uncertainty associated with imputing the missing *Salmonella* sample data. Therefore, it understates the uncertainty around the predicted means to some degree, as suggested by previous comments.

The likelihood of illnesses increasing with the inspection system change was estimated from the uncertainty distributions generated in @Risk. The Monte Carlo simulation results reflect the aggregate estimated change in total illnesses across the market hog slaughter establishments. To estimate this aggregate value, the $\lambda_{avoided}$ values for the market hog *Salmonella* model were summed for each iteration of a Monte Carlo simulation.

The results of this assessment for all market hog establishments (Table 12) and for 35 large and small market hog establishments (Table 13 and Table 14) indicate that a decrease in illnesses is more likely to occur than an increase under all implementation scenarios considered. Based on the mean (expected) value of the simulated uncertainty distribution, each scenario is expected to result in at least some amount of illness reduction. The estimated decrease in illnesses under the most feasible SP+SNP+U scenario using a sample size of 22,631 (model Version 2) is expected to be 2,533 (90% CI: 768- 4,287), with a probability of decreasing illnesses of approximately 96%. The estimated decrease in illnesses under the most feasible SP+SNP+U scenario using the empirical data with a sample size of 2,330 (model Version 1) is expected to be 2,533 (90% CI: −1,719 - 6,685) with a probability of decreasing illnesses of approximately 80.0%.

Sensitivity Analysis

This sensitivity analysis examined how the final model output ($\lambda_{avoided}$) is influenced by changes in the model inputs. First, the analysis examined the relative influence of the main stochastic inputs on the final multicomponent uncertainty distribution for illnesses avoided when evaluated as the only changing variables in the SP+SNP+U model. This involved analyzing the sensitivity of the output to changing just one of the stochastic inputs while holding the others constant at their mean value. Second, the analysis examined the sensitivity of the partial derivative of $\lambda_{avoided}$ versus stochastic input values for insight about the effect of alternative input values. The sensitivity analysis is derived from @Risk 7.0 advanced sensitivity analysis.

Figure 3 through Figure 5 show the cumulative percentile distributions, describing the range of values obtained for illnesses avoided with implementation of the three single-adjustment discriminate scenarios under the 35 plant NSIS adoption scenario. It is important to note that the spread of the cumulative percentile distributions is related to the contributions of each variable to the uncertainty in the resulting numbers of salmonellosis cases avoided. The spread is widest for Disc(SP) and narrowest for Disc(SNP). The spread for Disc(U) is intermediate.

Figure 6 depicts the contribution of the SP, U, and SNP inspection procedure category variables to the estimated output about the reduction in salmonellosis cases in the SP+SNP+U scenario. This figure is a spider graph based on the percentiles of each distribution and is centered at the mean of each percentile distribution. The slopes indicate which variable contributes the most change in output for unit change in input and least to the estimated output about illness reduction. It can be seen that the SP variable has the most contribution to output about illness reduction while the SNP variable has the least contribution to the output. Also, the U variable has less of a contribution than the SP variable but more of a contribution than the SNP variable.

Figure 7 depicts a tornado graph in which the bar sizes are indicative of variable contribution to the output in the SP+SNP+U scenario illnesses avoided estimate. The horizontal axis shows the number of illnesses avoided according to the breadth of the three tornado layers. The greatest contribution to output is from the SP variable with the widest breadth (highest on the graph) and the least contribution is from the SNP variable with the narrowest breadth (lowest on the graph). The contribution from the U variable is intermediate.

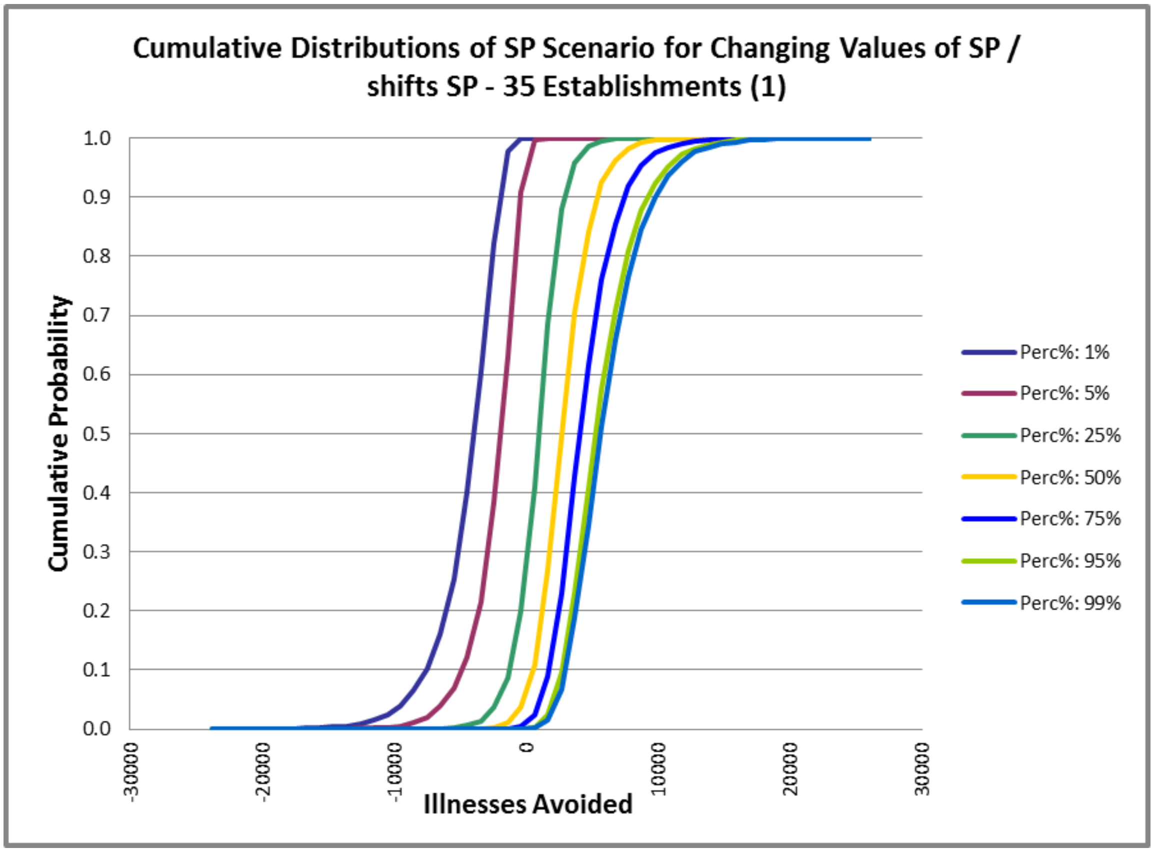

Figure 3: Cumulative Percentile Distributions for Disc(SP) λavoided Sensitivity Analysis (Version 1)[a]

Estimated change in the annual *Salmonella* human illness rate when offline SP inspection procedures are increased in 35 large and small non-HIMP market hog establishments with sample size 2,330**.** Figure depicts the discriminate SP scenario that increased scheduled and performed procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: SP = scheduled and performed procedures.

Source: FSIS analysis of Agency generated data (2010-2011).

[a]In Version 1, the model has been run in this case using 2,330 sample days.

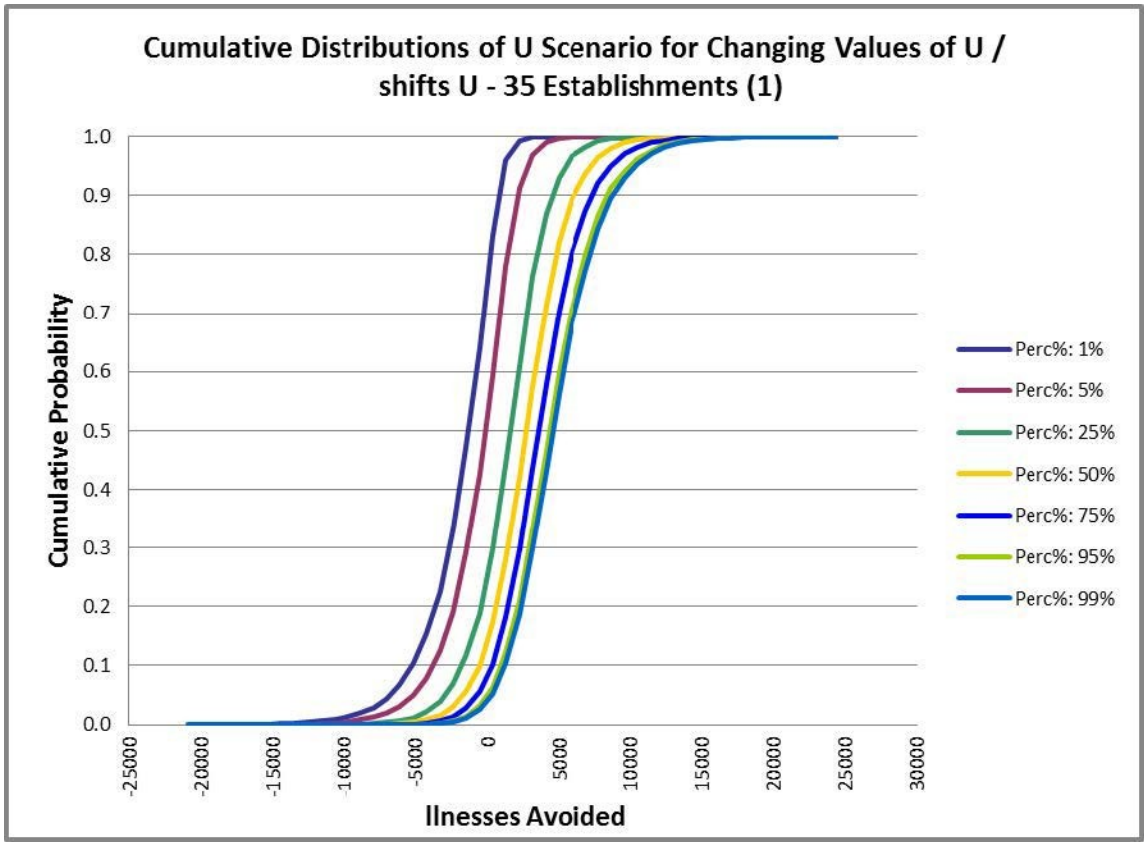

Figure 4: Cumulative Percentile Distributions for Disc(U) λavoided Sensitivity Analysis (Version 1)[a]

Estimated change in the annual *Salmonella* human illness rate when offline U inspection procedures are increased in 35 large and small non-HIMP market hog establishments with sample size 2,330**.** Figure depicts the discriminate U scenario that increased unscheduled procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: U = unscheduled procedures performed.

Source: FSIS analysis of Agency generated data (2010-2011).

[a]In Version 1, the model has been run in this case using 2,330 sample days.

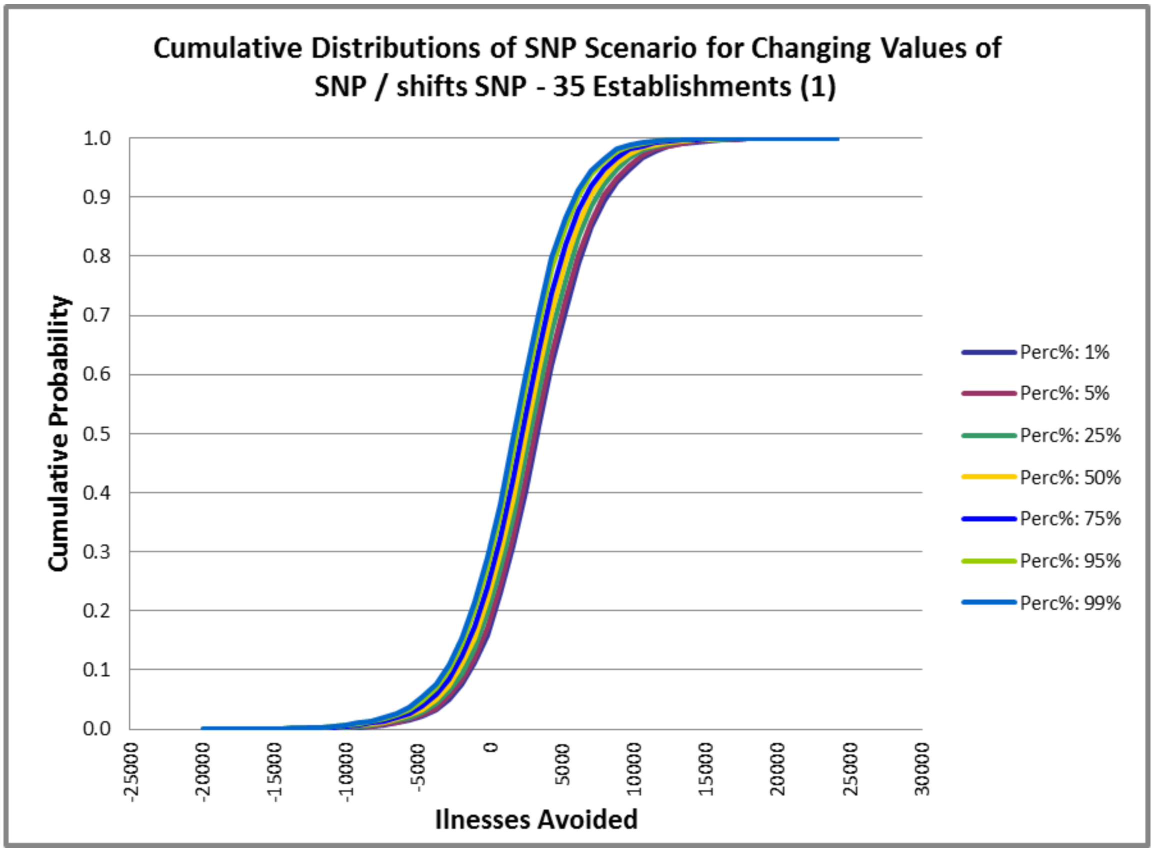

Figure 5: Cumulative Percentile Distributions for Disc(SNP) λavoided Sensitivity Analysis (Version 1)[a]

Estimated change in the annual *Salmonella* human illness rate when offline SNP inspection procedures are decreased in 35 large and small non-HIMP market hog establishments with sample size 2,330**.** Figure depicts the discriminate SNP scenario that decreased scheduled but not performed procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: SNP = scheduled not performed procedures.

Source: FSIS analysis of Agency generated data (2010-2011).

[a]In Version 1, the model has been run in this case using 2,330 sample days.

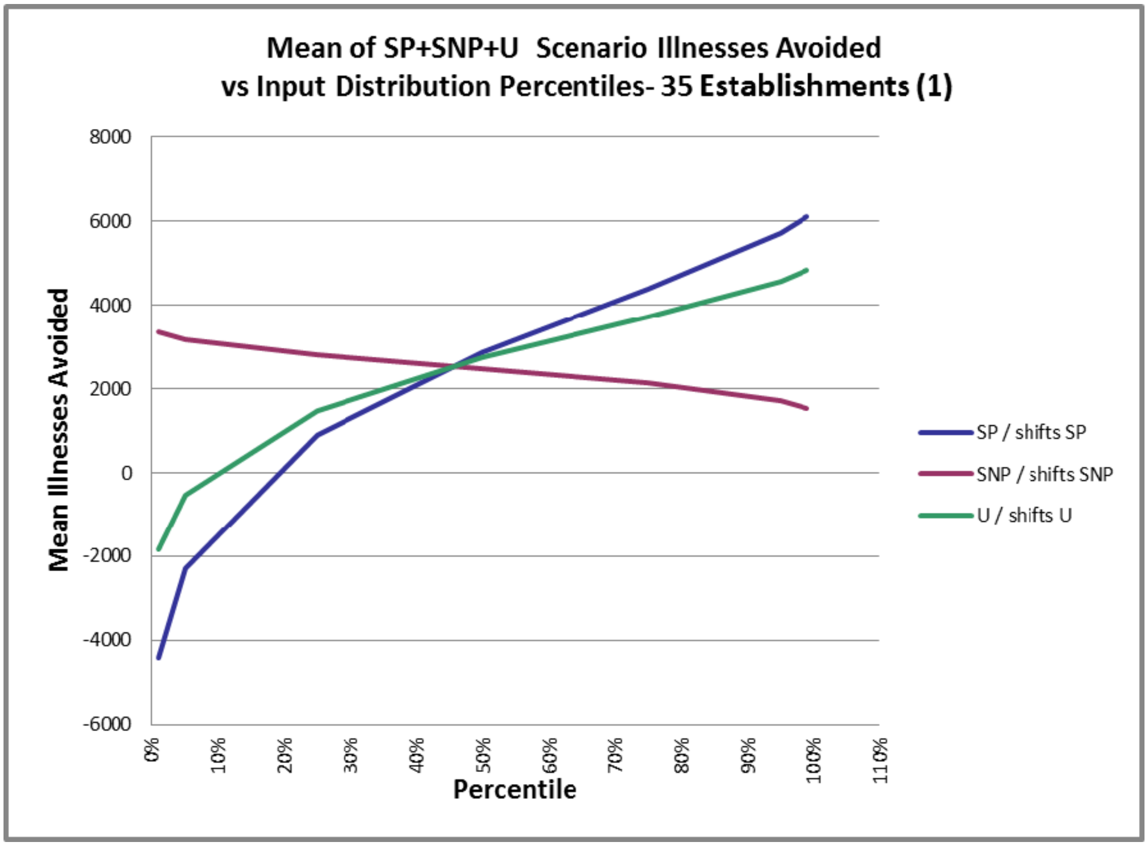

Figure 6: Percentiles of Indiscriminate Scenario in 35 Large and Small Establishments Illnesses Avoided (λavoided) vs. Input Decision Variable Distribution Percentiles (SP, SNP, and U) (Version 1)[a]

Estimated change in the annual *Salmonella* human illness rate when offline SP and U inspection procedures are increased and SNP procedures are decreased with sample size 2,330.

Abbreviations: SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.

Source: FSIS analysis of Agency generated data (2010=2011).

[a]In Version 1, the model has been run in this case using 2,330 sample days.

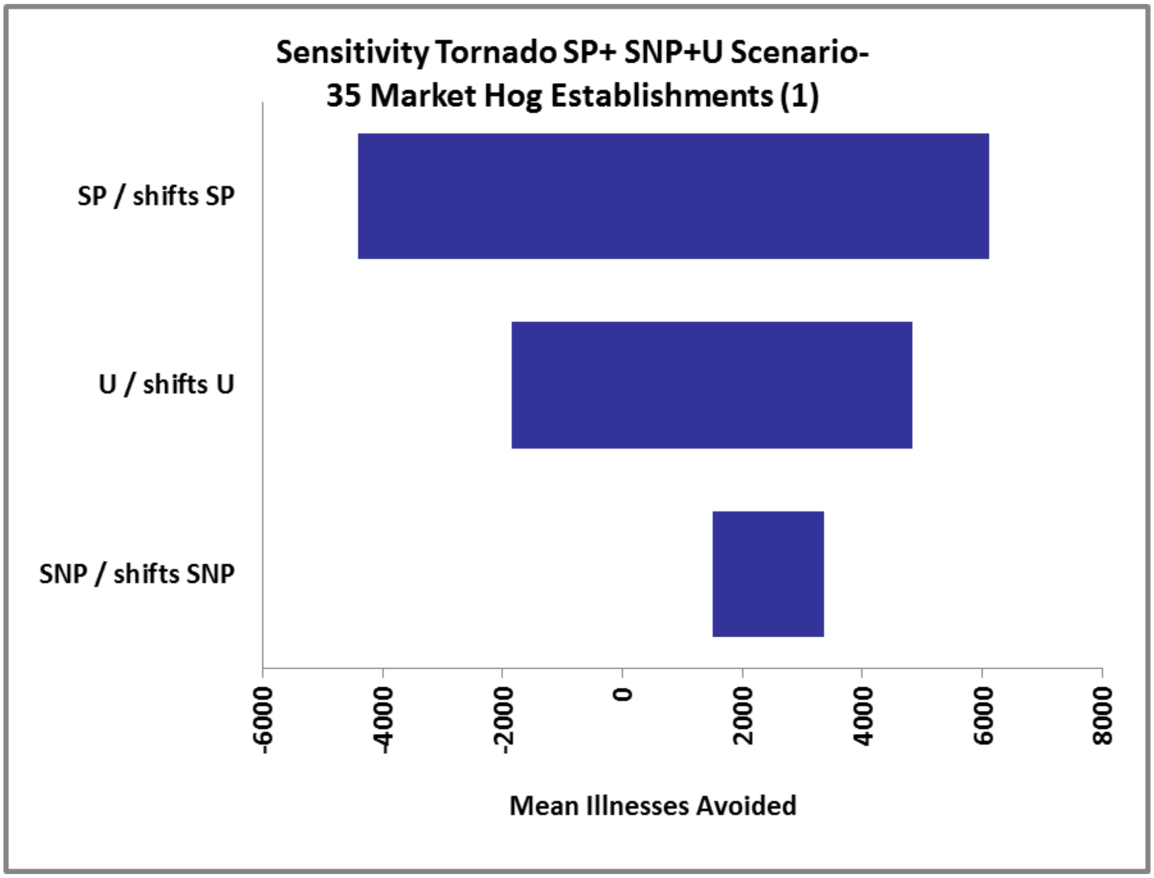

Figure 7: Sensitivity Graph for Decision Variables in Market Hog-Salmonella Model SP+SNP+U Indiscriminate Scenario for 35 Large and Small Establishments (Version 1)[a]

This tornado graph illustrates the relative sensitivity of each inspection variable category to the $\lambda_{avoided}$ estimate with respect to the scheduled and performed procedures (SP), unscheduled procedures (U), and scheduled not performed procedures (SNP logistic model coefficients). Thirty-five establishments with sample size 2,330.
Abbreviations: SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.
Source: FSIS analysis of data generated from the model.
[a]In Version 1, the model has been run in this case using 2,330 sample days.

Uncertainty Analysis

Three main stochastic inputs contribute uncertainty to the final distribution of $\lambda_{avoided}$: i) the baseline annual rate of foodborne *Salmonella* illness (λ_{ill}) that is modeled as a lognormal distribution of all commodity illnesses proportionally decreased by two *Pert* distributions and a fourth *Pert* distribution representing the total uncertainty of market hog-attributable illnesses; ii) adjustment factors (A_i) that are modeled as *Pert* distributions; and iii) beta coefficients (β_i) that are modeled in a multivariate Normal distribution. The analysis examined how each of these uncertainty distribution inputs influence total uncertainty about $\lambda_{avoided}$ by simulating the model with only one of the three stochastic inputs outlined as affecting the illness avoided at a time. The variability from a simulation with just one stochastic input is compared to the simulation results when all inputs are stochastic.

Results of analysis of the relative contribution of uncertainty about $\lambda_{avoided}$, using data from the subset of market hog establishments, are shown in Figure 8. The indiscriminate scenario for market hog *Salmonella* was simulated with all of the three main stochastic inputs (λ_{ill} [lambda], A_i, and β_i [beta]); the uncertainty about $\lambda_{avoided}$ is shown as the "Illnesses Avoided" distribution. Alternatively, the same model was simulated with just one of these uncertain inputs (while holding the other two at their expected values); the resulting distributions for $\lambda_{avoided}$ are labeled as "*A* Uncertainty", "Beta Uncertainty", and "Lambda Uncertainty". These results demonstrate that the "λ_{ill} Uncertainty" distribution nearly replicates the "Illnesses Avoided" distribution. Therefore, uncertainty about λ_{ill} contributes most to total uncertainty about $\lambda_{avoided}$ compared to A_i and β_i. Uncertainty about λ_{ill} contributes intermediately to total uncertainty about $\lambda_{avoided}$. This leaves the uncertainty about β_i to denote the smallest contributing uncertainty. A simulation where all three inputs are fixed at their expected values ("No variability") is included to demonstrate that the model simply returns an expected value for $\lambda_{avoided}$.

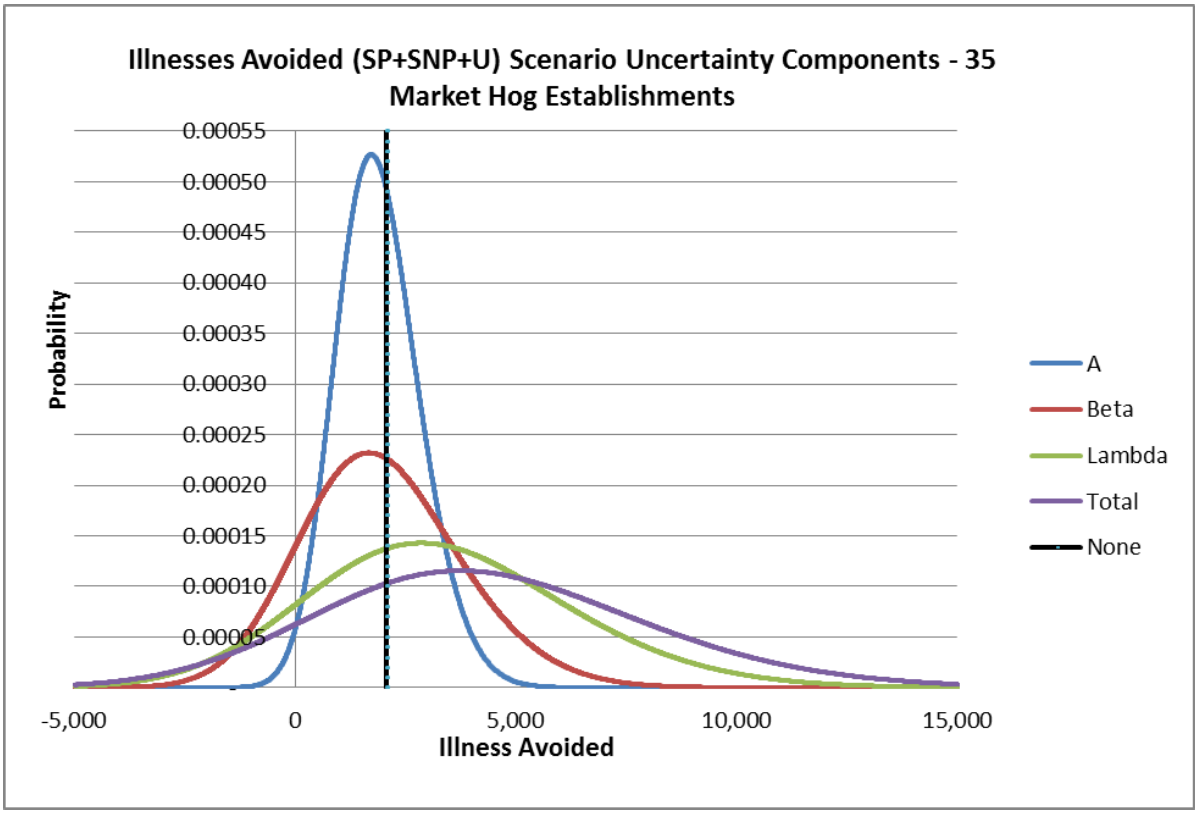

Figure 8: Relative Contributions to Uncertainty in Illnesses Avoided (λavoided) Estimate for 35 Market Hog Establishments (Version 1)[a].

The indiscriminate scenario for market hog Salmonella was simulated with three main stochastic inputs (λill [lambda], Ai and βi [beta]); the uncertainty about λavoided is shown as the "Illnesses Avoided" distribution. Alternatively, the same model was simulated with just one of these uncertain inputs (while holding the other two at their expected values); the resulting distributions for λavoided are labeled as "A Uncertainty", "Beta Uncertainty" and "Lambda Uncertainty". *Source: FSIS analysis of Agency generated data.*

[a]In Version 1, the model has been run in this case using 2,330 sample days.

DISCUSSION

This report considers multiple alternative scenarios to predict the potential public health effects of modifying the allocation of FSIS inspection resources in non-HIMP market hog slaughter establishments. Although more complicated models to relate occurrences of microbial pathogens to human illnesses may be conceived, the approach taken here makes the best use of available data. The model and analyses presented examine available data to describe the quantitative relationship between observed *Salmonella*-positive hog carcass samples and inspection activities taking place in market hog slaughter establishments. The relationship is modeled using a number of potential decision variables in individual- and combined-adjustment scenarios. It is assumed that the observed association of decision variable rates and percentage *Salmonella* positive samples is predictive of the underlying relationship. It is further assumed that there is a proportional relationship between observed *Salmonella* positive samples in market hog slaughter establishments and market hog-attributable human salmonellosis. A great deal of the quantitative portion of this risk assessment focuses on these two relationships. The methods used here have been applied extensively in other peer reviewed published risk assessments (Bartholomew *et al*., 2005; Williams and Ebel 2012; Ebel *et al*., 2012; Withee *et al*., 2009). The risk assessment provides answers to each of the three risk management questions discussed below.

What predicted effects will various models for increasing the number of offline inspection tasks in non-HIMP establishments have on human salmonellosis rates?

On the basis of CDC and FSIS data, the mean of the uncertainty distribution for the total annual salmonellosis cases attributed to market hogs is estimated to be 69,857 (80% confidence interval (CI): 38,834 – 97,963; 90% CI: 34,237-111,673). Model results indicate that under all scenarios considered it is likely that modifying non-HIMP establishments' inspection procedure rates to be similar to HIMP will decrease salmonellosis illnesses rather than increase salmonellosis illnesses.

The infeasible indiscriminate scenario (SP+SNP+U+NR) model changes in the rates treating four inspection procedure variables as decision variables and modifying them in combination. Under the infeasible indiscriminate scenario and assuming that all 159 non-HIMP market hog establishments adopt a NSIS based on 5,049 samples), *Salmonella* prevalence at post-chill is estimated to decrease 10.49% (80% CI: 6.55% decrease – 14.82 % decrease; 90% CI: 5.44% increase – 16.49% decrease). This reduction in prevalence corresponds to an estimated 7,327 (80% confidence interval: 4,578 – 10,357 decrease; 90% CI: 3,804 decrease – 11,518 decrease) market hog-attributable human salmonellosis cases prevented. Under the infeasible indiscriminate scenario, if the 35 large and small non-HIMP market hog establishments adopt NSIS (based on sample model version 2), *Salmonella* prevalence at post-chill is estimated to decrease 9.20% (80% CI: 2.48% – 16.67% decrease; 90% CI: 0.69% -19.61% decrease), corresponding to an estimated 6,426 (80% CI: 1,732 – 11,643 decrease; 90% CI: 484 – 13,699) market hog-attributable human salmonellosis cases prevented.

For Disc(SP), the discriminate scenario which adjusts the rates of scheduled and performed procedures only, the estimated reduction in market hog-attributable salmonellosis cases is 1,651 cases annually (80% CI: 983 increase – 3,344 decrease; 90% CI: 983 increase – 3,836 decrease) assuming that all 159 non-HIMP market hog establishments adopt a NSIS, or 770 cases annually (80% CI: 2,441 increase – 3,637 decrease; 90% CI: 3,757 increase – 4,464 decrease) assuming the 35 large and small establishments adopt the system under sampling model version 1). Disc(SNP) predicts a decrease of 2,016 cases annually (80% CI: 1,526 – 2,603 decrease; 90% CI: 1,447 – 2,853 decrease) or 1,257 (80% CI: 574 -2,079 decrease; 90% CI: 460 – 2,428 decrease) assuming that all non-HIMP market hog establishments or the 35 large and small establishments, respectively, adopt a NSIS. The Disc(U) scenario estimates a reduction of 1,277 cases annually (80% CI: 41 increase– 2,456 decrease; 90% CI: 552 increase – 2,800 decrease) or 506 cases annually (80% CI:1,547 increase – 2,350 decrease; 90% CI: 2,361 increase – 2,873 decrease) assuming that all non-HIMP market hog establishments or the 35 large and small establishments, respectively, adopt a NSIS. Under the infeasible discriminate scenario, Disc(NR), the estimated reduction in market hog-attributable salmonellosis cases is 2,383 cases annually (80% CI: 1,643 – 3,261 decrease; 90% CI: 1,515 – 3,631 decrease) or 3,893 cases annually (80% CI: 2,284 – 5,799 decrease; 90% CI: 2,001 – 6,594 decrease) assuming that all non-HIMP market hog establishments or the 35 large and small establishments, respectively, adopt a NSIS.

Because some instances of noncompliance are directly related to fecal and microbial carcass contamination, NRs might be expected to be positively associated with an increase in product contamination. That is, an establishment that does not have consistently good food safety practices in place might be expected to demonstrate an increased contamination rate compared with an establishment with good food safety practices. Alternatively, an inspector may be above average in his or her level of vigilance to violations and any given establishment in which this inspector works might demonstrate a relatively lower contamination rate for its number of NRs. The expected relationship between this variable and illnesses depends on which of these two correlations is more frequently correct. If the former predominates, an increase in NR procedures would be expected to lead to an increase in illnesses. If the latter predominates, an increase in NR procedures would be expected to lead to a decrease in illnesses. The relationship between NR and *Salmonella* prevalence can change over time in a given establishment if that establishment's practices improve. It is also plausible that both correlations were not noticeably dominant and, therefore, the NR rate is not an important predictor of contamination rates and illnesses. However, this possibility is not reflected in the data.

However, because of the uncertainty in the NR rate determining any reduction or increase in illnesses, and because the Agency does not schedule or direct inspectors to issue a specified number of NRs, this decision variable has been excluded from serious consideration as a determining factor in illness reduction. Rates of NRs are expected to be linked to illness rates because the frequency of noncompliance records is a known indicator of establishment performance at achieving public health standards. However, since this variable depends on individual inspectors and establishment processes, this risk assessment includes feasible scenarios where NR rates are not adjusted to some determined level.

The feasible scenarios include some combination of SP, SNP, and/or U decision variables. Further, that combination should be determined by available establishment practices in PHIS scheduling public heath related procedures and allowing more time and inspection program personnel availability so as to increase the number of scheduled procedures completed, reduce the number of scheduled procedures not performed, and increase the number of unscheduled public health related procedures.

Under the feasible scenario that treats SP, SNP, and U as decision variables (and treats NRs as a structural variable), the estimated reduction in market hog-attributable salmonellosis cases over all 159 establishments is 4,944 cases (80% CI: 2,386 – 7,481 decrease ; 90% CI: 1,481 increase – 8,357 decrease) assuming that all non-HIMP market hog establishments adopt a NSIS with a probability for adverse effect of 3.8%, or 2,533 cases (80% CI: 1,719 increase - 6,685 decrease ; 90% CI: 3,255 increase – 8,102 decrease) assuming the 35 large and small non-HIMP market hog establishments participate. Because of the small number of establishments and small sample size, the probability of an increase in the *Salmonella* case rate is 20.9%, or about an 80% likelihood that illnesses will decrease.

Additional analysis of the SP+SNP+U scenario improved the uncertainty expectation of illnesses avoided by increasing the sample size used for model predictions. The sample size was increased from 2,230 (model Version 1) to 22,632 (model Version 2) by using all inspection data from 2010 through 2011 which included all days of inspection recorded, whether or not *Salmonella* samples were taken.

Using a larger imputed dataset of 22,631 inspection days to create model Version 2, the feasible scenario (SP+SNP+ U) has an estimated reduction in market hog-attributable salmonellosis cases of 2,533 cases (80% CI: 768 – 4,287 decrease; 90% CI: 147 – 4,892 decrease) assuming the 35 large and small non-HIMP market hog establishments participate. The probability of an increase in the *Salmonella* case rate is 4.0%.

Where within a hog slaughter establishment can relocated inspectors have the most impact toward reducing microbial prevalence and corresponding human illness?

Among all scenarios, the highest estimated mean reduction in illnesses is obtained under the infeasible indiscriminate scenario, which increases SP and U variable rates, but decreases SNP and NR variable rates in combination. This result suggests that targeting the SP, SNP, U, and NR inspection procedure categories in combination would obtain the maximum salmonellosis case reduction and the greatest public health effect. Issuances of NRs, however, cannot be decreased to some desired level simply by reallocating FSIS inspection resources. Among the feasible implementation scenarios, the highest estimated mean reduction in illnesses is obtained under the indiscriminate scenario (SP+SNP+U). As noted above, however, the results suggest a tradeoff between expected gains and the degree of confidence in doing no harm.

Discriminate scenarios ranked in order of impact on illnesses for the 35 selected establishments were: SNP (decreased 1,257 illnesses); SP (decreased 770 illnesses); and U (decreased 506 illnesses). However, the sensitivity analysis showed that the greatest change in illnesses avoided per unit change in decision variable were ranked SP>U>SNP in the SP+SNP+U scenario. Therefore, the best choice is implementation of the indiscriminate SP+SNP+U scenario. But if any one discriminate scenario is employed, the SP scenario seems the best choice even though the distribution mean is larger for SNP (SNP>SP>U). On the other hand, the SNP scenario has no downside, with an adverse effect probability essentially zero, while the SP and U scenarios each have an adverse probability of over one-sixth (>16.67%). Examination of the distribution graphics of illnesses avoided versus each discriminate distribution shows that although the distribution of the SNP's mean is slightly greater than the others', the slope and scope of the SP and U distributions are much greater than for SP (see Figure 9, Figure 10 and

Figure 11).

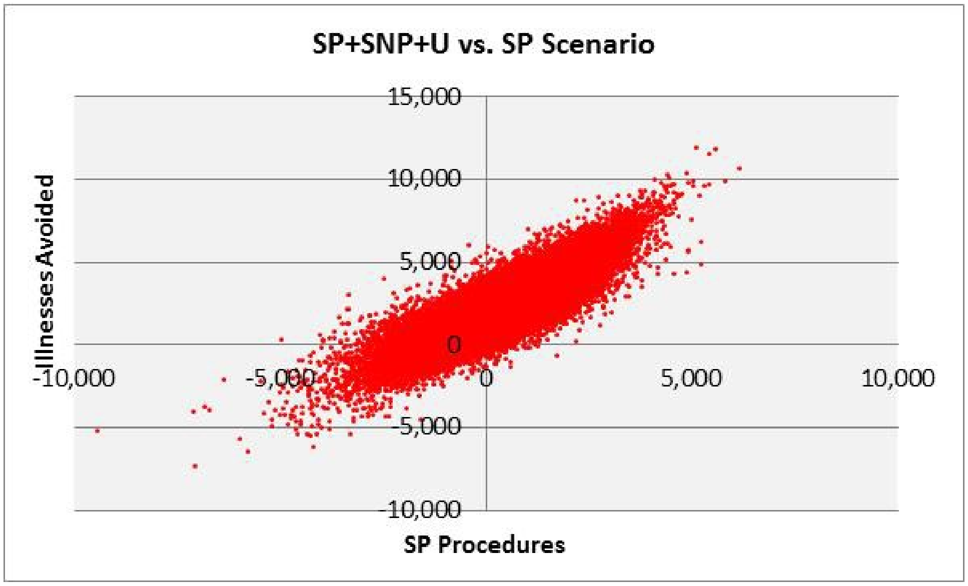

Figure 9: Scatterplot for Total Illnesses Avoided Scenario (SP+SNP+U) versus SP Decision Variable Illnesses Avoided

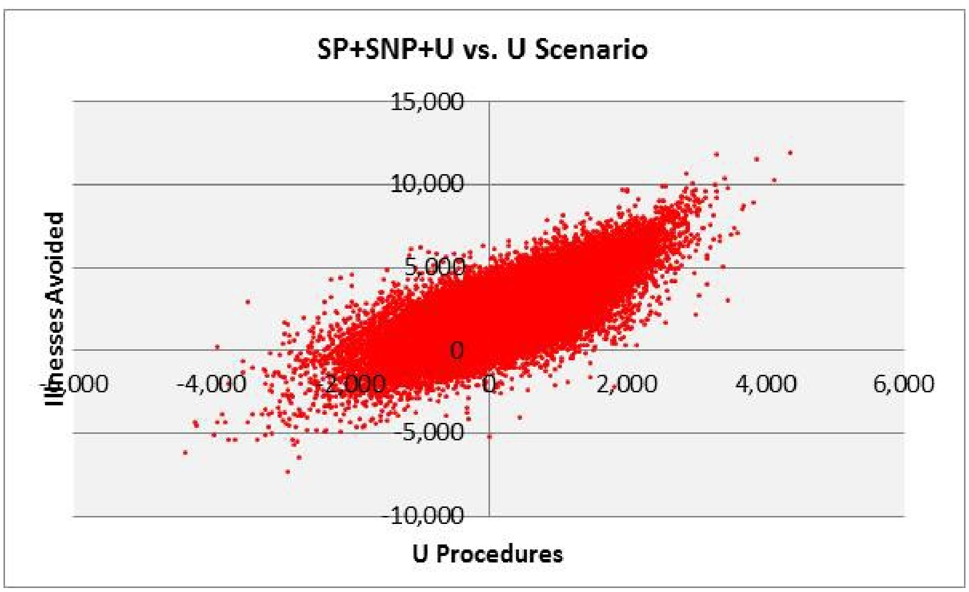

Figure 10: Scatterplot for Total Illness Avoided Scenario (SP+SNP+U) versus U Decision Variable Illness Avoided

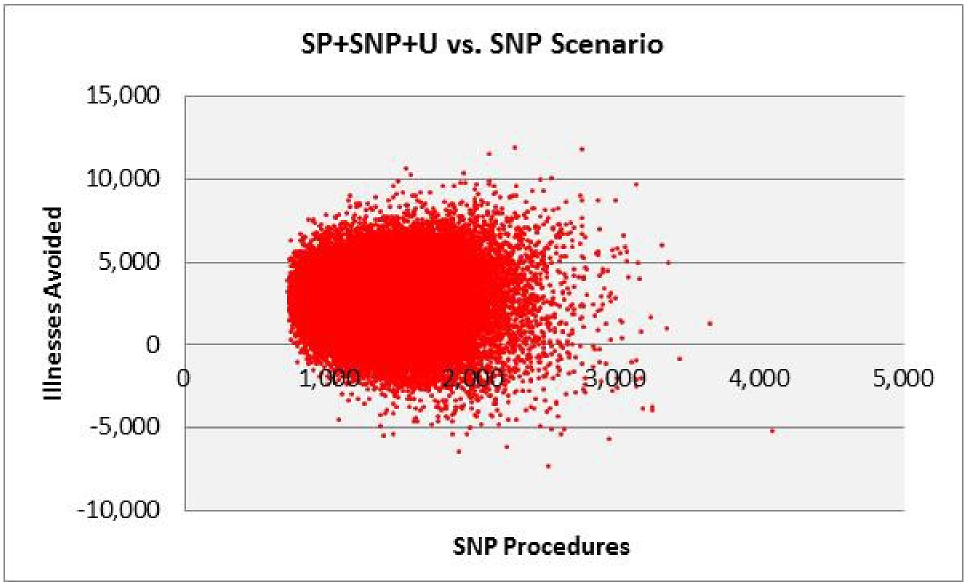

Figure 11: Scatterplot for Total Illness Avoided Scenario (SP+SNP+U) versus SNP Decision Variable Illness Avoided

What is the magnitude of uncertainty about these predicted prevalence and illness effects?

Our modeling approach includes the inherent uncertainty about the relationship between the structural variables and frequency of inspection activities and observed pathogen prevalence, the actual change in future inspection activities that would likely be observed, and the rate of human salmonellosis attributable to the consumption of pork products derived from market hogs. The magnitude of the uncertainty is such that while the mean of the estimated uncertainty distribution suggests a reduction in illnesses under all scenarios considered, the estimated probability of increased illnesses exceeds 5% in the SP+U scenario using the 22,631 sample size. The feasible SP+SNP+U scenario has the smallest probability of mean illness increase at 4.0% while reducing illnesses an average of 2,533. However, only targeting the SNP decision variable has a probability of increased illnesses of less than 0.01% while reducing illnesses an average of 1,257.

Our modeling approach includes the inherent uncertainty in the estimate of total salmonellosis cases due to the consumption of market hog products, the variability in the individual *Pert* distributions estimating the change in the number of inspection procedures done at post-chill (A_i), and the regression model coefficients. The uncertainty distribution of the total illness distribution (λ, lambda) provided the greatest contribution to overall uncertainty, as its magnitude is the largest. The combined regression coefficient uncertainty distribution (β, Beta) is the smallest contributor. Because each iteration of the model was carried out by solving for a prevalence estimate using an average of all 7,471 inspection records for each independent variable (X_i), the variability in inputs was assumed to follow random variation. No additional adjustments were made to account for input variability. Effort was made to determine if modeled scenarios produced uncertainty bounds that would include either zero or increased cases of market hog-attributable salmonellosis.

Assuming all market hog establishments adopt a NSIS, the uncertainty distribution for the human foodborne salmonellosis cases avoided under the infeasible indiscriminate (SP+SNP+U+NR) scenario results in a 5th percentile estimate of a decrease in 4,578 cases and 95th percentile estimate of a decrease of 11,518 cases. The feasible indiscriminate (SP+SNP+U) scenario results in a 5th percentile estimate of a decrease of 2,386 cases and 95th percentile estimate of a decrease of 8,357 cases. The discriminate scenarios produced percentile estimates as follows: Disc(SP) estimated a 5th percentile increase of 983 cases and a 95th percentile reduction of 3,836 cases; Disc(SNP) estimated a 5th percentile reduction of 1,447 cases and a 95th percentile reduction of 2,853 cases; Disc(U) estimated a 5th percentile increase of 552 cases and a 95th percentile reduction of 2,800 cases; and infeasible Disc(NR) estimated a 5th percentile reduction of 1,515 cases and a 95th percentile reduction of 3,631 cases.

Assuming that only the 35 large and small non-HIMP market hog establishments adopt a NSIS and using the inspection dataset of size 2,330 (Version 1), the estimated uncertainty distribution of human foodborne salmonellosis cases avoided under the infeasible indiscriminate scenario (SP+SNP+U+NR) has a 5th percentile of 484 cases averted and a 95th percentile of 13,699 cases averted. For the discriminate scenarios for the 35 plants, Disc(SP) estimated a 5th percentile increase of 3,757 cases and a 95th percentile decrease of 4,464 cases. Disc(SNP) estimated a 5th percentile decrease of 460 cases and a 95th percentile decrease of 2,428 cases. Disc(U) estimated a 5th percentile increase of 2,361 cases and a 95th percentile decrease of 2,873 cases. Infeasible Disc(NR) estimated a 5th percentile decrease of 2,001 cases and a 95th percentile decrease of 6,594 cases. Disc(SP+SNP+U) (for which NRs is a structural variable) estimated a 5th percentile increase of 3,255 illnesses and a 95th percentile decrease of 8,102 illnesses.

However, using the larger inspection dataset of size 22,631 (Version 2), the estimated uncertainty distribution of human foodborne salmonellosis cases avoided under the infeasible indiscriminate scenario (SP+SNP+U+NR) has a 5th percentile of 4,003 cases averted and a 95th percentile of 9,309 cases averted. For the discriminate scenarios for the 35 plants, Disc(SP) estimated a 5th percentile increase of 1,037 cases and a 95th percentile decrease of 2,286 cases. Disc(SNP) estimated a 5th percentile decrease of 883 cases and a 95th percentile decrease of 1,807 cases. Disc(U) estimated a 5th percentile increase of 754 cases and a 95th percentile decrease of 1,563 cases. Infeasible Disc(NR) estimated a 5th percentile decrease of 3,300 cases and a 95th percentile decrease of 4,746 cases. Disc(SP+SNP+U) (for which NRs is a structural variable) estimated a 5th percentile decrease of 147 illnesses and a 95th percentile decrease of 4,892 illnesses. The 10th and 90th percentiles of this distribution are 768 and 4,287. This scenario has a probability of increased illnesses of 4.0% compared to the SP (19.0%); SNP (<0.01%); and U (20.2%) feasible scenarios.

REFERENCES

Bartholomew M.J., Vose, D.J., Tollefson, L.R., and Travis C.C. (2005). "A Linear Model for Managing the Risk of Antimicrobial Resistance Originating in Food Animals". *Risk Analysis* 25(1).

CDC, 2001-2007. OutbreakNet: Foodborne Outbreak Online Database, http://wwwn.cdc.gov/foodborneoutbreaks/.

Cox, L.A. (2006) Quantitative Health Risk Analysis Methods: Modeling the Human Health Impacts of Antibiotics Used in Food Animals. New York: Springer.

Crouch, E.A., LaBarre, D., Golden, N.J., Kause, J.R., and Dearfield, K.L. (2009). Application of quantitative microbial risk assessments for estimation of risk management metrics: *Clostridium perfringens* in ready-to-eat and partially cooked meat and poultry products as an example. *Journal of Food Protection*, 72(10):2151–2161.

Ebel, E. D., Williams M. S., Golden, N. J., and Marks, H. (2012). Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. *Food Control* 28:250-257.

Ebel, E.D., Williams, M.S., Tameru, B. (2019) Relatedness of Salmonella contamination frequency on chicken carcasses and parts when processed in the same establishment. *Food Control* 100: 198-203.

Ebel, E. D.; Williams, M. S. (2015); When Are Qualitative Testing Results Sufficient to Predict a Reduction in Illnesses in a Microbiological Food-Safety Risk Assessment? *Journal of Food Protection*, 78(8):1451-1460.

FSIS (1996) Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule. 9 CFR Part 304, *et al.*

FSIS (2011a) Evaluation of HACCP Inspection Models Project (HIMP), United States Department of Agriculture Food Safety and Inspection Service. http://www.fsis.usda.gov/PDF/Evaluation_HACCP_HIMP.pdf

FSIS (2011b) The Nationwide Microbiological Baseline Data Collection Program: Market Hogs Survey August 2010-August 2011. http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES.

FSIS (2013) Compliance Guideline for Controlling *Salmonella* in Market Hogs. https://www.fsis.usda.gov/wps/wcm/connect/f970603e-96ce-4476-9dfd-5f768298bef7/Controlling-Salmonella-in-Market-Hogs.pdf?MOD=AJPERES.

FSIS (2014) Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection. July 2014. http://www.fsis.usda.gov/wps/wcm/connect/5eab5fe5-e113-491c-afc7-c4d351443679/PSRA+-++2014-07-30+-+Final.pdf?MOD=AJPERES

FSIS (2014) Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs. United States Department of Agriculture Food Safety and Inspection Service. https://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AJPERES.

Haas, C.N., Rose, J.B., and Gerba, C.P. (1996). Quantitative Microbial Risk Assessment. New York: John Wiley and Sons.

Hosmer, D.W., and Lemeshow, S. (2000) Applied Logistic Regression, New York: John Wiley and Sons.

Muth, M. (2007). Pork Slaughter and Processing Sector Facility-Level Model. https://www.rti.org/sites/default/files/resources/muth_pork-slaughter_final.pdf.

National Advisory Committee on Meat and Poultry Inspection (2008) February Meeting http://www.fsis.usda.gov/Regulations_&_Policies/National_Advisory_Committee_on_Meat_&_Poultry/index.asp#2008

Painter, J.A., Hoekstra, R.M., Ayers, T., Tauxe, R.V., Braden, C.R., Angulo, F.J, and Griffin, P.M. (2013). Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. *Emerging Infectious Diseases*, 19(3):407-415. http://dx.doi.org/10.3201/eid1903.111866.

Picard, RR, and Berk, KN, Data Splitting. *The American Statistician* Vol. 44, no. 2, May 1990.

Press, W.H., Teukolsky, S.A., Vetterling, W.T., and Flannery, B.P. (2007) Numerical Recipes 3rd Edition: The Art of Scientific computing. Cambridge University Press.

Scallan, E. Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M-A, Roy, S.L., Jones, J.L. and Griffin, P.M. (2011) Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Disease*.17 no. 1, 7-15.

Williams, M.S., Ebel, E.D., and Vose, D. (2011) Framework for Microbial Food-Safety Risk Assessments Amenable to Bayesian Modeling Risk Analysis. *Risk Analysis*, Vol. 31, no. 4, 548-565.

Williams, M. S., and Ebel, E.D. (2012). Estimating Changes in Public Health Following Implementation of HACCP in the United States Broiler Slaughter Industry. *Foodborne Pathogens and Disease* 9:59-67.

Withee, J., Williams, M., Disney, T., Schlosser, W., Bauer, N., and Ebel, E. (2009). Streamlined analysis for evaluating the use of preharvest interventions intended to prevent *Escherichia coli* O157:H7 illness in humans. *Foodborne Pathogens and Disease*, 6(7):1-9.

APPENDIX A: Regression Modeling Methods and Observational Data Sets

This appendix explains the results of regression modeling that are the foundation of this risk assessment. It is here that evidence on the occurrence of pathogens on hog carcasses is statistically linked to evidence on possible explanatory variables. Based on these findings, the body of this report estimates human illnesses avoided following implementation of a hog slaughter inspection system similar to the HIMP inspection system. With such a modernized slaughter there would be a shift of the online inspectors to offline inspection duties as in HIMP establishments. The first stage of the model is a regression model developed to assess the relationship between the performance of offline inspection procedures and the annual percent positive rate of *Salmonella* on market hog carcasses. A binary logistic regression with coefficients that is weighted by slaughter volume estimates the relationship between offline inspection procedures and the annual percent positive rate of *Salmonella* on market hog carcasses. The second stage of the model uses Monte Carlo generated distributions for the *Salmonella* illnesses estimated to be avoided in the scenario analysis. The second stage of the model depends on the regression relationship between offline procedures and illnesses avoided.

Regression Model Approach

The basic regression model is estimated to account for the *Salmonella* target pathogen paired with market hog food commodities. For the product-pathogen pair, a multivariate binary logistic model is fit to *Salmonella* presence or absence and inspection procedure categories corrected for establishment confounding variation. The model weights the data by establishment slaughter volume and accounts for the clustered nature of the data and model variable correlations. It uses pseudo-likelihood estimation and employs a correction for over-dispersion.

The model evaluates pathogen prevalence as the annual percent positive rate of *Salmonella* on market hog carcasses in relation to four offline inspection procedure categories: (i) scheduled and performed; (ii) scheduled but not performed; (iii) unscheduled; and (iv) noncompliance records. These four categories of inspection procedures encompass the totality of procedure elements across six classes of standard offline procedures completed by FSIS personnel: (i) sanitation; (ii) HACCP; (iii) wholesomeness/economic consumer protection; (iv) sampling; (v) sanitation performance standards; and (vi) food defense.

The four defined categories were chosen in the poultry slaughter risk assessment (FSIS, 2013) and evaluated, using the hog slaughter data, in this risk assessment because the expected/intended effect of the modeled alternative scenarios was consistent for procedures within each category. For example, the proposed increase in offline inspectors is expected to increase scheduled and performed, and unscheduled procedures while reducing scheduled but not performed procedures. It also is assumed that noncompliance records may initially increase with more offline inspectors in slaughter establishments, but, in the long run, may decrease because such establishments would attain appropriate process control.

Because of the observational nature of the data, a set of structural variables were used to control confounding. These structural variables pertained to non-inspection activities but included consideration of establishment size, temporal, spatial, and other establishment factors[10]. The regressions are estimated using SAS Proc Logistic version 9.4 software. The logit link function is used for the dependent variable and quasi-maximum likelihood estimates (correcting for over dispersion) of the structural and decision variable regression coefficients are obtained using the Fisher scoring algorithm. Wald statistics are calculated for assessing the significance of regression coefficients.

The general form of the weighted binary model (weighting factors are not shown in equations for simplicity) relating unconditional probabilities (p) to the regression coefficients (b_i) in standardized form with X_i as the regressors is:

$$p = \frac{e^{(b_0 + b_1X_1 + b_2X_2 + \dots + b_nX_n)}}{1 + e^{(b_0 + b_1X_1 + b_2X_2 + \dots + b_nX_n)}}$$

The logit link function relating the natural log of the odds ratio (p/(1-p)) to the standardized regression coefficients is:

$$log\left(\frac{p}{1-p}\right) = b_0 + b_1X_1 + b_2X_2 + \dots + b_nX_n$$

A single estimate of the linear component in the prevalence prediction equations is η which is equal to the logit or log ((p)/(1-p)):

[10] In some of the scenarios noncompliance records were considered as a structural, rather than decision, variable.

$$\eta = b_0 + b_1 X_1 + b_2 X_2 + \ldots + b_p X_p$$

The scalar quantity, η, is simplified as follows in the tables below where B and X are vectors of the b_i coefficients and the X_i values combined as a linear composition:

$$\eta = BX$$

The estimate of the **η** vector over all data points is a vector equation. Each vector element represents a data point from the **X** matrix of n data points and p variables plus the intercept.

In the case of the model, n=7,471 and p=22 (four of which are the decision variables, and an additional variable is added for the intercept).

$$\boldsymbol{\eta}(n,1) = \mathbf{X}(n, p+1)\, \mathbf{b}(p+1,1)$$

At each iteration of the multivariate normal distribution of regression coefficients in the simulation model first stage, a **b*** vector is produced.

$$\mathbf{b}^*(n,1) = \mathbf{b} + \mathbf{z}C,$$

where C’C = S, the variance-covariance matrix taken from the SAS model output and C is the upper triangular Cholesky factor of S. The result is that for each iteration for the vector, **b***, a new set of multivariate normal regression coefficients is estimated. The coefficient vector, **b**, has the initial quasi-likelihood regression coefficient estimates, and **z** is a vector of random normal deviates. So, at each iteration the vector, **η*,** is produced.

$$\boldsymbol{\eta}^*(n,1) = \mathbf{X}(n, p+1)\mathbf{b}^*(p+1,1)$$ **η***(n,1) = **X**(n,p+1)**b***(p+1,1)

The equation for estimating a single prevalence for a single η estimate is the inverse logistic equation.

$$p = \frac{1}{1 + e^{-\eta}}$$

The equation for estimating the prevalence vector over all data points is the vectorized inverse logistic equation.

$$p(n,1) = \frac{1}{1 + e^{-\boldsymbol{\eta}(n,1)}}$$

At each of the 100,000 iterations of the model which were found to provide stable estimates, the weighted average of the **p** vector is taken and then divided by the baseline prevalence. The weighted prevalence of the **p** vector is the weighted average.

$$p_{ave} = \sum_{1}^{n} w_i p_i / \sum_{1}^{n} w_i$$

The ratio of the average weighted prevalence to the baseline prevalence is the simple ratio of p_{ave} to $p_{baseline}$. The baseline prevalence is estimated from the single prevalence estimating equation where η is calculated with the b_i values taken at their maximum quasi-likelihood estimates.

APPENDIX B: Data sets

This appendix summarizes the data used in this risk assessment.

The core microbiological data come from the FSIS "Market Hog Baseline" (August 2010 through August 2011) and the FSIS PR/HACCP *Salmonella* verification program (August 2010 through December 2011). The baseline provides data for *Salmonella* sampling at pre-evisceration and post-chill establishment locations. The verification program only provides data at the post-chill location. The combined data set provided matching numbers of inspection procedures done on the same days and in the same establishments.

Data from 159 market hog slaughter establishments provided 3,846 baseline results for *Salmonella,* with an additional 3,625 PR/HACCP post-chill results added to the combined *Salmonella* dataset. In the baseline data there were 1,925 samples taken pre-evisceration and 1,921taken at post-chill. There are 2,790 positive *Salmonella* results out of 7,471 total results.

Data from all five HIMP plants were used in the data set, and all five provided data for the baseline study (each of these provided pre-evisceration and post-chill data; four provided routine samples outside the baseline study). The "Total" column in Table B 1 shows there were 164 plants participating of which five were HIMP and the remainder were not HIMP establishments. Routine verification samples were collected at Post-Chill and statistical comparison showed no difference, so the Routine and Baseline Post-Chill samples were combined when evaluated in the model (Table B 2).

Table B 1: Number of Establishments with Samples Collected

Establishment	Baseline		PR-HACCP	
Type	Pre-Evis	Post-Chill	Routine	Total
non-HIMP	142	143	16	159
HIMP	5	5	4	5
Total	**147**	**148**	**20**	**164**

Table B 2: Number of *Salmonella* Samples by Establishment Type

Establishment	Pre-Evis	Post-Chill	Routine	Total
non-HIMP	1,638	1,634	3,412	6,684
HIMP	287	287	213	787
Total	1,925	1,921	3,625	7,471

Table B 3 provides the numerator and denominator for a crude prevalence estimate from the Baseline pre-evisceration and post-chill sampling and PR HACCP post-chill samples as well as percent positive for *Salmonella*. In the risk model the post-chill from the baseline and PR HACCP sampling were combined because there was not statistical difference in the crude prevalence. It can be seen from this table that the HIMP establishments' small number of *Salmonella* positives from post-chill from both Baseline and PR HACCP necessitated combining these samples in order to have 4 positives in the HIMP post-chill group which is a bare minimum for statistical significance in the risk model. Table B 4 represents the samples as combined in the risk model for comparison with Table B 3. The percent positives are divided into pre-evisceration and post-chill for HIMP and non-HIMP establishments based on totals are similar to those found in the HIMP report.

Table B 3: Number of *Salmonella* Positive Samples Used in Model

Establishment Type	Number of Samples	Number of Samples Positive for *Salmonella*	% Positive
Non-HIMP			
Pre-Evisceration[a]	1,638	1,163	71.0
Post-Chill[a]	1,634	48	2.94
Routine[b]	3,412	97	2.84
Total	6,684	1,308	19.6
HIMP			
Pre-Evisceration[a]	287	175	61.0
Post-Chill[a]	287	2	0.697
Routine[b]	213	2	0.939
Total	787	179	22.7
All			
Pre-Evisceration[a]	1,925	1,338	69.5
Post-Chill[a]	1,921	50	2.60
Routine[b]	3,625	99	2.73
Total	**7,471**	**1,487**	**19.9**

[a]Samples from establishments in the market hog baseline
[b]Samples from establishments from PR/HACCP sampling

Table B 4: Summary of Baseline and Routine Sampling Results by Establishment Type

	Number of Samples	Number of Samples Positive for *Salmonella*	% Positive
Non-HIMP Establishments			
Pre-Evisceration	1,638	1,163	71.0
Post-Chill	5,046	145	2.87
Total	6,684	1,308	19.6
HIMP Establishments			
Pre-Evisceration	287	175	61.0
Post-Chill	500	4	0.800
Total	787	179	22.7
All Establishments			
Pre-Evisceration	1,925	1,338	69.5
Post-Chill	5,546	149	2.69
Total	7,471	1,487	19.9

Table B 5 includes the average ratios for *Salmonella* positives samples per establishment, the average total number of annual samples per establishment, and the average percentage *Salmonella* positive samples per establishment. These figures are similar to those found in the HIMP report. Also, these are the aggregated sampling types from both the Market Hog Baseline and the routine sampling from PR HACCP from HIMP and non-HIMP establishments. Table B 6 represents the sample type breakdown for the average aggregated positive ratios as used in the risk model per establishment, the average number of samples per establishment, and the averaged crude percent positive samples per establishment for pre-evisceration and post-chill samples in HIMP and non-HIMP establishments. Table B 7 through Table B 11 describe more details of the data sources and the alternate models.

Table B 12 provides ratios for sums of HIMP decision variables divided by non-HIMP decision variable best indicate the upper limits for decision variables that are consistent with their respective *Pert* distributions. However, the upper limit of the NR decision variable is not well explained. Therefore, a wider upper limit was chosen.

Table B 5: Summary of Total Sampling Results by Establishment Type as Used in Model

	Number of Establishments	Number of Samples	Number of Samples Positive for *Salmonella*	% Positive
Non-HIMP				
Pre-Evisceration [a]	142	11.54	8.19	71
Post-Chill [a]	143	11.43	0.34	2.94
Routine[b]	16	213.25	6.06	2.84
HIMP				
Pre-Evisceration [a]	5	57.4	35	60.98
Post-Chill [a]	5	57.4	0.8	0.14
Routine[b]	4	53.25	0.5	0.23

[a] Samples from establishments in the market hog baseline

[b] Samples from establishments from PR/HACCP sampling

Table B 6: Mean Annual Values for Combined Sampling Data by Establishment Type as Used in Model

	Plants	Samples	Positives	% Positive
Non-HIMP				
Pre-Evisceration	142	11.54	8.19	71
Post-Chill	159	31.74	0.91	2.87
HIMP				
Pre-Evisceration	5	57.4	35	60.98
Post-Chill	5	55.33	0.65	1.17

Abbreviations: HACCP, Hazard Analysis Critical Control Point; HIMP-based Inspection Models Project.

Table B 7: Allocation of Total Inspection Procedures by Decision Variable Inspection Category Used in Model

	SP	SNP	U	NR	W3NR	SP+SNP+U+NR
Non-HIMP						
Pre-Evisceration	34,324	2,749	15,535	1,501	840	54,109
Post-Chill	60,793	5,329	29,514	2,321	1,309	97,957
Total	95,117	8,078	45,049	3,822	2,149	152,066
HIMP						
Pre-Evisceration	7,190	753	4,157	563	406	12,663
Post-Chill	13,103	1,237	7,388	792	566	22,520
Total	20,293	1,990	11,545	1,355	972	35,183
Total All Plants	115,410	10,068	56,594	5,177	3,121	187,249

Abbreviations: NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table B 8: Non-HIMP Data Set from Market Hog Risk Assessment

	Number of Procedures by Establishment Size											
	Scheduled, Performed			Scheduled, Not Performed			Unscheduled			Noncompliance Records		
	L	S	VS	L	S	VS	L	S	VS	L	S	VS
Sum	3,168	13,772	68,157	1,459	6,580	41,043	16,940	26,244	108,296	2,611	1,231	3,939
Mean	158	255	226	73	127	153	847	495	357	124	23	14
Standard Deviation	117	46	64	56	56	67	702	255	186	88	22	16
CV%	73.9	18.0	68,157	76.2	43.9	43.8	83	51.5	52.1	71.0	93.1	119.7
N	20	53	302	20	52	268	20	53	303	21	53	288
Min	3	34	8	2	4	5	24	55	4	26	1	1
Max	352	474	459	192	244	251	2,099	1,340	1,424	300	92	145
10^{th} Percentile	800	13,720	33,250	314	1,092	13,320	3,318	10,897	166	945	170	576
90^{th} Percentile	6,418	14,909	77,010	3,172	11,586	62,256	38,096	41,266	590	5,712	3,116	9,216
Median	128	256	254	54	141	162	11,240	24,963	4,967	91	17	9
Mode	N/A	254	254	54	21	157	N/A	N/A	N/A	45	1,231	5
CL 0.01	(114)	148	120	2	55	-3	(53)	168	119	11	(4)	(7)
CL 0.99	431	362	375	144	198	239	1,747	822	596	237	51	35

Abbreviations: CL, Confidence Level; L, Large; Min, Minimum; Max, Maximum; S, Small; VS, Very Small.

Table B 9: Non-HIMP Data Set from All Market Hog Slaughter 2010

Large	SP	SNP	U	NR	Small	SP	SNP	U	NR
sum	15,276	3,181	11,810	502	sum	57,422	15,299	29,750	685
mean	4.82	1.00	3.73	0.16	mean	4.32	1.15	2.24	0.05
stdev	3.97	0.82	1.83	0.51	stdev	2.42	1.38	1.31	0.26
CV%	82.28	81.54	48.97	321.60	CV%	56.06	119.44	58.64	505.32
N	3,168	3,168	3,168	3,168	N	13,287	13,287	13,287	13,287
min	0	0	0	0	min	0	0	0	0
max	21	10	19	5	max	20	13	11	6
P_0.1	3	0	3	0	P_0.1	3	0	0	0
P_0.9	12	1	6	1	P_0.9	7	3	3	0
median	3	1	3	0	median	3	1	3	0
CL_0.1	(0.26)	(0.05)	1.39	(0.49)	CL_0.1	1.22	-0.61	0.56	-0.28
CL_0.9	9.91	2.05	6.07	0.81	CL_0.9	7.43	2.91	3.92	0.39
mode	3	1	3	0	mode	3	1	3	0
Very Small	SP	SNP	U	NR	N-Weighted	SP	SNP	U	NR
sum	227,680	92,707	156,778	1,967	sum	192,914.48	77,165.12	131,346.50	1,710.27
mean	3.35	1.36	2.31	0.03	mean	3.56	1.32	2.35	0.04
stdev	1.68	1.45	1.30	0.20	stdev	1.94	1.42	1.33	0.23
CV%	50.08	106.64	56.51	691.78	CV%	54.65	108.08	56.54	614.45
N	67,971	67,971	67,971	67,971	N	84,426	84,426	84,426	84,426
min	0	0	0	0					
max	13	13	13	8					
P_0.1	2	0	0	0					
P_0.9	6	3	3	0					
median	3	1	3	0					
CL_0.1	1.20	-0.50	0.64	-0.23					
CL_0.9	5.50	3.23	3.98	0.29					
mode	3	1	3	0					

Abbreviations: CL, confidence level, CV, correlation of variance; max, maximum; min, minimum; stdev, standard deviation.

Table B 10: HIMP Data Set from Market Hog Risk Assessment and All HIMP Data from 2010

HIMP[a]	HIMP[a]	HIMP[a]	HIMP[a]	HIMP[a]	HIMP[b]	HIMP[b]	HIMP[b]	HIMP[b]	HIMP[b]
Plant_Large	**SP**	**SNP**	**U**	**NR**	**Plant_Large**	**SP**	**SNP**	**U**	**NR**
sum	20,293	1,990	11,545	1,355	sum	237,289	17,973	132,751	14,730
mean	26	3	15	2	mean	10	1	6	1
stdev	11	4	7	3	stdev	4	1	2	1
CV%	43.4	143.5	49.4	174.2	CV%	41.2	173.2	40.6	147.5
N	787	787	787	787	N	23,433	23,433	23,433	23,433
min	0	1	2	3	min	0	0	0	0
max	55	20	40	16	max	21	16	18	5
Pctl0.1	9,129	0	4,722	0	P_0.1	117,165	0	70,299	0
Pctl0.9	33,054	6,296	18,888	3,935	P_0.9	351,495	46,866	187,464	46,866
median	25	0	14	0	median	11	0	5	0
mode	24	0	12	0	mode	11	0	5	0
CL_0.1	11	(2)	5	(2)	CL_0.1	4.78	-0.94	2.72	-0.56
CL_0.9	40	7	24	6	CL_0.9	15.47	2.47	8.61	1.82

[a] HIMP Data Set from Risk Assessment.
[b] HIMP Data Set from All Procedures Performed in 2010.
Abbreviations: CL, confidence level, CV, correlation of variance; max, maximum; min, minimum; stdev, standard deviation.

Table B 11: non-HIMP Data Set from Market Hog Risk Assessment and All non-HIMP Data from 2010

non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP
Large	SP	SNP	U	NR	Small	SP	SNP	U	NR
sum	15,276	3,181	11,810	502	sum	57,422	15,299	29,750	685
mean	4.82	1.00	3.73	0.16	mean	4.32	1.15	2.24	0.05
stdev	3.97	0.82	1.83	0.51	stdev	2.42	1.38	1.31	0.26
CV%	82.28	81.54	48.97	321.60	CV%	56.06	119.44	58.64	505.32
N	3,168	3,168	3,168	3,168	N	13,287	13,287	13,287	13,287
min	0	0	0	0	min	0	0	0	0
max	21	10	19	5	max	20	13	11	6
P_0.1	3	0	3	0	P_0.1	3	0	0	0
P_0.9	12	1	6	1	P_0.9	7	3	3	0
median	3	1	3	0	median	3	1	3	0
CL_0.1	(0.26)	(0.05)	1.39	(0.49)	CL_0.1	1.22	-0.61	0.56	-0.28
CL_0.9	9.91	2.05	6.07	0.81	CL_0.9	7.43	2.91	3.92	0.39
mode	3	1	3	0	mode	3	1	3	0
Very Small	SP	SNP	U	NR	N-Weighted	SP	SNP	U	NR
sum	227,680	92,707	156,778	1,967	sum	192,914.48	77,165.12	131,346.50	1,710.27
mean	3.35	1.36	2.31	0.03	mean	3.56	1.32	2.35	0.04
stdev	1.68	1.45	1.30	0.20	stdev	1.94	1.42	1.33	0.23
CV%	50.08	106.64	56.51	691.78	CV%	54.65	108.08	56.54	614.45
N	67,971	67,971	67,971	67,971	N	84,426	84,426	84,426	84,426
min	0	0	0	0					
max	13	13	13	8					
P_0.1	2	0	0	0					
P_0.9	6	3	3	0					
median	3	1	3	0					
CL_0.1	1.20	-0.50	0.64	-0.23					
CL_0.9	5.50	3.23	3.98	0.29					
mode	3	1	3	0					

Table B 12: Compare Ratios of N-Weighted HIMP Statistics with N-Weighted non-HIMP Statistics

HIMP	HIMP	HIMP	HIMP	HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP	non-HIMP
Plant_Large	**SP**	**SNP**	**U**	**NR**	**Plants_Combo**	**SP**	**SNP**	**U**	**NR**
Sum	257,582	3,783	144,296	16,085	sum	192,914	77,165	131,347	1,710
mean	10.52	1.065	6.29	1.03	mean	3.56	1.32	2.35	0.04
stdev	4.41	3.34	6.04	1.12	stdev	1.94	1.42	1.33	0.23
CV%	41.88	313.72	95.91	108.71	CV%	54.65	108.08	56.54	614.45
N	24,220	24,220	24,220	24,220	N	84,426	84,426	84,426	84,426
Ratio	**SP**	**SNP**	**U**	**NR**					
Sum	1.34	0.05	1.10	9.40					
mean	2.96	0.81	2.68	27.64					
stdev	2.27	2.35	4.54	4.89					
CV%	0.77	2.90	1.70	0.18					
N	0.29	0.29	0.29	0.29					

APPENDIX C: Model Selection

Linear Model Predictability

Because multiple variables were identified as possible contributors to the logistic regression model, the SAS stepwise, forward, and backward selection procedures in Proc logistic were used to include structural variables in the model data set. This method proved adequate for identifying structural variables to include in the model and each of the approaches (stepwise, forward, and backward) produced equivalent results for the dataset. Structural variables to evaluate for model inclusion include season, establishment size, establishment location, sample location in establishment, establishment district, number carcasses restricted, number carcasses condemned, number of inspectors, and HIMP or non-HIMP establishment. The model selection was based on standard statistics: AIC; R-squared (Nagelkerke corrected); Hosmer-Lemeshow test; AUC (area under the curve) as the c coefficient; and the validation statistic. Collinearity analysis along with residual and leverage plots were also used to evaluate variables for model inclusion. Each of these statistics was captured from the SAS Proc logistic output. The best model is identified by the smallest AIC, the largest R-squared, a p-value for the Hosmer-Lemeshow Chi-square test greater than 0.05, a significant c coefficient representing the area under the ROC curve, negligible collinearity, minimal leverages, explained outliers, and a stable validation statistic consistent with number of variables in the model.

Regression Diagnostics

Table C 1 shows the initial variable dataset parameters before beginning stepwise regression. Stepwise procedure results are found by adding the most significant variables one at a time with the option of deleting variables that may become insignificant ($p < 0.05$ to include, or $p > 0.05$ to remove from the regression). The same order of variable entry was found for forward selection, and the same reversed order was found for backward deletion of variables in the model as shown in Table C 2.

Table C 1: Stage 1 Initial Parameter Selection Summary (n=7471 p=23-1)

Parameter	Reference	Estimate	Standard Error	Wald Chi-Sq	Pr > ChiSq	Standardized Estimate
Intercept		-0.7464	0.2268	10.8328	0.001	
HIMP	1	-0.6506	0.2133	9.3065	0.0023	-0.5457
HIMP*COLL	1	0.3088	0.1114	7.6917	0.0055	0.3468
logNbrEmp*COLL	-1	-0.8824	0.0863	104.4547	<.0001	-1.7606
COLL	-1	-1.4670	0.1488	97.1547	<.0001	-1.6018
Fall	Winter	-0.1292	0.0566	5.2087	0.0225	-0.1017
Spring	Winter	0.0641	0.0573	1.2504	0.2635	0.0501
Summer	Winter	-0.0464	0.0520	0.7949	0.3726	-0.0399
MidWest	West	-0.3475	0.1177	8.7181	0.0032	-0.2648
NorthEast	West	-0.4741	0.1632	8.4453	0.0037	-0.2248
South	West	0.2456	0.1175	4.3722	0.0365	0.152
District1	District5	-0.5604	0.1246	20.2312	<.0001	-0.2846
District2	District5	-0.4199	0.1008	17.3414	<.0001	-0.2685
District3	District5	0.1313	0.0956	1.8864	0.1696	0.0747
District4	District5	0.6393	0.1393	21.0612	<.0001	0.3398
lognbrpass		-0.2468	0.0997	6.1259	0.0133	-0.3609
logsuspect		0.6225	0.1510	17.0032	<.0001	1.394
logpmcond		-0.2300	0.0788	8.5121	0.0035	-0.166
lognbrrestrict		-0.4069	0.1821	4.9939	0.0254	-0.7481
SP*COLL	-1	-0.0068	0.0035	3.8437	0.0499	-0.1845
SNP*COLL	-1	0.0170	0.0103	2.7093	0.0998	0.0663
U*COLL	-1	-0.0125	0.0059	4.5570	0.0328	-0.1706
NR*COLL	-1	0.0916	0.0152	36.0892	<.0001	0

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled. Standardized estimates are all measured in unitless scale. All variables have zero mean and unit variance.

Table C 2: Stepwise Stage 1 Parameter Statistics

			Summary of Stepwise Selection				Summary of Joint Tests					
							Residual Tests			Joint Test Results		
Step	Effect Entered	R Sq Max	AIC	DF	Global Chi-Sq	Pr > ChiSq	DF	Resid. Chi-Sq	Pr > ChiSq	DF	ChiSq	Pr > ChiSq
1	COLL	0.94	17415.71	1	8961.15	<.0001	18	1523.08	<.0001	1	246.09	<.0001
2	Region	0.95	16660.27	4	8385.77	<.0001	14	927.14	<.0001	3	296.74	<.0001
3	logNbrEmp*COLL	0.95	16250.54	5	7822.82	<.0001	13	508.09	<.0001	1	239.43	<.0001
4	NR*COLL	0.95	16114.83	6	7869.12	<.0001	12	363.59	<.0001	1	104.85	<.0001
5	District	0.95	16026.17	10	7827.20	<.0001	8	262.81	<.0001	4	99.18	<.0001
6	HIMP	0.95	15853.21	11	7803.36	<.0001	7	88.19	<.0001	1	27.82	<.0001
7	SP*COLL	0.95	15831.30	12	7816.34	<.0001	6	65.12	<.0001	1	12.48	0.0004
8	Season	0.95	15817.51	15	7809.26	<.0001	3	45.43	<.0001	3	22.09	<.0001
9	HIMP*COLL	0.95	15793.58	16	7808.73	<.0001	2	16.26	<.0001	1	8.33	0.004
10	U*COLL	0.95	15785.65	17	7810.08	<.0001	1	6.44	0.01	1	8.79	0.003
11	SNP*COLL	0.95	15781.34	18	7802.57	<.0001	-	-	-	1	9.88	0.002

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table C 1 also shows the increase in R-Square, the decrease in Akaike Information Criterion (AIC), the significance of each variable's addition to the global model, and the significance of the residual variance with each additional variable.

The final model chosen is a crossover or interaction model that excludes some main effects shared with the Coll dummy variable (sample collection location, pre-evisceration vs. post-chill) and the decision variables and the log number of inspectors. This was decided on the basis of which model was the better predictor at post-chill and also had the best fit to the logistic distribution. In order to use this model, comparison analyses with the models including all main effects (main effects1) and main effects with all dummy variable interactions (main effects2) were done. The comparison analysis showed that there was no advantage in using the full main effects model because the predictability for post-chill was slightly better using the crossover model (VanderWele, 2014).

Table C 3 shows the final parameter selection and significance levels. All variables not meeting the selection probabilities to stay in the model were deleted.

The level of stringency for the final parameter selection was justified according to the collinearity analysis in the next section and the graphical residual and leverage analysis.

Figure C 1 plots the differences (model 1 – model 2) in standardized (Pearson) residuals for model 1 and 2 (as in Table C 1, also p. 22) and model 2 (the final model as in Table C 3, also p. 18). The symbols plotted show a number of residual differences of model 1 from 2. This plot indicates that model 1 tends to have more outliers compared to model 2.

In Figure C 2 the Hat matrix diagonal elements (leverage) differences are compared. There are some leverage differences exceeding 0.005 which also indicate model 1 gives more variable results due to leverage points exceeding those of model 2.

Figure C 3 shows the differences between the models in the DF Beta statistics plotted against their sample day numbers. This statistic measures the effect of each data point on the value of the respective regression coefficient. The differences in the SP, SNP, U, NR, and HIMP regression coefficients are examined. Only the model differences between the HIMP and SP beta estimates are large enough for concern. This means that model 1 data for the HIMP variable tends to add bias to these model 1 regression coefficients. Therefore model 2 is preferred, but should be carefully evaluated for collinearity.

Table C 3: Final Stage 1 Parameter Statistics for Interaction (Crossover) Model (n=7471 p=19-1)

Parameter	β Estimate	β Error	Wald Chi-Square	p-value	Std est	Mean X
Intercept	-1.6492	0.0933	312.4038	<.0001		1
HIMP vs non-HIMP	0.2916	0.0859	11.5186	0.0007	0.2446	0.7893
HIMP*Coll	0.202	0.1088	3.4502	0.0632	0.2269	0.4277
logNbrEmp*Coll	-0.818	0.0822	99.1233	<.0001	-1.6319	0.5182
Post-Chill vs Pre-Evis (Coll)	-1.47	0.1456	101.8778	<.0001	-1.6051	0.4847
Fall vs Winter	-0.1368	0.0566	5.8374	0.0157	-0.1077	0.0046
Spring vs Winter	0.0671	0.0575	1.3641	0.2428	0.0525	-0.0023
Summer vs Winter	-0.046	0.0522	0.7781	0.3777	-0.0396	0.0945
MidWest vs West	-0.5738	0.1062	29.2146	<.0001	-0.4373	0.4086
NorthEast vs West	-0.5713	0.1565	13.3195	0.0003	-0.2708	0.0207
South vs West	0.4543	0.1066	18.1709	<.0001	0.2811	0.0941
District1 vs District5	-0.3037	0.1188	6.532	0.0106	-0.1542	0.1241
District2 vs District5	-0.364	0.1004	13.1539	0.0003	-0.2327	0.2463
District3 vs District5	0.1106	0.0833	1.763	0.1842	0.0629	0.1857
District4 vs District5	0.6176	0.1346	21.0471	<.0001	0.3282	0.2004
SP*Coll	-0.0079	0.0035	5.1672	0.023	-0.2131	4.3344
SNP*Coll	0.0286	0.0102	4.0913	0.0431	0.0809	0.4101
U*Coll	-0.011	0.0057	3.6384	0.0565	-0.1491	1.4386
NC*Coll	0.0978	0.0148	43.405	<.0001	0.2676	0.1404

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

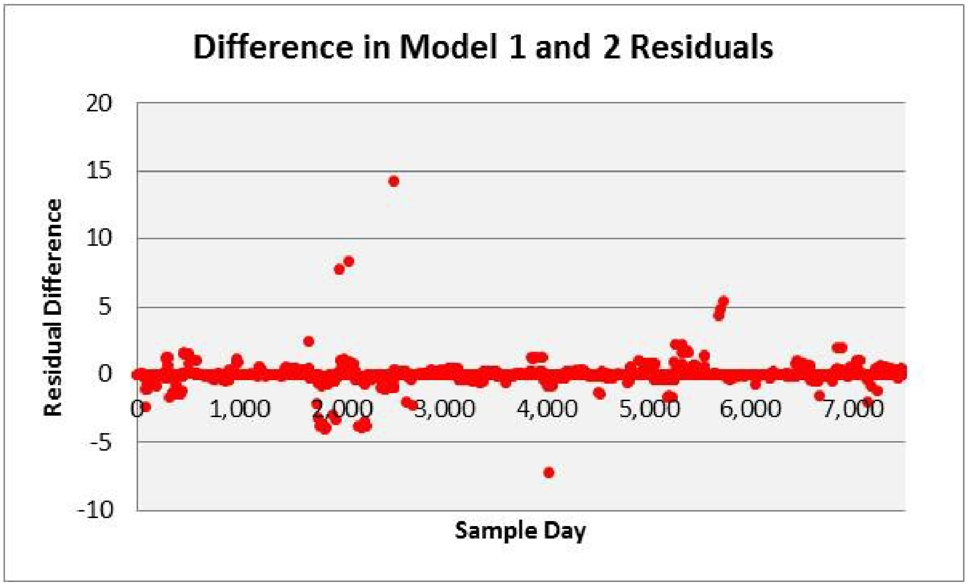

Figure C 1: Comparison of Residuals from Models 1 and 2

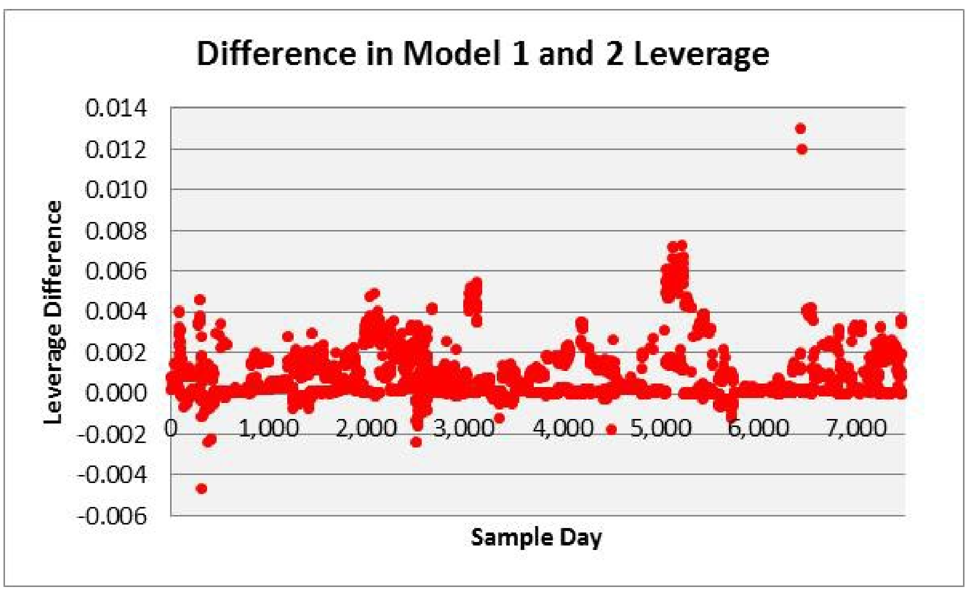

Figure C 2: Comparison of Leverage Statistics from Models 1 and 2

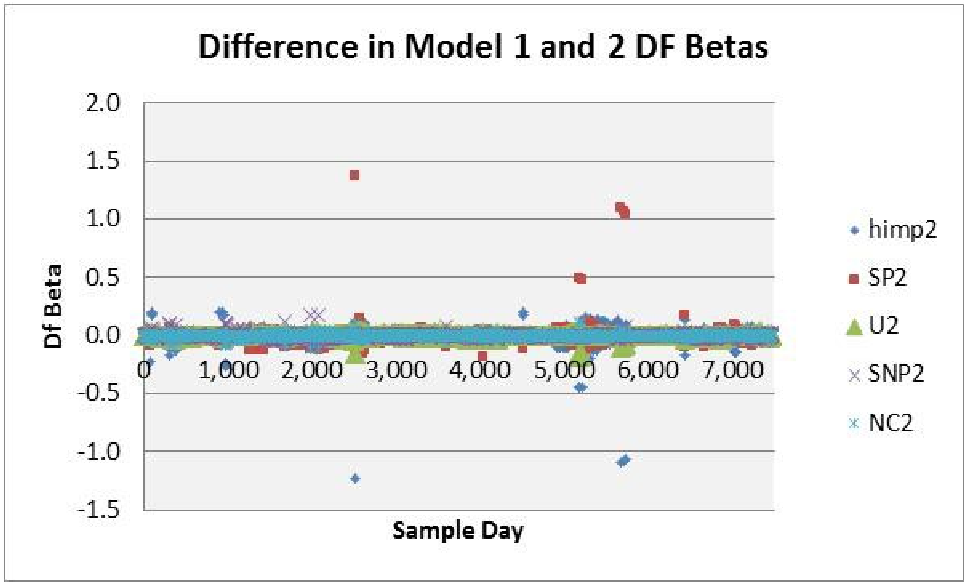

Figure C 3: Differences in DF Beta Statistics for Models 1 and 2
Abbreviations: HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NC, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Unconditional maximum likelihood estimates are used because the total sample size in the data structure is sufficiently large. A conditional analysis was assessed, but offered no advantage. The conditional analysis shows an advantage when the total sample size is small (in the hundreds or less). The expected requirements for a valid unconditional maximum likelihood analysis are met for the *Salmonella* dataset.

Multiple Collinearity Analysis

Multiple collinearity in the full model (model 1 as in the previous section) and non-HIMP post-chill submodel were evaluated using the collinearity diagnostics in SAS Proc Reg. The weighting variable was used with the complete dataset of 7,474 observations in four submodels and the subset of 5,046 observations in only the non-HIMP post-chill submodel. The variance inflation factors and tolerances were evaluated for unacceptable deviations. Table C 4 shows full model tolerances range from 0.06263 to 0.7525 and the square root of the variance inflation factors do not exceed 2.5 for the decision variables and do not exceed 4.0 for structural variables. The variables affected with moderate collinearity are the collection site and the log number of employees and not the HIMP variable. Certain leeway for structural variables is allowed if this is not carried into the decision variables. But, from the graphical analysis the SP decision variable is likely affected.

Table C 5 provides evidence for excluding the carcasses Restricted, Post-Mortem Condemnations, Suspects, and Carcasses Passed variables as a group from model 1. The square root variance inflation factors exceed five in two of these variables. However, when retaining the Restricted and Condemned variables in the model, they do not reach significance for model inclusion like the HACCP Size variable. Model 2 is used as the preferred model for stage 1.

Because the submodel is concerned with the results of most interest, collinearity in the submodel is problematic. However, there is no indication of collinearity in the submodel. All the tolerances range from 0.25 to 0.89 and the squared variance inflation factors are all less than 2.0 with a largest squared variance inflation factor of 1.7. Therefore, there is no important multicollinearity that may interfere with model results interpretation.

Table C 4: Collinearity Diagnostics: Regression Variable Tolerances and Variance Inflation Factors[a]

	Model 2 – All Sub-Models (164 Plants 7,471 samples)				non-HIMP Post Chill (159 Plants; 5,046 samples)			
Variable	**Beta**	**Tolerance**	**VIF**	**sqrt(VIF)**	**Beta**	**Tolerance**	**VIF**	**sqrt(VIF)**
Intercept	0.3575	.	0	0	0.0607	-	0	0
HIMP	0.0334	0.7525	1.3289	1.1528	0.0000	.	0	0
HIMPCOLL	-0.0146	0.1421	7.0362	2.6526	0.0000	.	0	0
COLLlognbremp	-0.0158	0.0626	15.9659	3.9957	-0.0326	0.4235	2.3616	1.5367
COLL	-0.3064	0.0667	15.0041	3.8735	0.0000	.	0	0
Fall	-0.0114	0.6648	1.5041	1.2264	0.0008	0.6618	1.5111	1.2292
Spring	0.0023	0.6649	1.5039	1.2263	0.0015	0.6686	1.4957	1.2230
Summer	-0.0010	0.6989	1.4308	1.1961	-0.0015	0.7031	1.4223	1.1926
MidWest	-0.0281	0.2430	4.1159	2.0288	-0.0058	0.2507	3.9895	1.9974
NorthEast	-0.0353	0.2904	3.4431	1.8556	-0.0308	0.3185	3.1403	1.7721
South	0.0328	0.3682	2.7161	1.6481	0.0165	0.3690	2.7103	1.6463
District1	-0.0223	0.3464	2.8871	1.6991	-0.0105	0.3008	3.3248	1.8234
District2	-0.0119	0.3733	2.6789	1.6367	-0.0074	0.3692	2.7084	1.6457
District3	0.0135	0.6913	1.4465	1.2027	-0.0024	0.6843	1.4614	1.2089
District4	0.0441	0.3166	3.1583	1.7772	0.0105	0.3173	3.1513	1.7752
COLLSP	-0.0008	0.1580	6.3302	2.5160	0.0005	0.3431	2.9144	1.7072
COLLSNP	0.0002	0.7501	1.3331	1.1546	-0.0002	0.8985	1.1129	1.0550
COLLU	-0.0013	0.2124	4.7091	2.1701	0.0011	0.3953	2.5298	1.5905
COLLNR	0.0089	0.7227	1.3837	1.1763	-0.0002	0.7769	1.2873	1.1346

[a] Diagnostics evaluated using Proc Reg.
Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table C 5: Collinearity Diagnostics: Regression Variable Tolerances and Variance Inflation Factors Model 1: non-HIMP Post Chill (164 Plants, 5,046 samples)[a]

Variable	Beta	Tolerance	VIF	sqrt(VIF)
Intercept	0.3984	-	0	-
HIMP	-0.0663	0.05468	18.2884	4.2765
HIMPCOLL	-0.0076	0.13861	7.2143	2.6859
COLLlognbremp	-0.0430	0.05392	18.5448	4.3064
COLL	-0.2619	0.05614	17.8137	4.2206
Fall	-0.0090	0.65897	1.5175	1.2319
Spring	0.0015	0.65966	1.5159	1.2312
Summer	-0.0008	0.69812	1.4324	1.1968
MidWest	-0.0232	0.2079	4.8099	2.1932
NorthEast	-0.0172	0.27664	3.6148	1.9013
South	0.0035	0.26447	3.7812	1.9445
District1	-0.0421	0.31414	3.1833	1.7842
District2	-0.0254	0.36151	2.7662	1.6632
District3	0.0188	0.47264	2.1158	1.4546
District4	0.0364	0.3133	3.1918	1.7866
logpmcond	0.0086	0.06602	15.1479	3.8920
lognbrpass	0.0730	0.01623	61.6078	7.8491
lognbrrestrict	-0.0118	0.38134	2.6223	1.6194
logsuspect	-0.0579	0.01569	63.7320	7.9832
COLLSP	-0.0006	0.15757	6.3464	2.5192
COLLSNP	-0.0004	0.74735	1.3381	1.1567
COLLU	-0.0011	0.21134	4.7317	2.1752
COLLNR	0.0092	0.72039	1.3881	1.1782

[a] Diagnostics evaluated using Proc Reg.
Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

APPENDIX D: Inspection Procedure Decision Variables

There are six general ISP code activity categories captured in the FSIS database (Table D 1). Sums of daily scheduled and unscheduled procedures performed, as well as unperformed procedures and noncompliance reports, were collected for individual establishments and were matched with same-day positive and negative *Salmonella* results.

The ISP codes from the FSIS database were tabulated daily for all scheduled procedures, unscheduled procedures, uncompleted procedures, non-compliances, and total procedures performed for each establishment. Scheduled procedures are assigned to each establishment's shift according to a systematic process by an automated Performance-Based Inspection System. Unscheduled procedures are performed according to in-establishment inspector availability that goes beyond the time allocated for performing scheduled procedures; they typically involve regulatory inspection activities such as fecal checks for zero-tolerance beyond the requirement of twice per line per shift or other procedures not regularly scheduled or performed. Unscheduled procedures also are performed in response to unforeseen hazards, such as metal or plastic in product which are identified during operations and were not previously seen at this stage in operations, or unsanitary conditions arising from Sanitation Standard Operating Procedures (Sanitation SOP) failures, and PR/HACCP corrective actions.

Among the six general inspection system procedure activities, 47 specific ISP codes were used. The complete listing is in the main body of the report under the "Data Sources and Structure" section of the Methods Stage 1 section (Table 5). These included five Sanitation (01) codes, 17 PR/HACCP (03) codes, 11 Wholesomeness/Economic Consumer Protection (04) codes, six Sampling (05) codes, four Other Inspection Requirements (06) codes and four Emergency Activity (08) codes (Table 5). Ultimately, these specific codes were designated in the database as scheduled and performed (SP), scheduled and not performed (SNP), unscheduled (U) and noncompliance (NR). The inspection procedures used in the model are shown in Table D 1. The code sum variable denotes the summed procedure elements on each sample day while the detail sum variable gives specific details of each inspection procedure element included in the daily sums.

Table D 1: Inspection System Procedure Codes and General Inspection Categories Employed in the Risk Model

Number	Inspection System Procedure Code	Category
1	01A01	01 Sanitation
2	01B01	01 Sanitation
3	01B02	01 Sanitation
4	01C01	01 Sanitation
5	01C02	01 Sanitation
6	03A01	03 HACCP
7	03B01	03 HACCP
8	03B02	03 HACCP
9	03C01	03 HACCP
10	03C02	03 HACCP
11	03E01	03 HACCP
12	03E02	03 HACCP
13	03F01	03 HACCP
14	03F02	03 HACCP
15	03G01	03 HACCP
16	03G02	03 HACCP
17	03H01	03 HACCP
18	03H02	03 HACCP
19	03I01	03 HACCP
20	03I02	03 HACCP
21	03J01	03 HACCP
22	03J02	03 HACCP
23	04A01	04 W/ECP
24	04A02	04 W/ECP
25	04A03	04 W/ECP
26	04A04	04 W/ECP
27	04B01	04 W/ECP
28	04B02	04 W/ECP
29	04B03	04 W/ECP
30	04B04	04 W/ECP
31	04C02	04 W/ECP
32	04C03	04 W/ECP
33	04C04	04 W/ECP
34	05A01	05 Sampling
35	05A02	05 Sampling
36	05C01	05 Sampling

Number	Inspection System Procedure Code	Category
37	06A01	06 Sanitation Standards
38	06B01	06 Sanitation Standards
39	06D01	06 Sanitation Standards
40	06D02	06 Sanitation Standards
41	08S14	08 Food Defense
42	08S15	08 Food Defense
43	08S16	08 Food Defense
44	08S17	08 Food Defense

Abbreviations: HACCP, Hazard Analysis Critical Control Points; W/ECP = Wholesomeness/Economic Consumer Protection

The total activity for each of these four categories was calculated as the sum across all codes for that category. The categories are repetitive such that all are the same except for unscheduled procedure which include the extra food defense (08) elements. The four categories are sub-categorized with the common name for the procedure followed in parentheses by the procedure element code:

SP = scheduled and performed procedures for sanitation(01), HACCP(03), wholesomeness/economic consumer protection(04), sampling(05), other inspection requirements(06), sanitation performance standards (06D01), raw ground (03B), raw not ground (03C), fecal check (03J), economic hog kill (04C04)

SNP = scheduled not performed procedures for sanitation(01), HACCP (03), wholesomeness/economic consumer protection(04), sampling (05), other inspection requirements (06), sanitation performance standards(06D01), raw ground (03B), raw not ground (03C), fecal check(03J), economic hog kill (04C04)

U = unscheduled procedures performed for sanitation(01), HACCP(03), wholesomeness/economic consumer protection(04), sampling(05), other inspection requirements(06), sanitation performance standards(06D01), raw ground(03B), raw not ground(03C), fecal check (03J), economic hog kill (04C04), food defense (08)

NR = noncompliance record procedures for sanitation(01), HACCP(03), wholesomeness/economic consumer protection(04), sampling(05), other inspection requirements(06), sanitation performance standards(06D01), raw ground(03B), raw not ground(03C), fecal check(03J), economic hog kill(04C04).

W3NR = noncompliance record procedures for sanitation plan currency (01A01), sanitation (01B01, 01B02, 01C01, 01C02), and HACCP (03A01, 03J01, 03J02).

APPENDIX E: Structural Variables

A minimal set of structural variables were found to contribute most to reducing the model deviance, controlling confounding, and providing the best overall model fit to the data as assessed by the Hosmer-Lemeshow test for model conformance to the logistic distribution. Structural variables were selected using stepwise regression in the SAS logistic procedure with the probability to enter the model taken as 0.05. Fourteen structural variables were tested and several eliminated providing the best model[1,2] (i.e., the inclusion of these structural variables significantly reduces the model deviance). These structural variables tested are:

1. The **categorical** collection variable distinguishes between two locations of sample collection (one column in data matrix):
    a. Market hog baseline pre-evisceration
    b. Market hog baseline and PR/HACCP post-chill (*Salmonella* positives not significantly different)
2. The **categorical** season (time of year) variable distinguishes four seasons (three columns in data matrix):
    a. Spring
    b. Summer
    c. Fall
    d. Winter
3. The **categorical** regions variable distinguishes four regions of the United States (three columns in data matrix):
    a. North-East
    b. North-West
    c. South
    d. West
4. The **categorical** district variable contains ten FSIS districts grouped in pairs to make five groups (four columns in data matrix):
    a. District Group 1
    b. District Group 2
    c. District Group 3
    d. District Group 4
    e. District Group 5

5. The **continuous** variable for the number of establishment inspectors[2] (one column in data matrix),
6. The **categorical** HACCP Inspection Models Project (HIMP) variable (one column in data matrix):
    a. HIMP establishment
    b. Non-HIMP establishment
7. The **categorical** HACCP size for three sizes of establishments (two columns in data matrix):
    a. Large establishment
    b. Small establishment
    c. Very Small establishment
8. The **continuous** variable for the number of carcasses restricted per establishment as a daily total (one column in data matrix)
9. The **continuous** variable for the number of daily post mortem condemnations per establishment (one column in data matrix)
10. The **continuous** variable for the number of daily suspects per establishment (one column in data matrix)
11. The **continuous** variable for the number of carcasses passed per establishment as a daily total (one column in data matrix)
12. The **continuous** variable for the number of scheduled and performed (SP) procedures per establishment as a daily total (one column in data matrix)
13. The **continuous** variable for the number of scheduled and not performed (SNP) procedures per establishment as a daily total (one column in data matrix)
14. The **continuous** variable for the number of unscheduled (U) procedures per establishment as a daily total (one column in data matrix)
15. The **continuous** variable for the number of noncompliance records (NR) procedures per establishment as a daily total (one column in data matrix)

Therefore, the total of variable columns in the data matrix is 23 (p=22), three of which are always decision variables, one of which is treated as either a decision or structural variable (NR) depending on the scenario, and 14 of which are always structural control variables.
(Please note that variables 7, 8, 9, 10, and 11 do not appear in the final model because they were eliminated due to not meeting significance criteria (variable 7) or did not warrant inclusion due to outliers contributing to excess leverage and collinearity and were excluded to improve model efficiency).

Final Model

Table E 1 lists the estimated regression coefficients, standard errors, the means, and the standard deviations for all decision and structural variables in the market hog slaughter model. All coefficients have significant contributions according to a 0.05 significance assumption and were retained in the final model. The same set of variables was retained in the split data sets and the data set where the W3NR variable replaces the NR variable for consistency.

The model showed that the coefficients for all decision variables were significant, indicating a non-negligible risk contribution. The signs for SP and U coefficients were negative, suggesting that increasing these procedures (while holding other variables constant) would decrease the prevalence of *Salmonella*. The coefficient for SNP and NR as well as W3NR were positive, indicating decreasing the amount of scheduled not performed procedures decreases *Salmonella* prevalence as expected.

The baseline prevalence predictions from the model and split data models are derived by setting all independent variable to their respective means. Comparing these predictions to unweighted prevalence values from the data suggests that the model reasonably reflects the empiric evidence. Table E 2 and Table E 3 provide the submodel estimates of *Salmonella* percent positive rates over the two year sampling frame and provides comparison with the crude rates. For example, the hog-*Salmonella* model predicts a post-chill prevalence in non-HIMP establishments to be 0.0201 versus a crude average of 0.0287 from the raw data (Table E 2). Differences between predicted and raw values generally reflect the additional weighting for other structural factors (e.g., temporal factors, spatial factors, HIMP participation, etc.) included in the predicted values (but not included in the simple weighting of the raw data prevalence levels).

The weighting scheme does not seem to unduly bias the percent positive estimates (in plant prevalence for this sample of establishments) because the crude (unweighted) percent positive values are reasonably close to the model estimates as evidenced by the standard errors of the crude estimates. It also must be realized that the percent positive estimates from the crude data or the model are not necessarily equivalent to FSIS baseline values and are unique only to this sample of establishments.

Table E 1: Analysis of Maximum Likelihood Estimates[a]

Parameter	DF	β Estimate	β Error	Wald Chi-Square	Pr > ChiSq	Standard Estimate
Intercept	1	-1.1965	0.1096	119.0777	<.0001	
HIMP	1	0.5930	0.1014	34.2209	<.0001	349.20
HIMP*COLL	1	0.2617	0.1149	5.1877	0.0227	195.50
logNbrEmp*COLL	1	-0.7630	0.1450	27.6963	<.0001	-1192.40
COLL	1	-1.5591	0.2715	32.9863	<.0001	-1150.20
Fall	1	-0.2080	0.0543	14.6912	0.0001	-106.90
Spring	1	0.0465	0.0569	0.6657	0.4145	23.25
Summer	1	-0.1081	0.0510	4.4908	0.0341	-60.59
MidWest	1	-1.2001	0.1561	59.0845	<.0001	-451.10
NorthEast	1	0.3288	0.2405	1.8693	0.1716	55.58
South	1	-0.2463	0.1703	2.0910	0.1482	-82.11
District1	1	-0.2542	0.1417	3.2174	0.0729	-64.56
District2	1	-0.6771	0.1234	30.1016	<.0001	-276.70
District3	1	0.1470	0.1110	1.7543	0.1853	50.62
District4	1	0.4075	0.1681	5.8766	0.0153	124.70
S*COLL	1	-0.0143	0.0029	23.8850	<.0001	-303.10
SNP*COLL	1	0.0286	0.0087	10.7760	0.001	86.64
U*COLL	1	-0.0125	0.0050	6.3021	0.0121	-132.00
NR*COLL	1	0.0850	0.0121	49.0231	<.0001	197.70

[a]Parameters Used in Stage 1 Regression Model, n=7471 p=19-1.

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled. All variables are standardized to a unit scale

Table E 2: Estimates of BX Vector β* by the Submodel Vectors using X Means for Non-HIMP Establishments

Parameters	Beta	Prev X	Post X	Post X'	Post X''	Prev BX	Post BX	Post BX'	Post BX''
Intercept	-1.6490	1	1	1	1	-1.6490	-1.6490	-1.6490	-1.6490
HIMP	0.2920	1	1	1	1	0.2920	0.2920	0.2920	0.2920
HIMP*Coll	0.2020	-1	1	1	1	-0.2020	0.2020	0.2020	0.2020
logNbrEmp*Coll	-0.8180	-1.7362	1.2666	1.7618	1.8410	1.4202	-1.0361	-1.4412	-1.5059
Coll	-1.4700	-1	1	1	1	1.4700	-1.4700	-1.4700	-1.4700
Fall	-0.1370	-0.0330	0.0099	-0.0193	-0.0193	0.0045	-0.0014	0.0026	0.0026
Spring	0.0670	-0.0403	0.0065	-0.0163	-0.0163	-0.0027	0.0004	-0.0011	-0.0011
Summer	-0.0460	0.0427	0.1084	0.124	0.1240	-0.0020	-0.0050	-0.0057	-0.0057
MidWest	-0.5740	0.6294	0.3512	0.7395	0.7395	-0.3613	-0.2016	-0.4245	-0.4245
NorthEast	-0.5710	-0.0079	0.0398	-0.0339	-0.0339	0.0045	-0.0227	0.0194	0.0194
South	0.4540	0.1954	0.1136	0.1451	0.1451	0.0887	0.0516	0.0659	0.0659
District1	-0.3040	0.0702	0.0969	0.0622	0.0622	-0.0213	-0.0295	-0.0189	-0.0189
District2	-0.3640	0.3803	0.2170	0.4386	0.4386	-0.1384	-0.0790	-0.1597	-0.1597
District3	0.1110	0.1972	0.1742	0.2176	0.2176	0.0219	0.0193	0.0242	0.0242
District4	0.6180	0.1355	0.2216	0.0755	0.0755	0.0838	0.1369	0.0467	0.0467
SP*Coll	-0.0080	-20.9548	12.0478	19.2567	24.4980	0.1676	-0.0964	-0.1541	-0.0653
SNP*Coll	0.0210	-1.6783	1.0561	1.3223	2.0310	-0.0352	0.0222	0.0278	0.0142
U*Coll	-0.0110	-9.4841	5.8490	8.8717	3.1484	0.1043	-0.0643	-0.0976	-0.0462
NR*Coll	0.0980	-0.9164	0.4600	0.8605	1.0376	-0.0898	0.0451	0.0843	0.0339
BX Sum						1.1558	-3.8854	-4.6569	-4.6455
Pos% Model						0.7606	0.0201	0.0094	0.0095
Pos% Crude						0.7100	0.0287	0.0189	-
StdDev Crude						0.4539	0.1671	0.1361	-
N						1,638	5,046	2,330	22,631

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled; all variables are unit-standardized.

Table E 3: Estimates of BX Vector β* by the Submodel Vectors using X Means for HIMP Establishments

Parameters	Model Beta	HIMP Prev X	HIMP Post X	HIMP Prev BX	HIMP Post BX	Total Average
Intercept	-1.6490	1	1	-1.6490	-1.6490	
HIMP	0.2920	-1	-1	-0.2920	-0.2920	
HIMP*Coll	0.2020	1	-1	0.2020	-0.2020	
logNbrEmp*Coll	-0.8180	-1.6373	1.5881	1.3393	-1.2990	
Coll	-1.4700	-1	1	1.4700	-1.4700	
Fall	-0.1370	-0.0174	0.0860	0.0024	-0.0118	
Spring	0.0670	-0.0523	0.0620	-0.0035	0.0042	
Summer	-0.0460	0.0244	0.1640	-0.0011	-0.0075	
MidWest	-0.5740	0.4599	0.2360	-0.2640	-0.1355	
NorthEast	-0.5710	-0.0035	-0.0640	0.0020	0.0365	
South	0.4540	-0.1812	-0.2760	-0.0823	-0.1253	
District1	-0.3040	0.3693	0.4340	-0.1123	-0.1319	
District2	-0.3640	0.2125	0.1220	-0.0774	-0.0444	
District3	0.1110	0.2404	0.2320	0.0267	0.0258	
District4	0.6180	0.1777	0.2120	0.1098	0.1310	
SP*Coll	-0.0080	-25.0523	26.2060	0.2004	-0.2096	
SNP*Coll	0.0210	-2.6237	2.4740	-0.0551	0.0520	
U*Coll	-0.0110	14.4843	-14.7760	-0.1593	0.1625	
NR*Coll	0.0980	-1.9617	1.5840	-0.1922	0.1552	
BX Sum				0.4644	-5.0109	
Pos% Estimate				0.6141	0.0066	0.2044
Pos% Crude				0.6098	0.0080	0.1990
StdDev Crude				0.4887	0.0892	0.3993
N				287	500	7,471

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Model Validation

The validation statistic, v, is calculated as the average sum of squares of the predicted prevalence minus the cross-validated prevalence (using N-1 deletion in Proc logistic) divided by (1- leverage (h))^2. In this case n=N in the formula below.

$$v = \sum_{i=1}^{n} \frac{\left(\frac{p_i - pcv_i}{1-h_i}\right)^2}{N}$$

The relationship between the validation statistic and R-squared provide evidence that the model is not over-parameterized if the Nagelkerke parameter corrected R-squared is increasing when the validation statistic is not increasing or relatively stable. This means that for the sample size the increasing R-squared that naturally increases with an increasing number of parameters in the model is offset by the increasing information in the model. The point at which R-squared and v increase together after stabilizing is where too many parameters have been added to the model even though they may be significant. The resultant graphical validation for the number of parameters in the model is shown in Figure E 1 for the market hog *Salmonella* full data set. Table E 4 shows that stability of R-Square with increasing v-statistic is achieved with 15 variables (similar categorical variables combined). There are 22 variables plus the intercept with one degree of freedom each in the model, four of which are the potential decision variables and the rest are structural or control variables.

The binary logistic regression model was evaluated for lack of fit to the data using the standard Hosmer-Lemeshow test for fit to the logistic distribution (Table E 4). Model over-dispersion was evaluated with the deviance Chi-square divided by the degrees of freedom. The deviance dispersion parameter statistic indicating over-dispersion requires multiplication of the covariance matrix to correct for the over-dispersion when greater than 2.0. Since this was exceeded, a correction was applied. This adjustment converts the regression coefficient estimates to quasi-likelihoods and appropriately decreases the regression coefficient significance by increasing the standard errors of the estimates effectively converting the model dispersion parameter to unity. No correction is required when the deviance statistic is sufficiently small, but in this case a dispersion correction was applied. The standard Hosmer and Lemeshow test was not considered significant with a p-value so close to 0.05 indicating that the data sufficiently fit the logistic distribution and the model provided a reasonably good fit.

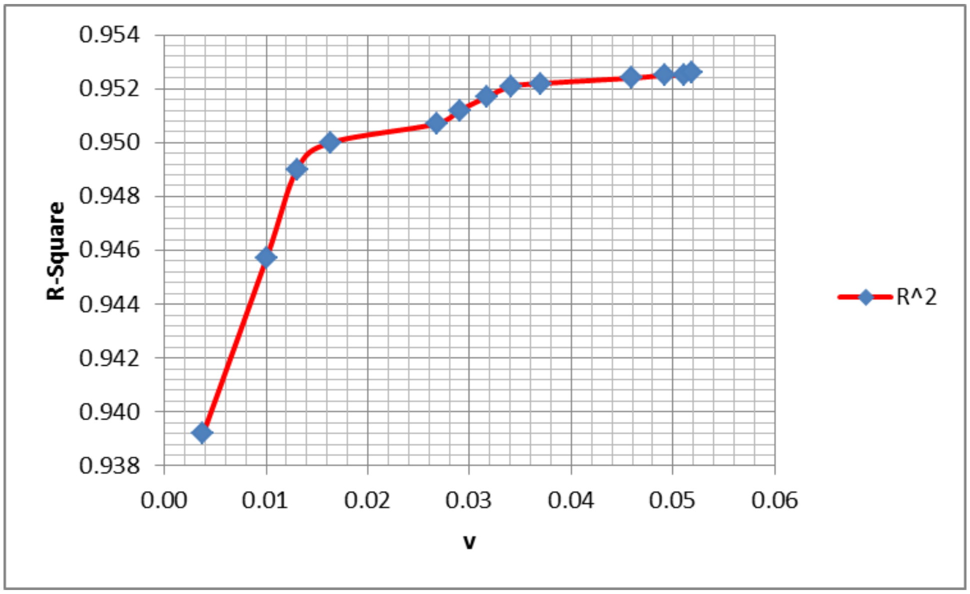

Figure E 1: Model Stage 1 Parameter Number Validation

Table E 4: Partitions for Hosmer and Lemeshow Tests

		Salmonella Positive		*Salmonella* Negative	
Group	**Total**	**Observed**	**Expected**	**Observed**	**Expected**
1	747	2	2.46	745	744.54
2	747	5	4.32	742	742.68
3	744	15	8.71	729	735.29
4	747	17	14.39	730	732.61
5	747	20	22.36	727	724.64
6	748	22	31.93	726	716.07
7	747	44	45.67	703	701.33
8	747	246	251.86	501	495.14
9	747	505	521.1	242	225.9
10	750	611	633.59	139	116.41

Hosmer and Lemeshow Goodness-of-Fit Test

Chi-Square	**DF**	**Pr > ChiSq**
15.8623	8	0.0444

Figure E 2 shows the Receiver Operating Characteristic (ROC) plot for the model. The interpretation of this plot is that the model is more predictive the greater the distance the curve is away from the imaginary diagonal dividing the figure in half. The best predictors are the closest to the 100% sensitivity and 0% (1 - specificity) corner point. Sensitivity is defined as the number of positives (taken as the number of positives with a given cut point) divided by the total positives (taken as the number of FSIS positive tests). The false positive rate is defined as (1 – specificity), where the specificity is the number of negatives (taken as the number of negatives with the same cut point) divided by the total negatives (taken as the number of FSIS negative tests).

The curve described by ROC plot follows the various cut points dividing the positives and negatives from the total positives and total negatives thus producing corresponding pairs of sensitivity and 1-specificity on the ROC curve.

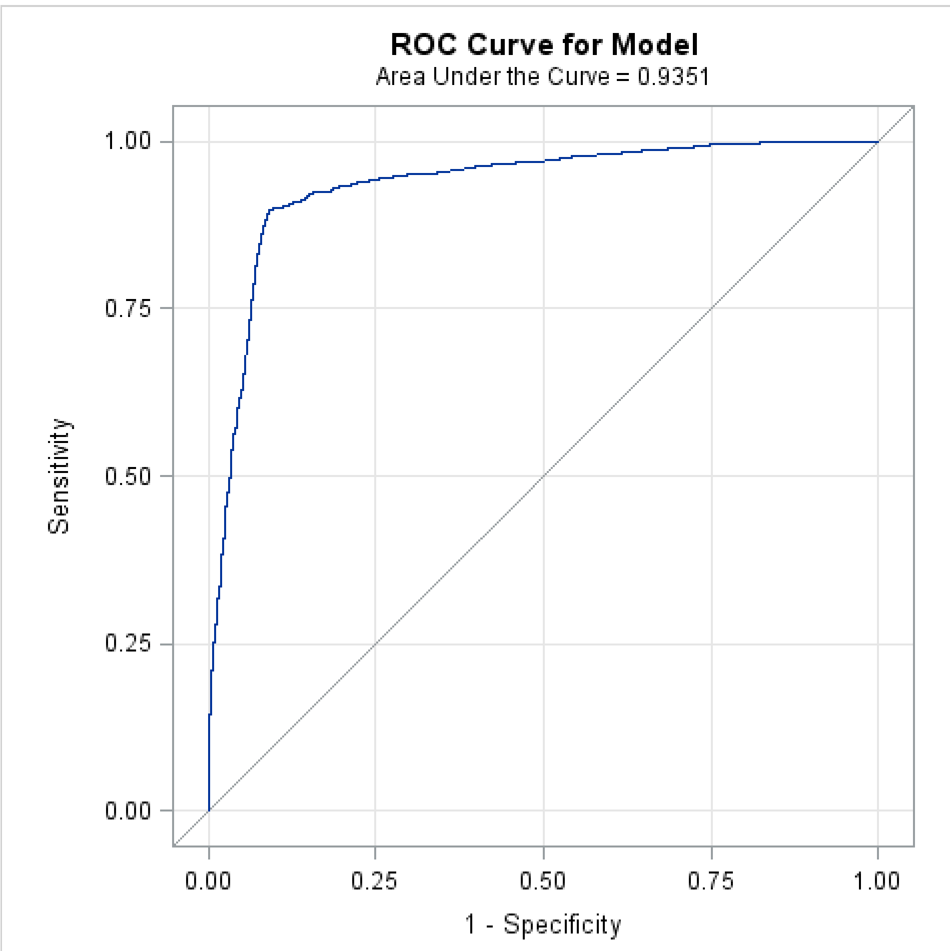

Figure E 2: Risk Model Receiver Operating Characteristic Curve

Table E 5 shows the full ROC curve derivation. The ROC analysis shows that the model is a good predictor of positive and negative Salmonella sample results. A standard method for ROC curve evaluation is to estimate the area under the curve (AUC). This can be done using the SAS logistic procedure output for binary response models. The c-statistic provided by SAS is equivalent to the area under the ROC curve (AUC). The c-statistic was evaluated for significance against the c = 0.5 non-significant alternative and passed the z-test with $p>0.05$ (Hosmer and Lemeshow, 2000). Further by a standard rule of thumb because the c value is greater than 0.93, the model is highly predictive and reliable. The probability of a sample being positive or negative for Salmonella can be predicted using the model independent variables. Taking the cut point for a positive to be greater than 0.5 probability and a negative to be less than or equal to 0.5 probability the model sensitivity is 86.4% and the specificity is 91.8% with a false positive rate of 27.6% and a false negative rate of 3.5%.

Table E 5: Classification Table for Predicted Outcomes at Different Probability Levels

	Correct		Incorrect		Percentages				
Probability Level	Event	Non-Event	Event	Non-Event	Correct	Sens-itivity	Spec-ificity	FALSE POS	FALSE NEG
0.00	1487	0	5984	0	19.9	100	0	80.1	.
0.02	1454	2674	3310	33	55.3	97.8	44.7	69.5	1.2
0.04	1417	3907	2077	70	71.3	95.3	65.3	59.4	1.8
0.06	1385	4753	1231	102	82.2	93.1	79.4	47.1	2.1
0.08	1352	5175	809	135	87.4	90.9	86.5	37.4	2.5
0.10	1340	5330	654	147	89.3	90.1	89.1	32.8	2.7
0.12	1338	5373	611	149	89.8	90	89.8	31.3	2.7
0.14	1338	5393	591	149	90.1	90	90.1	30.6	2.7
0.16	1338	5397	587	149	90.1	90	90.2	30.5	2.7
0.18	1338	5397	587	149	90.1	90	90.2	30.5	2.7
0.20	1338	5399	585	149	90.2	90	90.2	30.4	2.7
0.22	1338	5399	585	149	90.2	90	90.2	30.4	2.7
0.24	1338	5401	583	149	90.2	90	90.3	30.3	2.7
0.26	1338	5405	579	149	90.3	90	90.3	30.2	2.7
0.28	1338	5406	578	149	90.3	90	90.3	30.2	2.7
0.30	1338	5409	575	149	90.3	90	90.4	30.1	2.7
0.32	1337	5409	575	150	90.3	89.9	90.4	30.1	2.7
0.34	1336	5416	568	151	90.4	89.8	90.5	29.8	2.7
0.36	1335	5419	565	152	90.4	89.8	90.6	29.7	2.7
0.38	1334	5426	558	153	90.5	89.7	90.7	29.5	2.7
0.40	1334	5433	551	153	90.6	89.7	90.8	29.2	2.7
0.42	1332	5445	539	155	90.7	89.6	91	28.8	2.8
0.44	1326	5452	532	161	90.7	89.2	91.1	28.6	2.9
0.46	1313	5470	514	174	90.8	88.3	91.4	28.1	3.1
0.48	1303	5484	500	184	90.8	87.6	91.6	27.7	3.2

0.50	***1285***	***5495***	***489***	***202***	***90.8***	***86.4***	***91.8***	***27.6***	***3.5***
0.52	1270	5510	474	217	90.8	85.4	92.1	27.2	3.8
0.54	1248	5521	463	239	90.6	83.9	92.3	27.1	4.1
0.56	1230	5543	441	257	90.7	82.7	92.6	26.4	4.4
0.58	1204	5559	425	283	90.5	81	92.9	26.1	4.8
0.60	1176	5567	417	311	90.3	79.1	93	26.2	5.3
0.62	1130	5586	398	357	89.9	76	93.3	26	6
0.64	1074	5609	375	413	89.5	72.2	93.7	25.9	6.9
0.66	1001	5639	345	486	88.9	67.3	94.2	25.6	7.9
0.68	937	5676	308	550	88.5	63	94.9	24.7	8.8
0.70	855	5722	262	632	88	57.5	95.6	23.5	9.9
0.72	783	5767	217	704	87.7	52.7	96.4	21.7	10.9
0.74	685	5804	180	802	86.9	46.1	97	20.8	12.1
0.76	574	5846	138	913	85.9	38.6	97.7	19.4	13.5
0.78	486	5881	103	1001	85.2	32.7	98.3	17.5	14.5
0.80	416	5908	76	1071	84.6	28	98.7	15.4	15.3
0.82	362	5936	48	1125	84.3	24.3	99.2	11.7	15.9
0.84	316	5947	37	1171	83.8	21.3	99.4	10.5	16.5
0.86	271	5958	26	1216	83.4	18.2	99.6	8.8	17
0.88	227	5967	17	1260	82.9	15.3	99.7	7	17.4
0.90	199	5973	11	1288	82.6	13.4	99.8	5.2	17.7
0.92	145	5974	10	1342	81.9	9.8	99.8	6.5	18.3
0.94	70	5977	7	1417	80.9	4.7	99.9	9.1	19.2
0.96	12	5983	1	1475	80.2	0.8	100	7.7	19.8
0.98	0	5984	0	1487	80.1	0	100	.	19.9

Table E 6 shows additional classification statistics. Concordance is 93.5% with a discordant rate of 6.5%. There are no ties in the data. The c statistic shows that 93.5% of the ROC curve area is accounted for indicating a high predictive rate for the model. Other measures of association are also very large: Somer’s D and Gamma are both 0.87 and Tau-a is 0.277.

Table E 6: Model Classification Statistics - Association of Predicted Probabilities and Observed Responses

Percent Concordant	**93.5**	**Somers' D**	**0.87**
Percent Discordant	6.5	Gamma	0.87
Percent Tied	0	Tau-a	0.277
Pairs	8898208	c	0.935

APPENDIX F: Data Splitting/W3NR Model Analysis

Additional model evaluation and validation was done using systematic 50:50 data set division, where the dataset used in model development was split so as to equally divide the data into a modeling data set used to derive the model coefficients, and the second half of the data was used for prediction of positive and negative *Salmonella* results. The regression coefficients for each subset of data were re-estimated ten times with sequential retrieval of daily plant data and the stability of the prevalence estimates were assessed using the remaining half of the data (Picard *et al*. 1990).

Table F 1 shows the results of splitting the market hog dataset for *Salmonella*, and Table F 2 shows the parameter estimates for the split data model which are compared with estimates from the original model.

Table F 2 also shows the prevalence estimates from two of the split models compared to the unadjusted prevalence estimates from the full dataset. The model appears to be stable when splitting the data since all estimates for the mean, post-chill, pre-evisceration, and the HIMP and non-HIMP counterparts are for the most part in close agreement. Discrepancies appear with the HIMP estimates because of the extremely small sample size of five. Also, the post-chill prevalence is within the sampling error of the post-chill prevalence found in the FSIS Market Hog HIMP report (FSIS 2011a). The only matter of concern is the estimation of the model weighted mean prevalence which is lower than the unweighted overall prevalence. This is likely due to the model weighting compensating from the relatively high prevalence at re-hang and the low prevalence at post-chill.

The parameter estimates from Table B 2, Table E 1, Table E 2, and Table F 3 are used to calculate the prevalence estimates in Table F 2. The BX element as described above equal to η* and is the sum of cross products of the B regression parameters and the mean scenario X variable components in the model. By back transforming BX through the inverse logit function the estimated prevalence is obtained. The inverse logit function is defined as:

$$P = \frac{1}{1 + e^{-BX}}$$

Table F 1: Analysis of Maximum Likelihood Estimates for a Split Data Set Example (n=3,735 p=19-1)

Parameter	DF	Beta Estimate	Beta Error	Beta Chi-Sq	p-Value	Standard Est	Mean	Standard Deviation
Intercept	1	-0.4905	0.1958	6.28	0.0122		1	0
HIMP vs No-HIMP	1	-0.9057	0.1839	24.26	<.0001	-0.7593	0.7896	0.6136
HIMP*Coll	1	0.125	0.0884	1.99	0.1575	0.1395	0.4421	0.897
logNbrEmp*Coll	1	-0.7923	0.0795	99.23	<.0001	-1.5735	0.5377	1.4452
Collection Post vs Prev	1	-1.3789	0.128	116.08	<.0001	-1.4974	0.4951	0.8689
Fall vs Winter	1	-0.1498	0.0521	8.28	0.004	-0.1181	0.0026	0.6762
Spring vs Winter	1	-0.0464	0.052	0.79	0.3721	-0.0363	-0.0042	0.671
Summer vs Winter	1	-0.0129	0.0478	0.07	0.7866	-0.0111	0.0926	0.7339
MidWest vs West	1	-0.1822	0.1086	2.82	0.0934	-0.1389	0.4079	0.6931
NorthEast vs West	1	-0.5756	0.1468	15.38	<.0001	-0.2729	0.0203	0.5086
South vs West	1	0.1752	0.1102	2.53	0.1119	0.1085	0.0942	0.5693
District1 vs District5	1	-0.6955	0.1159	36.04	<.0001	-0.3539	0.1241	0.4547
District2 vs District5	1	-0.4248	0.0945	20.19	<.0001	-0.272	0.2457	0.5323
District3 vs District5	1	0.1747	0.0906	3.72	0.0538	0.0994	0.1852	0.4989
District4 vs District5	1	0.9606	0.1303	54.35	<.0001	0.5107	0.1999	0.5079
SP*COLL	1	-0.0074	0.0032	5.24	0.0221	-0.1974	4.6287	19.214
SNP*COLL	1	0.0224	0.0094	5.58	0.0182	0.0868	0.4033	2.8994
U*COLL	1	-0.0167	0.0053	9.79	0.0018	-0.2258	1.6172	9.8219
NR*COLL	1	0.0556	0.0149	13.86	0.0002	0.1452	0.1568	1.8562

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table F 2: Estimates of BX Vector β* by the Scenario Vectors of X Means "The Solution of the Percent Positive Rate Predicted by Unsplit, Split, and W3NR Model"

Estimates	unsplit	split1	split2	W3NR
BX (all variables at means)[1]	-2.7039	-2.6483	-3.5987	-2.5991
BX (Post-Chill, no-HIMP)[2]	-3.4202	-3.4652	-3.4365	-2.8337
BX (Pre-Evis, no-HIMP)[3]	-0.1338	-0.0183	-0.2279	-1.5933
BX (Post-Chill, HIMP)[4]	-2.7006	-1.8498	-1.4178	0.3585
BX (Pre-Evis, HIMP)[5]	1.749	1.9891	1.6186	-0.4067
Percent Positive[1]	6.27%	6.61%	2.66%	6.92%
Percent Positive[2]	3.17%	3.03%	3.12%	5.55%
Percent Positive[3]	46.66%	49.54%	44.33%	16.89%
Percent Positive[4]	6.29%	13.59%	19.50%	58.87%
Percent Positive[5]	85.18%	87.96%	83.46%	39.97%
Unweighted Percent Positive[1]	19.57%	20.13%	19.67%	19.98%
Unweighted Percent Positive[2]	2.87%	2.84%	2.91%	3.02%
Unweighted Percent Positive[3]	71.00%	70.31%	71.73%	71.14%
Unweighted Percent Positive[4]	0.80%	0.00%	1.63%	0.54%
Unweighted Percent Positive[5]	60.98%	63.57%	58.50%	60.98%
Sample Size	7,471	3,735	3,736	7,471

Abbreviations: HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; Pre-Evis, Pre-evisceration.

The prevalence estimates for the mean, pre-evisceration, and post-chill are consistent within the sampling error across the dataset splits. Note that the prevalence estimates may be different that other sources due to log-volume weighting. This is because the difference in prevalence rather than absolute prevalence estimates were the focus of the risk assessment. Figure F 1 shows the spread of uncertainty among the different split models derived with the base model cumulative probability being the central estimate with extremes at the 50% points of (2,425, 2,736) bracketing the model mean of illnesses avoided at 2,533.

Table F 3: W3NR Model Alternative Scenario - NR Variable Replaced with W3NR Variable (n=7,471 p=19-1)

Parameter	DF	β Estimate	β Error	β Chi-Sq	p-value	Standard Est	Mean	SD
Intercept	1	-0.8579	0.1459	34.59	<.0001		1	0
HIMP vs No-HIMP	1	-0.6174	0.1351	20.88	<.0001	-0.5149	0.792	0.611
HIMP*Coll	1	0.041	0.0625	0.43	0.511	0.0459	0.4302	0.902
logNbrEmp*Coll	1	-1.3858	0.0676	420.79	<.0001	-1.911	0.3615	1.009
Collection Post vs Prev	1	-1.169	0.0938	155.43	<.0001	-1.2725	0.4865	0.873
Fall vs Winter	1	-0.1523	0.0366	17.35	<.0001	-0.1197	0.0007	0.676
Spring vs Winter	1	0.0915	0.0369	6.16	0.0131	0.0716	-0.0026	0.674
Summer vs Winter	1	-0.0571	0.0337	2.87	0.0904	-0.049	0.0897	0.733
MidWest vs West	1	-0.3661	0.0726	25.45	<.0001	-0.2796	0.4005	0.694
NorthEast vs West	1	-0.3548	0.1045	11.52	0.0007	-0.1682	0.0173	0.509
South vs West	1	0.4355	0.0748	33.89	<.0001	0.2715	0.0991	0.575
District1 vs District5	1	-0.1688	0.0828	4.16	0.041	-0.0872	0.1171	0.466
District2 vs District5	1	-0.1513	0.0655	5.34	0.021	-0.0977	0.2345	0.541
District3 vs District5	1	-0.094	0.0621	2.29	0.13	-0.054	0.1749	0.508
District4 vs District5	1	0.4019	0.0897	20.05	<.0001	0.2162	0.19	0.517
W3_SP8*Coll	1	0.0055	0.0051	1.15	0.284	-0.057	1.9689	7.591
W3_SNP8*Coll	1	0.0633	0.0186	11.61	0.0007	0.0742	0.0642	0.884
W3_U8*HIMP*Coll	1	-0.0169	0.0091	3.42	0.064	-0.0514	0.1373	2.236
W3_NR8*Coll	1	0.1112	0.0135	67.924	<.0001	0.2147	0.0835	1.369

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SD, Standard Deviation; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

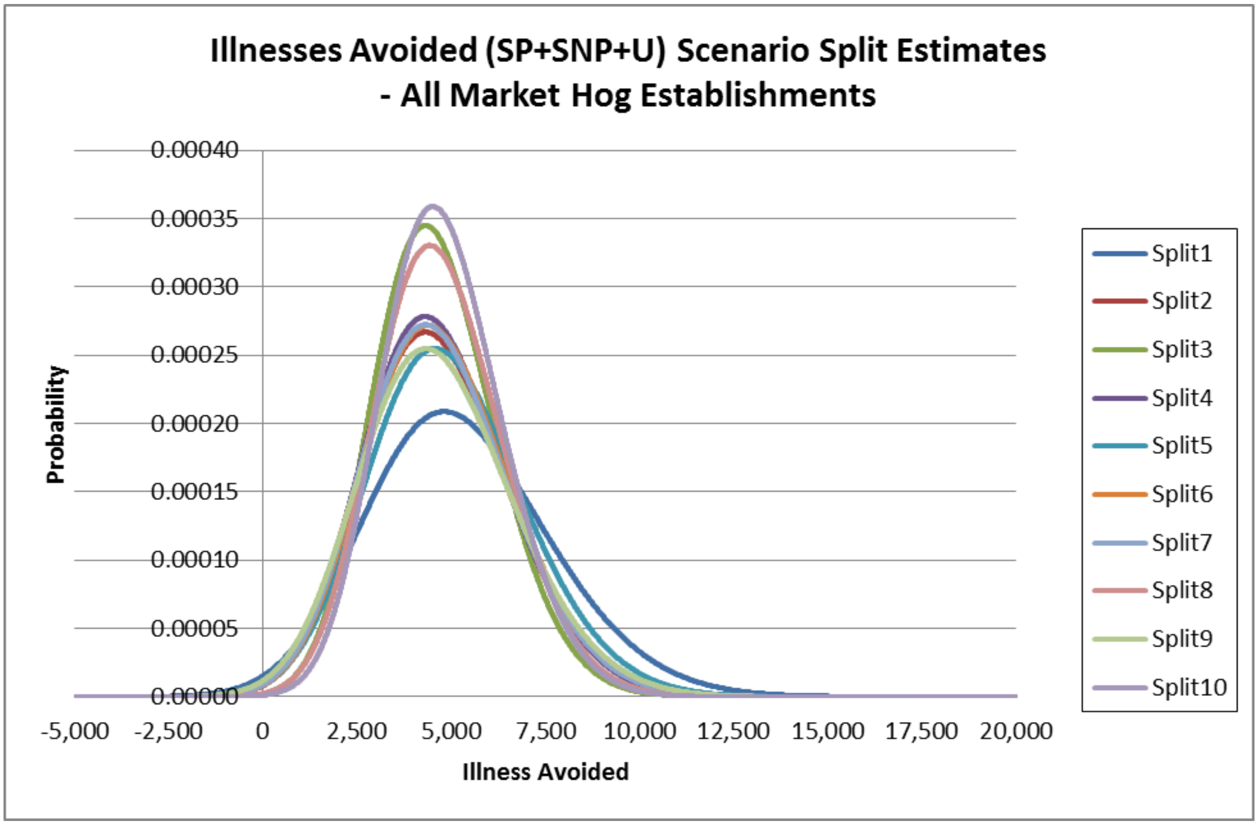

Figure F 1: Comparison of $\lambda_{avoided}$ Probability Distributions: Split Data Model Curves vs. Full Data Model Curve. The indiscriminate scenario for market hog Salmonella was simulated with three main stochastic inputs (λ_{ill} [lambda], Ai and βi [beta]); the uncertainty about λavoided is shown as the "Illnesses Avoided" distribution.

Table F 3 shows the maximum likelihood estimates for the W3NR data set—that is, the full model data set with the NR variable replaced by the W3NR variable which approximates public health risk based on PBIS data. Similar prevalence estimates are consistent with sampling error across the splits of data and are in general agreement with the split data sets and with the full dataset estimates. The estimates are in agreement with post-chill and pre-evisceration estimates from non-HIMP plants but have discrepancy with HIMP plant estimates due to uncertainty and sample size error.

The W3NR output distribution of *Salmonella* illnesses avoided using the Stage 1 parameters from Table E 1 versus the Stage 1 parameters from Table C 4 and Table C 5 to produce the respective output distributions from Stage 2 shown as cumulative probability distributions in Table F 4 are quite different. The W3NR distribution has a median of 1,848 while the base model distribution has a median of 2,523. These are

Table F 4: Statistics for Illnesses Avoided for Base Model, W3NR Base Model, Base Model-minus-Seven, and W3NR Base Model-minus-Seven

Statistic	Model	W3NR	Model-7	W3NR-7
Mean	2,533	1,919	4,101	2,943
Stdev	5,980	1,039	2,111	1,433
Median	2,535	1,848	3,954	2,841
P(0.10)	-2,010	-959	-2,165	-1,628
P(0.90)	7,099	3,122	6,558	4,612
P(ill % >0)	22.20	18.60	20.30	17.20

visually different. Both distributions are lognormal with an average difference at the medians of 723. This is most likely the result of differing regression coefficients for the W3NR and NR variables which are 0.1112 and 0.0978, respectively. On an absolute basis the W3NR coefficient will drive the illnesses avoided down with all data except the NR and W3NR inputs being the same. The other coefficients seem to contribute less to this effect due to similarity. Apparently, in this model configuration the W3NR noncompliances have less of an effect in increasing the number of illnesses avoided than the more numerous procedure noncompliances contained in the NR variable. This is evidence that using more seemingly non-public health related noncompliances as a decision variable is more predictive of reduction of *Salmonella* illnesses than the more limited number of inspection procedures contained in the W3NR variable.

Cumulative distribution curves for the same model data are shown in Figure F 2, but these are additionally augmented with summed ISP data representing the seven days before sample collection. This was also done for the W3NR model data. What these two curves show is that they are both moved to the right and appear more sensitive to detect positive *Salmonella* results. The model, when run taking into account the seven days before a positive, estimates a median of 3,954. This approach predicts 1,431 more illnesses avoided than the non-augmented model. Similarly, the W3NR- model, when run taking into account the seven days before a positive, estimates a median of 2,841–predicting 993 more illnesses avoided than the W3NR model.

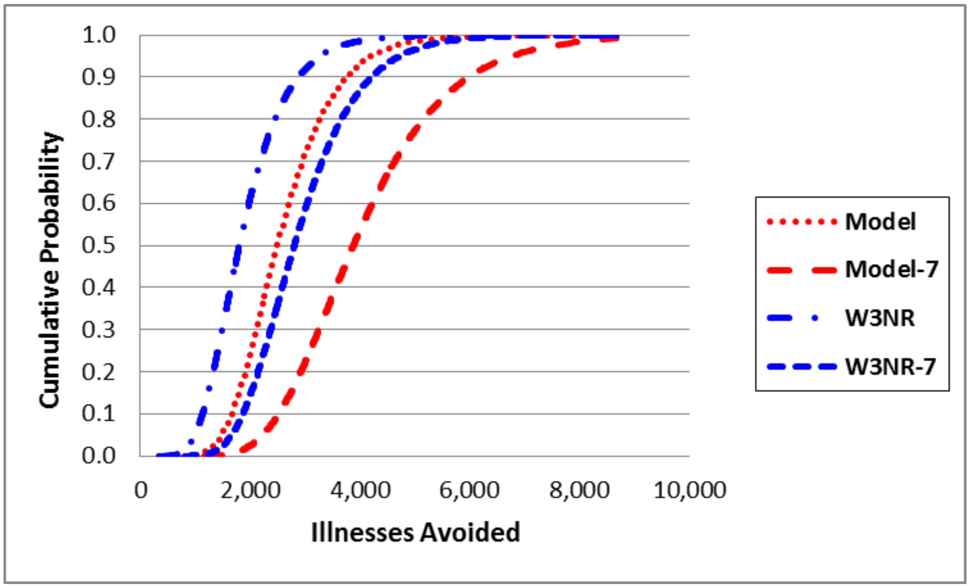

Figure F 2: Comparison of Risk Model (SP+SNP+U) Scenarios Cumulative Distributions: Standard Model, W3NR Model, Standard Model-7, and W3NR Model -7

APPENDIX G: Sensitivity and Uncertainty Analysis for Illnesses Avoided and Product Attribution

Sensitivity Analysis (Version 2)

The sensitivity analysis for 35 establishments expected to adopt the new inspection system was rerun with the complete inspection data over the 2010-2011 time period for these establishments. This increased the sample size from 2,330 to 22,631. The same mean reduction in illnesses was obtained with a much decreased uncertainty in illness reduction.

Figure G 1, Figure G 2, and Figure G 3 depict cumulative probability percentiles for the SP, SNP, and U decision variables, respectively, when determining the output of the SP+SNP+U scenario in units of illnesses avoided averages. The same sensitivity patterns as shown previously for the smaller dataset is observed but the percentiles show a much narrower range and the 5th percentiles of major concern are shifted to the right. The variability in percentiles is in order of greatest to least: SP, U, and SNP as with the smaller dataset. Figure G 4 shows the same trend in slope where the greatest change in illnesses avoided percentiles is in order of greatest to least SP, U, and SNP. Figure G 5 shows the relative change in illnesses avoided corresponding to graded shifts in each of the decision variables in the SP+SNP+U scenario. The greatest effect is SP as indicated by the span of the horizontal bar followed in descending order by the bar widths of U and SNP decision variables. The main differences between sensitivity analysis version 1 and sensitivity analysis version 2—besides the difference in sample size—are the shift to increasing illnesses avoided on all graphics Figure E 2 through Figure G 2. The percentile ranges are also narrower when additional samples are taken into account (see Figure G 1 through Figure G 3); component contributions to total illnesses avoided narrow as well (Figure G 5).

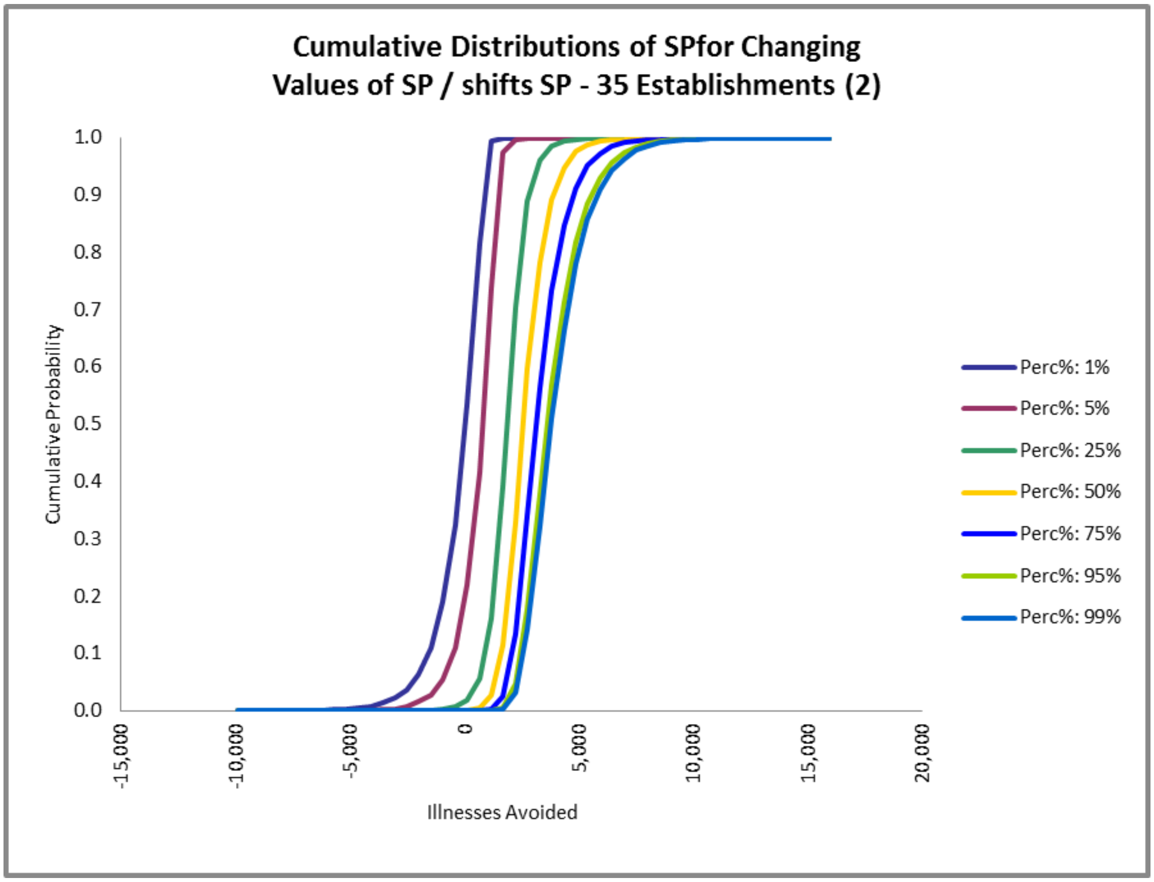

Figure G 1: Cumulative Percentile Distributions for Disc(SP) $\lambda_{avoided}$ Sensitivity Analysis (Version 2)

Estimated change in the annual *Salmonella* human illness rate when offline SP inspection procedures are increased in 35 large and small non-HIMP market hog establishments with sample size 22,631**.** Figure depicts the SP decision variable that increased scheduled and performed procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: SP = scheduled and performed procedures.

Source: FSIS analysis of Agency generated data (2010-2011).

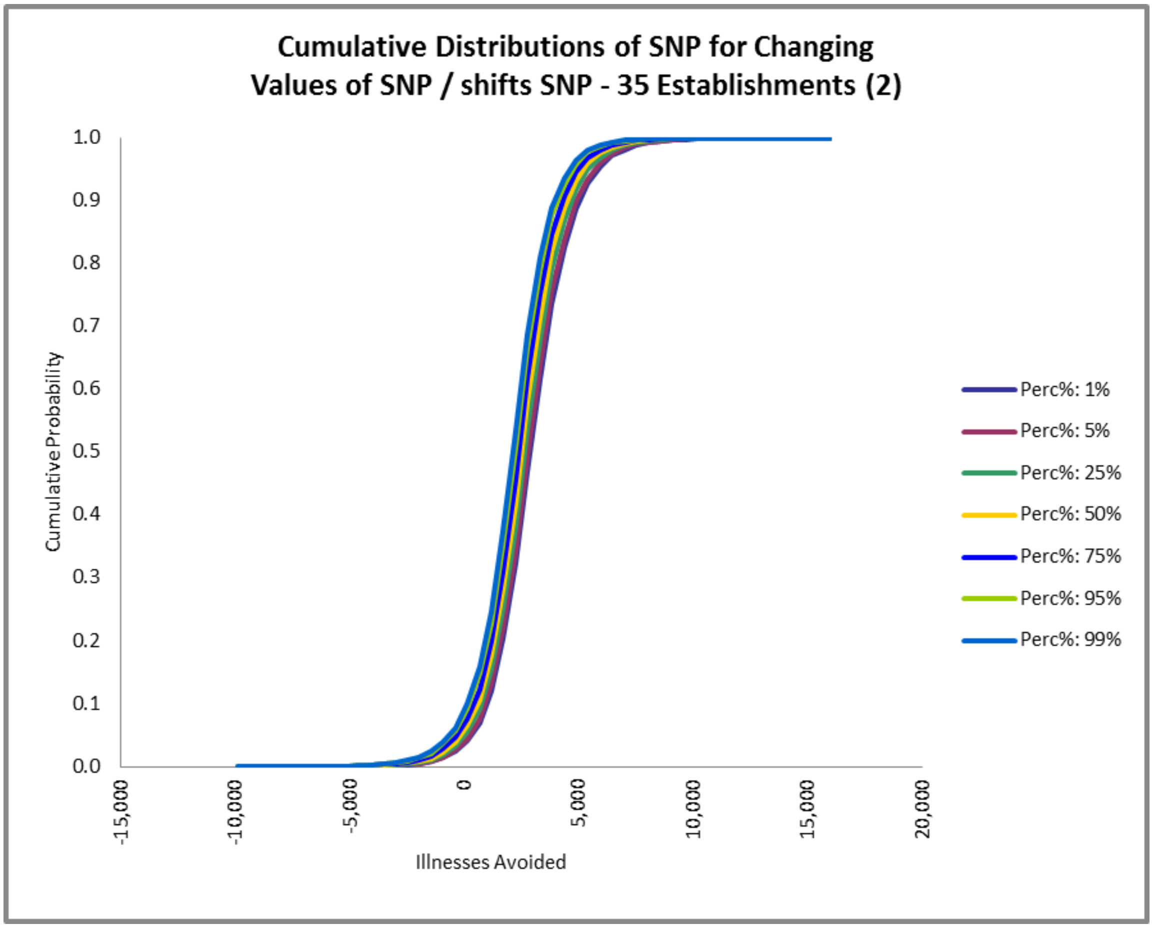

Figure G 2: Cumulative Percentile Distributions for Disc(SNP) $\lambda_{avoided}$ Sensitivity Analysis (Version 2)

Estimated change in the annual *Salmonella* human illness rate when offline U inspection procedures are increased in 35 large and small non-HIMP market hog establishments with sample size 22,631. **.** Figure depicts the SNP decision variable that increased unscheduled procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: U = unscheduled procedures performed.

Source: FSIS analysis of Agency generated data (2010-2011).

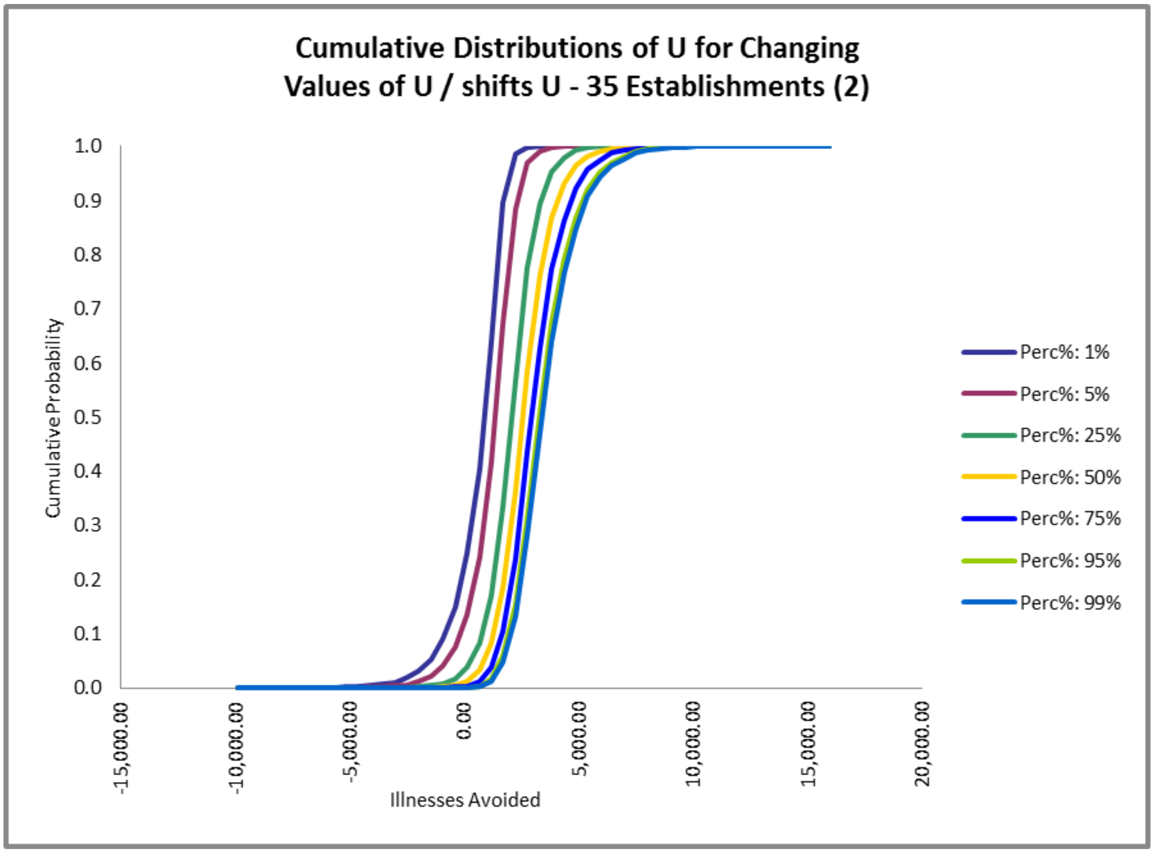

Figure G 3: Cumulative Percentile Distributions for Disc(U) $\lambda_{avoided}$ Sensitivity Analysis (Version 2)

Estimated change in the *Salmonella* human illness rate when offline SNP inspection procedures are decreased in 35 large and small non-HIMP market hog establishments with sample size 22,631**.** Figure depicts the U decision variable that decreased scheduled but not performed procedures with cumulative probability distributions labeled as percentiles from 1% to 99%.

Abbreviation: SNP = scheduled not performed procedures.

Source: FSIS analysis of Agency generated data (2010-2011).

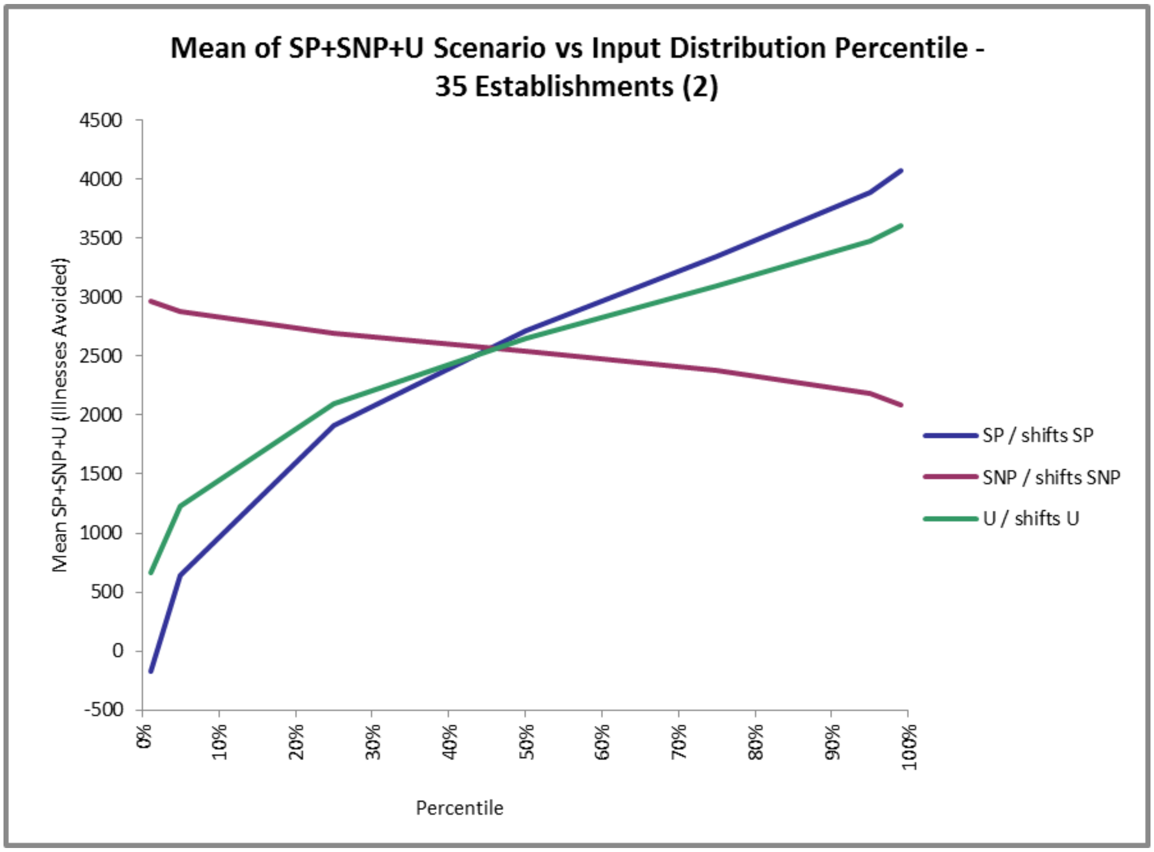

Figure G 4: Percentiles of Indiscriminate Scenario in 35 Large and Small Establishments Illnesses Avoided ($\lambda_{avoided}$) vs. Input Decision Variable Distribution Percentiles (SP, SNP, and U) (Version 2)

Estimated change in the annual *Salmonella* human illness rate when offline SP and U inspection procedures are increased and SNP procedures are decreased with sample size 22,631

Abbreviations: SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.

Source: FSIS analysis of Agency generated data (2010=2011).

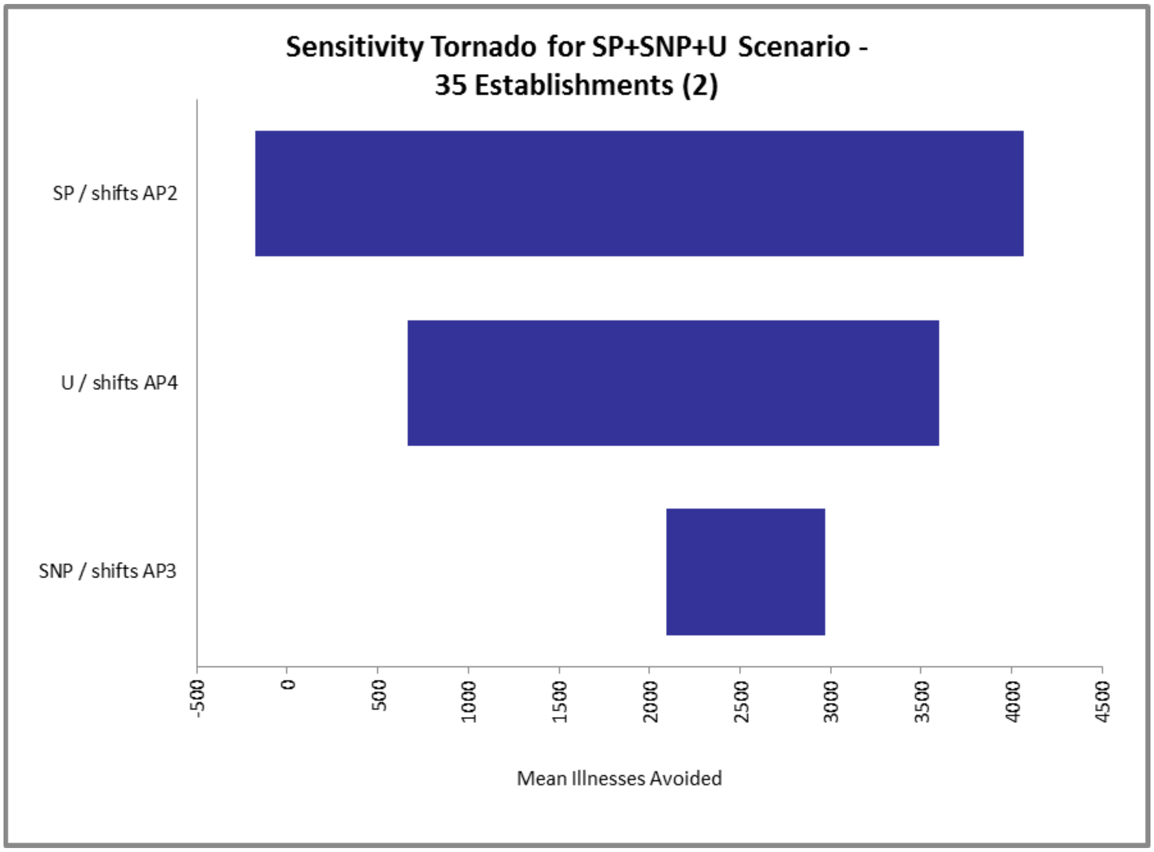

Figure G 5: Sensitivity Graph for Decision Variables in Market Hog-Salmonella Model Indiscriminate Scenario for 35 Large and Small Establishments (Version 2)

This tornado graph illustrates the relative sensitivity of each inspection variable category to the $\lambda_{avoided}$ estimate with respect to the scheduled and performed procedures (SP), unscheduled procedures (U), and scheduled not performed procedures (SNP logistic model coefficients). Sample size is 22,631.
Abbreviations: SNP = scheduled not performed procedures; SP = scheduled and performed procedures; U = unscheduled procedures performed.
Source: FSIS analysis of data generated from the model.

Uncertainty Analysis (Version 2)

Uncertainty about the total *Salmonella* illnesses per year attributable to market hogs is modeled by considering the uncertainty in the total annual domestically acquired foodborne illnesses for *Salmonella* in market hogs estimated by CDC (Scallan *et al.*, 2011), the percentage of cases attributable *Salmonella* in the pork commodity (Painter et al., 2013), and the percentage of pork attributed to market hogs (FSIS, 2010-2015) as our primary analysis. The mean estimated total cases (90% credibility interval) for *Salmonella* from market hogs was 69,857 (5th percentile 34,273; 95th percentile 111,673) (see Table 6 in body of report).

As presented in Table 6 in the main body of this report, the estimates of the portion of total illnesses per year attributable are: 1,085,707 to foodborne *Salmonella*, 6.3% to *Salmonella* in pork, and 96.3% to *Salmonella* in pork in market hogs. References also cite that figures for illnesses found are attributable to foodborne bacteria (42.4%), attributable to foodborne *Salmonella* (10.9%), and attributable to consumed swine products (6.3%) (Painter 2013; Scallan *et al*. 2011).[11] Analysis of FSIS slaughter data shown in Table G 1 also estimated the fraction of total *Salmonella* illnesses per year attributable to market hogs as 96.03%, of those illnesses attributable to pork on the basis of production volume for each class of pork. This attribution fraction is applied to the credibility intervals of (Scallan *et al*. 2011) to determine the 5th and 95th percentiles of a putative lognormal distribution. This treatment, however, does not consider uncertainty associated with the fraction of illnesses attributable to market hog consumption.

Table G 1: Domesticated Swine Slaughter Category Counts

Year	Boar/Stag	Market Hogs	Roaster	Sow	Total
2010	411,058	105,237,779	720,167	2,996,622	109,365,626
2011	418,869	103,556,138	815,644	3,066,951	107,857,602
2012	410,369	108,122,915	796,213	3,034,181	112,363,678
2013	413,395	107,289,722	805,376	2,987,086	111,495,579
2014	387,057	102,911,815	743,697	2,849,395	106,891,964
2015	361,765	111,542,005	768,305	2,906,959	115,579,034
Sum 2010-2015	**2,402,513**	**638,660,374**	**4,649,402**	**17,841,194**	**663,553,483**
Percentage of Total	**0.36%**	**96.03%**	**0.70%**	**2.69%**	**100%**

Data from FSIS, 2010-2015.

[11] Our assumed attribution for *Salmonella* in market hogs is within the range estimated by Painter *et al.* (2013), as in this paper the authors explain that outbreak data tend to under-represent market hogs as a source of *Salmonella* infection and further note that studies of sporadic infections implicate consumption of swine products as a risk factor.

Figure G 6 shows the relative uncertainty component contributions to overall uncertainty for the model incorporating all market hog establishments. Figure G 7 shows the relative uncertainty components for the 35 establishments most likely to adopt the new inspection system. Table G 2 shows the results for the total uncertainty distributions for all market hog establishments and the 35 selected market hog establishments. Two uncertainty distributions for the 35 establishment subsample of the 164 establishments used to develop the risk model were evaluated. The first subsample used data from 2,330 sample days on which *Salmonella* samples were taken during the 2010-2011 time period (model version 1). The second dataset for the 35 establishments used inspection data over the same time period incorporating results from a total of 22,631 days of inspection whether *Salmonella* samples were taken or not (model version 2). Therefore, the risk model was used as a predictive model based solely on inspection data to predict the public health uncertainty in both cases of uncertainty estimation. In addition to larger sample size, the second uncertainty estimates incorporate 2016 log-volume weights that reflect an average untransformed production volume increase of 8.9% by 2016. The change in total annual market hog production volume is shown in Table G 3. The annual change in production for the 35 selected market hog establishments is shown in Table G 4. This subset of establishments shows a change in production of 5.13% by 2016. This change in weighting also helped reduce the number of predicted *Salmonella* illnesses. Table G 5 shows the estimated mean and percentiles of the illnesses distribution resulting after NSIS is adopted in the selected 35 establishments.

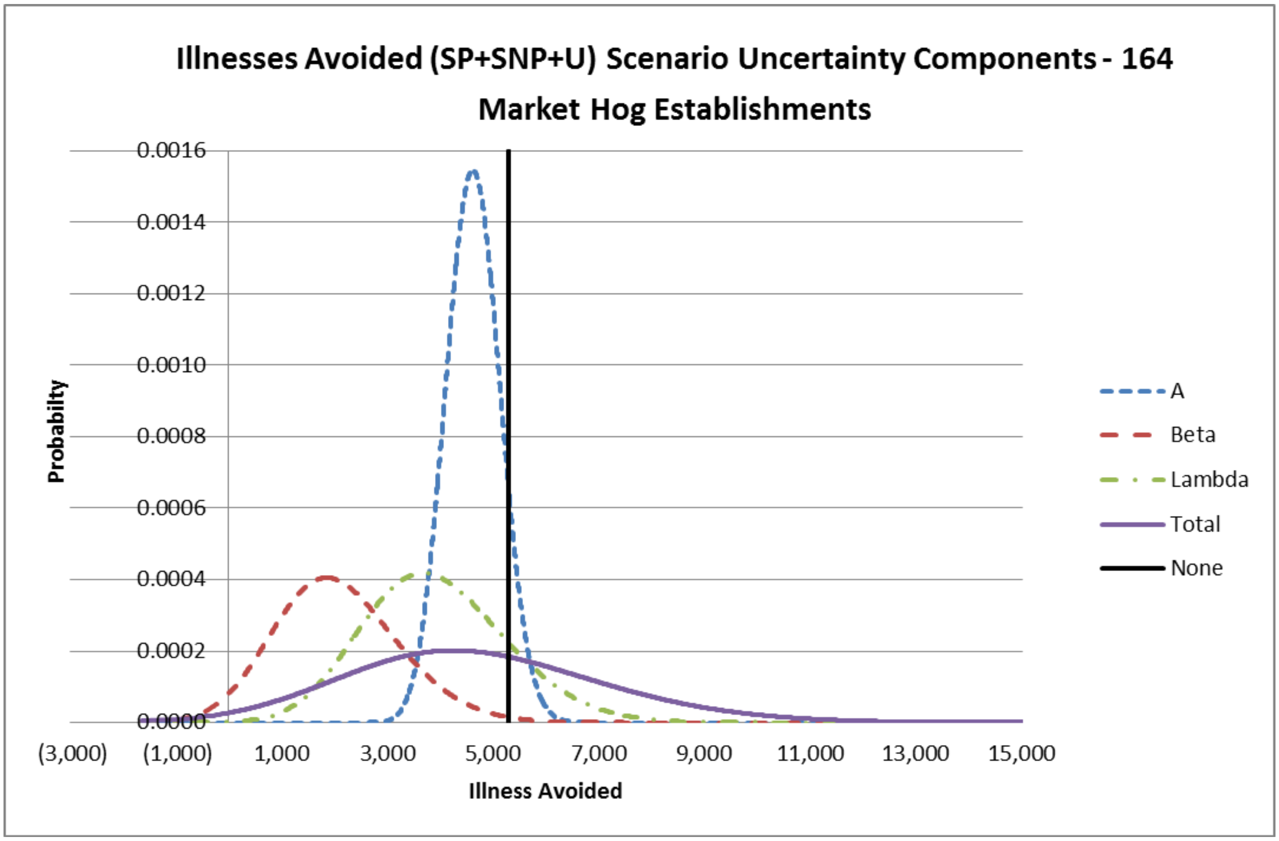

Figure G 6: Uncertainty Components for Illnesses Avoided (SP+SNP+U) Scenario – All Market Hog Establishments

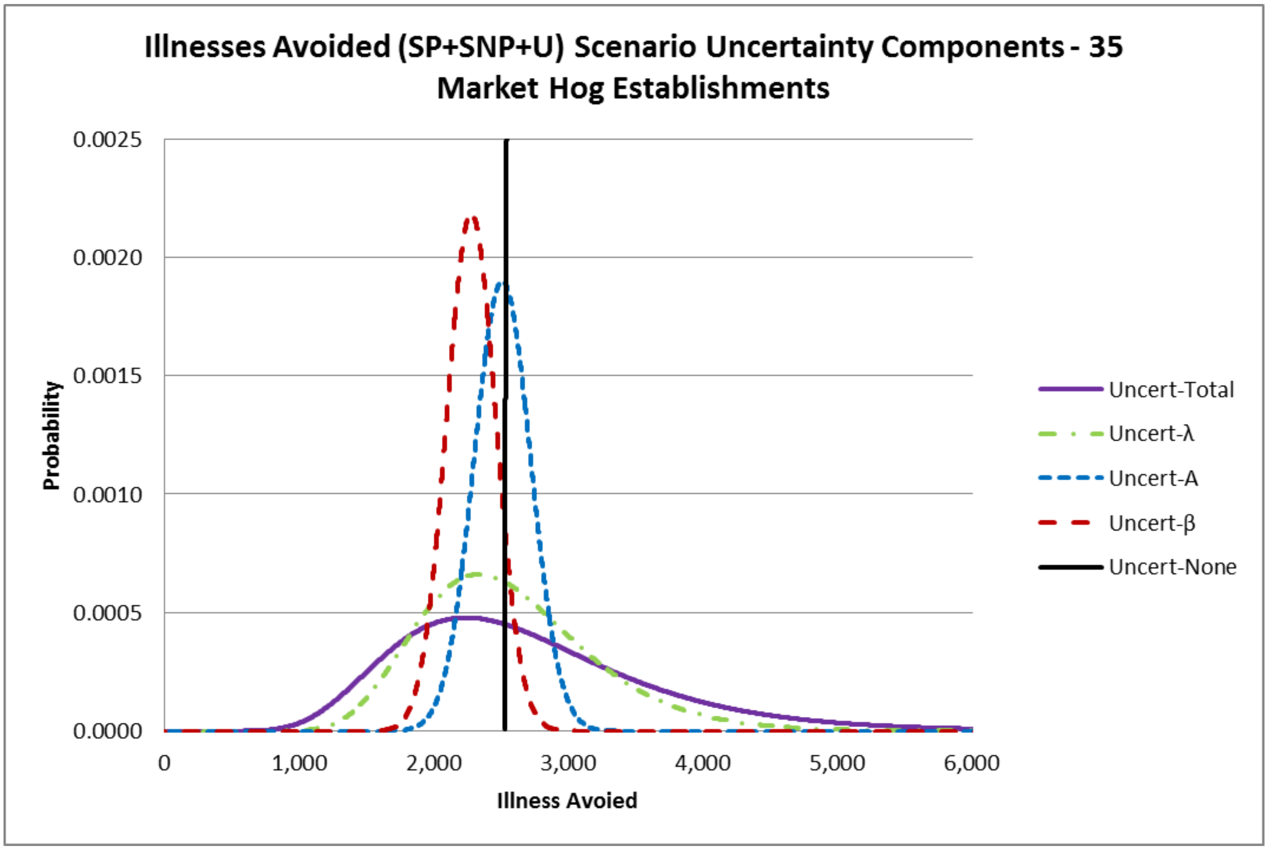

Figure G 7: Uncertainty Components for Illnesses Avoided (SP+SNP+U) Scenario – 35 Market Hog Establishments (Version 2)

Table G2: Illnesses Avoided Uncertainty Distribution for (SP+SNP+U) Scenario

Statistic	35 Est (Version 1)[a]	35 Est (Version 2)[a]	159 Est
N	2,330	22,631	6,684
Mean	2,533	2,533	4,944
Standard Deviation	3,801	1,698	2,745
Variance	14,445,473	2,883,204	7,535,695
Mode	3,169	2,879	4,992
5% Percentile	-3,255	147	1,481
10% Percentile	-1,719	768	2,386
15% Percentile	-767	1,146	2,939
20% Percentile	-61	1,429	3,348
25% Percentile	508	1,668	3,695
30% Percentile	994	1,865	3,979
35% Percentile	1,438	2,054	4,254
40% Percentile	1,847	2,226	4,503
45% Percentile	2,228	2,389	4,738
50% Percentile	2,607	2,549	4,970
55% Percentile	2,984	2,704	5,195
60% Percentile	3,360	2,864	5,423
65% Percentile	3,755	3,032	5,668
70% Percentile	4,181	3,210	5,925
75% Percentile	4,633	3,411	6,215
80% Percentile	5,171	3,637	6,542
85% Percentile	5,826	3,916	6,948
90% Percentile	6,685	4,287	7,481
95% Percentile	8,102	4,892	8,357

[a]Version 1: 2,330 sample days, 35 establishments; Version 2: 22,621 inspection days, 35 establishments.

Table G3: Change in Overall Market Hog Establishment Production Volume 2010-2016

	2010	2011	2012	2013	2014	2015	2016
Absolute Number							
Total Heads	105,120,258	103,432,042	107,897,272	106,989,932	102,607,237	111,140,093	114,473,371
Average	348,080	349,433	395,228	317,478	245,472	234,968	235,058
Plants	302	296	273	337	418	473	487
Percentage Change							
Heads	-	-1.61	2.64	1.78	-2.39	5.73	8.90
Average	-	0.39	13.55	-8.79	-29.48	-32.50	-32.47
Plants	-	-1.99	-9.60	11.59	38.41	56.62	61.26

Table G 4: Change in 35 Market Hog Establishments' Production Volume 2010-2016

	2010-2011	2012	2013	2014	2015	2016
Absolute Number						
Total Heads	80,950,372	86,582,261	85,781,244	81,433,021	88,499,852	93,036,565
Average	2,312,868	2,623,705	2,599,432	2,395,089	2,602,937	2,658,188
Plants[a]	35	33	33	34	34	35
Percentage Change						
Total	-	6.96	-0.93	-5.07	8.68	5.13
Average	-	13.44	-0.93	-7.86	8.68	2.12
Plants	-	-5.71	-5.71	-2.86	-2.86	0.00

[a]22 large and 13 small establishments; missing establishment years are all small establishments.

Table G 5: Estimated *Salmonella* Illnesses from Market Hogs Before and After (SP+SNP+U) Scenario Intervention

Statistic	Before	Change Due to Intervention	After
Mean	69,857	2,533	67,324
Standard Deviation	26,111	1,459	25,757
Variance	681,784,321	2,128,681	663,441,594
Mode	56,527	2,551	51,939
5% Percentile	35,774	147	33,715
10% Percentile	40,778	768	38,653
15% Percentile	44,706	1,148	42,532
20% Percentile	48,091	1,431	45,820
25% Percentile	51,071	1,670	48,787
30% Percentile	53,977	1,866	51,672
35% Percentile	56,801	2,056	54,456
40% Percentile	59,698	2,227	57,281
45% Percentile	62,531	2,391	60,085
50% Percentile	65,519	2,549	63,040
55% Percentile	68,676	2,706	66,115
60% Percentile	71,976	2,865	69,404
65% Percentile	75,505	3,034	72,922
70% Percentile	79,458	3,212	76,765
75% Percentile	83,852	3,412	81,166
80% Percentile	89,121	3,638	86,243
85% Percentile	95,454	3,918	92,600
90% Percentile	104,333	4,287	101,417
95% Percentile	118,842	4,892	115,502

APPENDIX H: Alternative Model Considerations

Alternative Model Considerations Summary

A number of alternative analyses were conducted in order to ensure that the model—that is, the unconditional fixed effects logistic regression—and data weighting used in the main risk assessment are appropriate. In addition, calculations were conducted to determine whether, given the data, there is adequate power to detect differences in prevalence. The results of all those analyses are presented in this appendix. All the alternative models considered are for stage 1, which characterizes the relationship between FSIS inspection activities and product contamination using a logistic regression model. A summary of the model comparison is presented in Box H 1, and Table H 1 lists the SAS procedures used. The results of these alternative models are given in Table H 2.

Comparison of Models

The purpose of these model comparisons is to evaluate whether, given the hierarchical (nested) design for sampling data, there is great disparity among the number of samples taken from each establishment. It was originally thought that clustering of each establishment's samples would yield a better model than the unconditional fixed effects logistic regression that was eventually used for the final model. Conditional logistic regression was not considered acceptable because the stratification required resulted in a model which would not be amenable to weighting. Repeated measures models, however, were considered.

More complex mixed models were considered, and such complexity would be achieved in this risk assessment by incorporating random effects in addition to the fixed effects. Random effects could be modeled for residuals, intercepts, and slopes which could also incorporate clustering of establishments. Additionally, general estimating equation models incorporating a known correlation structure to the random effects was also considered a viable alternative. These alternative models are characterized in Table H 2.

Box H 1: Comparison of Alternative Models[a]

Stage 1: Estimate the relationship between establishment variations in FSIS inspection activities and frequency of *Salmonella* positives on market hog carcasses.

I. Model used in the report: A binary slaughter volume-weighted logistic regression analysis was designed to estimate the relationship between off-line inspection procedures and the annual percent positive rate of *Salmonella* on market hog carcasses. Results shown in Table 9.

Data: 1) *FSIS Microbiological Data* **(**Table 1 and Table 2)

2) *Inspection Procedure Data* with 7,471 rows and 25 columns; initial model matrix incorporating procedures as delineated in Table 5.

- 7,471 rows (records) with each representing a given plant's individual sample day.
- 25 columns representing each of the variables incorporated for each record: one column for microbial contamination with *Salmonella* (0 – absent; 1 – present), plus model intercept values; 20 columns for plant structural characteristics; and four columns for procedure totals: SP, SNP, U, and NR.

Result of model output: Regression coefficients (β) for the relationship between inspection activities and contamination (Table 9).

II. Alternative model comparison: The objective of this section was to assess whether the model and weighting approach used in the risk assessment report are appropriate for the unique characteristics of the data and to achieve the best fit without unnecessary added complexity.

1) Random effects models: Not appropriate as data from all market hog establishments were included.

2) Mixed and main effects models: More complex mixed models considered (Table H 4, Table H 5, and Table H 6). All models performed the same with regard to prediction--91% prediction accuracy--hence, the best choice of models was the simplest one: fixed effects crossover (see Table H1).

3) Crossover with main effects models where all are fixed effects: The crossover model correctly predicted post-chill prevalence better than either main effects model (see Table H 3, Table H 4, Table H 5, and Table H 6).

III. Power calculation: Given the data, this section was incorporated to determine if the post-chill non-HIMP submodel had sufficient power to distinguish between small changes in prevalence.

Objective: To determine if the sample size (n =5,046) at post-chill non-HIMP submodel had sufficient power to distinguish between small changes in prevalence.

Method: Given the fixed sample size n =5,046 (as this could not be changed due to the observational type of study employed), using the NCSS12/PASS15 statistical software, analyzed the relationships between n and varying α (as α increases from 0.02 to 0.30, the statistical power to distinguish changes in prevalence also increases).

Result: The sample size at post-chill is adequate to distinguish a probability difference of 0.005 or greater with alpha equal to 0.05. The two dimensional graphs Figure H 1, Figure H 3, Figure H 5, and Figure H 7 illustrate the relationship of power vs. probability, and Figure H 2, Figure H 4, Figure H 6, and Figure H 8 employ three-dimensional graphics illustrate the relationship of power, probability, and alpha.

[a]Tables and figures cited with lettered prefixes refer to items in the appendices, while tables and figures cited without such prefixes refer to items in the main body of the report.

Table H 1: Mixed and Main Effects Models Compared with Published Report Model

SAS Procedures	Model	Model Used, Descriptions, Effects	Link Function
LOGISTIC	CROSSOVER	1. Volume weight 2. Log Volume weight	Logit
GLIMMIX	GENERALIZED LINEAR MIXED MODEL ESTIMATION	3. random intercept 4. random residual	Logit
GENMOD	Fits GENERALIZED LINEAR MODEL with a number of built-in link functions and probability distributions	5. Cluster, 6. GEE 7. Negative binomial 8. Poisson 9. Zero inflation	Logit, Log
FMM	FINITE MIXTURE MODELS	10. Beta binomial	Logit

Table H 2: Alternative Model Comparisons

MODEL	TC	AER	FN	FP	DEVRESID	PARAM	P-Post-Chill	Sd-Post-Chill
LOGISTIC-CROSSOVER Wt=Vol	90.9	9.1	13.2	8.1	1.0	19	0.0579	0.0566
GLIMMIX-RANDOM INT Wt=logVol	90.9	9.1	13.4	8.1	1.0	27	0.0111	0.0121
GLIMMIX-RANDOM RESID Wt=logVol	90.9	9.1	13.4	8.1	1.0	27	0.0299	0.0277
GENMOD-POISSON (CLUSTER) Wt=logVol	90.9	9.1	11.1	8.6	1.0	27	0.0302	0.0020
LOGISTIC-CROSSOVER Wt=logVol	90.8	9.2	27.6	3.5	1.0	19	0.0287	0.0239
GENMOD-NEG BIN (CLUSTER) Wt=logVol	90.8	9.2	14.7	7.8	1.0	26	0.0287	0.0202
FMM-BETABINOMIAL (CLUSTER) Wt=logVol	90.8	9.2	13.9	8.1	1.0	27	0.0304	0.0210
GENMOD-ZEROINFATION Wt=logVol	90.8	9.2	10.9	8.8	1.0	52	0.0292	0.0471
GENMOD-CLUSTER Wt=logVol	90.7	9.3	15.2	7.8	1.0	26	0.0287	0.0282
GENMOD-GEE (r=IND) Wt=logVol	90.7	9.3	13.4	8.1	1.0	27	0.0287	0.0282

Abbreviations: AER = absolute error rate; DEVRESID = standardized deviance residual; FN = false negative; FP = false positive; PARAM = the number of parameters estimated by the model; P-Post-Chill = prevalence at post-chill; std-post-chill = standard deviation of prevalence at post-chill; TC = total correct.

Prior to conducting the models presented in this appendix, all models considered used the logistic logit link function applied to the binomial distribution. It seemed feasible to look at other count distribution models for completeness, and the following models were considered: the Poisson distribution, zero inflated Poisson distribution, Negative Binomial distribution, and the Beta-binomial distribution. These models allowed weighting and all used the link function log, except the Beta-binomial (which uses the logit link function).

Also, comparisons in the model with all four submodels had no expectation of a significant difference for the two sub-models with five HIMP establishments' data. Clearly these HACCP-Inspection Model Project (HIMP) sub-models do not have sufficient power to make unqualified distinctions with the non-HIMP submodels.

Comparison of Fixed Effects and Random Effects Models

Because data from all market hog establishments were included in the risk assessment, fixed effects models were considered more appropriate than random effects models. Random effects models would be justified if additional establishments were operating within the same system and their sampling and procedure data could not be incorporated into this data set. Random effects models would also be useful if the assessment was intended to estimate prevalence level sampled from a larger population. However, an alternate weighting system that is not entirely risk-based may be used to determine a "national prevalence" estimate.

All models considered can take advantage of the hierarchical collection of data with repeated measures or clustering of different sample sizes on individual establishments. The order of the models considered is to first incorporate a clustering or repeated measures model design, test its significance and keep or delete this feature. Next, stratification of random effects for post-chill and pre-evisceration sample collection was incorporated and tested for significance. The final step was to add HIMP and non-HIMP establishment stratification to the model. All models were initialized using the same variables used in the crossover-design model, and were programmed using SAS 9.4 software.

Comparison of Mixed and Main Effects Models

Table H 2 shows all the feasible models tested with the same data with log-volume weighting. In this table, models are ranked by their number of total correct predictions

(TC), as this statistic was given greatest weight in comparing the models. With rounding, all models achieve 91% prediction accuracy. All models have been standardized, resulting in a deviance residual of 1.0 for each model and, therefore, demonstrating that overdispersion has been contained.

As illustrated in Table H 2, all models performed the same with regard to prediction regardless of which weighting or special random effects features were incorporated into the basic fixed effects model. The probability distributions were also independent. Under these circumstances, the best choice of models was the simplest one: fixed effects crossover.

Comparison of Crossover with Main Effects Models (All Models Fixed Effects)

Table H 3 shows parameter statistics for Decision Variable Main Effects-Only (maineffects1) and Main Effects plus Decision Variable Interaction (maineffects2) models. This table is an expansion from Table A16 in the risk assessment report, which shows only the crossover model (the final option chosen for the risk assessment report). The rationale for having selected the crossover model is that large establishments tend to have higher incoming contamination prevalence but are more effective than smaller establishments at reducing this contamination—indicated by the pre-evisceration prevalence being greater than the post-chill prevalence for large establishments but vice versa for smaller ones. The crossover model excludes some main effects shared between the dummy variable “Coll” (reflecting whether a given sample was collected at pre-evisceration or at post-chill) and the decision variables and the log number of inspectors. Further, as pre-evisceration prevalence is not affected by inspection procedures, it is only necessary to estimate an average prevalence for pre-evisceration rather than to predict it on a more granular level.

Table H 3: Alternative Stage 1 Model Parameter Statistics

Parameter	β estimate	β error	Chi-square	p-value	Std est	Mean X	Stdev X
Decision Variable Main Effects-Only Model (main effects1, n=7471 p=20-1)							
Intercept	-1.9807	0.0945	439.428	<.0001		1	0
HIMP	0.4117	0.0569	52.3851	<.0001	0.3454	0.7893	0.6140
HIMP*COLL	0.1264	0.0536	5.5513	0.0185	0.1419	0.4277	0.9040
logNbrEmp	-0.1941	0.0549	12.4859	0.0004	-0.1346	1.4053	0.6343
COLL	-2.7093	0.0547	2455.73	<.0001	-2.9583	0.4847	0.8748
Fall	-0.1551	0.0364	18.1644	<.0001	-0.1221	-0.0023	0.6704
Spring	0.1113	0.0373	8.8856	0.0029	0.087	0.0945	0.7330
Summer	-0.0593	0.0334	3.1502	0.0759	-0.051	0.0046	0.6754
MidWest	-0.6768	0.0724	87.3392	<.0001	-0.5157	0.4086	0.6928
NorthEast	-0.4579	0.1086	17.7761	<.0001	-0.2171	0.0207	0.5085
South	0.4453	0.0735	36.6896	<.0001	0.2755	0.0941	0.5688
District1	-0.3067	0.0777	15.562	<.0001	-0.1557	0.1241	0.4540
District2	-0.2228	0.0652	11.6827	0.0006	-0.1425	0.2463	0.5321
District3	0.1576	0.0552	8.1384	0.0043	0.0896	0.1857	0.4987
District4	0.5035	0.0885	32.3941	<.0001	0.2676	0.2004	0.5076
SP	-0.0215	0.00229	87.5447	<.0001	-0.3264	15.4477	12.5603
SNP	0.0191	0.00666	8.2078	0.0042	0.0662	1.3476	2.6360
U	-0.0129	0.00424	9.172	0.0025	-0.1036	7.5752	6.5064
NR	0.0777	0.00993	61.1633	<.0001	0.1941	0.6929	1.8207
Main Effects Plus Decision Variable Interaction Model (main effects2, n=7471 p=24-1)							
Intercept	-1.629	0.1762	85.4666	<.0001		1	0
HIMP	0.3459	0.1335	6.7096	0.0096	0.2901	0.7893	0.614
HIMP*Coll	0.2665	0.111	5.7696	0.0163	0.2993	0.4277	0.904
logNbrEmp	-0.1794	0.099	3.2864	0.0699	-0.1244	1.4053	0.6343
logNbrEmp*Coll	-0.8759	0.0849	106.406	<.0001	-1.7474	0.5182	1.4522
Coll	-1.5167	0.153	98.2836	<.0001	-1.656	0.4847	0.8748
Fall	-0.1509	0.057	7.0187	0.0081	-0.1188	0.0046	0.6754
Spring	0.0885	0.0581	2.3185	0.1278	0.0692	-0.0023	0.6704
Summer	-0.0528	0.0524	1.0155	0.3136	-0.0454	0.0945	0.733
MidWest	-0.5576	0.1122	24.6985	<.0001	-0.4249	0.4086	0.6928
NorthEast	-0.5767	0.1623	12.6259	0.0004	-0.2734	0.0207	0.5085
South	0.4464	0.1063	17.6294	<.0001	0.2762	0.0941	0.5688
District1	-0.3525	0.1203	8.5858	0.0034	-0.179	0.1241	0.454
District2	-0.3578	0.1004	12.7059	0.0004	-0.2288	0.2463	0.5321
District3	0.0988	0.0847	1.362	0.2432	0.0562	0.1857	0.4987
District4	0.6389	0.1377	21.5276	<.0001	0.3396	0.2004	0.5076
SP	-0.0226	0.00441	26.378	<.0001	-0.3445	7.5752	6.5064

Parameter	β estimate	β error	Chi-square	p-value	Std est	Mean X	Stdev X
SP*Coll	-0.0011	0.00411	0.0749	0.7844	-0.0268	4.3344	19.4329
SNP	0.0131	0.0174	0.5638	0.4527	0.0455	0.6929	1.8207
SNP*COLL	0.0037	0.0171	0.0459	0.8304	0.0143	0.4101	2.932
U	-0.0166	0.00721	5.2729	0.0217	-0.1334	0.4177	1.3155
U*COLL	-0.013	0.00619	4.4001	0.0359	-0.1767	1.4386	9.882
NR	-0.0122	0.0253	0.2306	0.6311	-0.0304	0.3629	1.1405
NR*COLL	0.0869	0.0243	12.8491	0.0003	0.238	0.1404	1.943

Abbreviations: Coll, Collection Date; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The decision logic behind comparing these models was to see which would provide the best prediction for contamination at post-chill and which had the best fit to the logistic distribution. A comparison analysis including sensitivity, specificity, number correct, false positives, false negatives, and the Hosmer-Lemeshow Goodness-of-Fit test was conducted (shown in Table H 4 and Table H 5), and this analysis demonstrated that the crossover model correctly predicted post-chill prevalence better than both main effects models. This type of crossover model is well-justified in the literature (VanderWeele, 2014).

Note that in the main effects2 model only two of the five main effects are significant; three of the five interactions are significant in the main effects2 model while all interactions are significant in the crossover model as used in the main risk assessment. As indicated in Table H 4 and Table H 5, sensitivity, specificity, number correct, false positives, and false negatives are essentially the same between models. The overall model fit is better for the crossover model according to the Hosmer-Lemeshow statistic. This test must be the deciding factor because each submodel has nearly identical absolute error rate (AER) in the post-chill sub-models. The crossover model also fits the logistic distribution. The regression coefficients for three models (main effects plus interactions, crossover, and main effects only model) are presented in Table H 6 for comparison.

Power Analysis

NCSS12/PASS15 SOFTWARE was used to determine power and sample size for logistic regression. The most important issue was to determine if the post-chill non-HIMP submodel had sufficient power to distinguish between small changes in prevalence. The sample size was pre-determined and could not be changed due to the observational type of study employed. All data are drawn from actual inspection procedures and sampling results in US market hog slaughter establishments and, thus, could not be optimized or randomized as with experimental studies.

Table H 4: Comparison of Fixed Effects Models for Overall Model (p=0.5)

Model	Correct: Event	Correct: Non-Event	Incorrect: Event	Incorrect: Non-Event	Percentages: Correct	Sensitivity	Specificity	False Positive	False Negative	Hosmer-Lemeshow Goodness-of-Fit Test: Chi-Square	DF	PR > Chi-Sq
Main Effects Version 1	1,289	5,494	490	198	90.8	86.7	91.8	27.5	3.5	30.441	8	0.0002
Crossover	1,285	5,495	489	202	90.8	86.4	91.8	27.6	3.5	15.862	8	0.0444
Main Effects Version 2	1,316	5,461	523	171	90.7	88.5	91.3	28.4	3.0	69.394	8	<0.001

Abbreviation: DF, Degrees of Freedom.

Table H 5: Comparison of Fixed Effects Models for Post-Chill Only (p=0.5)

	False Positive	False Negative	Absolute Error Rate (%)	Total Correct (%)	Total Positive	Total Negative
Main Effects Version 1	13.43	68.28	15	85	145	4,901
Crossover	13.49	64.83	14.96	85.03	145	4,901
Main Effects Version 2	13.73	57.93	15	85	145	4,901

Table H 6: Regression Coefficients for Different Models

Model	Scenario: SP	SNP	U	NR
Main Effects Plus Interactions	-0.2237	0.0168	-0.0279	0.0747
Crossover	-0.0079	0.0207	-0.0110	0.0978
Main Effects Only	-0.0215	0.0191	-.0129	0.0777

Abbreviations: NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The determination of power and sample size sufficiency was set up with parameters alpha at a range of 0.02 to 0.30 and fixed sample size of 5,046 (see Figure H 1 through Figure H 8). The result of the power analysis relationship with fixed sample size and adjustable power is presented in two-dimensional and three-dimensional graphics. The two-dimensional graphics (Figure H 1, Figure H 3, Figure H 5, and Figure H 7) depict power versus probability at alpha levels varying from 0.02 to 0.30. The three-dimensional graphics (Figure H 2, Figure H 4, Figure H 6, and Figure H 8) depict the relationship at varying power, probability, and alpha values on each dimension with fixed sample size. Graphics are provided for the decision variable probabilities for SP, SNP, and U decision variables and the combination of all three as a single variable. The program analyzed these relationships taking one variable in the multivariate logistic regression equation. Each of the decision variables is evaluated taking into consideration the correlations with all other variables in the equation.

It can be seen that power increases the farther away from the base prevalence of 0.01 is achieved. The SP decision variable reaches a power of 0.8 when the probability difference from 0.01 is 0.005 (Figure H 1 and Figure H 2). The SNP decision variable reaches a power of 0.98 at the same probability distance (Figure H 3 and Figure H 4). The decision variable U, also at probability difference 0.005, has a power of 0.95 (Figure H 5 and Figure H 6). The combination decision variable reaches a power of 0.95 with alpha at 0.05 and a probability difference of 0.005 (Figure H 7 and Figure H 8). Therefore, the sample size at post-chill is adequate to distinguish a probability difference of 0.005 or greater with alpha equal to 0.05.

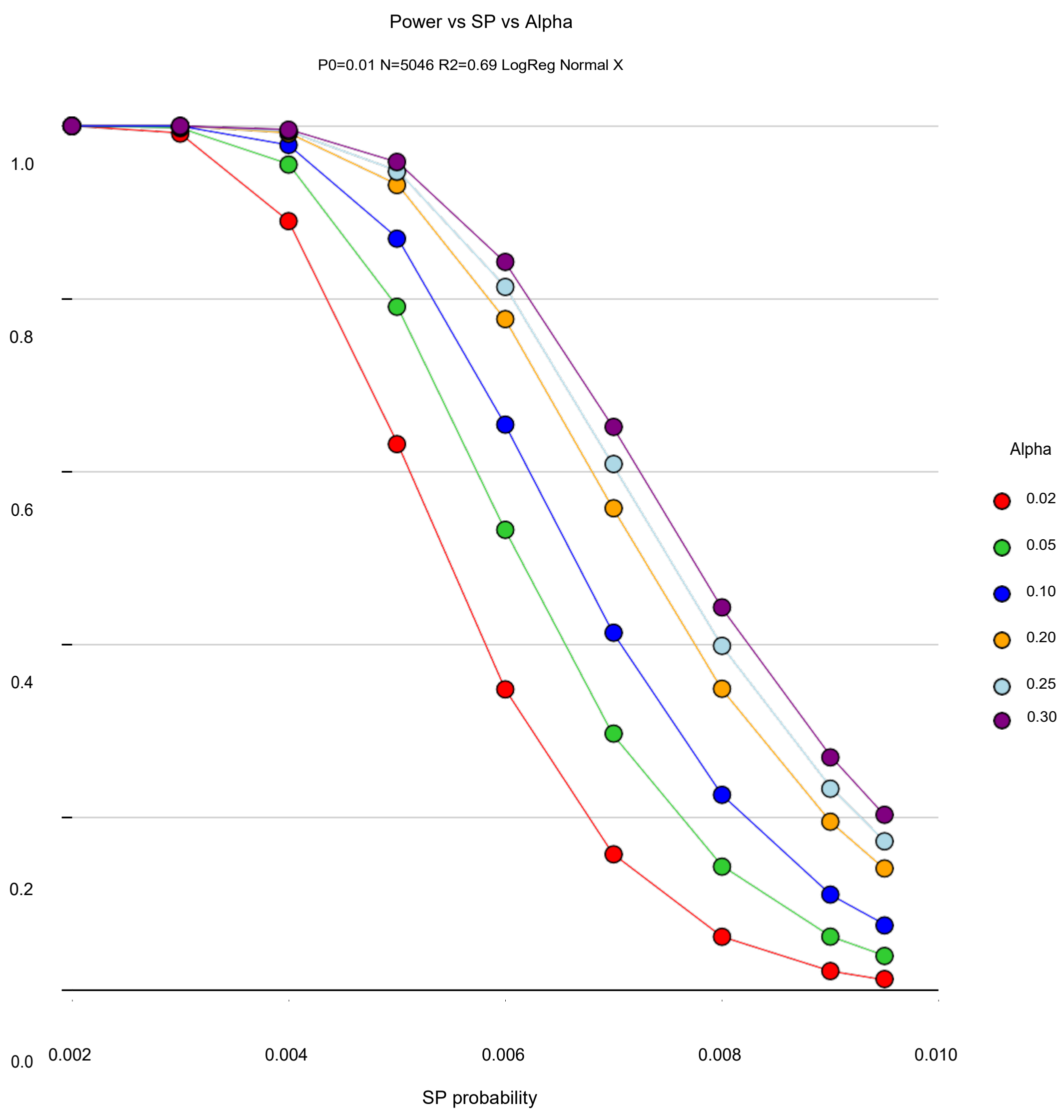

Figure H 1: 2-Dimensional Power vs. Probability Plot for Decision Variable Scheduled and Performed.

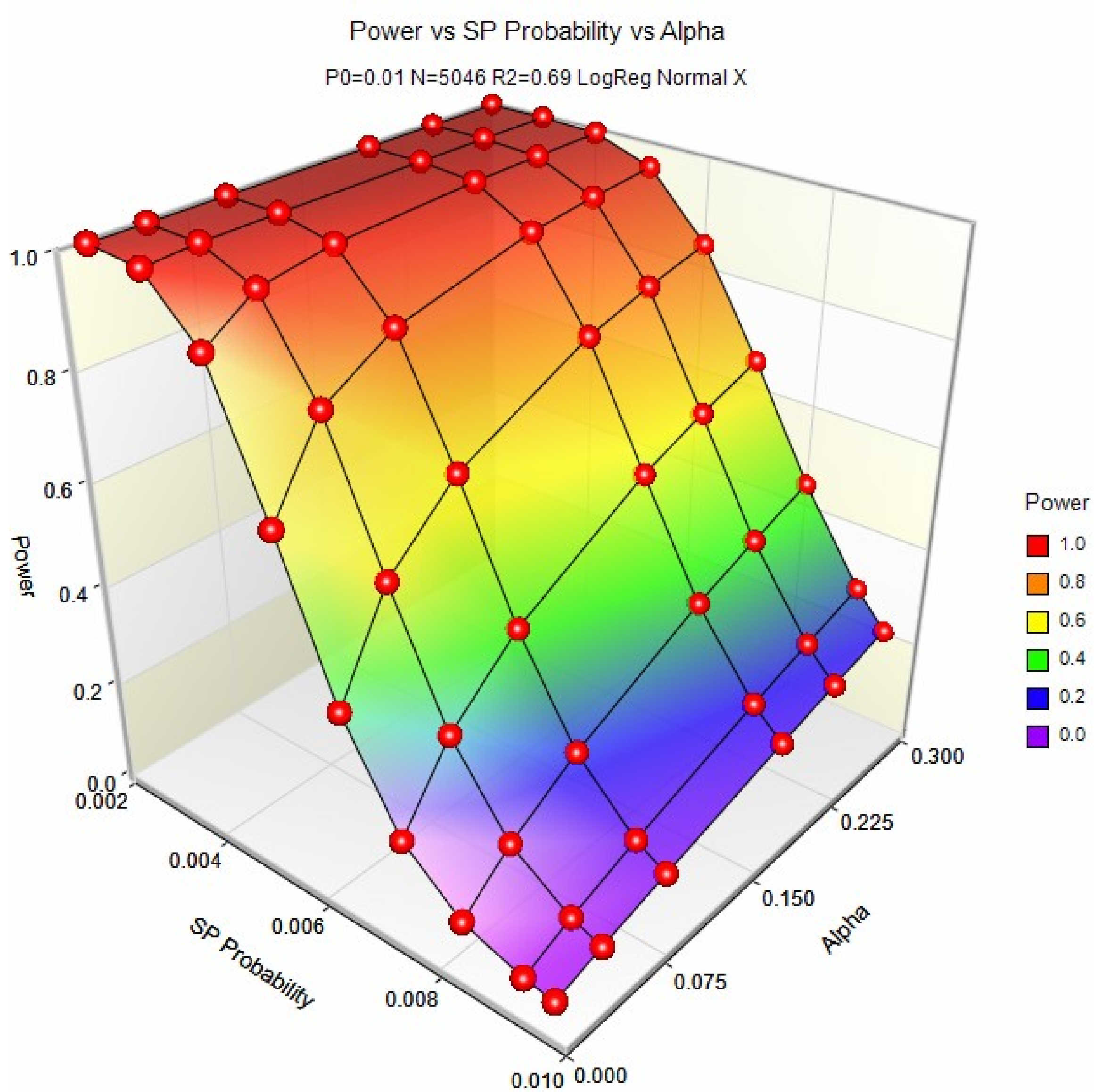

Figure H 2: 3-Dimensional Depiction of Power vs. Probability vs. Alpha for Decision Variable Scheduled and Performed (SP).

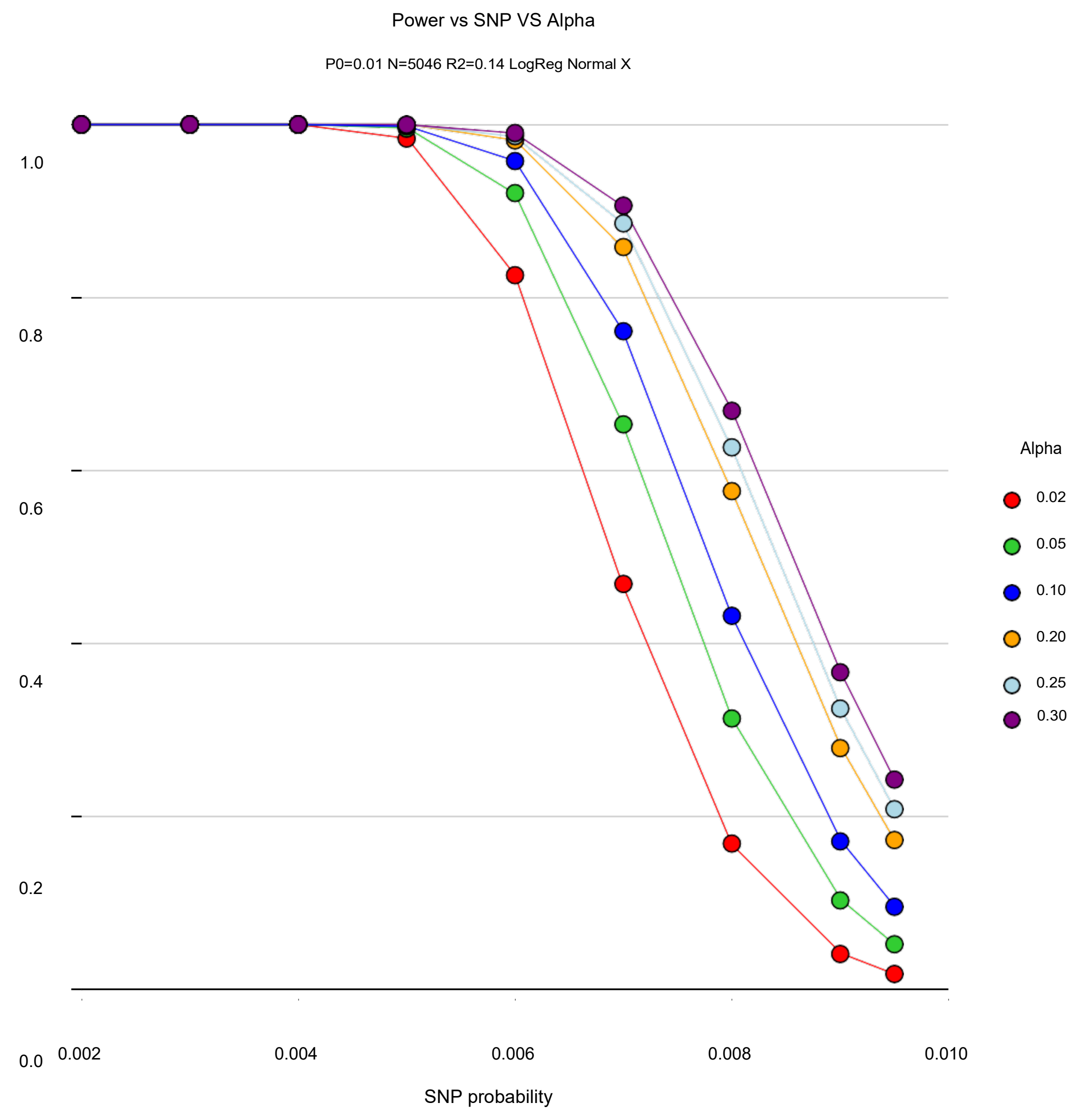

Figure H 3: 2-Dimensional Depiction of Power vs. Probability for Decision Variable Scheduled, Not Performed (SNP).

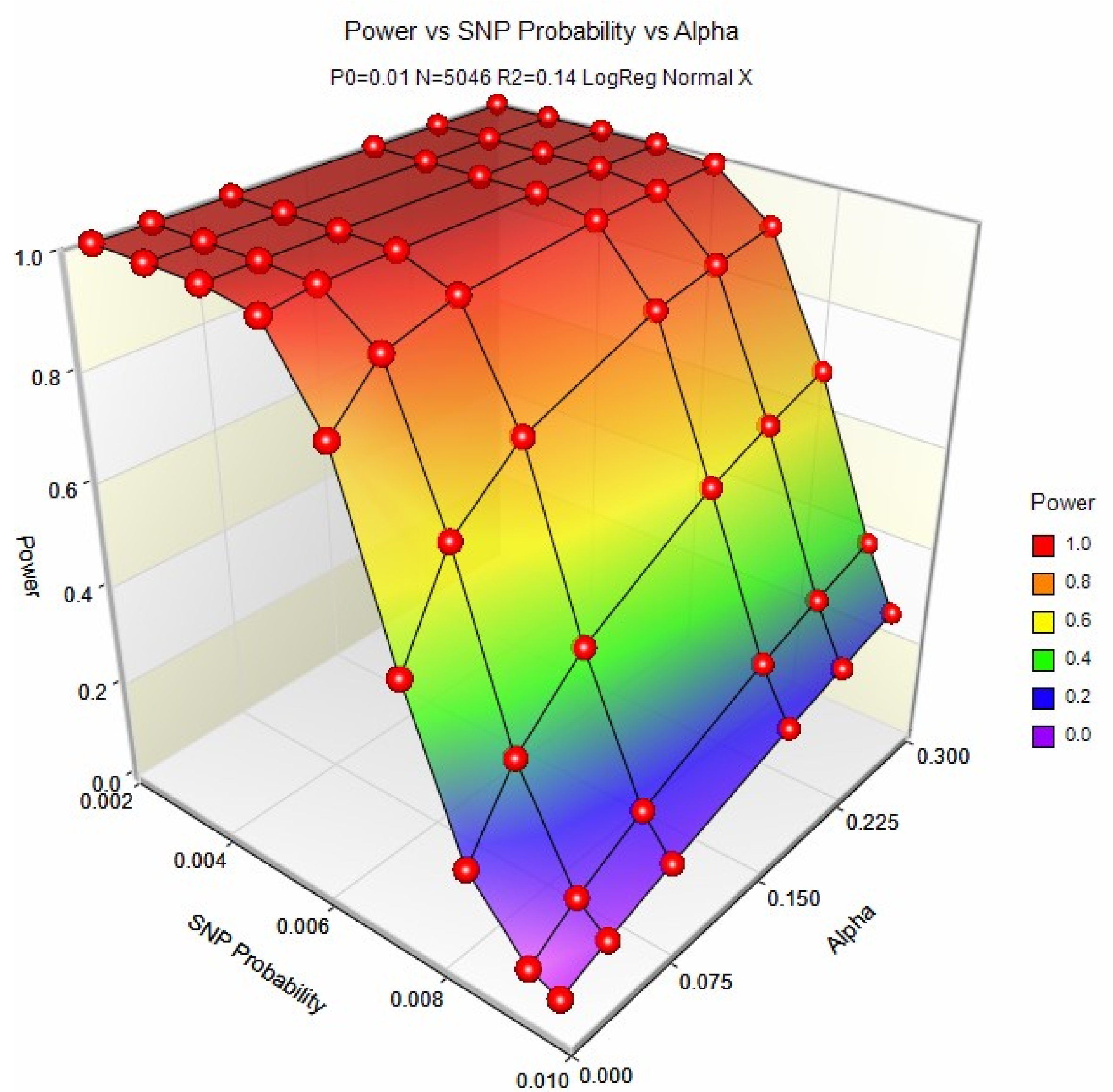

Figure H 4: 3-Dimensional Depiction of Power vs. Probability vs. Alpha for Decision Variable Scheduled, Not Performed (SNP).

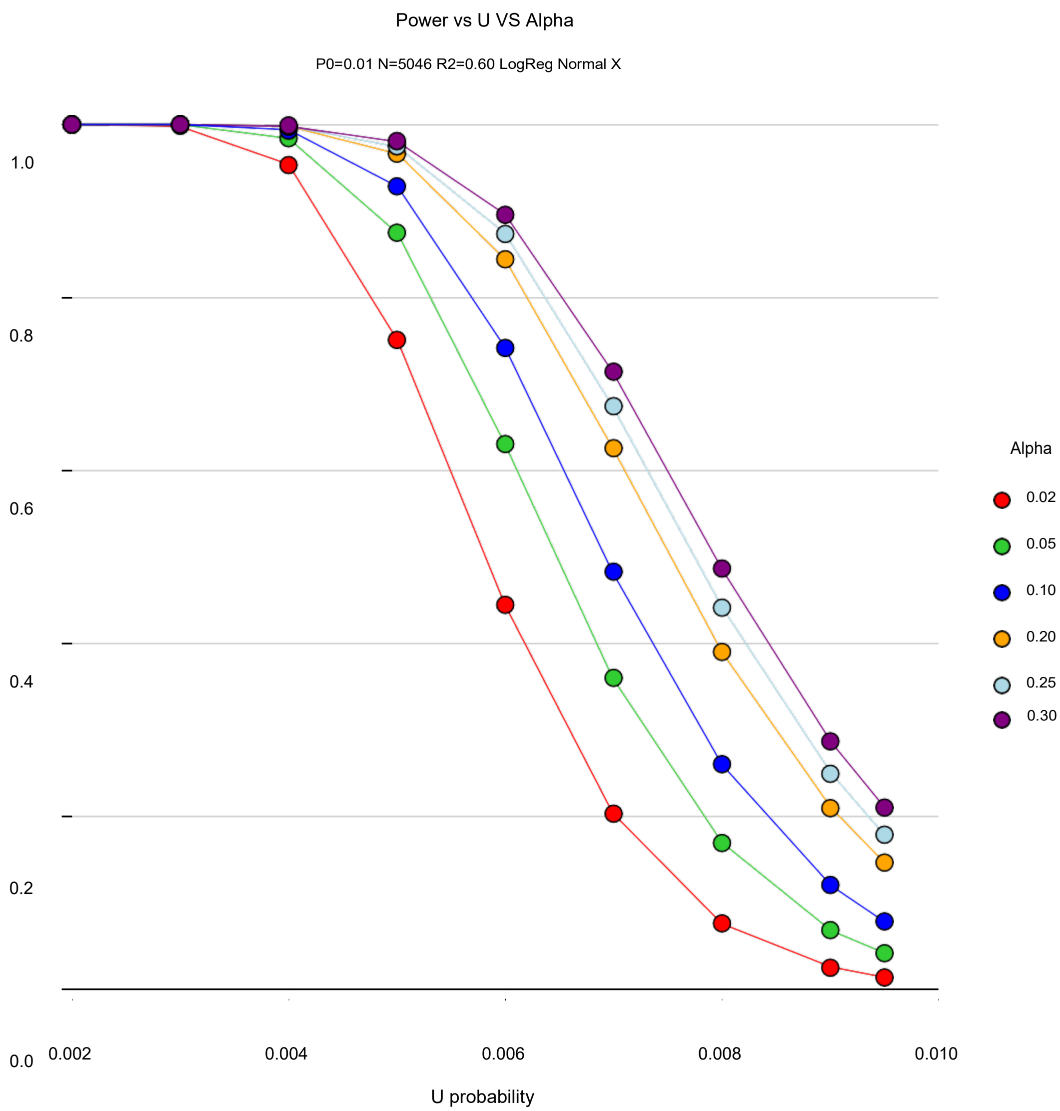

Figure H 5: 2-Dimensional Depiction of Power vs. Probability for Decision Variable Unscheduled (U).

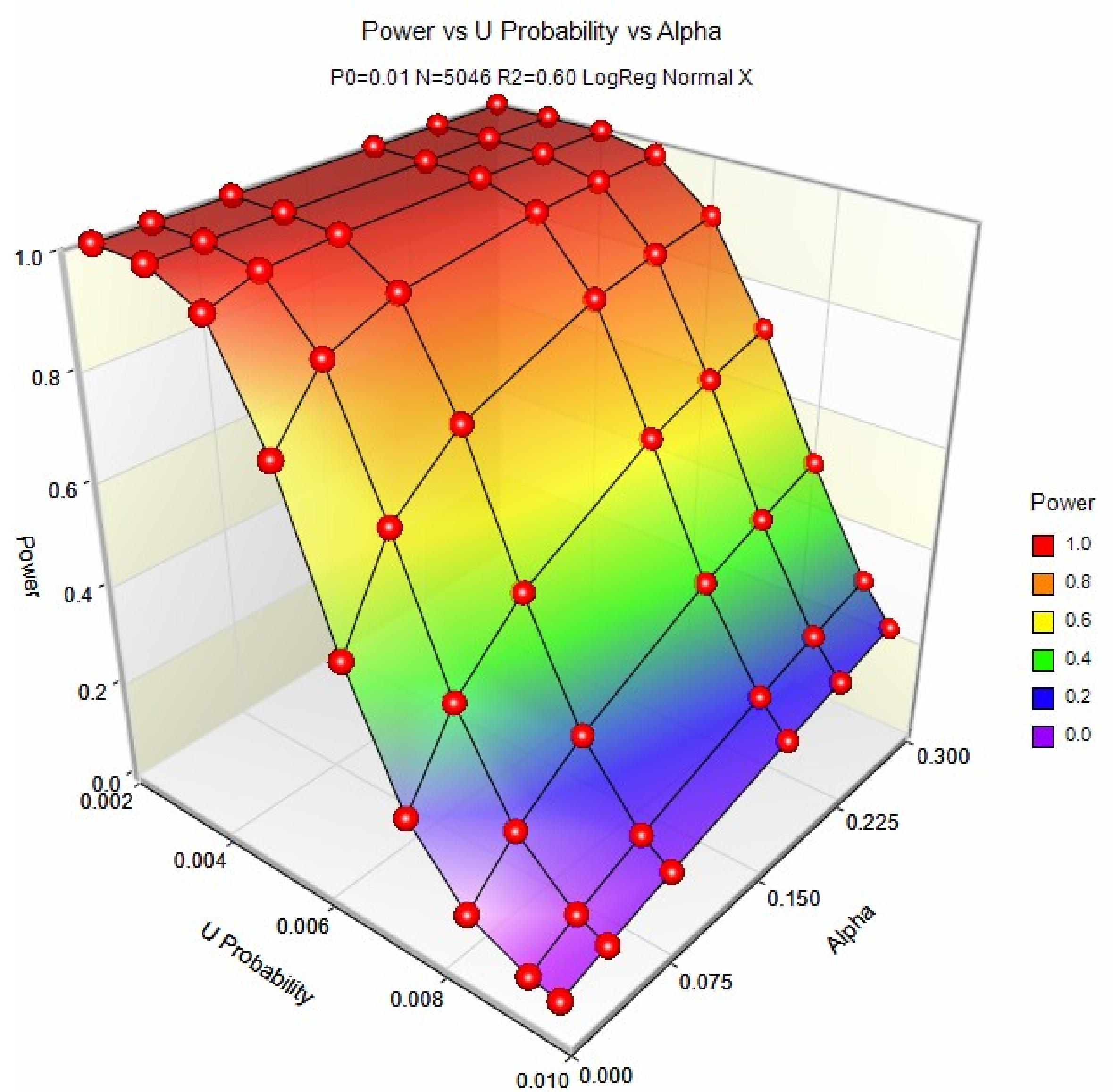

Figure H 6: 3-Dimensional Depiction of Power vs. Probability vs. Alpha for Decision Variable Unscheduled (U).

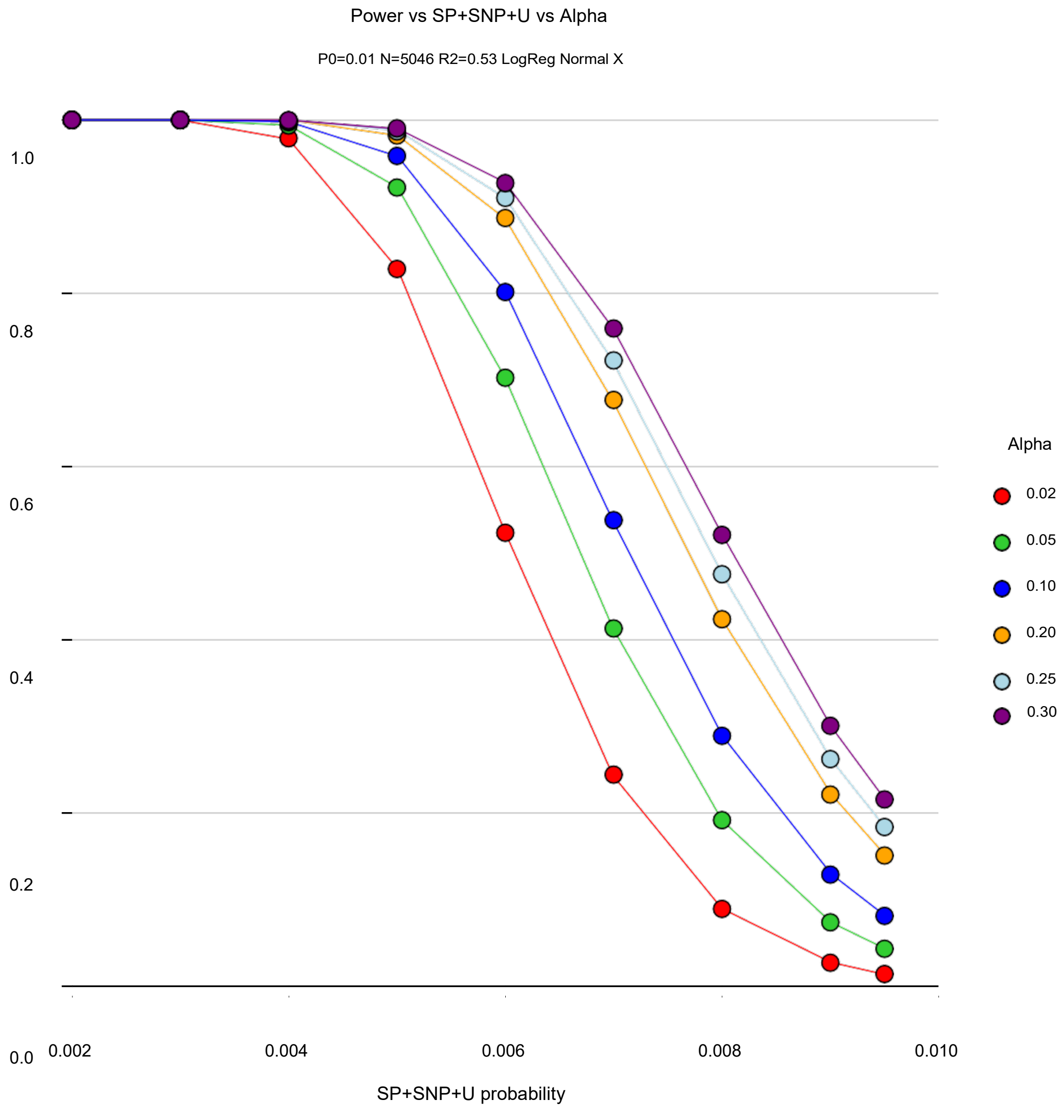

Figure H 7: 2-Dimensional Depiction of Power vs. SP+SNP+U Probability vs. Alpha for Decision Variables Scheduled, Performed + Scheduled, Not Performed + Unscheduled (SP+SNP+U).

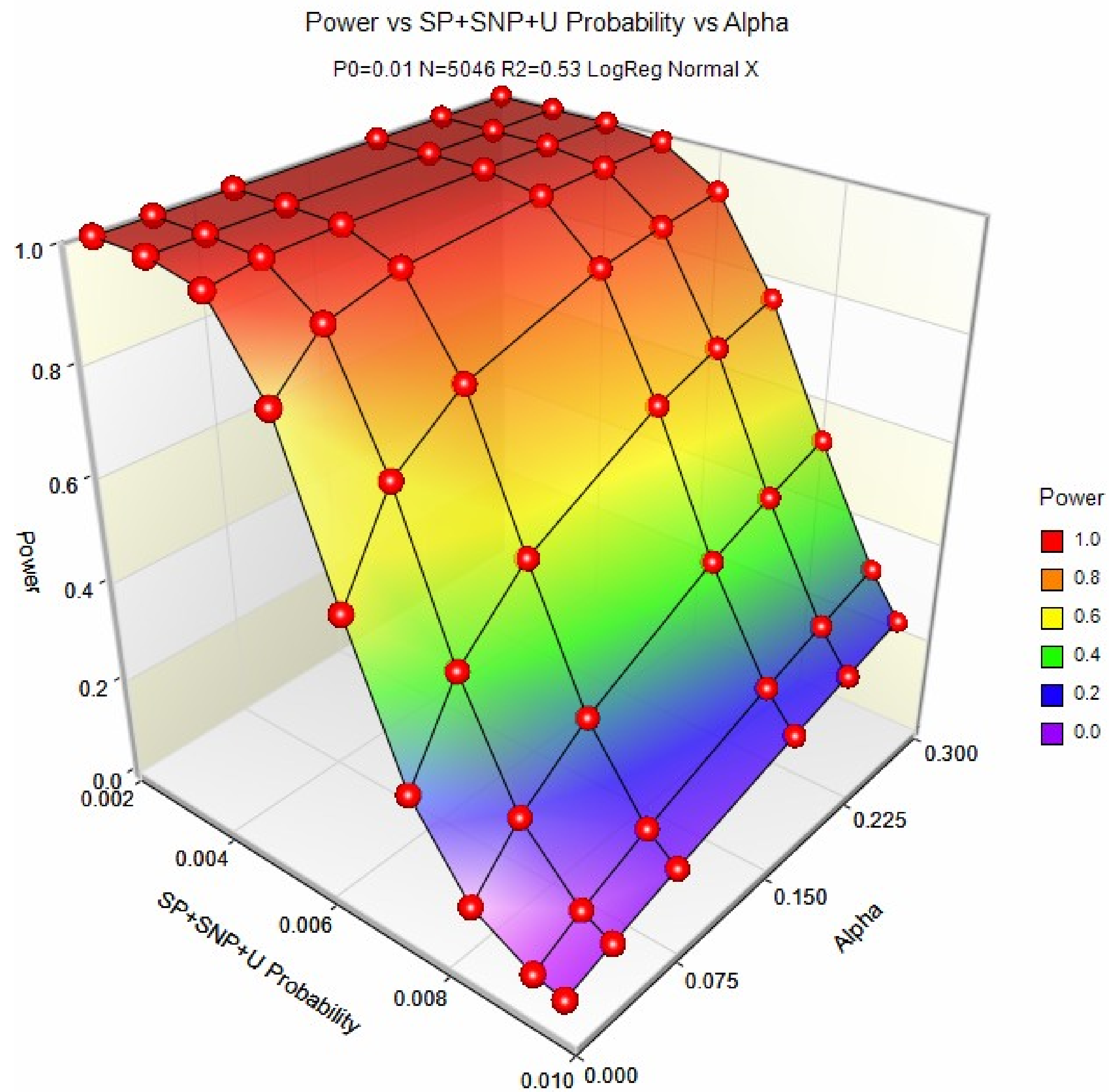

Figure H 8: 3-Dimensional Depiction of Power vs. Probability vs. Alpha for Decision Variables Scheduled, Performed + Scheduled, Not Performed + Unscheduled (SP+SNP+U).

Multicollinearity Diagnostics

Multiple collinearity diagnostics for both log volume-weighted and volume-weighted models were evaluated using the collinearity diagnostics in SAS Proc Reg. Using this diagnostic, the square root of the variance inflation factor (VIF) is an indication of collinearity. The ANOVA's variance inflation factors and tolerances were evaluated for unacceptable deviations. All the square root (VIF) for the log volume weighted scenarios are less than four, while for the volume weighted there are some variables which are above five (see Table H 7 and Table H 8).

Proc Reg from SAS 9.4 was used to determine if any multicollinearity effects distinguished the two models. Tolerance and variance inflation were evaluated for both models. The collection variable and log number of employees crossed with collection variable had the largest VIF that was acceptable for the log volume weighted model as the square of the VIF was less than ten, but was still quite large for the volume weighted model. Additionally, multicollinearity diagnostics showed similar trends that corresponded to the size of the condition index for each variable. There is mild collinearity in the log volume weighted model, and slightly more in the volume weighted model. These effects do not appear to be serious when the collinearity graphs are compared (Figure H 9 and Figure H 10).

Figure H 9 and Figure H 10 are comparable and only slightly different. The variables numbered 8 through 19 show similar peaks between the two graphs. The corresponding condition indices for the numbered variables in Table H 9 also indicate that variable numbers 14 and greater have condition indices greater than 4.0 indicating possible collinearity. The collinearity shown in the diagnostics graphs are mild and only slightly greater in the volume weighted model.

Table H 7: Regression Variable Tolerances and Variance Inflation Factors (VIF) for the log Volume Weighted Model

Variable	Beta	SE	t Value	Pr > |t|	Tolerance	VIF	sqrt(VIF)
Intercept	0.3595	0.0066	54.8200	<.0001	.	0.0000	
HIMP	0.0337	0.0051	6.6000	<.0001	0.7525	1.3289	1.1528
HIMPCollectionPOST	-0.0189	0.0088	-2.1600	0.0308	0.1421	7.0362	2.6526
Coll	-0.3002	0.0132	-22.8100	<.0001	0.0667	15.0041	3.8735
ColllogNbrEmp	-0.0228	0.0074	-3.0700	0.0021	0.0626	15.9659	3.9958
seasonFall	-0.0095	0.0058	-1.6500	0.0996	0.6648	1.5041	1.2264
seasonSpring	0.0016	0.0058	0.2700	0.7906	0.6649	1.5039	1.2263
seasonSummer	-0.0011	0.0052	-0.2000	0.8395	0.6989	1.4308	1.1961
RegionMidWest	-0.0265	0.0099	-2.6800	0.0073	0.2430	4.1159	2.0288
RegionNorthEast	-0.0442	0.0145	-3.0400	0.0023	0.2904	3.4431	1.8556
RegionSouth	0.0307	0.0099	3.1100	0.0019	0.3682	2.7161	1.6481
District1	-0.0263	0.0124	-2.1200	0.0338	0.3464	2.8871	1.6991
District2	-0.0153	0.0095	-1.6100	0.1073	0.3733	2.6789	1.6368
District3	0.0112	0.0078	1.4300	0.1529	0.6913	1.4465	1.2027
District4	0.0400	0.0124	3.2300	0.0013	0.3166	3.1583	1.7771
CollSP	-0.0004	0.0003	-1.2100	0.2245	0.1580	6.3302	2.5160
CollSNP	0.0000	0.0011	0.0400	0.9674	0.7501	1.3331	1.1546
CollU	-0.0008	0.0006	-1.4000	0.1605	0.2124	4.7091	2.1701
CollNR	0.0085	0.0016	5.3400	<.0001	0.7227	1.3837	1.1763

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table H 8: Regression Variable Tolerances and Variance Inflation Factors (VIF) for the volume weighted model

Variable	Beta	SE	t Value	Pr > |t|	Tolerance	VIF	sqrt(VIF)
Intercept	0.4069	0.0087	46.5800	<.0001	.	0.0000	
HIMP	0.0793	0.0051	15.4500	<.0001	0.6329	1.5801	1.2570
HIMPCollectionPOST	-0.0355	0.0085	-4.1900	<.0001	0.1441	6.9390	2.6342
Coll	-0.3109	0.0254	-12.2300	<.0001	0.0165	60.8059	7.7968
ColllogNbrEmp	-0.0077	0.0130	-0.5900	0.5545	0.0141	71.0845	8.4305
seasonFall	-0.0167	0.0058	-2.8800	0.0040	0.6501	1.5384	1.2403
seasonSpring	0.0008	0.0060	0.1300	0.8954	0.6366	1.5710	1.2534
seasonSummer	-0.0060	0.0052	-1.1600	0.2481	0.6781	1.4747	1.2144
RegionMidWest	-0.0830	0.0119	-6.9900	<.0001	0.2903	3.4449	1.8561
RegionNorthEast	0.0426	0.0197	2.1700	0.0303	0.5237	1.9094	1.3818
RegionSouth	-0.0445	0.0132	-3.3800	0.0007	0.2997	3.3370	1.8267
District1	-0.0227	0.0130	-1.7400	0.0811	0.5293	1.8892	1.3745
District2	-0.0465	0.0101	-4.5900	<.0001	0.3375	2.9634	1.7215
District3	0.0307	0.0085	3.6100	0.0003	0.6739	1.4839	1.2182
District4	0.0287	0.0127	2.2600	0.0239	0.3814	2.6222	1.6193
CollSP	-0.0009	0.0003	-3.0800	0.0021	0.1496	6.6844	2.5854
CollSNP	-0.0002	0.0009	-0.2000	0.8401	0.7414	1.3488	1.1614
CollU	-0.0009	0.0005	-1.8500	0.0649	0.1982	5.0460	2.2463
CollNR	0.0083	0.0013	6.5600	<.0001	0.6748	1.4820	1.2174

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

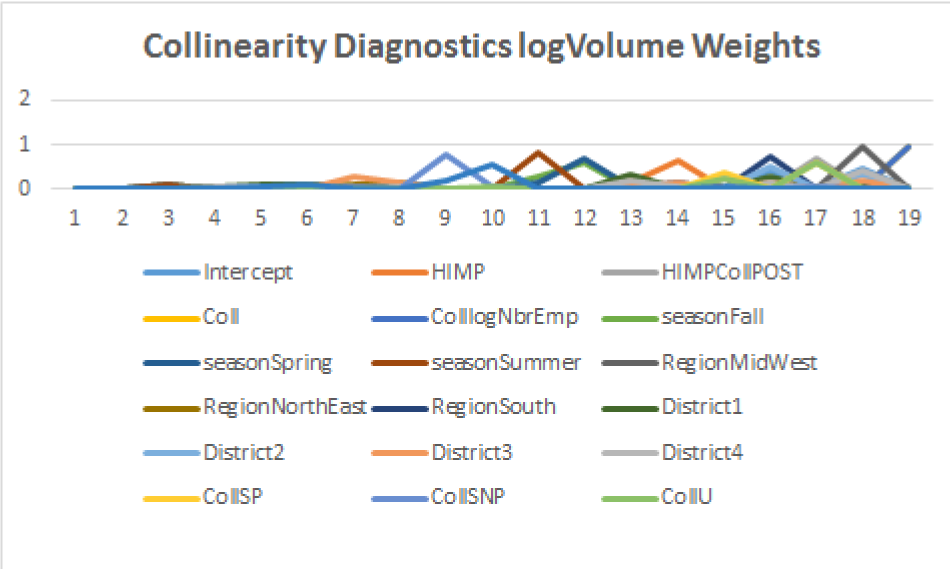

Figure H 9: Collinearity Diagnostics for LogVolume Weights

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

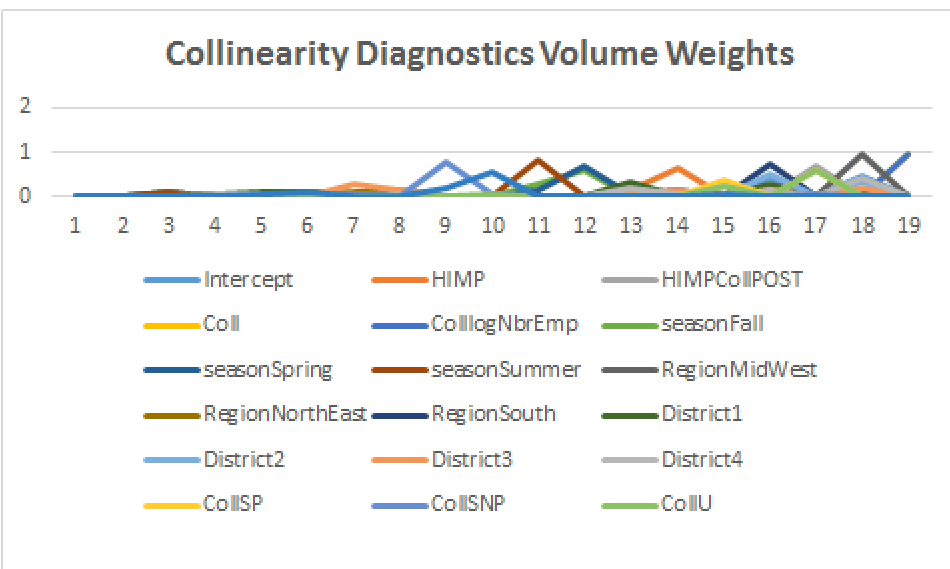

Figure H 10: Collinearity Diagnostics for Volume Weights

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Table H 9: Variable Condition Indices for logVolume- and Volume-Weighted Models

Variable	Condition Index	
	logVolume Weight	**Volume Weight**
Intercept	1	1
HIMP	1.30958	1.22543
HIMPCollectionPOST	1.49825	1.52054
Coll	1.5523	1.5952
ColllogNbrEmp	1.90795	1.8474
seasonFall	2.01913	2.04862
seasonSpring	2.27366	2.20763
seasonSummer	2.33316	2.29012
RegionMidWest	2.50977	2.56298
RegionNorthEast	2.85073	2.89148
RegionSouth	2.94187	2.98709
District1	3.08754	3.14731
District2	3.73244	3.58692
District3	3.81056	4.11337
District4	4.70316	5.37287
CollSP	5.33545	6.78909
CollSNP	8.19325	8.37163
CollU	8.64833	9.01925
CollNR	12.18342	24.70739

Abbreviations: Coll, Collection Variable; HACCP, Hazard Analysis and Critical Control Point; HIMP-based Inspection Models Project; NbrEmp, Number of Employees; NR, Noncompliance Record; SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Effect of Transformation of Volume Data on Illnesses Avoided

Figure H 11 through Figure H 16 show how log transformation of the volume data affects the estimated illnesses avoided for: i) the SP+SNP+U scenario for with a 5,046 sample size collected from 159 plants (Figure H 11); ii) the SP+SNP+U scenario for with a 2,330 sample size collected from 35 plants (Figure H 12); iii) and the four scenarios looking at: SP alone, SNP alone, U alone, and SP+SNP+U for a 22,631 sample size collected from 35 plants (Figure H 13 through Figure H 16). The scenario graphics are for non-HIMP plants at post-chill. It needs to be emphasized that non-risk weighting leads to a noticeable increase in illnesses avoided in all examples. This is because risk weighting (logVolume) gives weight to all establishment's contamination while non-transformed Volume weighting gives risk to the largest volume establishments. In the SP+SNP+U scenario shown in Figure H 11 the mean difference is an increase in illnesses avoided of 8,698. The mean values for illnesses avoided are summarized in Table H 10. The means all occur when the respective cumulative probability curves cross the horizontal line at probability = 0.5.

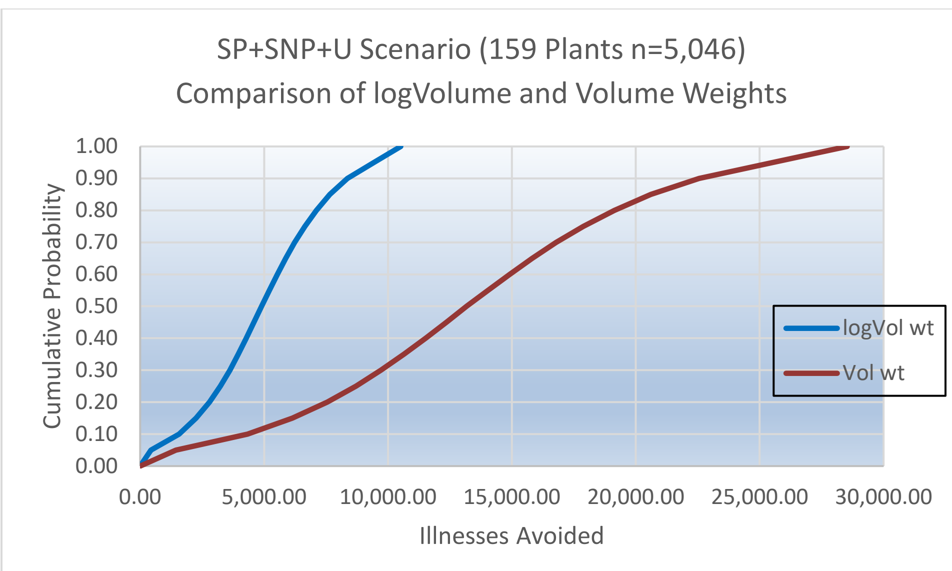

Figure H 11: SP+SNP+U Scenario Model, Volume- and logVolume-Weighted.
The SP+SNP+U scenario shown in Figure H 11 has a mean difference increase of 8,385. This scenario shows the intermediate increase effect seen with the second largest shift to the right for volume weighting. This scenario has 159 plants and a sample size of 5,049. Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled; V, volume.

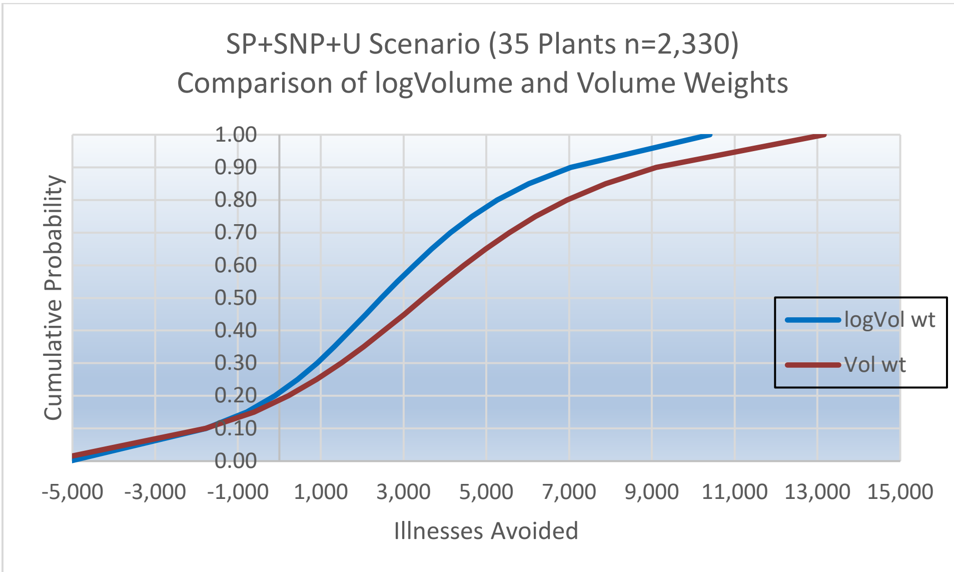

Figure H 12: SP+SNP+U Scenario Model, Volume- and logVolume-Weighted.

The SP+SNP+U scenario shown in Figure H 12 has a mean difference increase of 1,030. This scenario shows the greatest increase effect seen with the largest shift to the right for volume weighting. This scenario has 35 plants and a sample size of 2,330. Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled; Vol/V Wt, Volume Weight.

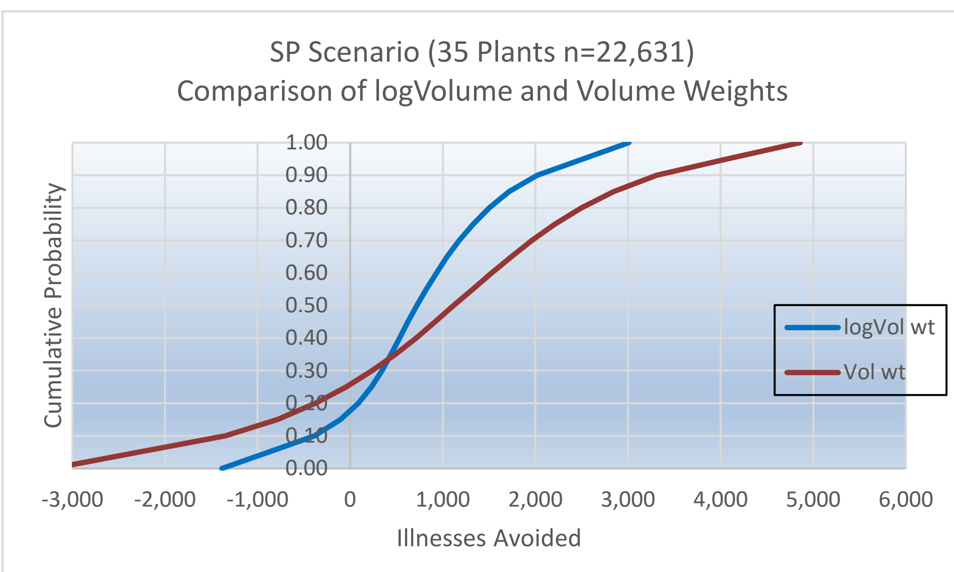

Figure H 13: SP Scenario Model, Volume- and logVolume-Weighted.

The SP scenario shown in Figure H 13 has a mean difference increase of 263.This scenario has 35 plants and a sample size of 22,631. Abbreviations: SP, Scheduled and Performed; Vol/V Wt, Volume Weight.

Figure H 14: SNP Scenario Model, Volume- and logVolume-Weighted

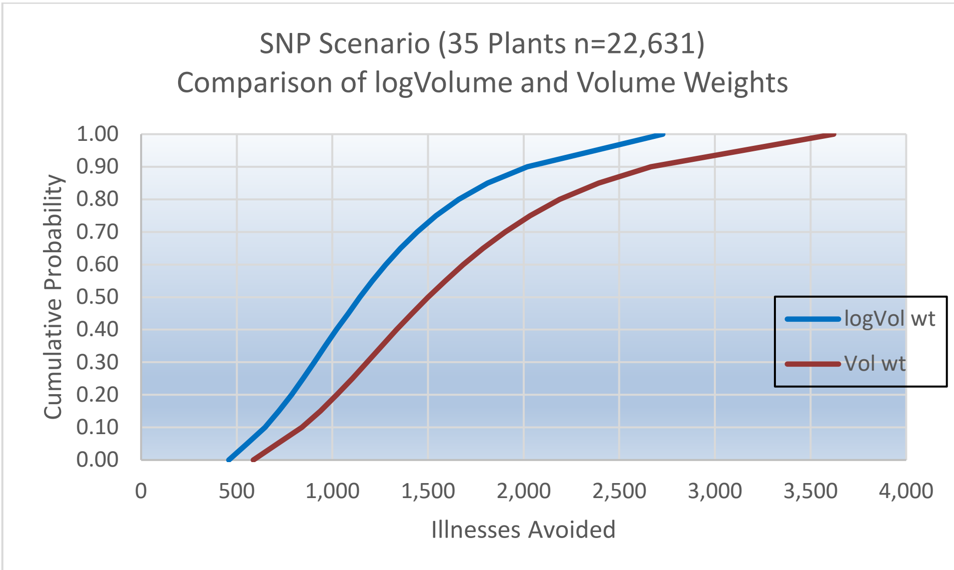

Figure H 14: SNP Scenario Model, Volume- and logVolume-Weighted

The SNP scenario shown in H14 has a mean difference increase of 396. This scenario has 35 plants and a sample size of 22,631. Abbreviations: SNP, Scheduled Not Performed; Vol/V Wt, Volume Weight.

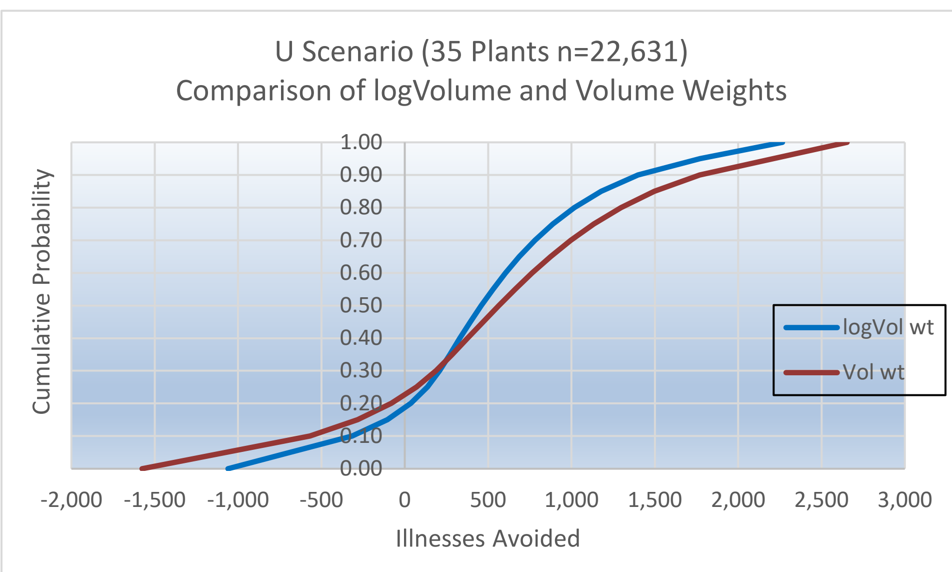

Figure H 15: U Scenario Model, Volume- and logVolume-Weighted

The U scenario shown in H15 has a mean difference increase of 78. This scenario shows the smallest increase effect seen with the smallest shift to the right for volume weighting. This scenario has 35 plants and a sample size of 22,631. Abbreviations: U, Unscheduled; Vol/V Wt, Volume Weight.

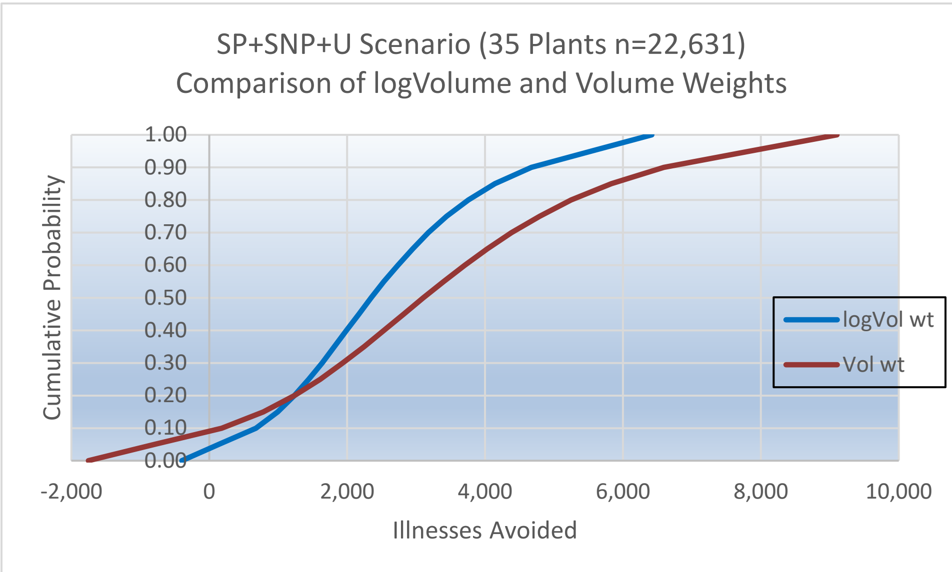

Figure H 16: SP+SNP+U Scenario Model, Volume- and logVolume-Weighted

The SNP scenario shown in H16 has a mean difference increase of 737. This scenario has 35 plants and a sample size of 22,631. Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled; Vol/V Wt, Volume Weight.

Table H 10: Scenario Illnesses Avoided

		Post-Chill Scenario			
Weighting	**Estimate**	**SP**	**SNP**	**U**	**SP+SNP+U**
159 Establishments, N = 5,046 Samples					
logVolume	Mean	1,651	2,016	1,277	4,944
Volume	Mean	4,419	5,527	3,441	13,387
	Mean Difference	**2,768**	**3,511**	**2,164**	**8,698**
35 Establishments, N = 2,330 or 22,631					
logVolume	Mean	770	1,257	506	2,533
Volume	Mean	2,061	3,446	1,363	6,871
	Mean Difference	**1,291**	**2,189**	**857**	**4,338**

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Sensitivity Analyses for Crossover Model with Different Weights

To further illustrate the sensitivity of the analyses to the variability and uncertainty in the input parameters, tornado plots and graphs of the effects of correlation were generated (Figure H 17 through Figure H 32). Sensitivity graphs record the effect of uncertainty inputs and correlations on the final output of decision variable means. The correlations are Spearman rank correlations, illustrating the relative sensitivity of each inspection variable category to the $\lambda_{avoided}$ estimate with respect to each logistic model coefficient. These analyses refer to Version 2 of the model, where the 35 establishments most likely to adopt NSIS are included with 22,631 days of inspection data.

As demonstrated in Figure H 17, the SP scenario mean is affected most by the SP-*Pert* uncertainty, next by the U-*Pert* uncertainty, then the SNP-*Pert* uncertainty followed by total illness uncertainty, swine-*Pert*, and market hog-*Pert* components. Figure H 18 demonstrating the sensitivity of the SP scenario to correlations of six inputs, follow the same pattern.

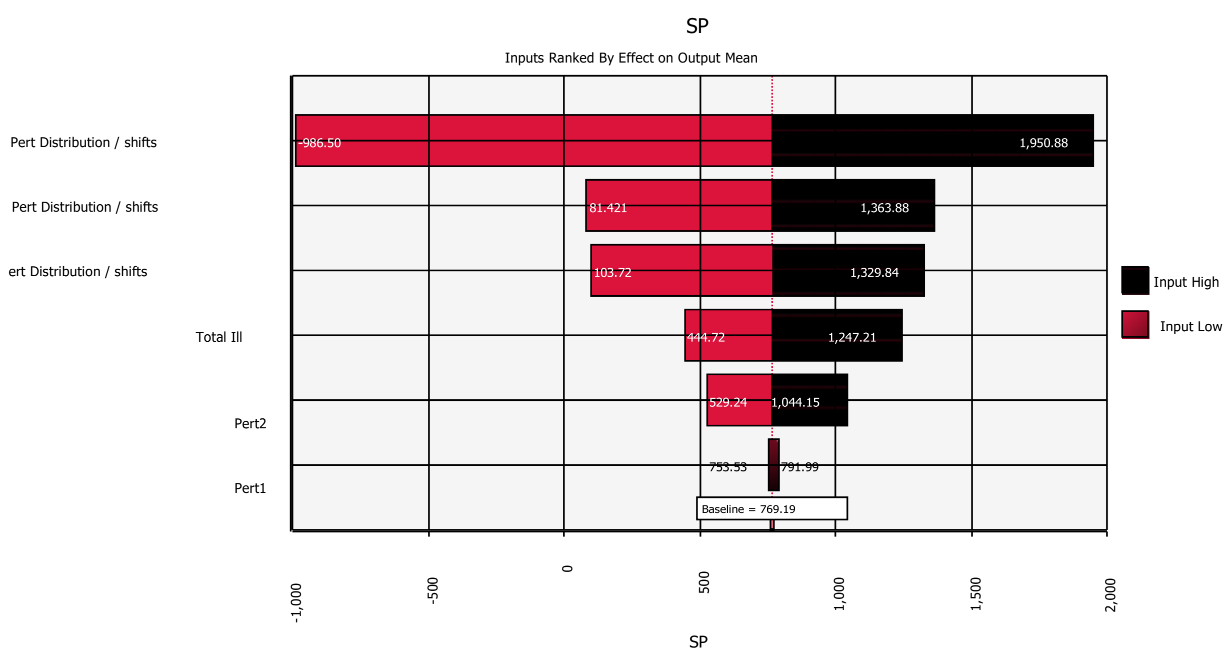

Figure H 17: Effects of Seven Uncertainty Inputs on the SP Scenario Mean for logVolume Weights.

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

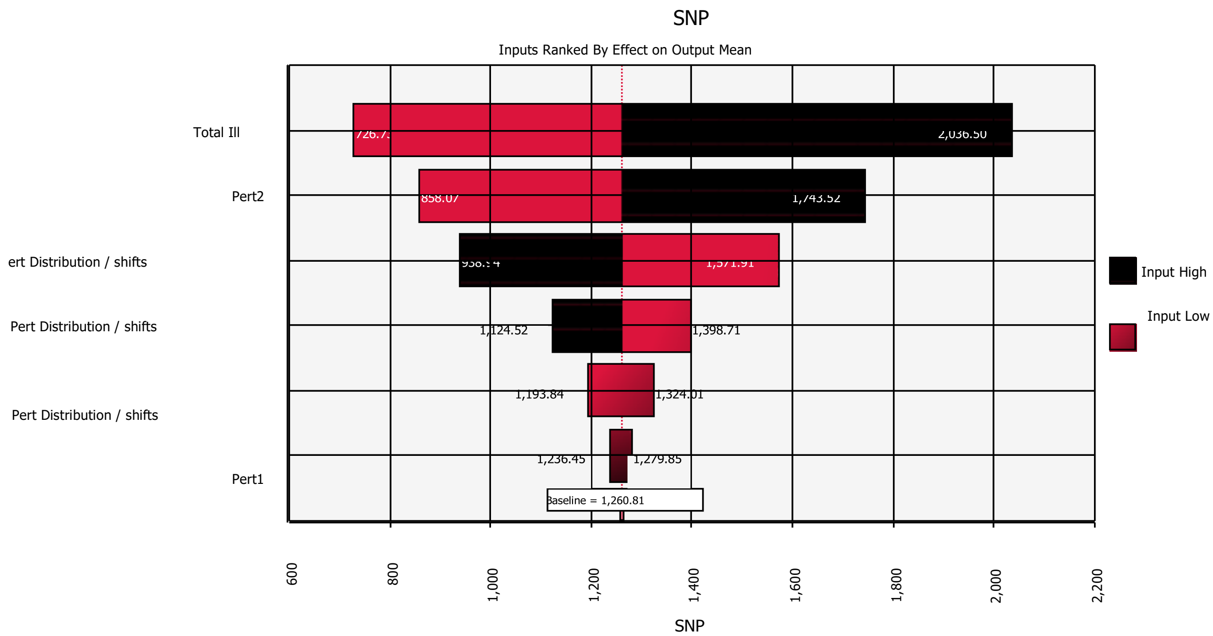

Figure H 18: Effects of Seven Uncertainty Inputs on the SNP Scenario Mean for logVolume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The SNP scenario mean, on the other hand, is affected most by total illness uncertainty, then swine-*Pert*, SNP-*Pert*, SP-*Pert*, U-*Pert*, and market hog-*Pert* uncertainties. This pattern of correlation is similar whether running the model with logVolume-weighted data and seven sources of uncertainty (H18) or correlations of six sources of uncertainty (Figure H 19)—though the latter scenario produces negative correlations from the three *Pert* uncertainty inputs.

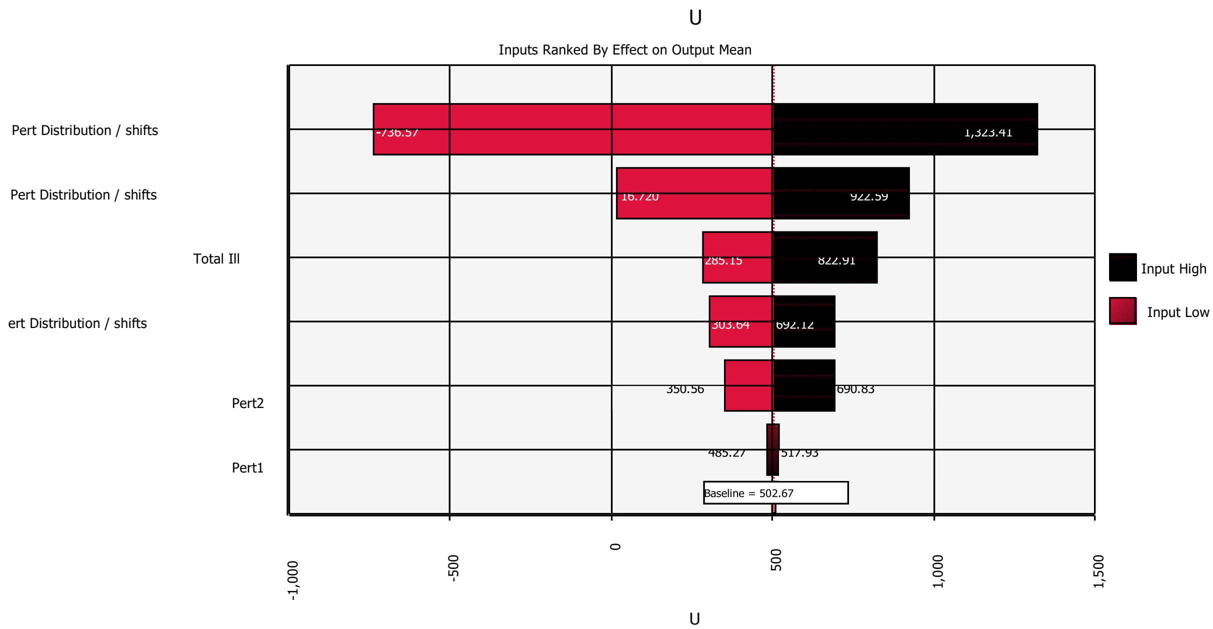

Figure H 19: Effects of Seven Uncertainty Inputs on the U Scenario Mean for logVolume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The U scenario mean is affected (shown in Figure H 19) most by the U-*Pert* uncertainty, then SP-*Pert*, total illness, SNP-*Pert*, swine-*Pert*, and market hog-*Pert* uncertainty components when the model is run with seven sources of uncertainty Figure H 22, describing the U scenario with correlations of six sources of uncertainty, illustrates the same pattern with all positive correlations.

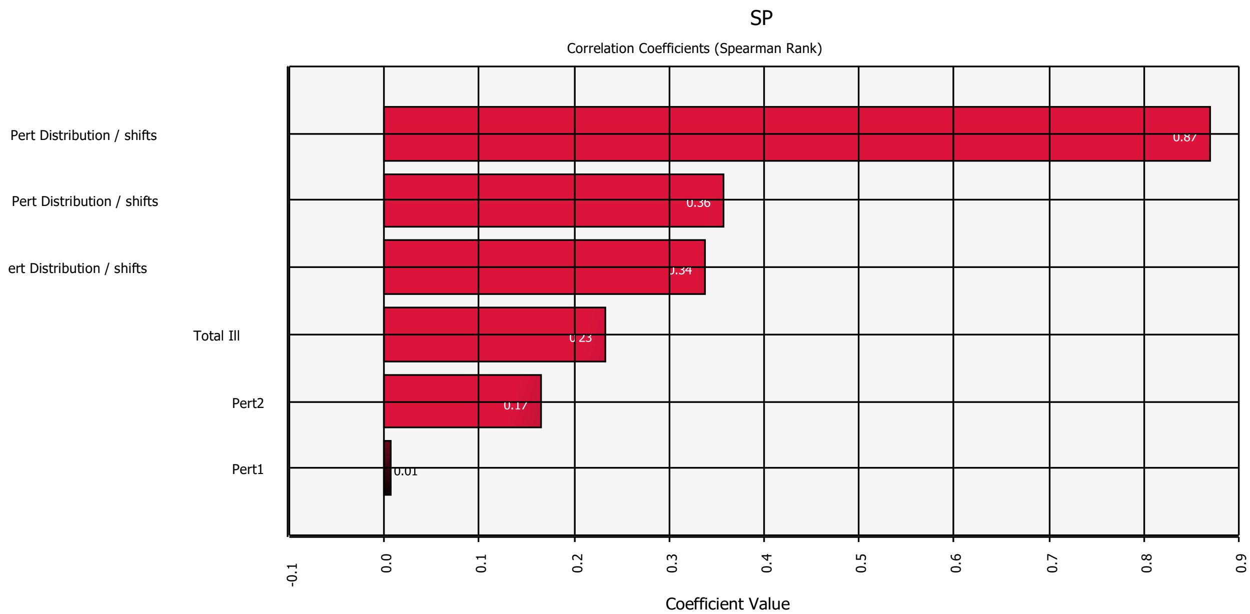

Figure H 20: Effects of Correlations of Six Uncertainty Inputs on the SP Scenario Mean for logVolume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

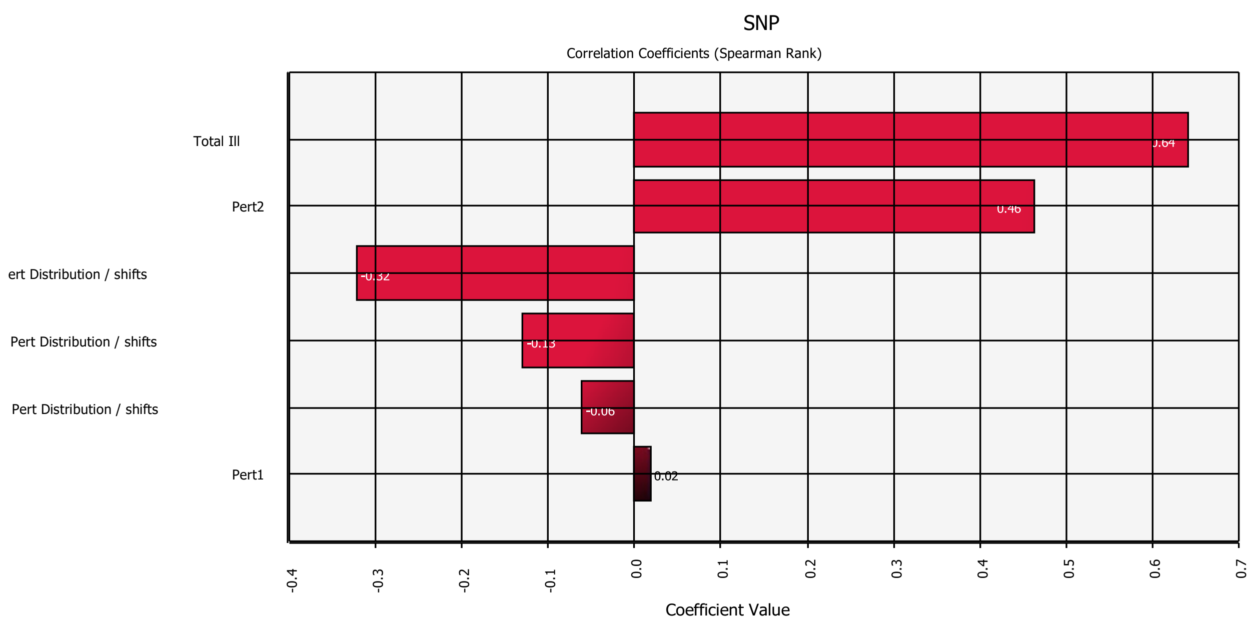

Figure H 21: Effects of Correlations of Six Uncertainty Inputs on the SNP Scenario Mean for logVolume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

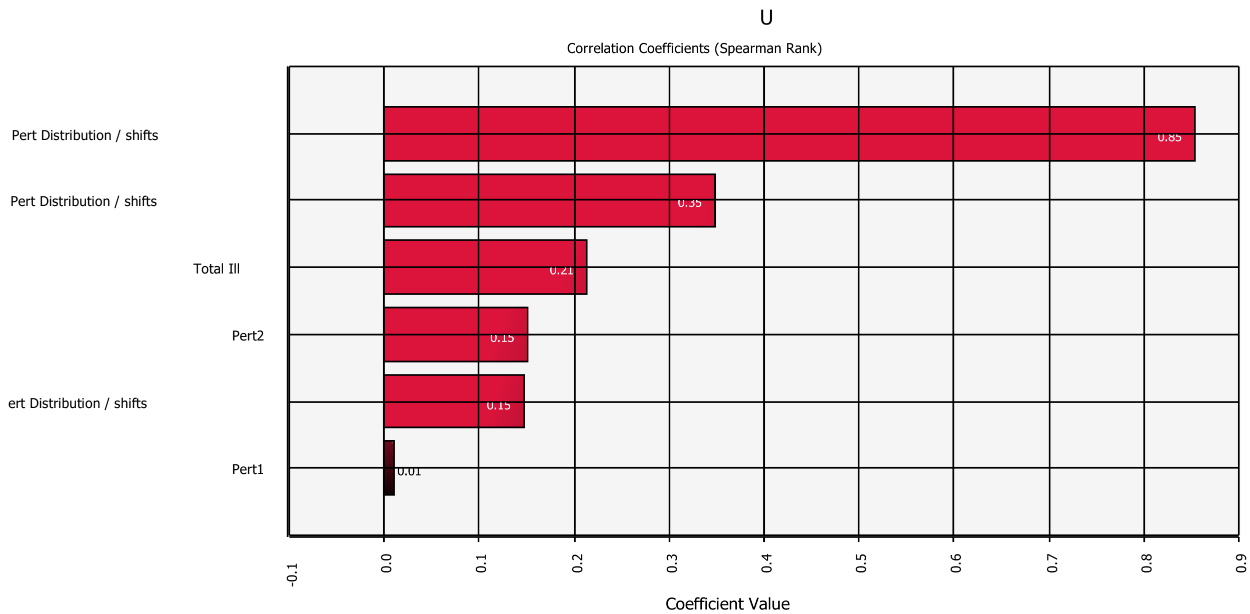

Figure H 22: Effects of Correlations of Six Uncertainty Inputs on the U Scenario Mean for logVolume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

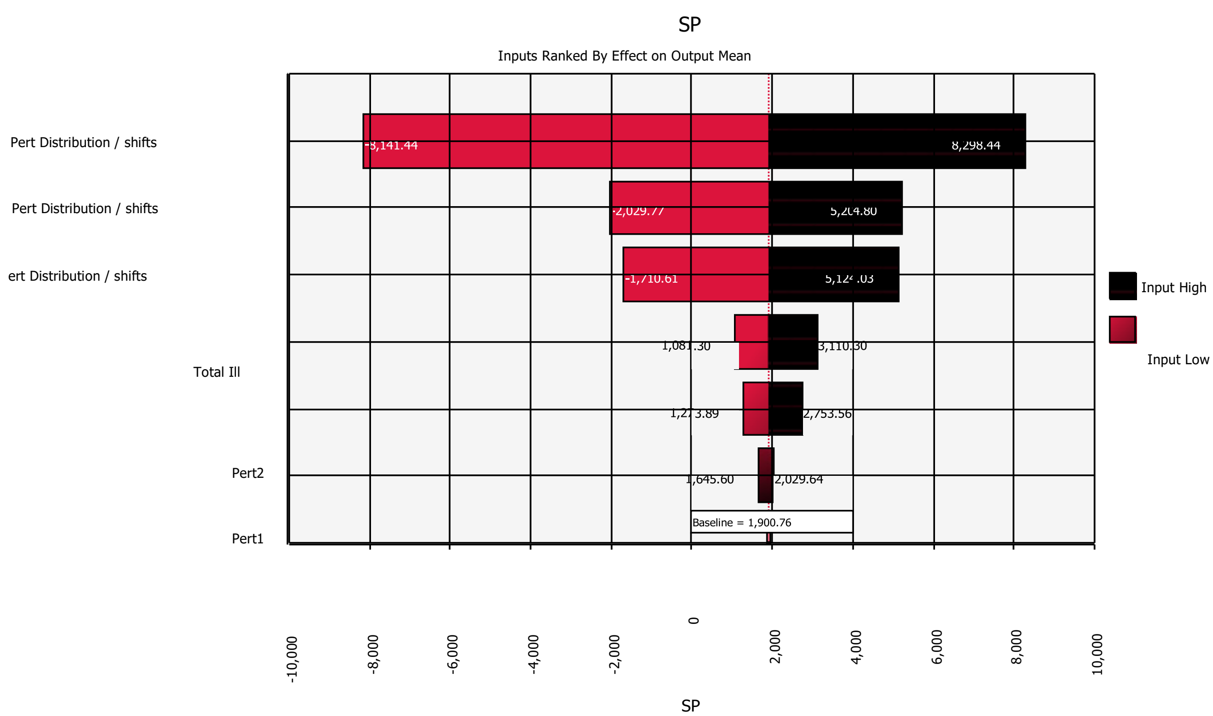

Figure H 23: Effects of Six Uncertainty Inputs on the SP Scenario Mean for Volume Weighting

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The mean effects and correlation effects are in the same direction for SP uncertainty components except the mean components for volume weights exceed those for logVolume weights.

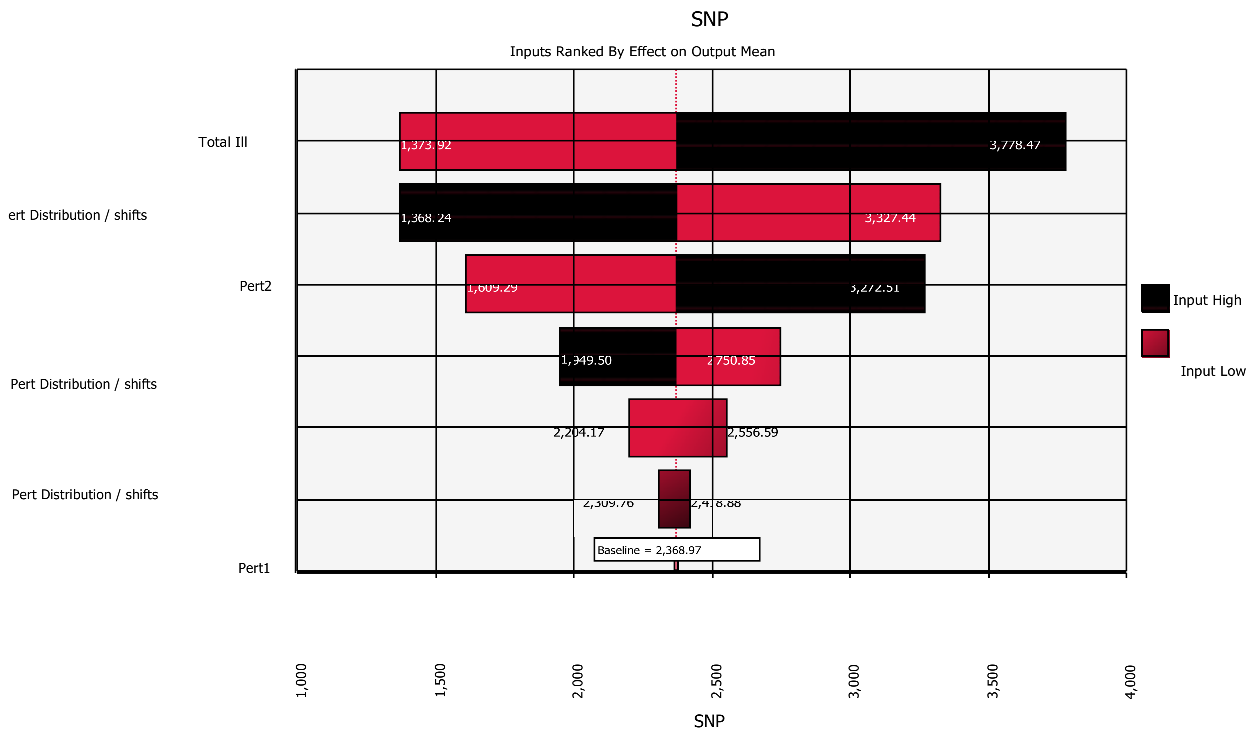

Figure H 24: Effects of Six Uncertainty Inputs on the SNP Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The mean effects and correlation effects are in the same direction for SNP uncertainty components except the mean components for volume weights exceed those for logVolume weights.

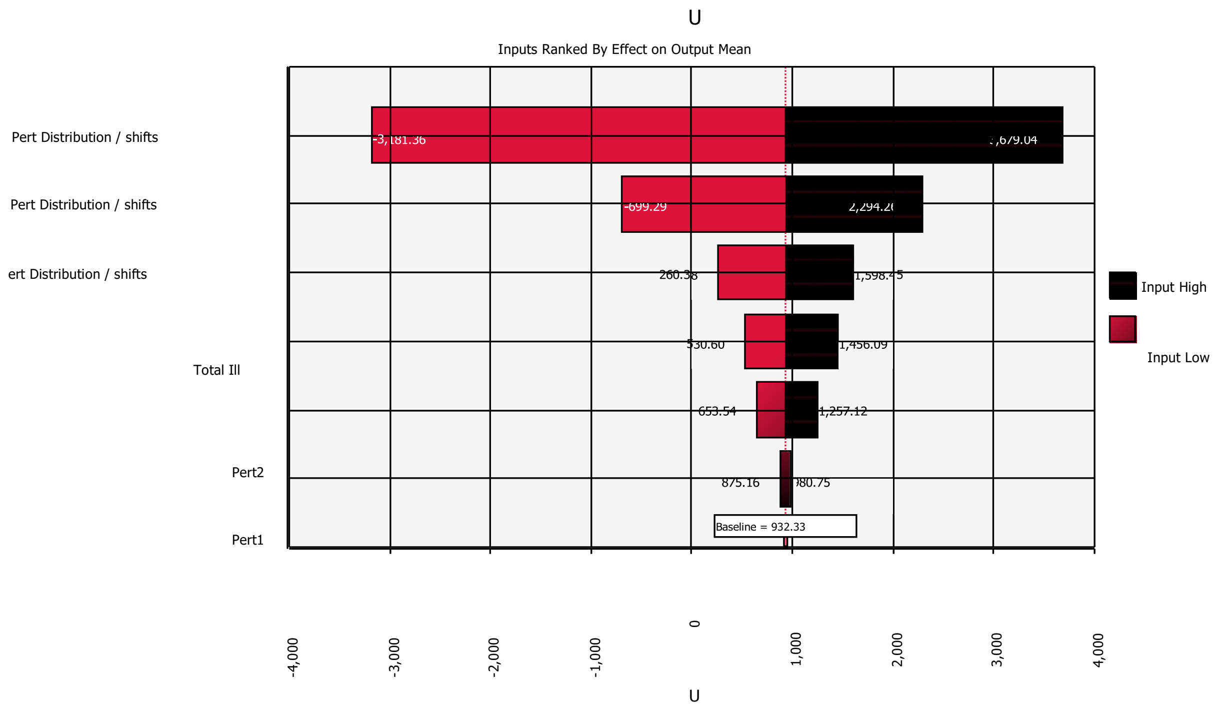

Figure H 25: Effects of Six Uncertainty Inputs on the U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The mean effects and correlation effects are in the same direction for U uncertainty components except the mean components for volume weights exceed those for logVolume weights.

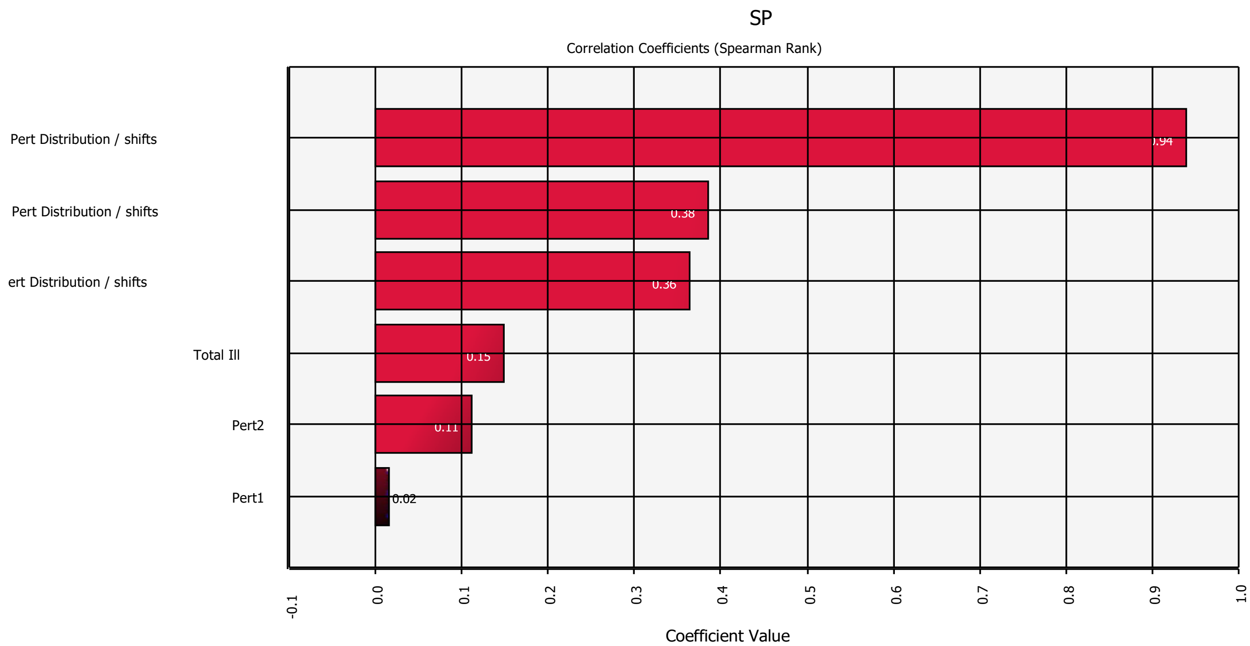

Figure H 26: Effects of Correlations of Six Uncertainty Inputs on the SP Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

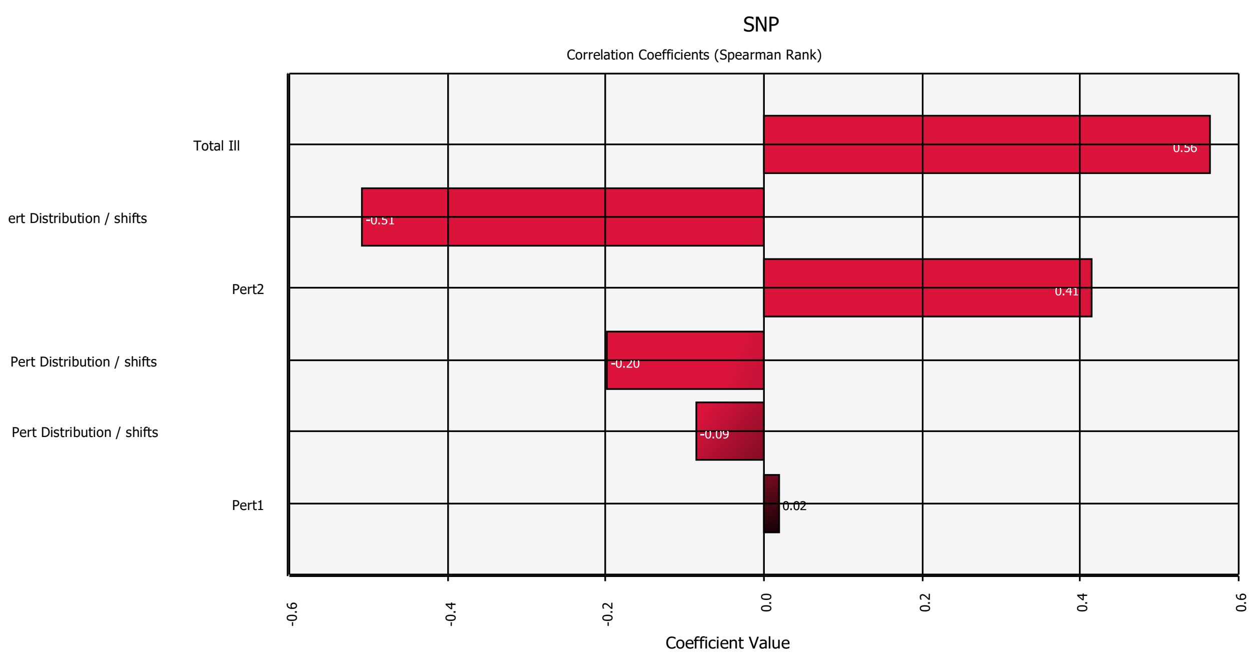

Figure H 27: Effects of Correlations of Six Uncertainty Inputs on the SNP Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

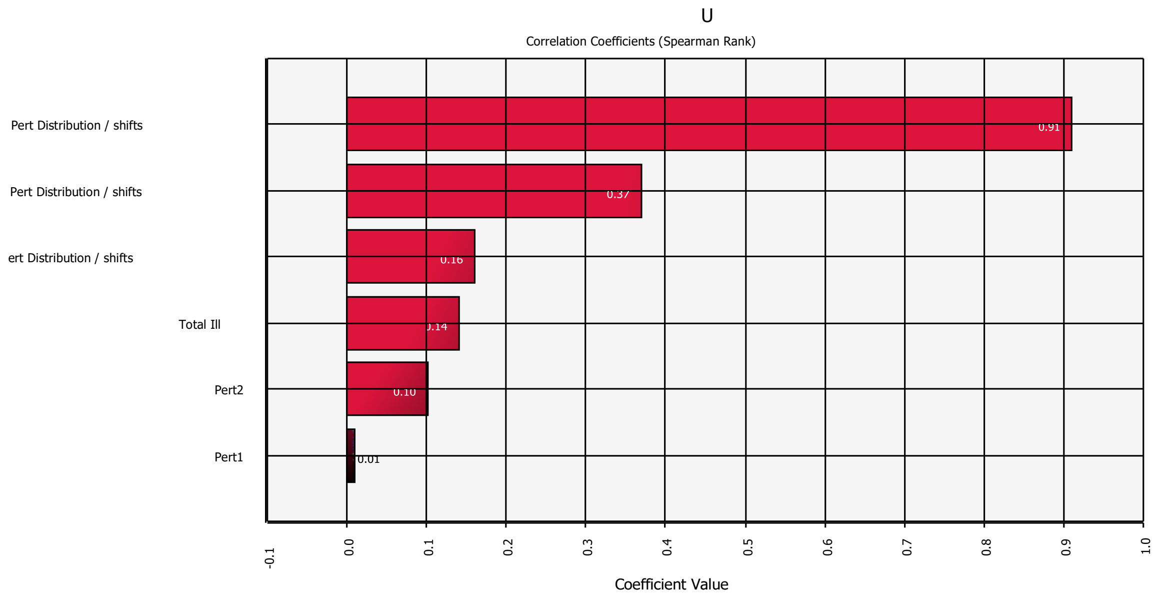

Figure H 28: Effects of Correlations of Six Uncertainty Inputs on the U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

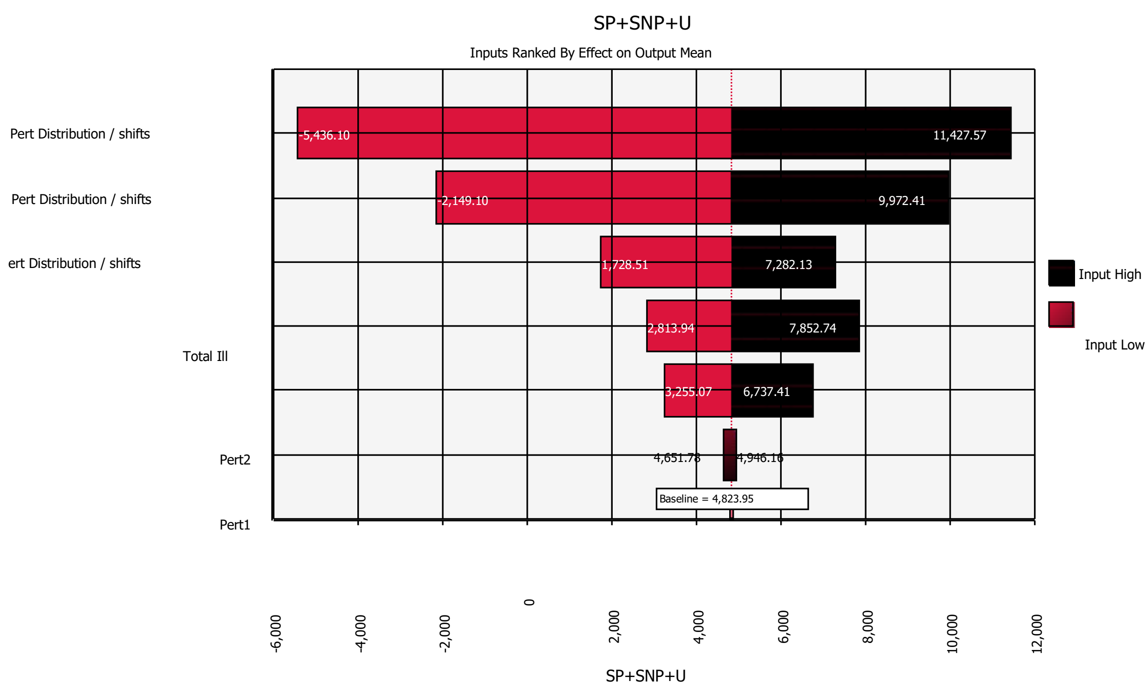

Figure H 29: Effects of Six Uncertainty Inputs on the SP+SNP+U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

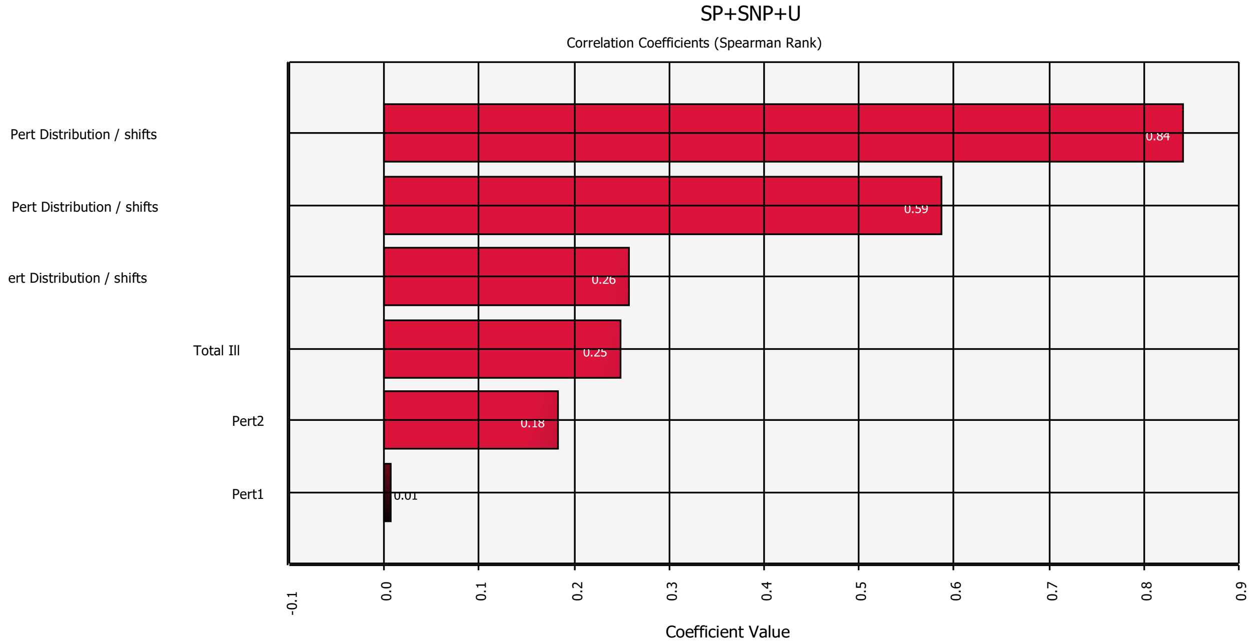

Figure H 30: Effects of Correlations of Six Uncertainty Inputs on the SP+SNP+U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

The mean effects and correlation effects are in the same direction for SP+SNP+U uncertainty components except the mean components for volume weights exceed those for log Volume weights.

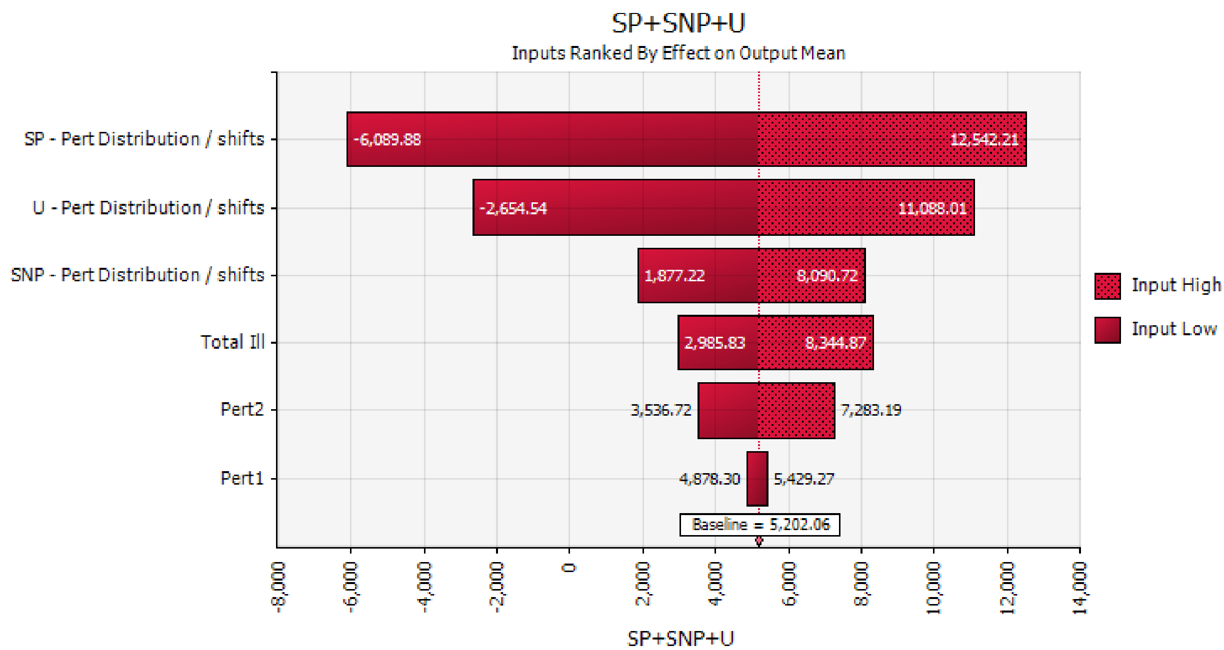

Figure H 31: Effects of Six Uncertainty Inputs on the SP+SNP+U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

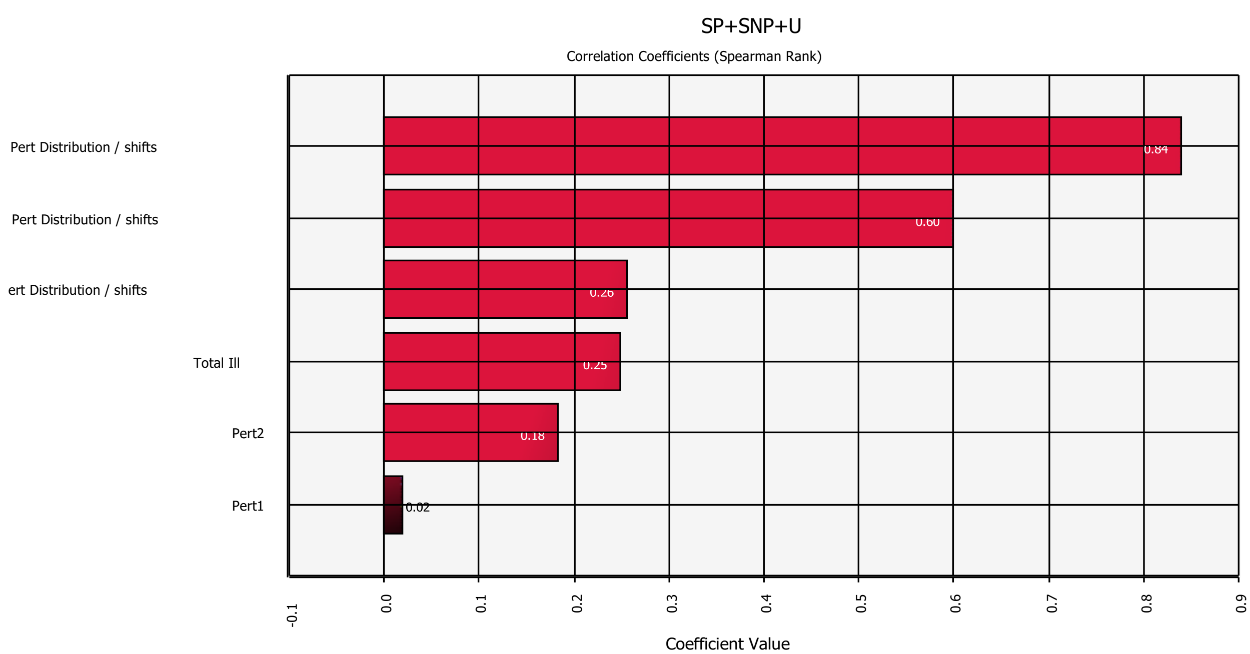

Figure H 32: Effects of Correlations of Six Uncertainty Inputs on the SP+SNP+U Scenario Mean for Volume Weights

Abbreviations: SNP, Scheduled Not Performed; SP, Scheduled and Performed; U, Unscheduled.

Figure H 33 shows the data used for modeling in a scatter plot of the four sub-models. The LogOdds ratios are plotted against the log number of inspectors in order to see the linearity.

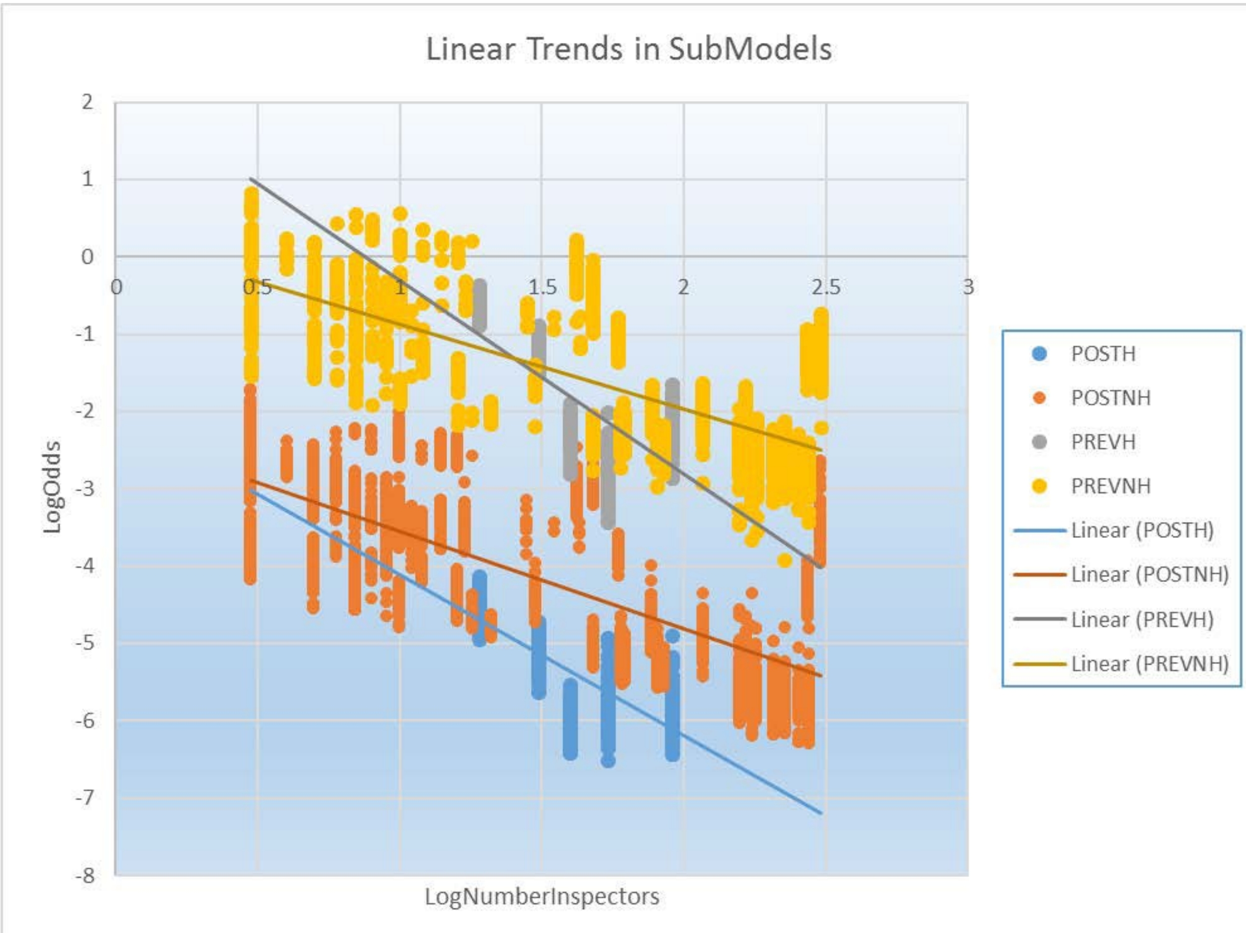

Figure H 33: Scatter Plot of Original Data Showing Least Squares Regression Lines

Rationale for Decreased Uncertainty with Expanded Sample Size

Uncertainty can be reduced with new information that reduces that uncertainty. In contrast, variability cannot be reduced given a fixed set of variables contributing to that variability. However, there is an increase in information in the newly added independent variables with their respective imputed responses because only 40% of these variable patterns are repeated and add no new information. There is an increase in new independent variable patterns of 60% (13,483 of 22,601). Increasing the sample size for the set of variables contributing to variability increases the amount of information about each establishment that is incorporated in the simulation; however, it does not account for all the uncertainty associated with imputing the missing *Salmonella* sample data and seems to increase the precision of the average variability. In the uncertainty analysis, components of uncertainty were identified as the illness distribution, the aggregate of the *Pert* uncertainty distributions, and the regression coefficient variability. For the variability in the input risk variables, multiplying by the regression coefficients possessing a MVN error distribution was considered a totally characterized fixed distribution with no uncertainty.

When the original data for the 35 plants considered to convert had a fixed sample size of 2,330, the majority of the uncertainty for illnesses avoided was characterized by the illness distribution uncertainty components (illness distribution multiplied by two *Pert* distributions), and the uncertainty components of the P/P_0 ratio came mainly from three possible *Pert* distributions, multiplying the decision risk variables and the respective regression coefficients with their associated MVN error distribution. Additional variability was introduced at each iteration from random draws from the *Pert* and MVN distributions.

When the set of input risk variables was expanded from 2,330 to 22,631, the distribution of uncertainty components multiplying the regression coefficients was changed. The apparent variability in the risk variables had decreased leading to an overall decrease in the P/P_0 ratio uncertainty.

The apparent difference in uncertainty components is shown by the uncertainty component bar graphs for standardized means both the same for 2,330 inspection days and for 22,631 inspection days in Figure H 34. The simulation was run for 100,000 iterations.

The standard deviations change for some of the uncertainty distributions after 100,000 iterations as shown in Figure H 35. The size of numerical change is shown in Table H 11.

The most important changes are the reductions in the standard deviations resulting in increased illnesses avoided in each of the decision variables. The source of these changes can be traced back through the illness reduction equation. The equation is as follows

$$\text{Illnesses Avoided} = \text{Total Illness Distribution}_{\text{market hogs}} \times (1 - P/P_0)$$

The ratio P/P_0 is the only plausible source of illness reduction because the total illness distribution is fixed with no new information provided which would reduce its uncertainty bounds. The SP, SNP, and U (1-P/P_0) multipliers all produced lower standard deviations after simulations for 22,631 sample days (model version 2), when compared to model runs using data from 2,330 sample days (model version 1).

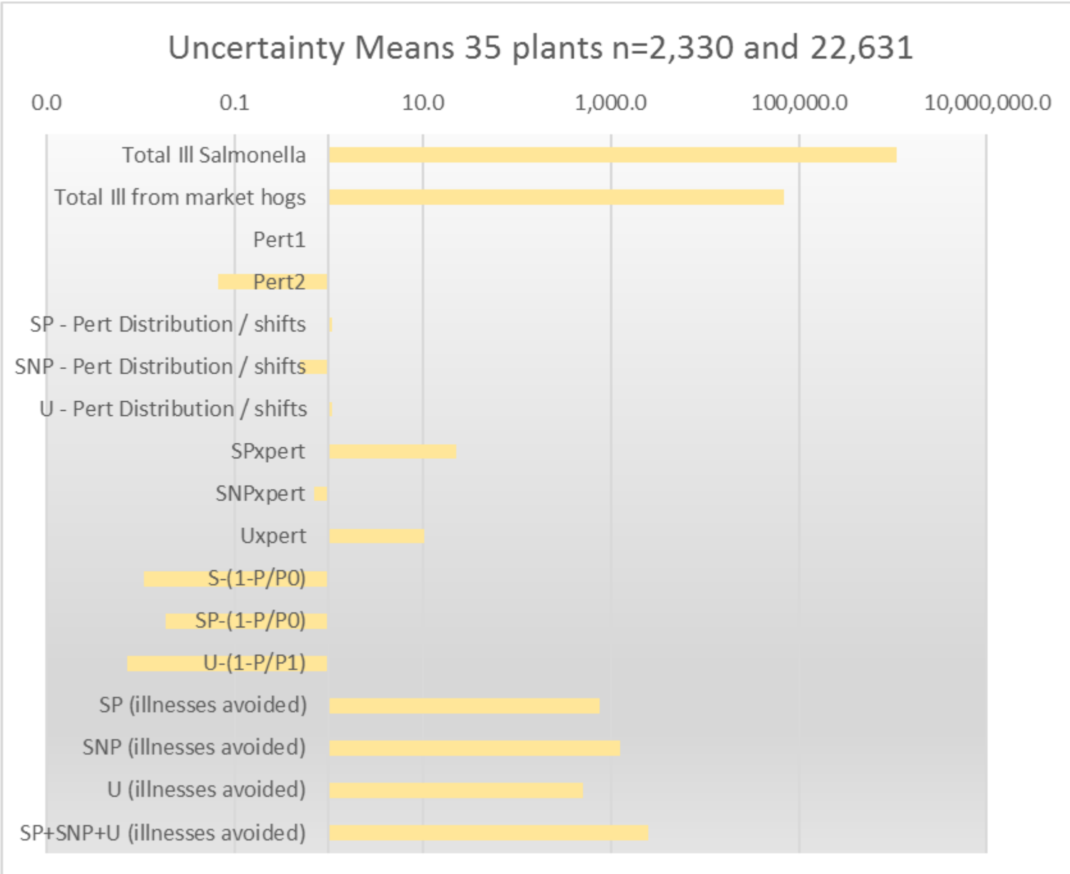

Figure H 34 Relative Size of Means for Uncertainty Distributions after Simulation

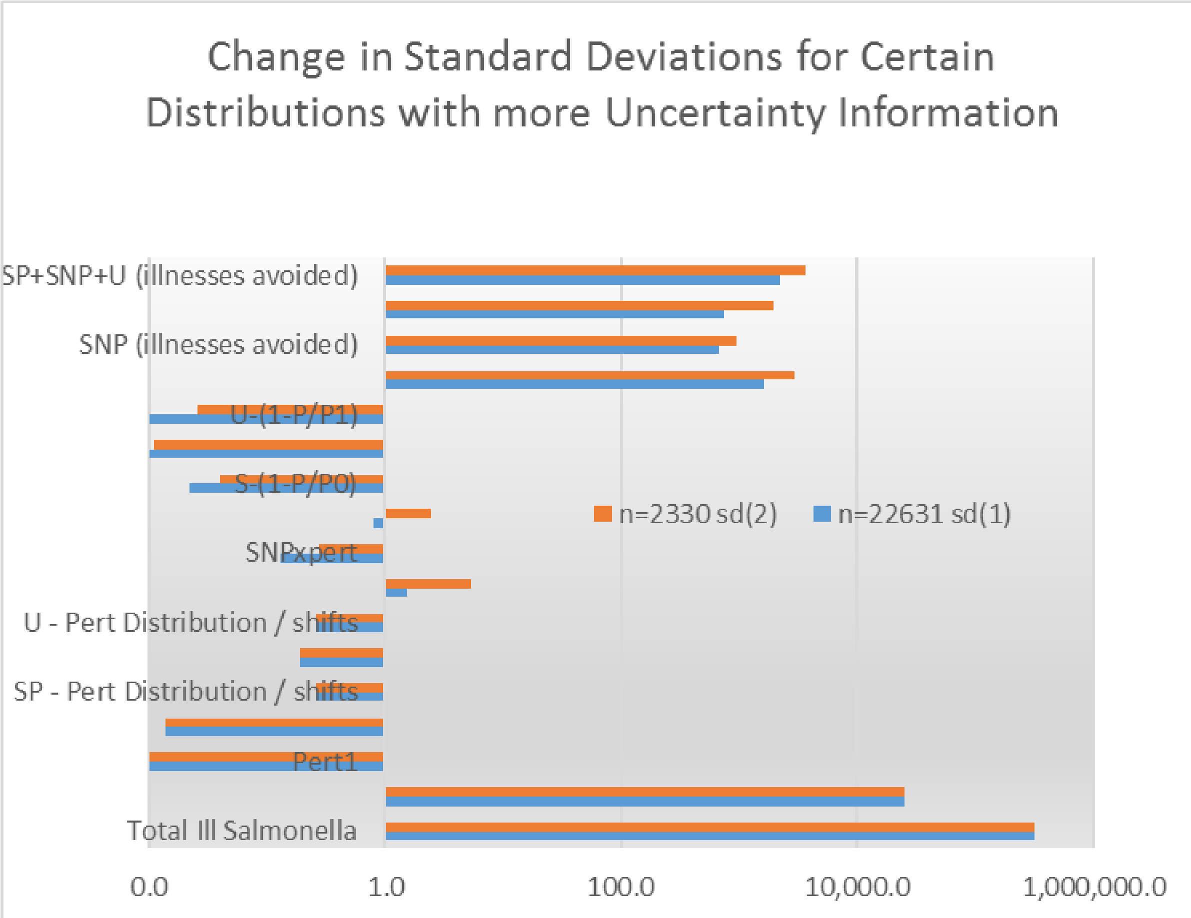

Figure H 35: Relative Size of Standard Deviations for Uncertainty Distributions after Simulation

Table H 11: Summary of Uncertainty Distribution Components for 35-Establishment Simulation Model[a]

logvol Weights				
35 plants	ver 2. n=22,631		ver. 1 n=2,330	
uncertainty components	means	sd	means	sd
Total Ill Salmonella	1,085,711	322,826	1,085,711	322,826
Total Ill from market hogs	69,897	25,704	69,897	25,704
Pert1	0.9583	0.0094	0.9583	0.0094
Pert2	0.0672	0.0138	0.0672	0.0138
SP - Pert Distribution / shifts	1.0833	0.2539	1.0833	0.2539
SNP - Pert Distribution / shifts	0.5000	0.1890	0.5000	0.1890
U - Pert Distribution / shifts	1.0833	0.2539	1.0833	0.2539
SPxpert	24.4980	1.5432	19.2567	5.2812
SNPxpert	2.0310	0.1279	1.3223	0.2699
Uxpert	3.1484	0.7933	8.8717	2.4331
SP-(1-P/P0)	0.0122	0.0217	0.0108	0.0390
SNP-(1-P/P0)	0.0212	0.0053	0.0183	0.0111
U-(1-P/P1)	0.0046	0.0098	0.0071	0.0257
SP (illnesses avoided)	765	1,648	770	2,907
SNP (illnesses avoided)	1,302	667	1,257	947
U (illnesses avoided)	497	754	506	1,932
SP+SNP+U (illnesses avoided)	2,564	2,217	2,533	3,681

[a]logVolume weights used.
[b]Pert1= *Pert(0.930,0.970.0.980)* percent market hogs
[c]Pert2= *Pert(0.036,0.063,0.114)* percent swine

The mathematical underpinning of these smaller standard deviations is primarily that the two data sets have different numerator prevalence (P) values. The reduction is produced where SP, SNP, and U inspection variables are multiplied with their respective *Pert* uncertainty distributions (SPxDisc(SP), SNPxDisc(SNP), and UxDisc(U)). All other uncertainty distributions remain unchanged. As suggested before, the SP, SNP, and U variability distributions have changed due to the addition of 20,301 new pieces of information regarding the decision variable distributions which were modeled as complete distributions before being linked to sample days when *Salmonella* samples were collected. The assumption of predicting prevalence from the inspection data is that the *Salmonella* status for a given sample day need not be known—only inspection data for a particular day is needed in order to estimate that day's prevalence in this model.

Explicitly, this is calculated using the following equation:

$$P = B_0+B_1X_1+B_2X_2+\ldots+B_{16}X_{SP}Pert_{SP}+B_{17}X_{SNP}Pert_{SNP}+B_{18}X_UPert_U+B_{19}\ X_{19}$$

P_0 is calculated using the same equation except the *Pert* uncertainty distributions are not used.

Table H 12 presents a summary of the uncertainty distributions for the various decision variable scenarios using all inspection data (Version 2) and inspection data from the day that the sample was pulled (Version 1). As can be seen, the version does not affect the mean number of illnesses avoid, and in most cases has only a small effect on the standard deviation.

Table H 12: Summary of Uncertainty Distributions for Standardized and Non- Standardized Scenario Simulation Model

	Ver. 2		Ver. 1	
Uncertainty Components	**Mean ver.2**	**Std Dev ver.2**	**Mean ver.1**	**Std Dev ver.1**
Standardized	n=22,631		n=2,330	
SP	770	1,064	770	3,945
SNP	1,257	585	1,257	1,032
U	506	770	506	2,511
SP+SNP+U	2,533	1,698	2,533	3,801
Not Standardized	n=22,631		n=2,330	
SP	765	1,648	770	2,907
SNP	1,302	667	1,257	947
U	497	754	506	1,932
SP+SNP+U	2,564	2,217	2,533	3,681

References

VanderWeele, T.J., and Knol, M.J. (2014) A Tutorial on Interaction. *Epidemiol. Methods* 3(1): 33-72.

APPENDIX I: Data Variable Descriptions

Table I 1 describes the variables and coding used to denote data in the risk assessment model.

Table I 1: Descriptions of Variables Used in Model

Column Name	Description
Nbr	Serial number or Record line number of the data used in SAS Model
Locid	Establishment ID / EstID
Collection0	5 categories of sample collection location (4 market hog baseline (B48Post1, B48Post2,B48PREV1 and B48PREV2) + routine (1)
Volume	annual heads slaughtered, where volume equals annual number of market hogs slaughtered
w1	weight used log10 of volume for each plant
w2	not used
Sal	Salmonella culture positive (1); Salmonella culture negative (0)
HIMP0	HIMP Plant = 1; non-HIMP Plant = 0
NH	character variable, HIMP Plant = H; non-HIMP Plant = N
Cat4	4 categories simplified from Collection0 variable (routines not significantly different from postN): PREV H OR N for pre-evisceration; POST H OR N for post-chill sampling locations
HIMP	same indexing as NH variable but categorical-numeric, with -1 for HIMP and 1 for non-HIMP
Collection	character variable: POST for post-chill and PREV for pre-evisceration
COLL	numeric categorical variable: 1 for post-chill and -1 for pre-evisceration
Season	character variable for four seasons (winter, spring, summer, and fall)
Size	character variable for establishment HACCP size: Large, Small, and Very Small
Region	character variable for four regions: MidWest, NorthEast, South, and West
RelDistrict90	numeric number for 10 districts to be relative to district 90's combination
District	numeric containing 10 districts into category combinations of 1-5 with 5 containing district 90
S	total scheduled procedures over same day sampling period
SP	total scheduled and performed procedures over same day sampling period
SNP	total scheduled procedures not performed over same day sampling period
U	total unscheduled procedures performed over same day sampling period
NC	total non-compliant procedures occurring over same day sampling period
W3NR	total W3NR (NR related to public health) procedures occurring over same day sampling period (SUBSET of procedures related to public health from PBIS data) defined in risk assessment
PHR	public health related procedures from PBIS data (similar SUBSET of procedures to W3NR)
Pmcond	number of animals condemned at postmortem during same day sampling period

Column Name	Description
Nbrpass	number of animal suspects at ante mortem passed for slaughter during same day sampling period
Nbrrestrict	number of animals restricted and passed for cooking during same day sampling period
Suspect	number of animals held for inspection by veterinarian at ante mortem during same day sampling period
NbrEmp	total annual number of assigned inspectors for establishment (greater than the inspectors assigned daily to plant (includes relief))
Logpmcond	log of pmcond +2
Lognbrpass	log of nbrpass +2
Lognbrrestrict	log of nbrrestrict +2
Logsuspect	log of number suspects +2
LogNbrEmp	log of NbrEmp +2
PlantName	Establishment Number