FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection

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Executive Summary

BACKGROUND

Food Safety and Inspection Service on-line inspectors examine every young poultry carcass to ensure it is unadulterated, free of feathers, bruises, and defects and disease. FSIS off-line inspectors verify that establishments maintain sanitary operations and perform other health and safety-related assignments. By allowing FSIS personnel to perform additional wholesomeness, sanitation, sampling, and other offline procedures, it may be possible to reduce the number of human illnesses from *Salmonella*.

RISK MANAGEMENT QUESTIONS

This risk assessment addresses four risk management questions:

- Can FSIS reallocate inspection activities in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?
- How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, affect human illness?
- Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?
- What is the uncertainty about these effects?

STRUCTURE AND SCOPE

This is a quantitative microbial food safety risk assessment. It evaluates variations in personnel assignments and inspection activities in FSIS poultry slaughter facilities with the prevalence of *Salmonella* on young chicken and, subsequently, attributable salmonellosis in humans. Data used in the risk assessment came from several sources. Data for the prevalence of *Salmonella* for poultry carcasses, representing 154 young chicken slaughter establishments, came from the USDA/FSIS *Salmonella* Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) verification sampling collection program for 2003-2005. Data for inspection procedures performed in an establishment came from the FSIS performance based inspection system (PBIS) database. These data were paired with *Salmonella* prevalence data for the same establishments and timeframes. The FSIS Resource Management and Planning Staff provided personnel assignment profiles for each establishment. A stochastic simulation model using multiple variable logistic regression techniques was used to account for uncertainty in estimates of the association between food safety procedure activities in the establishment and corresponding *Salmonella* prevalence on poultry.

Baseline estimates for the mean number of human salmonellosis from young chicken were based on surveillance data gathered by the Centers for Disease Control and Prevention (CDC). An uncertainty distribution was estimated around that mean number of attributable illnesses. Changes in the number of annual human salmonellosis cases due to inspection personnel activities were estimated as a function of predicted changes in *Salmonella* prevalence in young chicken slaughter establishments. A Poisson uncertainty distribution was used to incorporate both the variability in *Salmonella* illnesses per year and uncertainty about the relationship between changes in prevalence levels at the establishment level and corresponding number of attributable *Salmonella* illnesses. This procedure is documented in the microbial risk modeling literature.[18] For this risk assessment, *Salmonella* serotypes were not delineated on pathogenicity. That is, all *Salmonella* were assumed to have the same potential to cause human illness.

MODEL RESULTS

Key model results are summarized below. These results describe changes in estimated human salmonellosis cases associated with the number of unscheduled procedures performed in an establishment, the number of unperformed procedures in an establishment, and the number of non-compliances.

Six scenarios were modeled out to human illness impact based on changes in microbial contamination in the plants. Other scenarios were evaluated and provided no useful information when modeled out to human illness due to uncertainty in predicted changes in microbial contamination that were overwhelmed by the uncertainty distribution about estimates of attributable human illness.

A 50% increase in UNSCHEDULED SANITATION procedures (U-1)

An uncertainty distribution was developed for the expected change in human illnesses due to a 50% increase in all unscheduled sanitation procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 7,573 attributable *Salmonella* illnesses. The 95th percentile of the uncertainty distribution is a reduction of 2,593 illnesses.

A 50% increase in UNSCHEDULED SAMPLING procedures (U-5)

An uncertainty distribution was also developed for the expected change in human illnesses due to a 50% increase in all unscheduled sampling procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 19,780 attributable *Salmonella* illnesses. The 95th percentile of the uncertainty distribution is a reduction of 9,916 illnesses.

A 75% decrease in UNPERFORMED SAMPLING procedures (B-5)

Similarly, an uncertainty distribution was developed for the expected change in human illnesses due to a 75% decrease in all unperformed sampling procedures across all young chicken slaughter establishments. Just under 85% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 5,482 illnesses. The 85th percentile of the uncertainty distribution, however, shows an increase of 258 illnesses. This implies that there is a 15% probability that attributable *Salmonella* illnesses would not decrease because of a decrease in the number of unperformed sampling procedures.

A 75% decrease in UNPERFORMED HACCP procedures (B-3)

An uncertainty distribution was developed for the expected change in human illnesses due to a 75% decrease in unperformed HACCP procedures across all young chicken slaughter establishments. Over 70% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 2,060. The 75th percentile of the uncertainty distribution, however, shows an increase of 297 illnesses. This implies that there is a 25% probability that attributable *Salmonella* illnesses would not decrease because of a decrease in the number of unperformed HACCP procedures.

A 75% decrease in UNPERFORMED SANITATION procedures (B-1)

In addition, an uncertainty distribution was developed for the expected change in human illnesses due to a 75% decrease in unperformed sanitation procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 8,592

illnesses. The 95th percentile of the uncertainty distribution shows a reduction of 2,021 illnesses.

A 75% decrease in NON COMPLIANCES for SANITATION procedures (NC-1)

Finally, an uncertainty distribution was developed for the expected change in human illnesses due to a 75% decrease in non-compliances (NRs) for sanitation procedures across all young chicken slaughter establishments. Over 65% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 2,321 illnesses. The 70th percentile of the uncertainty distribution, however, shows an increase of 297 illnesses. Again, this implies that there is a 30% probability that attributable *Salmonella* illnesses would not decrease because of a decrease in the number of non-compliances (NRs) related to sanitation procedures.

CONCLUSIONS

The results of the risk assessment provide answers to each of the four risk management questions.

- Can FSIS reallocate inspection activities in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?

  Yes, risk assessment model results using 2003-2005 PR/HACCP *Salmonella* verification data from 154 young chicken slaughter establishments show that reallocating some on-line inspectors to off-line inspection duties (replacing some online inspector with establishment personnel) could be more effective at reducing *Salmonella* prevalence in establishments.

  Establishments with more off-line inspectors have lower *Salmonella* prevalence than establishments with fewer off-line inspectors.

- How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, effect human illness?

  This risk assessment suggests a high probability that *Salmonella* attributable illnesses could decline or remain the same when additional off-line inspection procedures are performed. Both increases in unscheduled sanitation procedures and increases in unscheduled sampling

procedures are associated with decreases in attributable human *Salmonella* illnesses with greater than 90% certainty. Other off-line duties, such as reducing the number of unperformed sanitation, sampling, and HACCP procedures, may also reduce attributable human *Salmonella* illnesses, but we are less certain about these (85%, 70%, and 70% certainty, respectively).

- Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?

  Relocated inspectors can have the most impact on reducing *Salmonella* prevalence and corresponding attributable illnesses by performing increased unscheduled sampling procedures (U-5) and increased unscheduled sanitation procedures (U-1). In addition, a reduction in uncompleted sanitation procedures (B-1) can lower *Salmonella* prevalence and illness.

- What is the uncertainty about these effects?

  Uncertainty in establishment-level *Salmonella* prevalence is accounted for using the mean of a Beta Inverse distribution incorporating available sampling data. Uncertainty in *Salmonella* prevalence across all young chicken slaughter plants is modeled using a bootstrap simulation analysis. Uncertainty about attributable human illness is based on the central limit theorem and is lognormal in shape. The uncertainty in the relationship between attributable *Salmonella* human illness and *Salmonella* prevalence is represented by the Poisson distribution.

FUTURE PLANS

In 2008, FSIS plans to have results from a new expanded FSIS microbiological baseline data collection program for young chicken slaughter establishments. These results will include rehang and post-chill observations for prevalence and bacterial counts of *Salmonella*, *Campylobacter*, *E. coli*, and other indicator organisms. The quantitative risk assessment model used in this analysis has been specifically designed to incorporate these data in combination with data from the FSIS' performance based inspection system (PBIS) program.

The explanatory inspection procedures records that were used in this analysis were aggregated across similar procedures codes. A new analysis is planned to disaggregate further the inspection procedures data used in the belief that individual procedure code records will provide results that are more specific when the model is used to guide resource allocation decisions.

There is also the ability to revise the current model to differentiate results based on available speciation categories from the forthcoming microbiological baseline data. This new information will facilitate the strengthening of the quantitative linkage between inspection activities in the establishment and attributable human cases of illness from *Salmonella*, *Campylobacter*, and *E. coli*.

In sum, the analytical capabilities of this risk assessment model, once the new FSIS microbiological baseline data for young chicken slaughter establishments are available, should prove useful for future establishment inspector assignment allocations within a given establishment based on that establishment's individual risk profile.

Introduction

In 1985[1] and 1987,[2] the National Academies of Science (NAS) published two reports arguing that current inspection methods do not reduce foodborne pathogens in meat and poultry and calling for a modern, public health-based approach to inspection, a call reiterated in a 1998 NAS report[3] (reviewed by Cates *et al.*).[4] On July 1996, FSIS issued its landmark rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) systems (9 CFR §417), which emphasizes the prevention and reduction of microbial pathogens on raw products, and clarifies the responsibilities that industry and government are to assume for food safety. Prior to PR/HACCP, inspection was based on organoleptic (sight, touch, and smell) methods. However, knowledge and concern regarding microbial pathogens has increased and industry continues to produce new technologies to control pathogens. As a result, new approaches to food safety are necessary.

In keeping with the basis of PR/HACCP, FSIS is proposing a public health-based inspection in poultry slaughter establishments. The system will be available first for young chicken slaughter establishments. Under the proposed rule, young chicken establishments will decide whether to operate under the current inspection system (9 CFR § 381.76) or the proposed new system. Table 1 below shows a summary of differences between the two systems. The proposed new system for young chicken slaughter establishments will allow FSIS resources to be used more efficiently by allowing more time and flexibility for FSIS personnel to perform off-line verification activities based on risk factors of individual establishments. The proposed new system will also drive technological innovation, as establishments will be encouraged to modernize equipment because they will be responsible for carcass sorting and establishing maximum line speeds. Consequently, establishments will design their own process control tasks that will incorporate new and improved equipment. This should result in the efficient production of poultry products of the highest quality and consistently lower *Salmonella* prevalence.

Table 1. Summary of differences between the current inspection system (9 CFR § 381.76) and the proposed new inspection system for young chicken slaughter establishments.

	Current Inspection System	Proposed New System
Carcass Sorting	FSIS determines condemnation of carcasses; establishments do not sort carcasses.	Establishments are required to sort carcasses and ensure carcasses are not adulterated before entering chilling tanks.
Performance Standards	Establishments will continue to address CFR § 381.65(e).	Establishments must meet the food safety performance standards for poultry slaughter defects (zero fecal, zero septicemia/toxemia) as well as animal disease performance standards.
Line Speed	Establishments will adhere to regulatory limits (CFR § 381.67). Line speeds are dependent on slaughter class.	No maximum line speeds. Rather, limits on line speed will be based on establishment's ability to maintain process control and meet performance standards.
Generic E. coli *Process Control*	Current CFR § 381.94(a) will apply.	New process control performance standards will be adopted.
Standards of Identity	New proposed Standards of Identity regulations will provide a standard of quality for whole chickens. All establishments will be required to maintain a process control plan to ensure that whole chickens meet the proposed standard of identity.	Standard of Identity regulations for standard of quality of whole chickens.
Time and Temperature	Establishments will adhere to CFR § 381.66.	Current poultry chilling requirements in CFR § 381.66 amended to provide more flexibility to establishments.
On-line Reprocessing	Establishments will adhere to CFR § 381.91.	On-line reprocessing of pre-chill poultry carcasses accidentally contaminated with digestive tract contents at slaughter.

SCOPE OF THE RISK ASSESSMENT

The risk assessment estimates the public health impact of converting from the current inspection system to the proposed new system for young poultry slaughter establishments. It addresses four risk management questions:

- Can FSIS reallocate inspections in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?

- How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, effect human illness?

- Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?

- What is the uncertainty about these effects?

The primary impact on human health from adoption of the proposed rule was assumed limited to the potential reallocation inspection activities within the slaughter establishment. Other aspects of the proposed rule including the establishment of standards of identity for products coming off the line, potential changes to current chilling regulations and new on-line reprocessing guidelines, are not addressed here.

STRUCTURE OF THE REPORT

The *FSIS Risk Assessment for Guiding Public Health-based Poultry Slaughter Inspection* report consists of four components.

- *Hazard Identification* describes the microbiology and epidemiology of *Salmonella*.

- *Hazard Characterization* describes the modeled relationship between *Salmonella* prevalence in young chicken slaughter establishments and illnesses in humans.

- *Exposure Assessment* provides data on the occurrence and level of *Salmonella* in young chicken slaughter establishments and estimates of annual illnesses from *Salmonella* attributable to young chicken consumption. In addition, the risk assessment model is described here.

- *Risk Characterization* describes the stochastic relationship between existing data on FSIS inspection activities and procedures completions and prevalence of *Salmonella* on young chicken in slaughter establishments.

SUMMARY

Based on calls for public health-based inspection, FSIS has proposed a new public health-based inspection system for young chicken slaughter establishments. The purpose of this risk assessment is to estimate the public health impact of converting from the current

inspection system to the proposed new system for young poultry slaughter establishments.

Hazard Identification

This chapter provides a brief overview of *Salmonella* on poultry, the disease caused by *Salmonella*, and the epidemiology of *Salmonella*.

SALMONELLA

The genus *Salmonella* consists of 2 species, 6 subspecies, and over 2,400 serotypes. *Salmonella* cells are Gram-negative, facultative anaerobes; they grow at temperatures of ~8 to 45°C and pH values of ~4 to 8, with optimal growth at ~37°C, pH 7.

Salmonella on Poultry

Data for *Salmonella* from USDA FSIS microbiological sampling programs for poultry are summarized in Table 2.

Table 2. Summary of data for *Salmonella* from FSIS routine testing programs, 1998 - 2005. For details, see http://www.fsis.usda.gov/Science/Progress_Report_ Salmonella_ Testing_Tables/index.asp.

Product	No. Samples Analyzed	No. Samples Positive	% Samples Positive
Broilers	63,754	7,778	12.2
Ground Chicken	2,255	532	23.6

These data show that *Salmonella* are present on a substantial portion of poultry inspected by FSIS. Furthermore, recent reports show that *Salmonella* are present on broilers and ground chicken sold at retail. Cui *et al.* recovered *Salmonella* from 61% of organic and 44% of conventionally reared chickens.[12] Using a polymerase chain reaction-based

method, Hong *et al.* detected *Salmonella* in 17% of retail chicken carcass rinses.[5] Zhao *et al.* found *Salmonella* on 4% of retail chickens in the Washington, D.C. area.[6]

Salmonella Disease Characteristics

Human cases of salmonellosis are characterized by diarrhea, fever, abdominal pain or cramps, vomiting, headache, and nausea. Incubation is from eight to 72 hours with symptoms lasting up to a week. Though the disease is typically self-limiting, fatalities may occur, especially among infants, elderly, and the immunocompromised.

Salmonella Epidemiology

Foodborne *Salmonella* cause an estimated 1,300,000 cases of human illnesses, 15,000 hospitalizations, and 500 deaths each year in the United States.[7] Of the 15,806 laboratory-diagnosed infections ascertained through the Foodborne Diseases Active Surveillance Network (FoodNet) in 2004, 6,464 (40.1%) were from *Salmonella*. From 1996-1998 to 2004, the estimated incidence of *Salmonella* infections decreased 8%.[8]

Hazard Characterization

This chapter describes methods used to estimate the attributable number of annual human illnesses from *Salmonella* on young chickens. It then describes the method used to model the relationship between changes in *Salmonella* prevalence on young chickens and changes in human illnesses from *Salmonella.*

ESTIMATING HUMAN ILLNESSES FROM *SALMONELLA* ON YOUNG CHICKENS

Table 3 summarizes the steps in estimating annual human illnesses from *Salmonella* on young chickens.

Table 3. Steps in estimating illnesses from *Salmonella* on young chickens.

Step	Input	*Salmonella*	Data Source/Estimation
1	Incidence of salmonellosis among the U.S. population	14.4/100,000	FoodNet Annual Report for 2003[9]
2	Population estimate 2003	290,788,976	US Census Bureau[10]
3	Underreporting multiplier	38	Mead *et al.*[7]
4	Foodborne fraction	0.95	Mead *et al.*[7]
5	Poultry attribution fraction	0.3351	Food Safety Research Consortium[11;12]
6	Young chicken fraction	0.838	ERS[13]
7	Total illnesses	1,591,197	Step = 1 x 2 x 3
8	Total foodborne illnesses	1,511,637	Step = 4 x 7
9	Total foodborne illnesses from poultry	498,840	Step = 5 x 8
10	Total foodborne illnesses from young chickens	424,389	Step = 6 x 9

Incidence of Illness from *Salmonella*

Incidence of human illness from *Salmonella* was from surveillance data ascertained by the Foodborne Diseases Active Surveillance Network (FoodNet) for the year 2003.[9]

U.S. Population Estimate for 2003

The 2003 population estimate of 290,788,976 was from the U.S. Census Bureau.[10]

Accounting for Underreporting

Cases of foodborne infection ascertained through FoodNet represent a fraction of those that occur in the surveillance population. The underreporting multiplier of 38 for *Salmonella* infections was from Mead *et al.*[7]

Estimating Proportion of Infections that are Foodborne

The proportion of *Salmonella* infections estimated to be foodborne, 95%, was from Mead *et al.*[7]

Estimating Proportion of Foodborne Infections from Poultry

The estimate of the proportion of foodborne *Salmonella* infections from poultry, 34%, was from an expert elicitation by the Food Safety Research Consortium.[11;12]

Estimating Proportion of Foodborne Infections from Young Chickens

Data from the Economic Research Service (ERS)[13] were used to estimate the proportion of poultry-related *Salmonella* infections from young chicken. Approximately, 84% of poultry production in the U.S. in 2004 was from young chickens (Table 4).

Table 4. U.S. poultry production and supply in 2003.

	Millions of lbs			
Category	Production Supply	Imports	Beginning Stocks	Total
Young Chickens (broilers)	32,399	12	763	33,173
Other Chicken	502	3	5	510
Turkey	5,577	2	333	5,912
Total	38,478	16	1,101	39,595

Adapted from USDA ERS.[13]

Steps 7 through 10 of Table 3 complete the estimate. Annual illnesses from *Salmonella* are the product of the values in steps 1, 2, and 3. The proportion of foodborne illnesses

from *Salmonella* is the product of the values in steps 4 and 7. The proportion of foodborne illnesses from *Salmonella* on poultry is the product of the values in steps 5 and 8. The proportion of foodborne illnesses from *Salmonella* on young chickens is the product of the values in steps 6 and 9. The final estimate for annual number of human illnesses from *Salmonella* on young chickens is 424,389.

Deriving uncertainty about annual number of human *Salmonella* illnesses attributable to poultry

Uncertainty about total *Salmonella* illnesses per year attributable to poultry can be derived by considering the uncertainty in the components used to derive the most likely (expected) value for attributable human *Salmonella* illnesses (as shown in Table 3). Alternatively, an approximation for this uncertainty is the assumption that the uncertainty about *Salmonella* illnesses attributable to poultry is proportional to the uncertainty about *E. coli* O157:H7 illnesses attributable to ground beef. This uncertainty analysis about attributable fractions of human illness to specific FSIS-regulated products was previously described by Powell *et al*.[18]

Proportional uncertainty between *Salmonella* in poultry and *E. coli* O157:H7 in ground beef implies equivalency in the coefficients of variation for these distributions. In other words,

$$cv_{E.coli/beef} = cv_{Salm/poultry} = \frac{\sqrt{Var\left(\lambda_{E.coli/beef}\right)}}{E\left[\lambda_{E.coli/beef}\right]} = \frac{\sqrt{Var\left(\lambda_{Salm/poultry}\right)}}{E\left[\lambda_{Salm/poultry}\right]}$$

By estimating all but $\sqrt{Var\left(\lambda_{Salm/poultry}\right)}$, we can calculate the variance about *Salmonella* illnesses attributable to poultry.

From Powell *et al*.,[18] we know the 2.5th and 97.5th percentiles of the uncertainty distribution for *E. coli* 0157:H7 illnesses attributable to ground beef (i.e., 9,478 and 29,171, respectively) (see Table 5). The median for this distribution was 15,904. Such a distribution is clearly skewed to the right; consequently, a lognormal distribution is assumed.[a] The 2.5th and 97.5th percentile values are fit to a lognormal distribution. The resultant lognormal parameters are $\mu = 9.7188$ and $\sigma = 0.29$. The expected value of this lognormal distribution is $E\left[\lambda_{E.coli/beef}\right] = 17,326$ and its standard deviation

[a] A lognormal distribution is reasonable given that the derivation of the distribution represented the product of many positive random variables; according to the central limit theorem, multiplying several random variables together will generate a distribution that is lognormal in shape.

is $\sqrt{Var\left(\lambda_{E.coli/beef}\right)} = 5073$. The resultant coefficient of variation for this distribution is $cv_{E.coli/beef} = 0.29$.

Equating $cv_{Salm/poultry}$ to $cv_{E.coli/beef}$ and assuming $E\left[\lambda_{Salm/poultry}\right] = 420,000$, the standard deviation of the uncertainty distribution for *Salmonella* illnesses attributable to poultry is $\sqrt{Var\left(\lambda_{Salm/poultry}\right)} = 122,972$. Using these moments of the distribution, we calculate that the parameters of this lognormal distribution are $\mu = 12.91$ and $\sigma = 0.29$.[b] The resulting distribution for $\lambda_{Salm/poultry}$ (or λ_{Ill} as defined in this assessment) is shown in Figure 1 below. The 5th percentile of this distribution is ~251,000, its median is ~403,000, and its 95th percentile is ~646,000.

Table 5. Uncertainty distributions for *E. coli* illnesses attributable to ground beef. Adapted from Powell *et al*.[18]

Epidemiologic Parameter	Distribution		
Reported rate of *E. coli* O157:H7 per 100,000 person-years	Discrete Uniform (2.04, 1.25, 1.51)		
U.S. Population (1998)	269.4 million		
P(Bloody case reported)	Beta (409 + 1, 480 - 409 + 1)		
P(Non-bloody case reported)	1 - Beta (409 + 1, 480 - 409 + 1)		
P(Laboratory cultures stool sample for O157)	*(Bloody)* Beta (182 + 1, 230 - 182 + 1) *(Non-bloody)* Beta (108 + 1, 230 - 108 + 1)		
P(Physicians obtain culture from patient)	*(Bloody)* Beta (1515 + 1, 1943 - 1515 + 1) *(Non-bloody)* Beta (699 + 1, 1943 - 699 + 1)		
P(Ill person seeks medical care)	*(Bloody)* Beta (32 + 1, 58 – 32 + 1) *(Non-bloody)* Beta (88 + 1, 1100 - 88 + 1)		
Proportion of cases attributable to ground beef	*Pert (minimum, most likely, maximum)*		
min = 16.3%	2.5th percentile of Beta (344 + 1, 1916 - 344 + 1) (the proportion of outbreak-associated illnesses due to ground beef)		
most likely = 18.0%	50th percentile of Beta (344 + 1, 1916 - 344 + 1)		
maximum = 40.3%	97.5th percentile of Beta (36 + 1, 115 - 36 + 1) (the proportion of outbreaks due to ground beef)		
Results		*Median*	*95% Confidence Interval*
Total non-bloody		60 495	38 206 – 102 541
Total bloody		13 838	9604 – 22 425
Total annual cases O157 US		74 346	49 844 – 120 964
Annual cases O157 US due to ground beef		15 904	9478 – 29 171

[b] If @Risk is used to simulate this distribution, the function takes the mean and standard deviation of the distribution as arguments rather than the distribution's parameters.

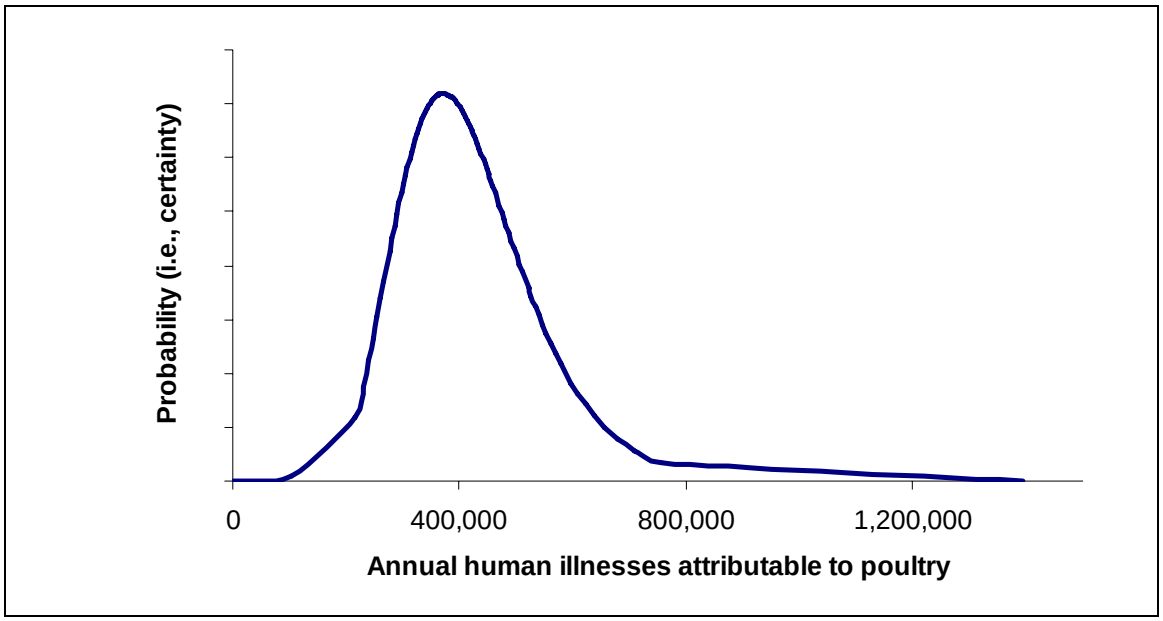

Figure 1. Uncertainty distribution for attributable annual illness from *Salmonella* on young poultry.

Exposure Assessment

This chapter describes the estimated prevalence of *Salmonella* on young chickens at slaughter establishments and the estimated number of annual cases of human illnesses from *Salmonella* attributable to young chicken consumption in the U.S. It then provides a description of the risk assessment model, including its structure, parameters, and the various model scenarios.

SALMONELLA ON YOUNG POULTRY IN SLAUGHTER ESTABLISHMENTS

Prevalence of *Salmonella* on young chicken in slaughter establishments was determined using data from FSIS microbiological HACCP data collection programs for the years 2003 through 2005. Detailed descriptions of the microbiological data collection programs are available at http://www.fsis.usda.gov/Science/Baseline_Data/index.asp.

In-establishment Inspection Procedures

Data from 154 young chicken slaughter/processing establishments in six general inspection system procedure (ISP) code activity categories (Sanitation, PR/HACCP, Economic/Wholesomeness, Sampling, Other Inspection Requirements, and Emergency Activities) were taken from the Performance Based Inspection System (PBIS) database for the 2003-2005 calendar years. A total of 2,395 monthly observations were used, representing the following inspection types: streamlined inspection system, SIS (595 observations), new enhanced line speed inspection system, NELS (467 observations), HACCP-based inspection models program, HIMP (317 observations), new eviscerations systems – Nu-Tech (Stork Gamco, Gainesville, GA) inspection system (146 observations) and MAESTRO (Meyn Poultry, Gainesville, GA) inspection systems (474 observations), and 295 observations from establishments with multiple lines representing

"MIXED" inspection systems. An additional 101 observations were from establishment inspection types that were undetermined. A major difference among these systems of inspection is the maximum regulated line speeds of 70 birds per minute for SIS, 91 birds per minute of NELS, 102 birds per minute for NuTech/MAESTRO, and unlimited line speed for HIMP. The average line inspector inspects about 35 carcasses a minute; therefore, higher line speeds (except for HIMP) result from having more than one inspector on a line with alternate carcass inspection.

The ISP codes taken from the PBIS database were tabulated monthly for all scheduled procedures, unscheduled procedures, uncompleted procedures, and non-compliances for each establishment. Scheduled procedures are assigned to each establishment's shift according to frequency of previous non-compliances by the automated PBIS management system. Unscheduled procedures are performed according to in-establishment inspector needs, and they typically involve regulatory inspection activities such as fecal checks for zero-tolerance twice per line per shift in SIS and NELS establishments but at four times that rate for HIMP establishments. Unscheduled procedures are also performed according to unforeseen hazards, unsanitary conditions arising from Sanitation Standard Operating Procedures (SSOP) failures, and PR/HACCP corrective actions. In addition, the numbers of monthly scheduled procedures not performed and the total monthly number of non-compliances were tabulated by ISP code.

The 6 ISP code activities were divided into procedure elements. Among the six general procedure activities, 44 specific ISP procedure codes were used, including 5 Sanitation codes, 11 PR/HACCP codes, 8 Economic/Wholesomeness codes, 5 Sampling codes, 3 Other Inspection Requirements codes, and 12 Emergency Activity codes. Sanitation procedures are prefixed by "01" followed by "A" for procedure verification, "B" for preoperational sanitation, and "C" for operational sanitation. Recorded ISP procedures include "01" and "02" suffixes for verification methodology for monitoring, verification, record keeping, corrective action, and reassessment requirements. The ISP codes for Sanitation were 01A01, 01B01, 01B02, 01C01, and 01C02.

Similarly, PR/HACCP procedures are prefixed by "03" followed by "B" for raw ground product, "C" for raw not ground product, "G" for fully cooked- not shelf stable, "H" for heat-treated- not fully cooked, and "J" for slaughter. The ISP codes for PR/HACCP were 03A01, 03B01, 03B02, 03C01, 03C02, 03G01, 03G02, 03H01, 03H02, 03J01, and 03J02. The ISP codes for Economic/Wholesomeness are prefixed by "04" followed by "A" for specific products suffixed by "02", "03", and "04" for product solution formulation, comminuted and mechanically separated products, and battered products respectively. The 04A01, 04A02, 04B01, 04B02, 04B03, and 04B04 ISP codes for determining product meets standard, packaging/labeling standards, stated label net weight, and product identification respectively were also included as was the 04C01 ISP code for meeting product lot requirements. The "05" prefix was used for Sampling ISP codes. The five codes used were 05A01 and 05A02 (establishment generic *Escherichia coli* record review), 05A03 (raw product sampling for *Salmonella*), 05B02 (select program requested samples and send to designated laboratory); and 05C01 (random sample selection for residues).

The "06" prefix was used for "Other Inspection Requirements." The three ISP codes selected were 06A01 (compliance with export requirements), 06D01 (compliance with sanitation performance standards), and 06D02 (random facility sanitation inspection compliance). The twelve ISP codes used for "Emergency Activities" involving biosecurity issues used the "08" prefix and the "S" activity code: 08S01, 08S03, 08S04, 08S05, 08S06, 08S07, 08S08, 08S09, 08S10, 08S11, 08S12, and 08S13. These codes cover a wide variety of activities such as facility, personnel, equipment, ingredients, and products checks for tampering, suspicious activity, and unusual circumstances.

To estimate the probability of *Salmonella* contamination from the observed prevalence data, the beta distribution was used:

$$p = \text{Beta}(\alpha_1, \alpha_2)$$

where

α_1 = the number of *Salmonella*-positive samples +1
α_2 = the total number of samples – the number of *Salmonella*-positive samples + 1

Thus, for example, supposing that of 11 samples collected from an individual processing establishment in a given month, 3 are *Salmonella*-positive, the probability of a *Salmonella*-positive sample in future tests may then be described as

$$p = \text{Beta}(3 + 1, 11 - 3 + 1) = \text{Beta}(4, 9)$$

The more samples taken from an establishment in a single month, the tighter the beta distribution will be for *Salmonella* prevalence estimate for that observation. For further details, see Vose.[14]

INSPECTOR ASSIGNMENT PROFILE DATA

Assignment profiles for young chicken establishments came from the FSIS Office of Field Operation's Resource Management and Planning Staff. These data give the number of FSIS inspectors assigned to on-line (OLS) and off-line (ISP) inspection activities during calendar year 2005. In most cases, an individual inspector's time in staff years (SY) is allocated between OLS and ISP tasks. In a few cases, a portion of an inspector's time is allocated to other duties.

On-line inspectors conduct hands-on appraisals of every young chicken carcass to ensure it is unadulterated. They make determinations about sorting and appropriate disposition of carcasses for presence of feathers, bruises, or other quality issues, contamination, and

disease. Off-line inspectors verify that establishments maintain sanitary operations, adhere to their HACCP plan(s), and perform other food safety-related assignments.

Under the current inspection system, there is approximately one off-line inspector for every six on-line inspectors; but this ratio varies between establishment inspection types. Under provisions of the proposed rule, the ratio of off-line to on-line inspectors will increase. On-line inspectors will still conduct critical hands-on appraisals of every young chicken carcass to ensure that adulterated or diseased carcasses receive appropriate disposition. Establishment inspection personnel will complete much of the sorting and disposition of carcasses prior to FSIS inspection. FSIS inspectors will still be responsible for inspecting every carcass leaving the slaughter line.

MODEL DESCRIPTION

This analysis was based on estimating change in one observed variable (*Salmonella* prevalence) as a function of other observed variables in the young chicken slaughter establishment (structural parameters, number of inspectors, and various measurements of completed/uncompleted PBIS procedures). Capturing these relationships allows the prediction of how the dependent variable (*Salmonella* prevalence) changes in response to increases or decreases in the independent decision variables (number of inspectors, number of PBIS procedure tasks completed) based on the observed data.

There was variability associated with the relationship between observed prevalence and chosen explanatory or dependent variables. This was expected, because prevalence sampling results from each establishment respond differently to changes in dependent variable values.[14] This variability can be thought of as random variations around a regression line – which are unknown. Uncertainty, in addition, still exists in a current regression equation because the true values of relationship parameters are unknown.

To analyze this uncertainty while accounting for the observation-to-observation variability, a least squares regression model can describe the relationship between random observations of the dependent and independent variables together, assuming both observations are drawn from approximate bivariate Normal distributions. Vose[14] describes a non-parametric Bootstrap procedure that allows regression coefficients to be collected as parameters in a bivariate Normal distribution. In this procedure, paired (or combinations in the case of multiple parameter regression) observations of the dependent and chosen independent variable at each Bootstrap replicate are resampled and the regression coefficient recalculated. If P, *Salmonella* prevalence, represents a function of prevalence for the dependent variable, and X the independent variable in the model, this relationship for a single bootstrap can be represented as

$$P_i = \hat{b}_0 + \sum_{h}^{11} \hat{b}_{hi} * x_{hi} + \sum_{j}^{13} \hat{b}_{ji} * x_{ji} + \sum_{k}^{10} \hat{b}_{ki} * x_{ki} \qquad \text{(Equation 1)}$$

where i represents the ith observation draw from a uniform distribution of observed combinations of prevalence and explanatory variables. Each observation represents the uncertainty estimate for establishment prevalence from microbial testing results for a 1-month period and the corresponding procedures done in that establishment during that month. Here, h = 1 to 11 representing 11 different structural variables describing that observation. Those 11 structural variables are described in Table 6 below. Similarly, j = 1 to 13 represents 13 different decision tracking variables combined with that monthly prevalence observation. Similarly, k = 1 to 10 represents 10 different performance deficiency tracking variables combined with that monthly prevalence observation. Those 23 decision/performance deficiency-tracking variables are described in Table 7 and Table 8 below. The intercept, b_0, and the slope parameters (b_{hi}, b_{ji}, and b_{ki}), are estimated at each bootstrap iteration.

Table 6. Description of structural parameters in the FSIS risk assessment model for guiding public health-based poultry slaughter inspection.

Description	Code	Value
Dummy variable for observation occurring in year 2003	YR=2003	1 if YR=2003, 0 otherwise
Dummy variable for observation occurring in year 2005	YR=2005	1 if YR=2005, 0 otherwise
Dummy variable for observation occurring in 2nd quarter	Q=2	1 if Q=2, 0 otherwise
Dummy variable for observation occurring in 3rd quarter	Q=3	1 if Q=3, 0 otherwise
Dummy variable for observation occurring in 4th quarter	Q=4	1 if Q=4, 0 otherwise
Dummy variable for observation if a NELS (inspection type) establishment	NELS	1 if NELS, 0 otherwise
Dummy variable for observation if a HIMP (inspection type) establishment	HIMP	1 if HIMP, 0 otherwise
Dummy variable for observation if a SIS (inspection type) establishment	SIS	1 if SIS, 0 otherwise
Dummy variable for observation if a Nu-Tech (inspection type) establishment	Nu-Tech	1 if Nu-Tech, 0 otherwise
Dummy variable for observation if a MAESTRO (inspection type) establishment	MAESTRO	1 if MAESTRO, 0 otherwise
2004 annual volume of production in establishment (source: CY 2004 ADRS and eADRS, 09/01/05)	volume	Annual production

Table 7. Description of decision tracking parameters in the FSIS risk assessment model for guiding public health-based poultry slaughter inspection.

Parameter Number	Description	Code	Source
1	Number of online inspectors	Online#	2005 inspector assignment profiles[1]
2	Number of offline inspectors	Offline#	2005 inspector assignment profiles[1]
3	Scheduled sanitation procedures	S-1	USDA/FSIS PBIS database (2003-2005)
4	Unscheduled sanitation procedures	U-1	USDA/FSIS PBIS database (2003-2005)
5	Scheduled PR/HACCP procedures	S-3	USDA/FSIS PBIS database (2003-2005)
6	Unscheduled PR/HACCP procedures	U-3	USDA/FSIS PBIS database (2003-2005)
7	Scheduled wholesomeness procedures	S-4	USDA/FSIS PBIS database (2003-2005)
8	Unscheduled wholesomeness procedures	U-4	USDA/FSIS PBIS database (2003-2005)
9	Scheduled sampling procedures	S-5	USDA/FSIS PBIS database (2003-2005)
10	Unscheduled sampling procedures	U-5	USDA/FSIS PBIS database (2003-2005)
11	Other scheduled inspection requirement procedures	S-6	USDA/FSIS PBIS database (2003-2005)
12	Unscheduled other inspection requirement procedures	U-6	USDA/FSIS PBIS database (2003-2005)
13	Unscheduled emergency/biosecurity procedures	U-8	USDA/FSIS PBIS database (2003-2005)

[1]2005 inspector assignment profiles were used as a proxy for current inspector numbers.

Table 8. Description of performance deficiency tracking parameters in the FSIS risk assessment model for guiding public health-based poultry slaughter inspection.

Parameter Number	Description	Code	Source
1	Uncompleted sanitation procedures	B-1	USDA/FSIS PBIS database (2003-2005)
2	Non compliances for scheduled sanitation procedures	NC-1	USDA/FSIS PBIS database (2003-2005)
3	Uncompleted PR/HACCP procedures	B-3	USDA/FSIS PBIS database (2003-2005)
4	Non compliances for PR/HACCP procedures	NC-3	USDA/FSIS PBIS database (2003-2005)
5	Uncompleted wholesomeness procedures	B-4	USDA/FSIS PBIS database (2003-2005)
6	Non compliances for wholesomeness procedures	NC-4	USDA/FSIS PBIS database (2003-2005)
7	Uncompleted sampling procedures	B-5	USDA/FSIS PBIS database (2003-2005)
8	Non compliances with sampling procedures	NC-5	USDA/FSIS PBIS database (2003-2005)
9	Uncompleted other inspection requirement procedures	B-6	USDA/FSIS PBIS database (2003-2005)
10	Non compliances for other inspection requirement procedures	NC-6	USDA/FSIS PBIS database (2003-2005)

Transforming the Dependent Variables

Monthly *Salmonella* prevalence estimates are generated from sampling results in young chicken slaughter establishments. To reflect uncertainty of the true prevalence rate for a given establishment, month, and year, the Beta distribution is used. Thus, at each bootstrap iteration the uncertainty function

$$Y_i = Beta(\alpha_1, \alpha_2) \qquad \text{(Equation 2)}$$

where α_1 is number of positive samples plus 1, and α_2 is number of total samples minus number of positives plus 1.

To evaluate the relationship in Equation 1 as a linear regression, the independent variable, Y_i, is transformed using a logit transformation according to the following formula[15]

$$Z_i = LN(Y_i/(1-Y_i)) \qquad \text{(Equation 3)}$$

This logit transformation of Y represents the dependent variable in each observation.

Simulation of Scenarios for Prevalence

Each bootstrap iteration in the risk assessment model drew 2,395 observations with replacement from the data set of 154 establishments (2,395 observations in total). Baseline estimates of *Salmonella* prevalence (still logit transformation) were determined by multiplying each of the estimated coefficients by the mean values of the independent variable:

$$\hat{\bar{Z}}_{iBASE} = \sum_{h}^{11} \hat{b}_{hi} * \bar{x}_{hi} + \sum_{j}^{23} \hat{b}_{ji} * \bar{x}_{ji} \qquad \text{(Equation 4)}$$

Note that the mean values of the independent variable change at each bootstrap iteration. Similarly, scenario estimates of *Salmonella* prevalence were determined as follows

$$\hat{\bar{Z}}_{ik} = \sum_{h}^{11} \hat{b}_{hi} * \bar{x}_{hi} + \sum_{j}^{23} (\hat{b}_{ji} * \bar{x}_{ji} + \hat{b}_{(k\ =\ j)i} * \gamma_k) \qquad \text{(Equation 5)}$$

where γ_k represents the "shock"[3] to decision/performance deficiency tracking variable *i*. This only occurs for $k = j$. To measure differences in prevalence estimates between baseline and scenario run, the dependent variable estimates were re-transformed into prevalence as

$$\hat{Y}_{iBASE} = EXP(\hat{\hat{Z}}_{iBASE}) / (1 + EXP(\hat{\hat{Z}}_{iBASE})) \qquad \text{(Equation 6)}$$

and similarly for the scenarios:

$$\hat{Y}_{ik} = EXP(\hat{\hat{Z}}_{ik}) / (1 + EXP(\hat{\hat{Z}}_{ik})) \qquad \text{(Equation 7)}$$

Change in expected *Salmonella* prevalence brought about by the shock was expressed as percentage using the following formula:

$$\Delta_{ik} = (\hat{Y}_{ik} - \hat{Y}_{iBASE}) / \hat{Y}_{iBASE} \qquad \text{(Equation 8)}$$

These changes, Δ_{ik}, were simultaneously calculated for each scenario, and collected. The procedure described above was repeated for each bootstrap iteration run using the risk assessment model. Results reported were summarized from the collection of 20,000 risk assessment model iterations.

THE SCENARIOS

Simultaneously at each bootstrap replicate, the baseline estimate for *Salmonella* prevalence was shocked for changes in each of the decision/performance deficiency tracking parameters independently. That shock file is described in Table 9. Each of these scenarios was implemented by evaluating each parameter estimate other than the decision parameter of interest at its mean value for each model iteration. The decision variable of interest was evaluated after shocking the mean value (Mean * shock). A difference between the scenario estimate of prevalence and the baseline estimate of prevalence captured the change in estimated prevalence that would be expected to be associated with those establishments where shock values were observed. These expected changes were captured at each bootstrap replicate. All scenarios depicted in Table 9, although chosen

[3] Shock analysis is similar to sensitivity analysis, where a subgroup of all baseline parameter values in a quantitative model is changed or "shocked" to reflect a shift in baseline assumptions. Differences between baseline and shock outcomes are measured as scenario impacts from the "shock."

independently of the data, were later shown to be inside one standard deviation of the mean of the data for that respective parameter.[4]

Table 9. Description of shock file used for decision/performance deficiency tracking scenarios in the FSIS risk assessment model for guiding public health-based poultry slaughter inspection.

Number of Scenarios	Description of Scenarios
1	Baseline using data values from bootstrap draw
5	25% increase in each scheduled procedure: sanitation (S-1), PR/HACCP (S-3), wholesomeness (S-4), sampling (S-5), random facility sanitation (S-6)
5	50% increase in each unscheduled procedure: : sanitation (U-1), PR/HACCP (U-3), wholesomeness (U-4), sampling (U-5), random facility sanitation (U-6)
5	75% reduction in each uncompleted procedure: sanitation (B-1), PR/HACCP (B-3), wholesomeness (B-4), sampling (B-5), random facility sanitation (B-6)
5	75% reduction in non-compliances for each procedure: sanitation (NC-1), PR/HACCP (NC-3), wholesomeness (NC-4), sampling (NC-5), random facility sanitation (NC-6)

MODELING ILLNESSES AVOIDED

Definitions

Y_{Base} is a random variable that describes uncertainty about average prevalence of *Salmonella* for the baseline (as is) scenario.

Y_k is a random variable that describes uncertainty about average prevalence of *Salmonella* for scenario *k*. Most of such scenarios involve reduced *Salmonella* prevalence.

Y_{Base} and Y_k are correlated random variables. Because both distributions are generated from the same data and regression model, the uncertainty about one is predictive of the uncertainty about the other.

R is a random variable of the ratio of prevalence in scenario *k* to prevalence in the baseline scenario (i.e. $R = \frac{Y_k}{Y_{Base}}$).

[4] There was one exception found post-analysis. The S-1 shock was found to be just outside the mean value plus one standard deviation for the s-1 procedure observations.

$P(ill \mid \exp osure)$ is the probability of illness given that a random person is exposed to a random contaminated serving. This probability describes the integration of the dose-response function with an exposure distribution that is truncated above zero. This exposure distribution essentially describes the frequency of dose levels given that a serving is contaminated.

V is the total number of servings of poultry consumed in one year. λ_{Ill} is the total number of *Salmonella* illness that occurs from consuming poultry per year.

If we assume the exposure distribution remains unchanged but prevalence of *Salmonella* on poultry was reduced from Y_{Base} to Y_k (where $Y_k < Y_{Base}$), then the reduction in human illnesses attributed to scenario *k* is:

$$Il\ln esesAvoided \approx Poisson\left(\left(Y_{Base} - Y_k\right) \times V \times P(ill \mid \exp osure)\right) \qquad \text{(Equation 9)}$$

In this equation, we assume the variability in total human *Salmonella* cases attributed to poultry can be described as a Poisson process with an average number predicted by $Y_{Base} \times V \times P(ill \mid \exp osure) = \lambda_{Ill}$. Therefore, if we already have a good estimate of λ_{Ill}, then the reduction in human illnesses from scenario *k* is simply

$$Il\ln esesAvoided \approx Poisson\left(\left(1 - \frac{Y_k}{Y_{Base}}\right) \times \lambda_{Ill}\right) = Poisson\left((1-R) \times \lambda_{Ill}\right) \qquad \text{(Equation 10)}$$

$$Change\ in\ il\ln esses \approx (-)Poisson\left((1-R) \times \lambda_{Ill}\right) \qquad \text{(Equation 11)}$$

In this prediction of the number of illnesses avoided by scenario *k*, we have avoided any need for an exposure distribution or a dose-response function. The change in human illnesses is the negative of illnesses avoided (i.e., a negative value for the change signifies a reduction in human illnesses per year while a positive value signifies an increase in human illnesses).

Given our equation for prediction of illnesses avoided by scenario *k*, we must also consider the uncertainty about Y_{Base}, Y_k, and λ_{Ill}. Monte Carlo methods are needed to properly correlate Y_{Base} and Y_k in the calculation of the distribution of *R*. Similarly, Monte Carlo methods are needed to multiply $(1-R)$ by λ_{Ill}. The resulting compound distribution can be used to determine our confidence about the number of illnesses avoided (e.g., what percent of iterations result in the number of illnesses avoided greater than zero?).

In this approach, we have incorporated both the variability in illnesses per year – that is Poisson distributed – and the uncertainties about the parameter of the Poisson. To separate the effects of variability and uncertainty would require second-order modeling techniques. Nevertheless, the effect of the Poisson variability is not expected to influence substantially decisions about this model's results. Therefore, second-order modeling is not done.

Risk Characterization

This chapter provides results from the FSIS risk assessment model for guiding public health-based poultry slaughter inspection and answers for the four risk management questions. The chapter then describes research needs identified during the assessment, and closes with some general conclusions.

MODEL RESULTS

The results of the risk assessment are shown in the following figures as cumulative frequency diagrams. It is important to understand that the values shown in the figures are not predictions per se, but rather, associations.

Cumulative Frequency Diagrams

A cumulative frequency shows the number of observations above or below a particular point. Cumulative frequency diagrams give a visual overview of a distribution, which is often preferable to tables. When viewing these diagrams, keep in mind the following:

- The x-axis in figures 5-7 represents average prevalence level among all poultry slaughter plants.
- The cumulative frequency diagram represents uncertainty about what that average prevalence is and is based on 20,000 iterations of the model.
- The median for the distribution is determined by locating the point at which the data line crosses the 50% label on the vertical axis and then locating the corresponding value on the x-axis

The first three figures on the following pages show associations between inspection activities within an establishment and prevalence of *Salmonella* on young poultry carcasses in establishments. The second group of figures shows associated estimates of changes in human illness associated with changes in selected activities inspection activities.

Changes in *Salmonella* prevalence

Increases in each of two scheduled procedures by 25% are associated with reduced *Salmonella* prevalence (Figure 2). An increase in scheduled wholesomeness (S-4) procedures by 25% is associated with lower *Salmonella* prevalence, at the mean value from 14% to 13.4%. An increase in scheduled sampling (S-5) procedures by 25% is associated with lower *Salmonella* prevalence, at the median value from 14% to 13.8%. Increases in other scheduled procedures, including scheduled PR/HACCP (S-3) procedures, scheduled sanitation procedures, and scheduled other inspection procedures are not associated with reduced *Salmonella* prevalence.

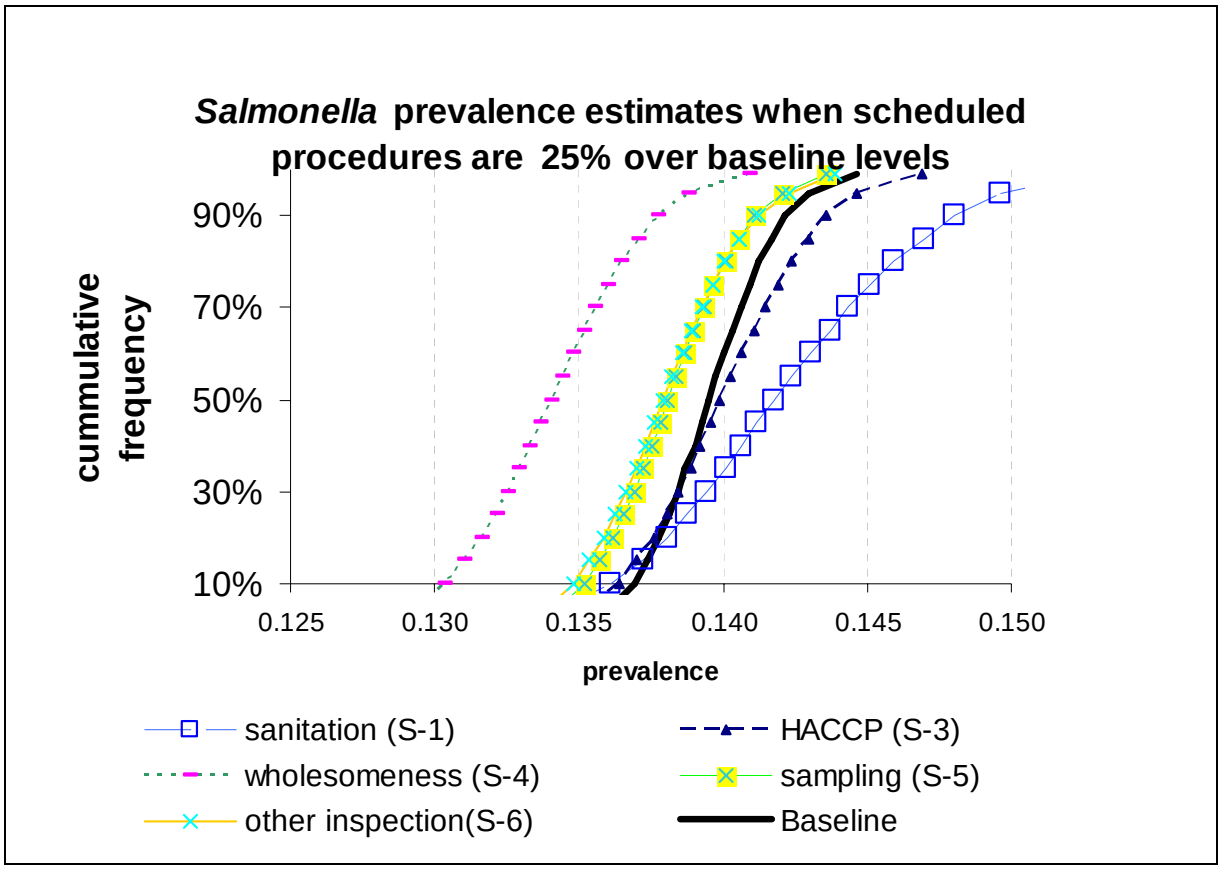

Figure 2. *Salmonella* prevalence on young chickens in slaughter establishments associated with a 25% increase over baseline levels in scheduled procedures.

The association between those establishments with 50% more unscheduled procedures and *Salmonella* prevalence on young chickens in slaughter establishments is shown in Figure 3. At the median value, increases in each of three scheduled procedures by 50% are associated with lower *Salmonella* prevalence. An increase in sampling (U-5) procedures by 50% is associated with lower *Salmonella* prevalence, at the mean from 14% to 13.3%. An increase in sanitation (U-1) procedures by 50% is associated with lower *Salmonella* prevalence, at the mean from 14% to 13.7%. An increase in unscheduled PR/HACCP (U-3) procedures is associated with small reductions in *Salmonella* prevalence, at the mean from 14% to 13.9%.

Increases in other unscheduled procedures - homeland security (U-8), wholesomeness (U-4), or random facility sanitation (U-6) procedures – are not associated with lowered *Salmonella* prevalence. A 50% increase in homeland security unscheduled procedures is associated with an increase in mean *Salmonella* prevalence from 14% to 14.2%. A 50% increase in wholesomeness unscheduled procedures is associated with an increase in mean *Salmonella* prevalence from 14% to 14.1%. An increase in other inspection unscheduled procedures by 50% is associated with no change in *Salmonella* prevalence. Thus, based on uncertainty distributions, increases in two of six unscheduled procedures will likely reduce *Salmonella* prevalence on young chickens in slaughter establishments.

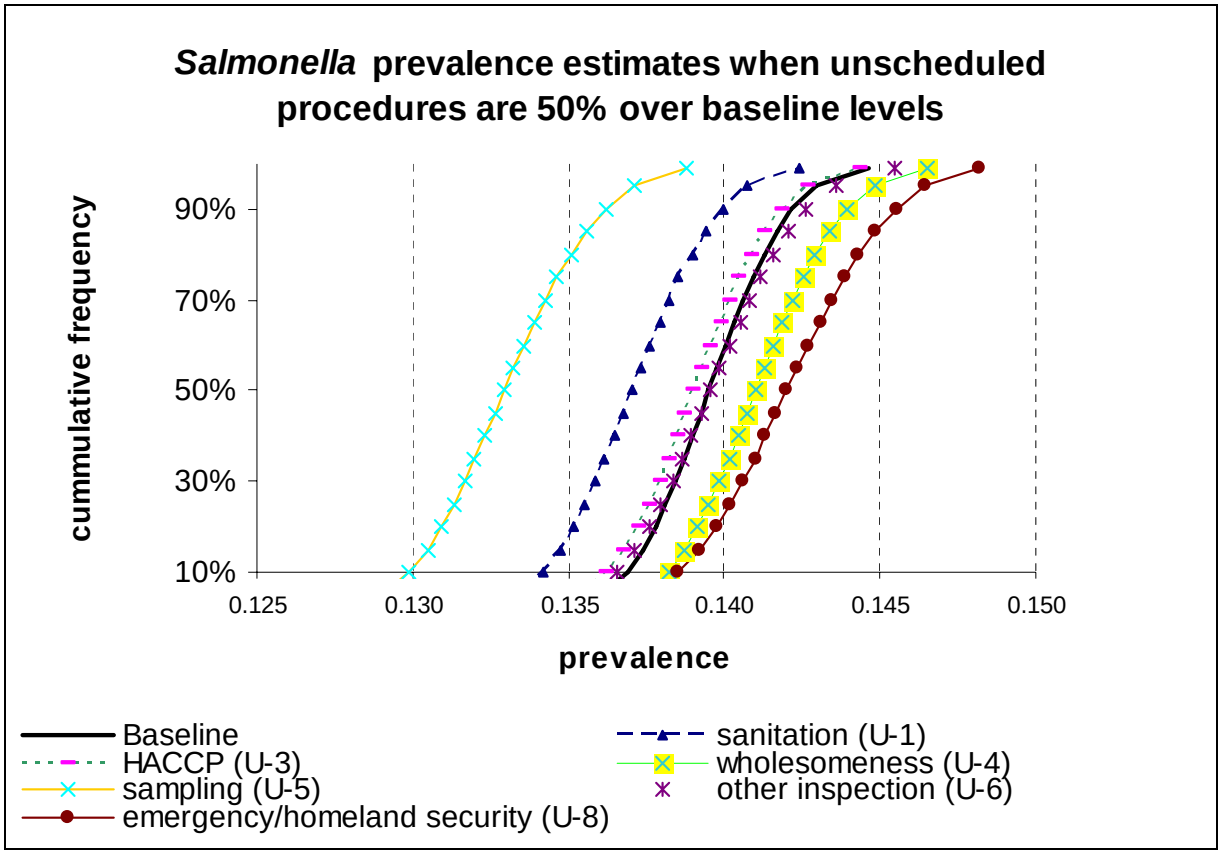

Figure 3. *Salmonella* prevalence on young chickens in slaughter establishments associated with a 50% increase over baseline levels in unscheduled procedures.

The association between those establishments with 75% more unperformed procedures and *Salmonella* prevalence on young chickens in slaughter establishments is shown in Figure 4. A decrease in each of three unperformed procedures by 75% is associated lower *Salmonella* prevalence. A decrease in unperformed sanitation (B-1) procedures by 75% is associated with lower *Salmonella* prevalence, at the mean from 14% to 13.7%. A decrease in unperformed sampling (B-5) procedures by 75% is associated with lower *Salmonella* prevalence, at the mean from 14% to 13.8%. A decrease in unperformed PR/HACCP (B-3) procedures by 75% is associated with lower *Salmonella* prevalence, at the mean from 14% to 13.9%.

Decreases in unperformed wholesomeness (B-4), or other facility sanitation (B-6) procedures are not associated with lower *Salmonella* prevalence.

One explanation for this is that inspection resources allow for maximum performance of sanitation S-1 and PR/HACCP S-3 procedures such that scheduling more procedures results in the same number performed since they are counted in with the two fecal checks per line per shift and the daily pre-operational and operational sanitation checks already performed. Similarly, because inspection resources are limited scheduling more sampling (S-5) or facility sanitation (S-6) procedures do not increase the total number of these procedures performed since the count will be moved from unscheduled procedures already being performed to the scheduled procedure category. On the other hand, scheduling more wholesomeness (S-4) procedures results in checks for parts and carcass defects and contamination at the pre-chill, post-chill, reconditioning, and quality control stations when resources allow these procedures to be performed. These can be looked upon as additional zero tolerance fecal checks that decrease the prevalence by increasing the total number of PR/HACCP-like (S-3) procedures. Because of plant management awareness for passing fecal checks and pre-operational and operational sanitation procedures which are heavily weighted in the (S-1) and (S-3) procedures, the results are biased. The prevalence associated with these categories cannot be decreased because the maximum number of procedures is already being performed and passed. By scheduling more procedures in a different category that can have the same effect, a significant net decrease in prevalence is seen due to the wholesomeness (S-4) category.

Thus, decreasing three of five unperformed procedures will likely reduce *Salmonella* prevalence on young chickens in slaughter establishments. As shown in Figure 4, at the 90^{th} percentile of the uncertainty distribution, these results hold.

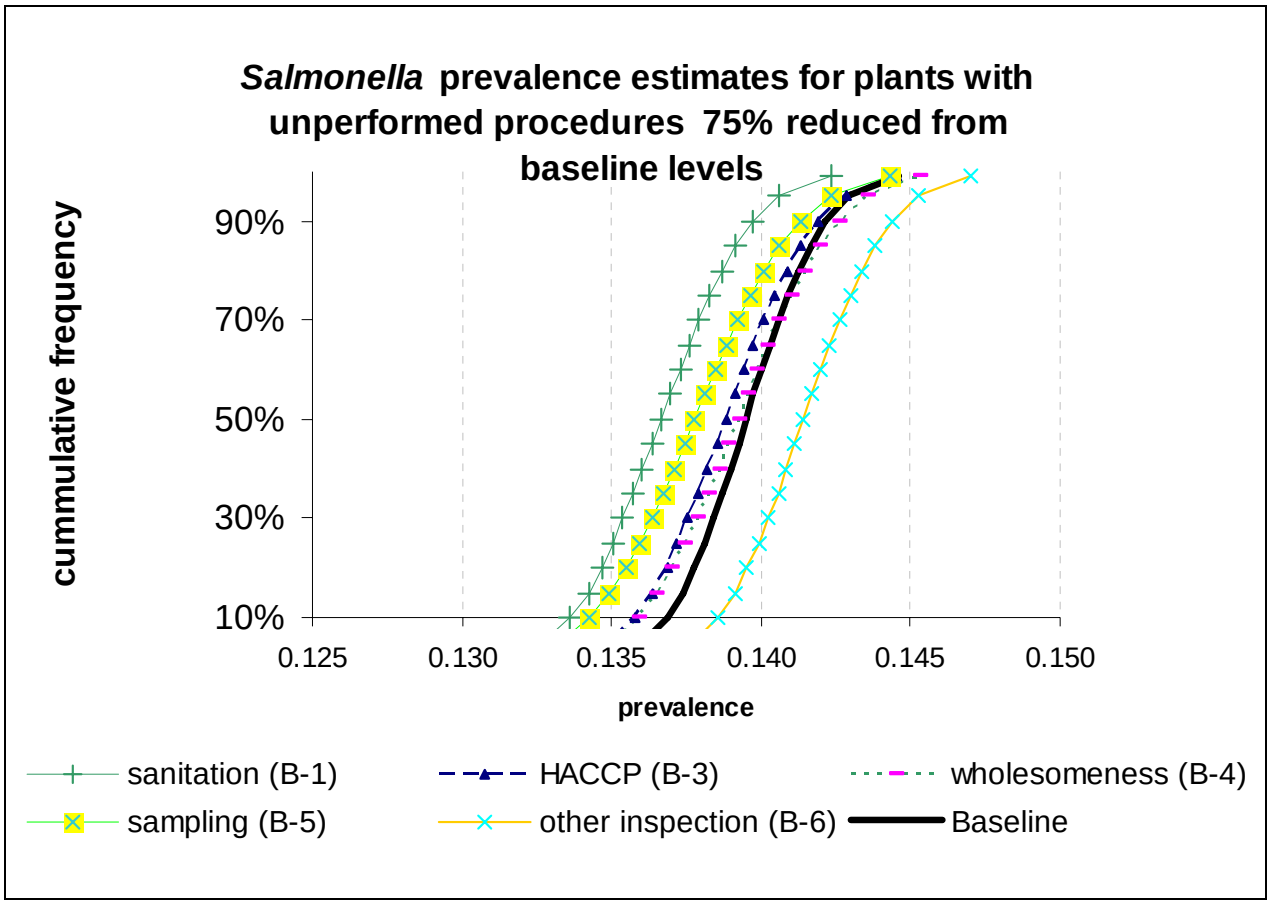

Figure 4. *Salmonella* prevalence on young chickens in slaughter establishments associated with a 75% decrease in unperformed procedures.

Changes in Human Illness

Simulation results describing the uncertainty distribution for baseline human illnesses attributable to consumption of young chickens are shown in Figure 5. With a mean expected value of 420,000 attributable illnesses, we are 90% confident that the true number of human *Salmonella* illnesses attributable to young chickens will be less than 583,000.

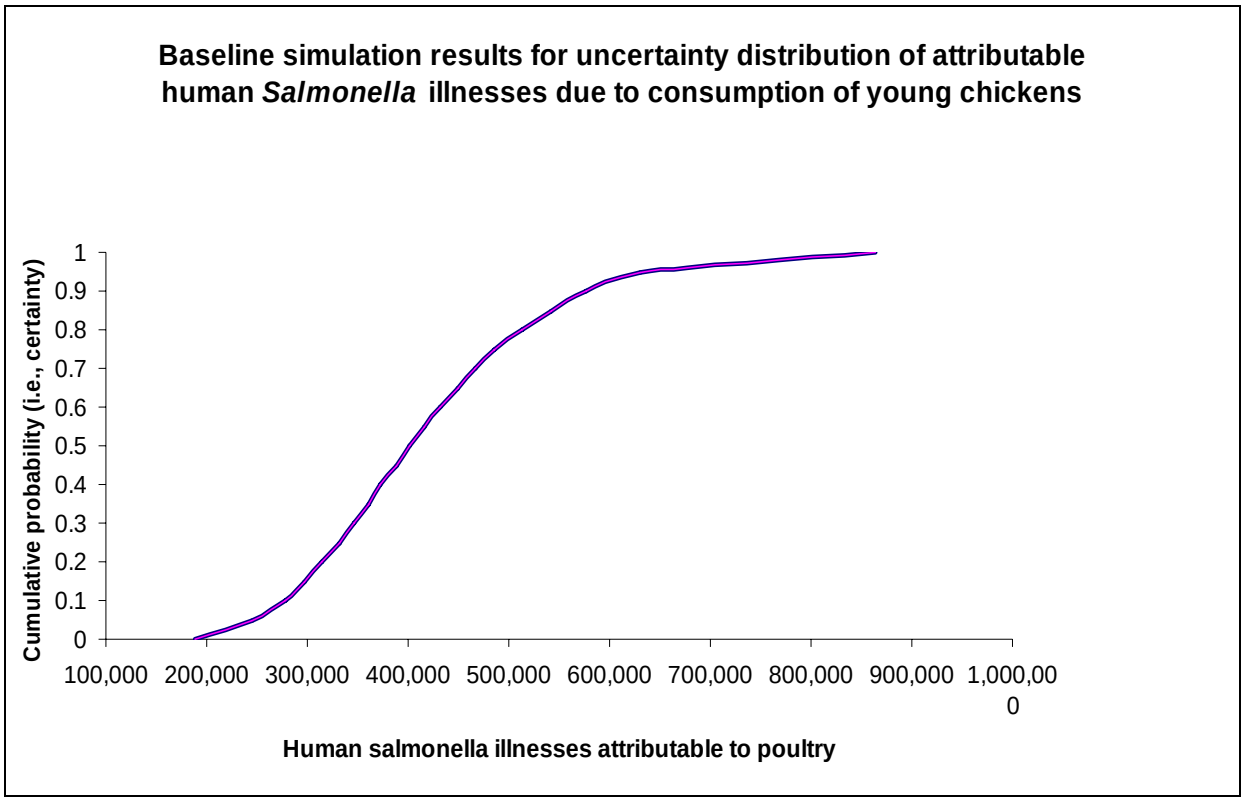

Figure 5. Baseline simulation results for uncertainty distribution of attributable human *Salmonella* illnesses due to consumption of young chickens.

Six scenarios were modeled out to human illness impact based on changes in microbial contamination in the plants. Other scenarios tried provided no additional information when modeled out to human illness due to a combination of insignificant changes in microbial contamination (see Figure 6 through Figure 11) and uncertainty about estimates of attributable human illness.

A 50% increase in UNSCHEDULED SANITATION procedures (U-1)

Figure 6 shows the uncertainty distribution for the expected change in human illnesses due to a 50% increase in all unscheduled sanitation procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 7,573 illnesses. The 90th percentile of the uncertainty distribution is a reduction of 3,302 illnesses.

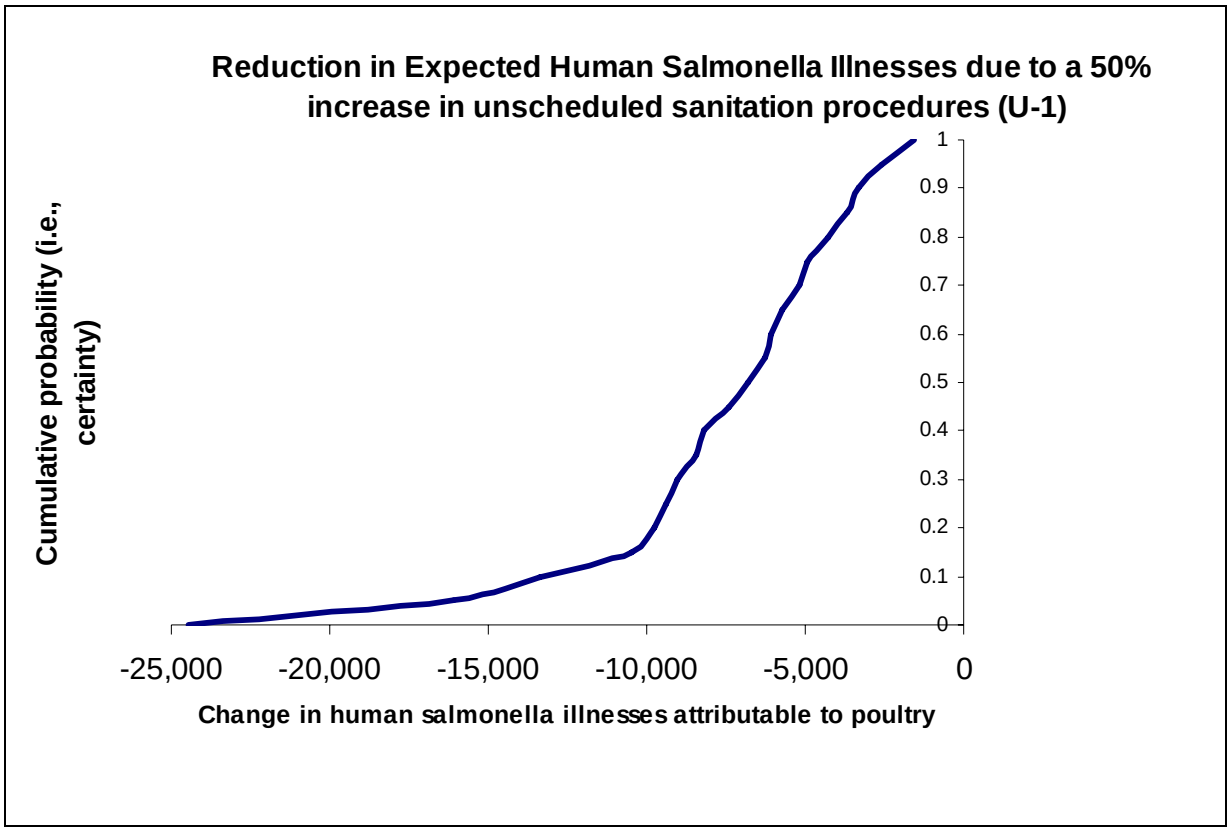

Figure 6. Reduction in Expected Human *Salmonella* Illnesses due to a 50% increase in unscheduled sanitation procedures (U-1).

A 50% increase in UNSCHEDULED SAMPLING procedures (U-5)

Figure 7 shows the uncertainty distribution for the expected change in human illnesses due to a 50% increase in all unscheduled sampling procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 19,779. The 90th percentile of the uncertainty distribution is a reduction of 10,865 illnesses.

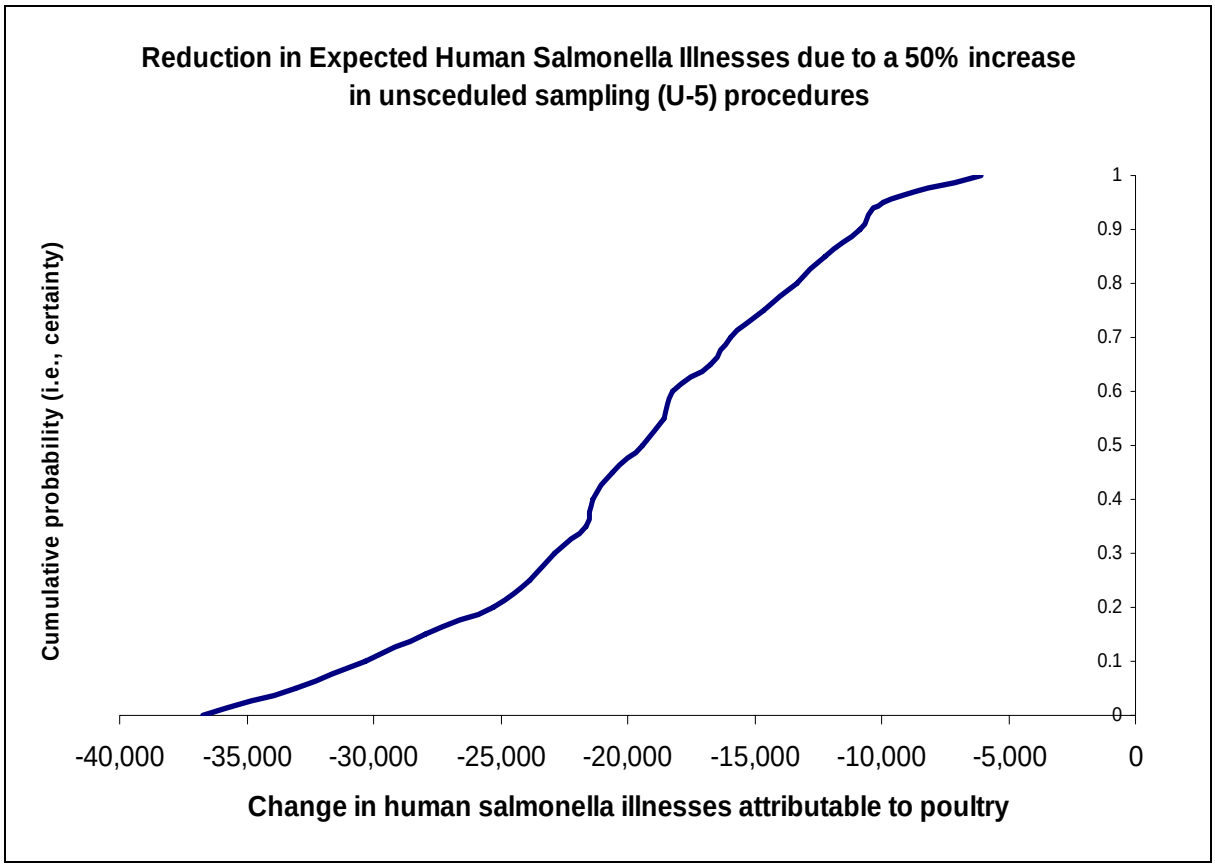

Figure 7. Reduction in Expected Human *Salmonella* Illnesses due to a 50% increase in unscheduled sampling (U-5) procedures.

A 75% decrease in UNPERFORMED SAMPLING procedures (B-5)

Figure 8 shows the uncertainty distribution for the expected change in human illnesses due to a 75% decrease in all unperformed sampling procedures across all young chicken slaughter establishments. Over 80% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 5,482 illnesses. The 90th percentile of the uncertainty distribution, however, shows an increase of 1,725 illnesses.

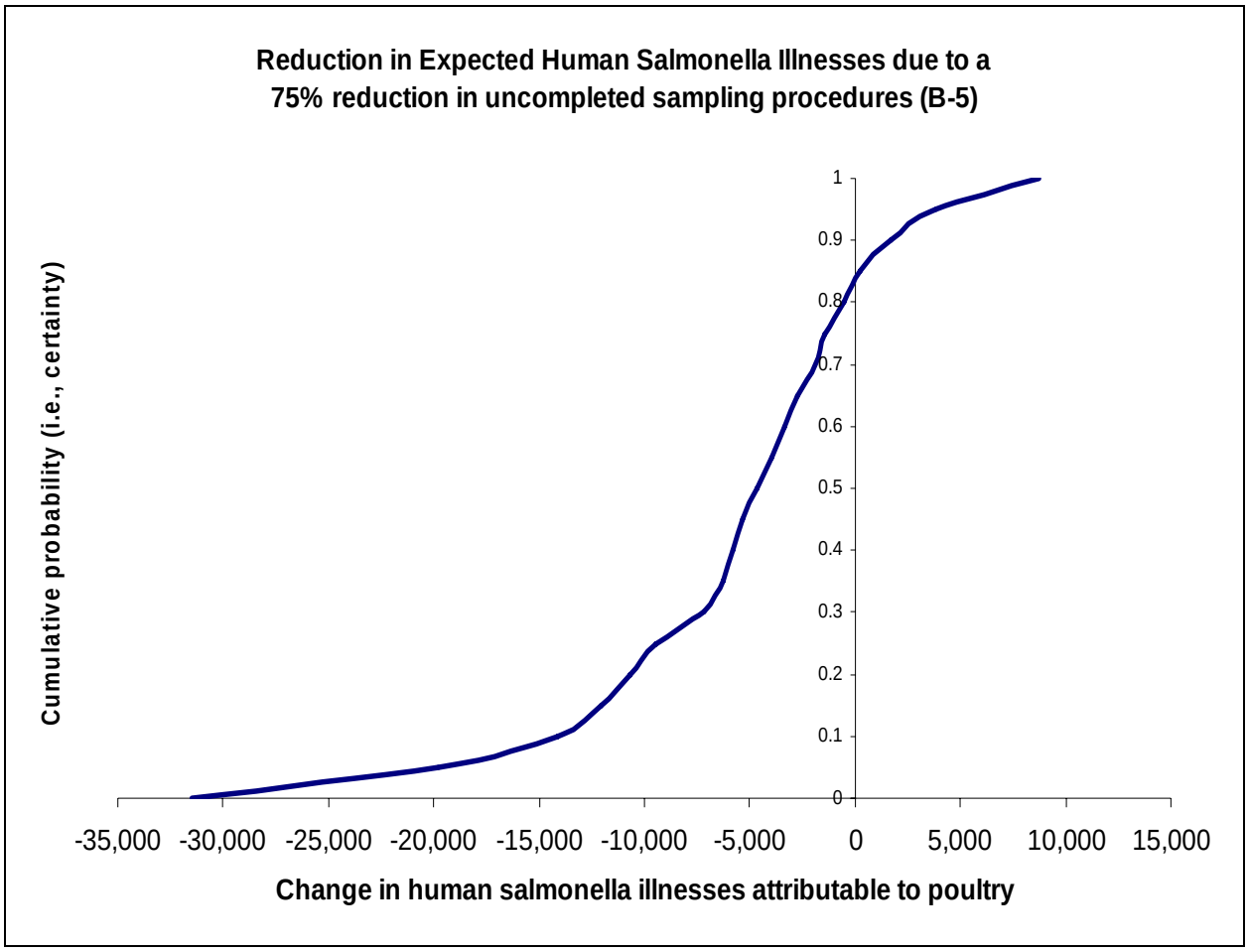

Figure 8. Reduction in Expected Human *Salmonella* Illnesses due to a 75% reduction in uncompleted sampling procedures (B-5).

A 75% decrease in UNPERFORMED HACCP procedures (B-3)

Figure 9 shows the uncertainty distribution for the expected change in human illnesses due to a 75% decrease in unperformed HACCP procedures across all young chicken slaughter establishments. Over 70% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 2,060 illnesses. The 90th percentile of the uncertainty distribution, however, shows an increase of 2,064 illnesses.

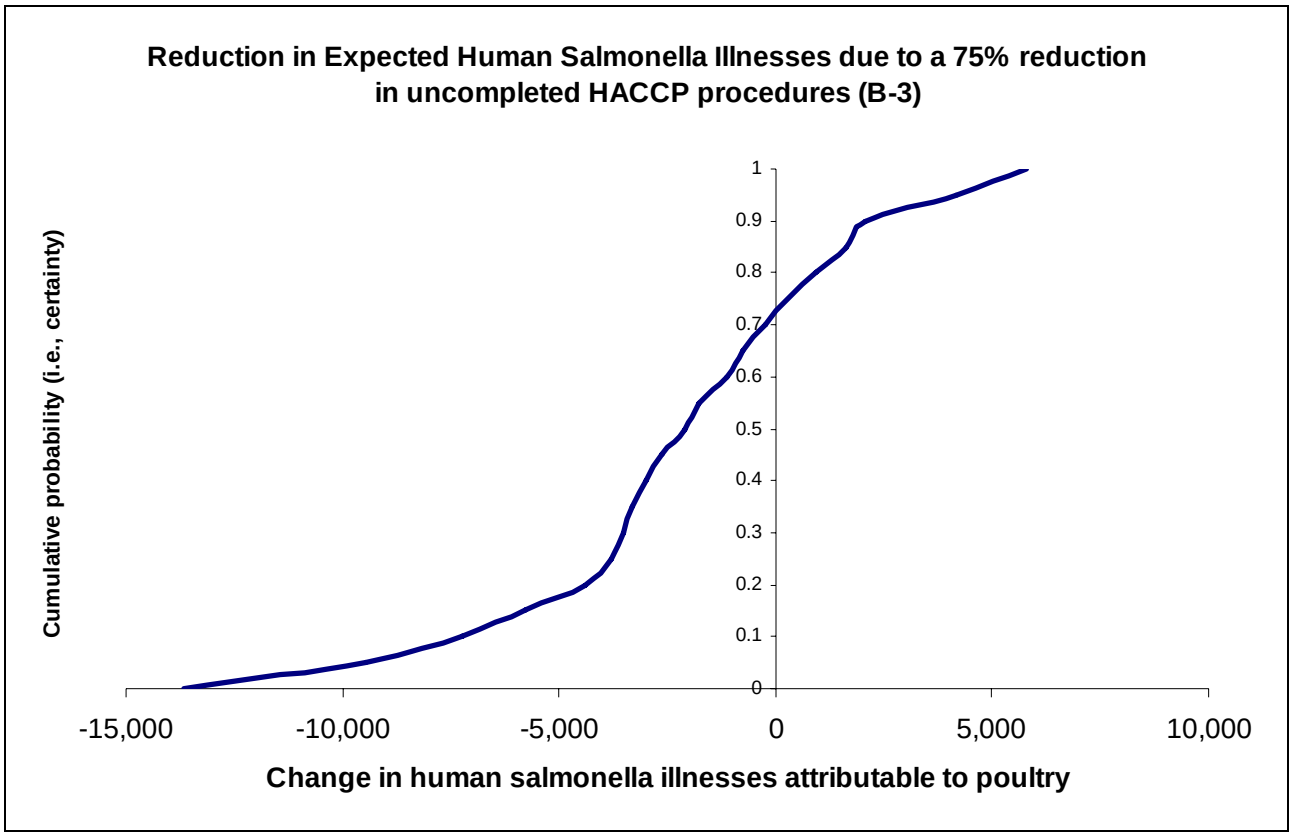

Figure 9. Reduction in Expected Human *Salmonella* Illnesses due to a 75% reduction in uncompleted HACCP procedures (B-3).

A 75% decrease in UNPERFORMED SANITATION procedures (B-1)

Figure 10 shows the uncertainty distribution for the expected change in human illnesses due to a 75% decrease in unperformed sanitation procedures across all young chicken slaughter establishments. Over 95% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 19,594. The 90th percentile of the uncertainty distribution shows a reduction of 8,592 illnesses.

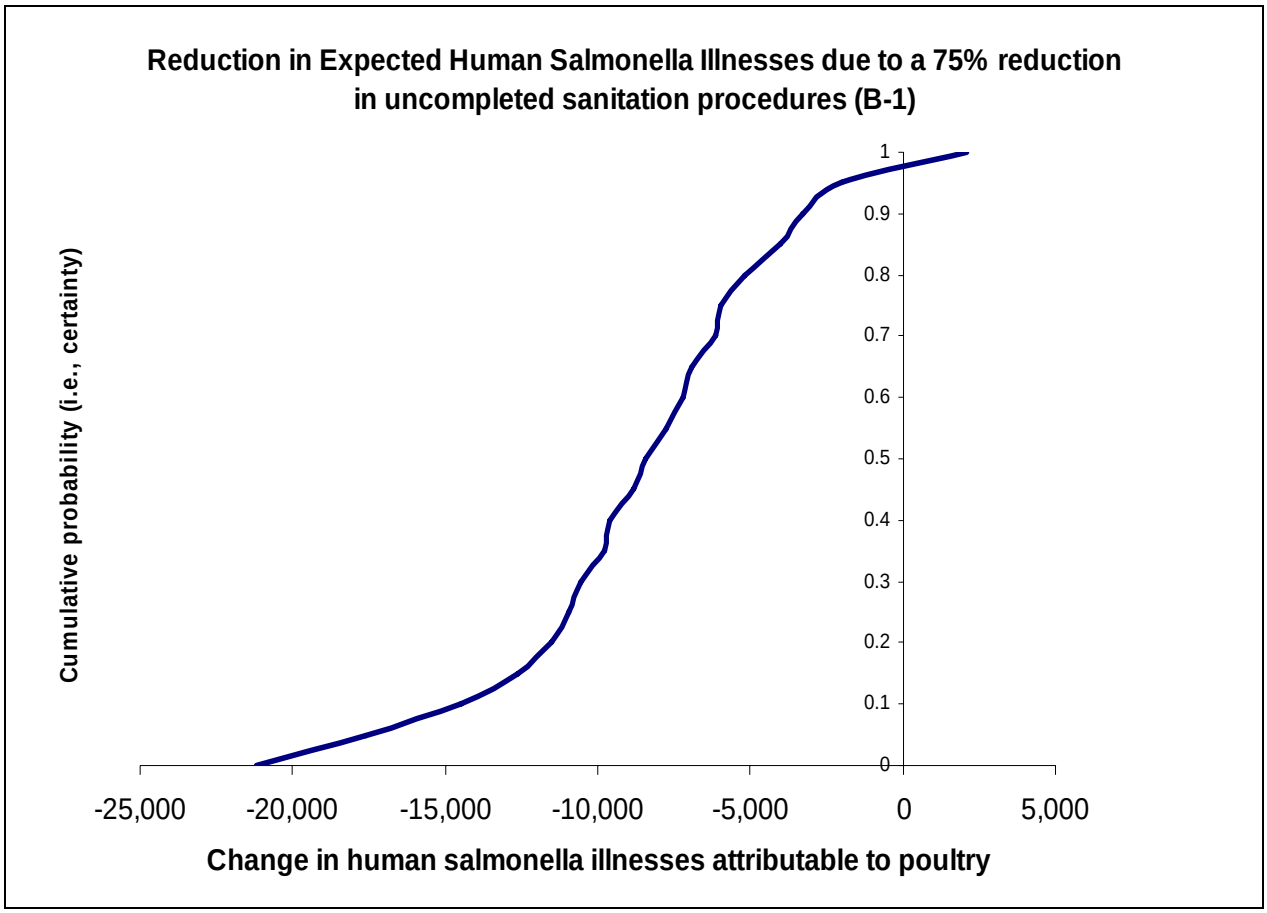

Figure 10. Reduction in Expected Human *Salmonella* Illnesses due to a 75% reduction in uncompleted sanitation procedures (B-1).

A 75% decrease in NON COMPLIANCES for SANITATION procedures (NC-1)

Figure 11 shows the uncertainty distribution for the expected change in human illnesses due to a 75% decrease in non-compliances (NRs) for sanitation procedures across all young chicken slaughter establishments. Over 65% of all iterations with the model show expected reduction in human *Salmonella* illnesses, with an average reduction of 2,321. The 90th percentile of the uncertainty distribution, however, shows an increase of 6,000 illnesses.

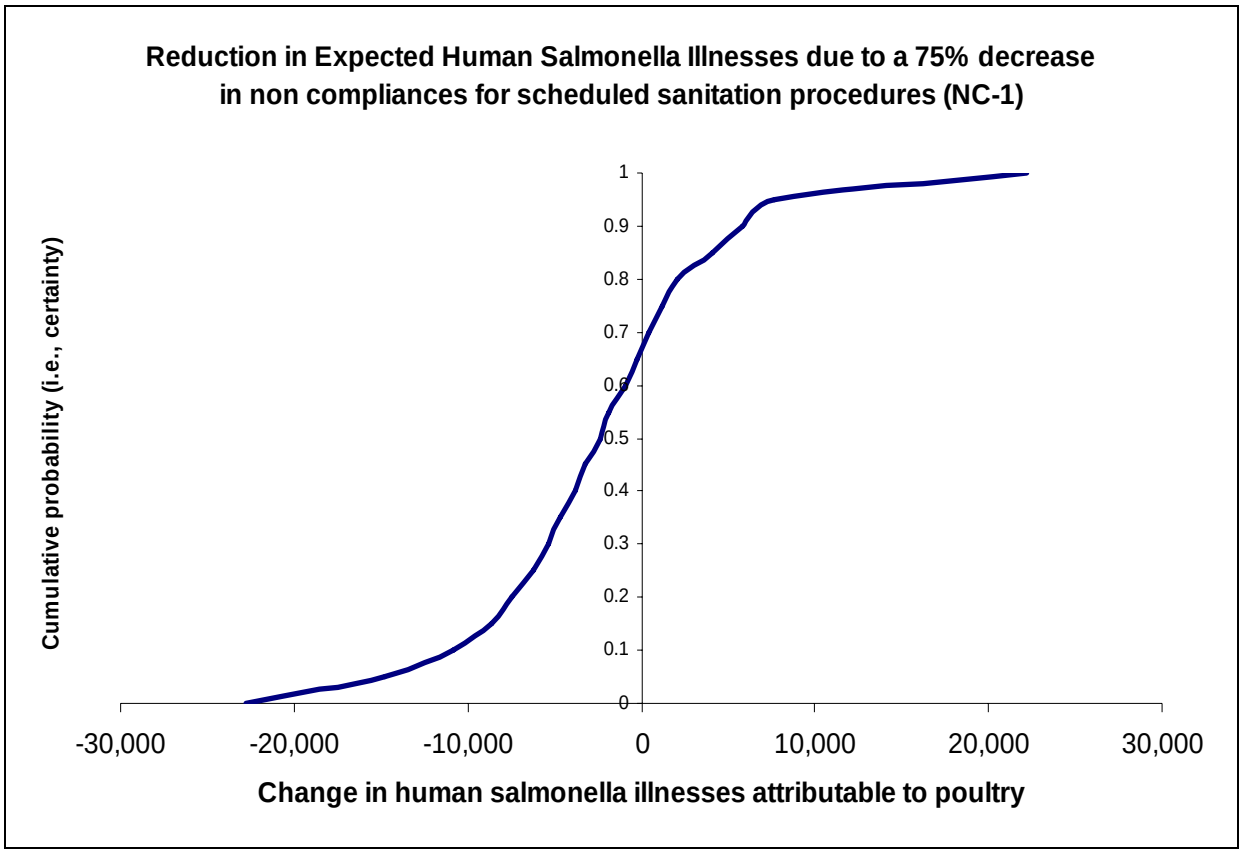

Figure 11. Reduction in Expected Human *Salmonella* Illnesses due to a 75% decrease in non-compliances for scheduled sanitation procedures (NC-1).

RISK ASSESSMENT FINDINGS IN RESPONSE TO RISK MANAGEMENT QUESTIONS

The following is a summary of responses to FSIS risk management questions based on the findings of this risk assessment:

- Can FSIS reallocate inspection activities in young chicken slaughter establishments without significant negative impact on microbial prevalence in the establishments?

  Yes, risk assessment model results using available data from 154 young chicken slaughter establishments show that reallocating some on-line inspectors to off-line inspection duties (replacing some online inspector with establishment personnel) could be more effective at reducing *Salmonella* prevalence in establishments.

Establishments with more off-line inspectors have lower *Salmonella* prevalence than establishments with fewer off-line inspectors.

- How will the relocation of on-line inspectors to off-line duties, or other areas within or outside the establishment, effect human illness?

  This analysis suggests a high probability that *Salmonella* attributable illnesses could decline or remain the same when additional off-line inspection procedures are performed. Both increases in unscheduled sanitation procedures and increases in unscheduled sampling procedures, as well as reducing the number of unperformed sanitation procedures are associated with decreases in attributable human *Salmonella* illnesses with 90% or higher certainty. Other off-line duties, such as reducing the number of unperformed sampling, and HACCP procedures, may also reduce attributable human *Salmonella* illnesses, but we are less certain about these (85% and 70%, respectively).

- Where within the establishment can relocated inspection activities have the most impact toward reducing microbial prevalence and corresponding human illness?

  Relocated inspectors can have the most impact on reducing prevalence and illness by performing increased unscheduled sampling procedures (U-5) and increased unscheduled sanitation procedures (U-1). In addition, a reduction in uncompleted sanitation procedures (B-1) can lower *Salmonella* prevalence and illness.

- What is the uncertainty about these effects?

  Uncertainty in establishment-level *Salmonella* prevalence is accounted for using the mean of a Beta Inverse distribution incorporating available sampling data. Uncertainty in *Salmonella* prevalence across all young chicken slaughter plants is modeled using a bootstrap simulation analysis. Uncertainty about attributable human illness is based on the central limit theorem and is lognormal in shape. The uncertain relationship between attributable *Salmonella* human illness and *Salmonella* prevalence is represented by the Poisson distribution.

DATA NEEDS

The model described in this report used FSIS microbiological data for *Salmonella* prevalence. As such, when estimating human illnesses, it was not possible to use a dose-response function. Use of a dose-response requires enumeration data for *Salmonella* on young poultry at slaughter. These data should be forthcoming following completion of future FSIS microbiological baseline sampling programs. In addition to qualitative and quantitative microbiological data for *Salmonella*, FSIS baseline sampling programs will provide prevalence and enumeration data for *Campylobacter* and *E. coli*, which will be used in a future version of this risk assessment model.

Second, additional data that provide further discrimination of *Salmonella* isolates should be collected. Examples of these data include serotype results, antimicrobials susceptibility profiles, and pulsed field gel electrophoresis (PFGE) patterns. This type of additional discrimination of isolates will allow for more precise results from future risk assessments for *Salmonella* attributable illness.

Third, additional collaborative studies with the Agricultural Research Service (ARS) to study 20 HIMP plants used in this risk assessment are planned and will provide additional prevalence and enumeration data for contamination on chicken carcasses at rehang and post-chill locations for *Salmonella* serotypes, *Campylobacter*, and generic *E. coli*. Additional data on new variables such as line speed will also be collected.

Fourth, a study by the Research Triangle Institute (RTI), in which FSIS young chicken data and an RTI-administered questionnaire on plant characteristics associated with *Salmonella*-positive cultures from 221 establishments are being analyzed, is nearing completion. The results of this analysis can provide support to the risk assessment model. Preliminary analysis for predictive *Salmonella* risk factors using classification and regression trees (CART) and factor analysis found facility sanitation (S-6), sanitation (S-1), PR/HACCP (S-3), and establishment size (slaughter totals, number of employees, and total sales) to be significant risk factors. Additional risk factors not included in this study were identified to be production area older than 20 years, number of employees, percent quality assurance trained employees, number of inspected plants owned, and the amount of raw poultry from outside sources to be significant. Examination of these additional risk factors using the risk assessment model seems warranted.

CONCLUSION

The results of this risk assessment suggest that FSIS can reallocate resources to further strengthen young chicken slaughter inspection, and subsequently, reduce illness and protect public health. Additional data, most importantly *Salmonella* enumeration data, will provide valuable data used to develop future version of this model to provide greater certainty in model estimates of the impact between allocation of inspection resources and reductions in human cases of salmonellosis attributable to young poultry.

Appendix I: Dependent and Independent Variable Distributions

DISTRIBUTION EVALUATION

The Vose model used for this analysis was the multivariate analog of a simple linear regression model evaluating population parameters of interest.[14] A bivariate normal distribution was assumed to apply to the dependent and independent variable in the simple regression model. The multivariate regression model also assumed bivariate normality between all pairs of variates. In fact, the joint distribution implied by the regression model is termed a multivariate normal distribution. In this risk assessment, categorical or structural variables were included in the regression equation. This in effect created partitions of the dependent and independent variable pairs, which stratified the data according to the structural variables in the model. In effect, subsets of multivariate normal variables were created that had to be evaluated separately if the distributions within categories were shown to be substantially different. Without very large datasets, joint normality is difficult to demonstrate statistically assuming no stratification. Given the modest amount of stratified data in this assessment, we attempted to evaluate each variable for univariate normality, bivariate normality, and multivariate joint normality using reasonably robust statistical methods.

Dependent Variable

The dependent variable was defined as the logit of *Salmonella* prevalence estimated by the beta cumulative distribution function. This was the variable analyzed for normality, although graphical output for evaluation uses the back transformed prevalence estimate as a percentage of the baseline prevalence. A linear relationship between the logit of the beta distribution *Salmonella* prevalence was assumed in the regression model with the independent variables in the equation. This was the dependent variable in the generalized logistic non-quantal regression model. There was only one dependent variable. In demonstrating bivariate or multivariate normality, the distinction between dependent and independent variables in the model is lost.

Independent Variables

There are 34 independent variables in the regression model: 11 structural, 13 decision tracking, and 10 performance deficiency variables. All the structural variables except volume, which is a continuous variable, were modeled as “dummy” variables. These are the categorical variables for years 2003, 2004, and 2005 and for the first, second, third, and fourth quarters of each year. Additionally, there are six plant category variables. Recall that dummy variables reduce the dimension of each of these respective variables by one, making a total of 10 dummy variables. Subsets created by these variables are of

primary interest in performing bivariate and multivariate tests given the failure of non-partitioned tests to detect normality. The remaining 23 variables (13 decision tracking and 10 performance deficiency) were the object of the partitioned tests for normality. The primary dataset used or distribution analysis consisted of 25 variables. These were the 23 decision tracking and performance deficiency variables plus the volume variable and the logit-dependent variable.

Univariate Distribution Evaluation

Univariate tests were done first without stratification. Only the dependent variable was transformed as required by the regression model. The natural scales of the independent variables were preserved without transformation to interpret the results easily. Normal probability plots were generated for each dependent and independent variable using the descriptive statistics routine in the Number Cruncher Statistical Systems 2004 version software.[17] This graph plots the original data points falling near the normal probability line with 95% confidence bands. Points falling outside the bands were considered suspect outliers if the following tests for univariate normality were failed. The probability level was found from the X^2 distribution with two degrees of freedom. The univariate test failure was set at $p<0.10$. Confidence in declaring a variable to have a normal distribution was gained for variables having an alpha probability greater than 0.05 by examining the results of the probability plot in conjunction with seven tests for normality employed in the NCSS software[17] available in the normality test section. These tests were Shapiro-Wilk, Anderson-Darling, Martinez-Inglewicz, Kolmogorov-Smirnov, D'Agostino Skewness, D'Agostino Kurtosis, and the D'Agostino Omnibus test.[18] Variables that failed all tests were considered not to have a normal distribution.

Table AI-1 shows the results for seven univariate tests for normality for the variables evaluated. Variables S8 and B8 did not have sufficient data to evaluate. The non-logit transformed beta function variable was included along with the logit transformed beta function. Note that very few variables passed these tests at the $p=0.10$ level. Note also that none of these tests considered stratification. Redundant values were problematic for all variables, but particular trends were not found. According to this analysis, only the variables for volume, On, NC-5, B-6, and NC-8 could likely be used in the simple non-stratified regression model without transformation. Variables demonstrating non-normal distribution behavior are not likely to have bivariate normal distributions. The overall accept rate for this table was 2.3%, calculated as the number of tests passed out of the total performed.

Levels of Stratification

The regression model was parameterized to account for stratification for calendar years 2003, 2004, and 2005. Years were further stratified by first, second, third, and fourth. These first two levels of stratification account for 3 x 4 partitions making 12 primary levels. Secondarily, the model was stratified within quarters for establishment inspection types of HIMP, MAESTRO, MIXED, NELS, NU-TECH, and SIS. These additional levels of stratification provided 12 x 6 partitions, for a total of 72 levels. Stratum levels

were numbered 1 to 71 in Tables AI-4 and AI-6 because one level of the NU-TECH inspection system was missing from the first quarter of 2003.

Univariate Tests within Strata

Each level of stratification was evaluated using the univariate statistics as before. Table AI-2 shows the results of the same seven tests as Table AI-1 for the same variable list stratified by years with three levels per variable. A reject, however, was recorded if all tests were failed and an "accept" was recorded if at least one test was passed. The overall accept rate for this table was 32.1%. Variables passing the test for normality in one or more years were Volume, On, S-1, S-3, S-4, S-5, NC-5, S-6, B-6, U-8, NC-8, and Logit. Table AI-3 lists the results for the same univariate tests recorded as in Table AI-2, except that the stratification is by year and quarter with twelve levels per variable. All variables in this table passed all or some of the stratified tests for normality, except variables U-1, NC-1, B-3, NC-4, U-6, and NC-6. The overall accept rate for this table was 42.9%. It was decided that further univariate tests would be conducted in conjunction with the tests for bivariate and multivariate normality because these tests would be constructed using the same statistics as described below in Appendix III. Table AI-4 shows the results of the univariate S-B tests that were used in the bivariate and multivariate normal tests. The overall accept rate for this table was 64.9%.

Table AI-1. Univariate non-stratified test results for normality – 2.3% accept rate.

Test*	Beta	Volume	On	Off	S1	U1	B1
Shapiro-Wilk	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Anderson-Darling	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Martinez-Inglewicz	Reject	Accept	Accept	Reject	Reject	Reject	Reject
Kolmorgorov-Smirnov	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Skewness	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Kurtosis	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Omnibus	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Distinct Values of 1519	123	156	35	14	74	51	51
	NC1	**S3**	**U3**	**B3**	**NC3**	**S4**	**U4**
Shapiro-Wilk	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Anderson-Darling	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Martinez-Inglewicz	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Kolmorgorov-Smirnov	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Skewness	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Kurtosis	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Omnibus	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Distinct Values of 1519	68	186	508	53	45	173	225
	B4	**NC4**	**S5**	**U5**	**B5**	**NC5**	**S6**
Shapiro-Wilk	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Anderson-Darling	Reject	Reject	Reject	Reject	Reject	Accept	Reject
Martinez-Inglewicz	Reject	Reject	Reject	Reject	Reject	Accept	Reject
Kolmorgorov-Smirnov	Reject	Reject	Reject	Reject	Reject	Reject	Reject
D'Agostino Skewness	Reject	Reject	Reject	Reject	Reject	Reject	Reject

D'Agostino Kurtosis	Reject	Reject	Accept	Reject	Reject	Reject	Reject
D'Agostino Omnibus	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Distinct Values of 1519	73	38	32	66	19	3	44
	U6	**B6**	**NC6**	**U8**	**NC8**	**logit**	
Shapiro-Wilk	Reject	Reject	Reject	Reject	Reject	Reject	
Anderson-Darling	Reject	Reject	Reject	Reject	Accept	Reject	
Martinez-Inglewicz	Reject	Accept	Reject	Accept	Accept	Reject	
Kolmorgorov-Smirnov	Reject	Reject	Reject	Reject	Reject	Reject	
D'Agostino Skewness	Reject	Reject	Reject	Reject	Reject	Reject	
D'Agostino Kurtosis	Reject	Reject	Reject	Reject	Reject	Reject	
D'Agostino Omnibus	Reject	Reject	Reject	Reject	Reject	Reject	
Distinct Values of 1519	215	12	50	115	7	123	

*For a description of the tests, see Shenton and Bowman.[18]

Table AI-2. Univariate test results for stratification by years only – 32.1% accept rate.

	Beta	**Volume**	**On**	**Off**	**S1**	**U1**	**B1**
2003	Reject	Accept	Accept	Reject	Accept	Reject	Reject
Distinct Values of 1519	77	125	33	14	48	85	38
2004	Reject	Accept	Accept	Reject	Accept	Reject	Reject
Distinct Values of 1519	92	138	33	14	42	87	37
2005	Reject	Accept	Accept	Reject	Reject	Reject	Reject
Distinct Values of 1519	98	152	35	14	47	85	34
	NC1	**S3**	**U3**	**B3**	**NC3**	**S4**	**U4**
2003	Reject	Reject	Reject	Reject	Reject	Accept	Reject
Distinct Values of 1519	46	124	154	38	32	118	123
2004	Reject	Accept	Reject	Reject	Reject	Accept	Reject
Distinct Values of 1519	46	126	232	36	33	120	142
2005	Reject	Reject	Reject	Reject	Reject	Reject	Reject
Distinct Values of 1519	55	140	366	40	38	124	160
	B4	**NC4**	**S5**	**U5**	**B5**	**NC5**	**S6**
2003	Reject	Reject	Reject	Reject	Reject	Accept	Accept
Distinct Values of 1519	36	28	29	52	15	2	42
2004	Reject	Reject	Accept	Reject	Reject	Accept	Reject
Distinct Values of 1519	38	25	28	52	16	3	38
2005	Reject	Reject	Accept	Reject	Reject	Accept	Reject
Distinct Values of 1519	71	26	30	59	17	2	42
	U6	**B6**	**NC6**	**U8**	**NC8**	**logit**	
2003	Reject	Accept	Reject	Accept	Accept	Reject	
Distinct Values of 1519	122	10	34	19	1	77	
2004	Reject	Accept	Reject	Accept	Accept	Reject	
Distinct Values of 1519	135	11	32	19	2	92	
2005	Reject	Accept	Reject	Accept	Accept	Accept	
Distinct Values of 1519	151	8	42	108	7	98	

Table AI-3. Univariate test results for stratification by years and quarters only - 42.9% accept rate.

Year	Quarter	Logit	Beta	Volume	On	Off	S1	U1
2003	Q1	Pass	Fail	Pass	Pass	Pass	Fail	Pass
2003	Q2	Pass	Fail	Pass	Pass	Pass	Pass	Fail
2003	Q3	Fail	Fail	Pass	Pass	Pass	Pass	Fail
2003	Q4	Fail	Fail	Pass	Pass	Fail	Pass	Fail
2004	Q1	Pass	Fail	Pass	Pass	Fail	Fail	Fail
2004	Q2	Pass	Fail	Pass	Pass	Pass	Fail	Fail
2004	Q3	Fail	Fail	Pass	Pass	Pass	Pass	Fail
2004	Q4	Fail	Fail	Pass	Pass	Pass	Fail	Fail
2005	Q1	Pass	Pass	Pass	Pass	Pass	Fail	Fail
2005	Q2	Pass	Pass	Pass	Pass	Pass	Pass	Fail
2005	Q3	Pass	Pass	Pass	Pass	Fail	Fail	Fail
2005	Q4	Pass	Fail	Pass	Pass	Fail	Pass	Fail
Total Pass		8	3	12	12	8	6	1
Total Fail		4	9	0	0	4	6	11
Year	**Quarter**	**B1**	**NC1**	**S3**	**U3**	**B3**	**NC3**	**S4**
2003	Q1	Fail	Fail	Pass	Pass	Fail	Fail	Fail
2003	Q2	Fail	Fail	Fail	Pass	Fail	Pass	Pass
2003	Q3	Pass	Fail	Pass	Fail	Fail	Fail	Fail
2003	Q4	Fail	Fail	Pass	Fail	Fail	Fail	Fail
2004	Q1	Fail	Fail	Pass	Fail	Fail	Fail	Pass
2004	Q2	Fail	Fail	Fail	Fail	Fail	Fail	Fail
2004	Q3	Fail	Fail	Pass	Fail	Fail	Fail	Pass
2004	Q4	Fail	Fail	Fail	Fail	Fail	Fail	Fail
2005	Q1	Fail	Fail	Pass	Fail	Fail	Fail	Fail
2005	Q2	Pass	Fail	Pass	Pass	Fail	Fail	Pass
2005	Q3	Fail	Fail	Pass	Fail	Fail	Fail	Pass
2005	Q4	Fail	Fail	Fail	Fail	Fail	Fail	Pass
Total Pass		2	0	8	3	0	1	6
Total Fail		10	12	4	9	12	11	6
Year	**Quarter**	**U4**	**B4**	**NC4**	**S5**	**U5**	**B5**	**NC5**
2003	Q1	Pass	Fail	Fail	Pass	Pass	Fail	Pass
2003	Q2	Fail	Fail	Fail	Pass	Pass	Fail	Pass
2003	Q3	Fail	Pass	Fail	Pass	Pass	Pass	Pass
2003	Q4	Fail	Fail	Fail	Fail	Pass	Fail	Pass
2004	Q1	Fail	Fail	Fail	Pass	Pass	Fail	Pass
2004	Q2	Fail	Fail	Fail	Pass	Fail	Fail	Pass
2004	Q3	Fail	Fail	Fail	Pass	Pass	Fail	Pass
2004	Q4	Fail	Fail	Fail	Fail	Pass	Fail	Pass
2005	Q1	Fail	Pass	Fail	Fail	Pass	Fail	Pass
2005	Q2	Pass	Fail	Fail	Pass	Fail	Fail	Pass
2005	Q3	Fail	Pass	Fail	Pass	Pass	Fail	Pass
2005	Q4	Fail	Fail	Fail	Pass	Fail	Fail	Pass
Total Pass		2	3	0	9	9	1	12

Total Fail		10	9	12	3	3	11	0
Year	**Quarter**	**S6**	**U6**	**B6**	**NC6**	**U8**	**NC8**	
2003	Q1	Pass	Fail	Fail	Fail	Pass	Pass	
2003	Q2	Fail	Fail	Pass	Fail	Pass	Pass	
2003	Q3	Fail	Fail	Pass	Fail	Pass	Pass	
2003	Q4	Fail	Fail	Pass	Fail	Pass	Pass	
2004	Q1	Fail	Fail	Pass	Fail	Pass	Pass	
2004	Q2	Pass	Fail	Fail	Fail	Pass	Pass	
2004	Q3	Fail	Fail	Pass	Fail	Pass	Pass	
2004	Q4	Fail	Fail	Fail	Fail	Pass	Pass	
2005	Q1	Pass	Fail	Fail	Fail	Pass	Pass	
2005	Q2	Pass	Fail	Pass	Fail	Pass	Pass	
2005	Q3	Pass	Fail	Pass	Fail	Pass	Pass	
2005	Q4	Pass	Fail	Pass	Fail	Pass	Pass	
Total Pass		6	0	8	0	12	12	
Total Fail		6	12	4	12	0	0	

Table AI-4a. Univariate test results for year, quarter, and inspection system - 64.9% accept rate.

Stratum	Logit	S-1	U-1	B-1	NC-1	S-3	U-3
1	Pass	Fail	Pass	Fail	Pass	Pass	Pass
2	Pass	Pass	Pass	Pass	Pass	Fail	Pass
3	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4	Pass	Pass	Fail	Pass	Pass	Pass	Pass
5	Pass	Fail	Fail	Pass	Pass	Pass	Fail
6	Pass	Fail	Fail	Fail	Fail	Pass	Fail
7	Pass	Fail	Fail	Fail	Pass	Fail	Pass
8	Pass	Fail	Fail	Fail	Fail	Fail	Fail
9	Pass	Pass	Pass	Fail	Pass	Pass	Pass
10	Pass	Fail	Fail	Pass	Pass	Pass	Fail
11	Pass	Fail	Fail	Fail	Pass	Fail	Fail
12	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	Pass	Fail	Pass	Pass	Pass	Pass	Pass
14	Fail	Fail	Pass	Fail	Pass	Pass	Pass
15	Pass	Pass	Fail	Fail	Pass	Pass	Fail
16	Pass	Fail	Pass	Fail	Pass	Pass	Fail
17	Fail	Fail	Fail	Fail	Pass	Fail	Fail
18	Pass	Fail	Fail	Pass	Pass	Pass	Fail
19	Fail	Fail	Fail	Pass	Fail	Fail	Pass
20	Pass	Fail	Pass	Fail	Pass	Fail	Pass
21	Pass	Fail	Fail	Fail	Pass	Fail	Pass
22	Pass	Fail	Fail	Fail	Pass	Pass	Pass
23	Fail	Fail	Fail	Fail	Fail	Fail	Fail
24	Pass	Fail	Pass	Fail	Pass	Pass	Pass
25	Pass	Fail	Pass	Fail	Pass	Pass	Pass
26	Pass	Fail	Pass	Fail	Pass	Fail	Pass
27	Pass	Pass	Fail	Fail	Pass	Fail	Pass

28	Pass	Pass	Pass	Pass	Fail	Pass	Fail
29	Pass	Fail	Fail	Fail	Pass	Fail	Fail
30	Pass	Fail	Fail	Pass	Pass	Pass	Fail
31	Pass	Fail	Pass	Fail	Fail	Fail	Pass
32	Pass	Pass	Pass	Fail	Pass	Fail	Fail
33	Pass	Pass	Fail	Fail	Pass	Pass	Pass
34	Pass	Pass	Pass	Fail	Pass	Pass	Pass
35	Pass	Fail	Fail	Fail	Fail	Fail	Pass
36	Pass	Pass	Pass	Pass	Pass	Pass	Pass
37	Fail	Fail	Fail	Pass	Pass	Fail	Pass
38	Pass	Fail	Pass	Pass	Pass	Fail	Pass
39	Pass	Fail	Pass	Pass	Pass	Fail	Pass
40	Pass	Pass	Fail	Pass	Pass	Pass	Pass
41	Pass	Fail	Fail	Pass	Pass	Fail	Fail
42	Pass	Pass	Pass	Pass	Pass	Pass	Pass
43	Pass	Fail	Pass	Pass	Pass	Pass	Pass
44	Fail	Pass	Pass	Pass	Pass	Pass	Pass
45	Pass	Fail	Pass	Fail	Fail	Pass	Pass
46	Pass	Fail	Fail	Fail	Pass	Pass	Pass
47	Pass	Fail	Pass	Fail	Pass	Pass	Pass
48	Pass	Fail	Pass	Fail	Pass	Pass	Fail
49	Pass	Pass	Fail	Pass	Fail	Pass	Fail
50	Pass	Fail	Pass	Fail	Pass	Pass	Pass
51	Pass	Pass	Pass	Pass	Fail	Pass	Pass
52	Fail	Pass	Pass	Pass	Pass	Pass	Pass
53	Pass	Fail	Fail	Fail	Fail	Pass	Fail
54	Pass	Pass	Pass	Pass	Pass	Fail	Pass
55	Pass	Fail	Pass	Fail	Fail	Fail	Pass
56	Pass	Fail	Pass	Pass	Pass	Fail	Pass
57	Pass	Pass	Fail	Pass	Fail	Pass	Fail
58	Pass	Fail	Pass	Pass	Pass	Fail	Pass
59	Pass	Fail	Fail	Fail	Pass	Pass	Fail
60	Pass	Fail	Pass	Pass	Fail	Pass	Fail
61	Pass	Fail	Fail	Pass	Pass	Fail	Pass
62	Pass	Fail	Fail	Pass	Pass	Fail	Pass
63	Pass	Fail	Fail	Pass	Pass	Fail	Pass
64	Pass	Fail	Fail	Fail	Pass	Fail	Fail
65	Pass	Fail	Fail	Fail	Fail	Fail	Fail
66	Pass	Fail	Pass	Pass	Pass	Pass	Pass
67	Pass	Fail	Fail	Fail	Fail	Fail	Fail
68	Pass	Fail	Fail	Pass	Pass	Fail	Pass
69	Pass	Fail	Fail	Fail	Pass	Fail	Pass
70	Pass	Fail	Pass	Pass	Pass	Pass	Pass
71	Pass	Fail	Fail	Fail	Fail	Fail	Fail
Total Pass	64	20	35	34	54	39	46
Total Fail	7	51	36	37	17	32	25
%Pass	90.1	28.2	49.3	47.9	76.1	54.9	64.8

Table AI-4b. Univariate test results for year, quarter, and inspection system.

Stratum	B-3	NC-3	S-4	U-4	B-4	NC-4	S-5
1	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2	Fail	Fail	Pass	Pass	Pass	Pass	Pass
3	Fail	Fail	Pass	Pass	Pass	Pass	Pass
4	Pass	Pass	Pass	Pass	Pass	Fail	Pass
5	Pass	Pass	Fail	Fail	Fail	Fail	Pass
6	Pass	Pass	Fail	Fail	Pass	Pass	Pass
7	Fail	Pass	Fail	Pass	Fail	Pass	Fail
8	Pass	Pass	Fail	Pass	Fail	Fail	Pass
9	Pass	Fail	Pass	Pass	Pass	Pass	Pass
10	Pass	Pass	Fail	Fail	Pass	Pass	Pass
11	Fail	Pass	Fail	Fail	Fail	Fail	Pass
12	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	Pass	Pass	Pass	Pass	Pass	Fail	Pass
14	Pass	Pass	Fail	Pass	Pass	Pass	Pass
15	Pass	Pass	Pass	Fail	Pass	Fail	Pass
16	Pass	Pass	Fail	Fail	Pass	Pass	Pass
17	Fail	Fail	Fail	Fail	Pass	Pass	Fail
18	Fail	Pass	Pass	Pass	Pass	Pass	Pass
19	Fail	Pass	Fail	Fail	Pass	Fail	Fail
20	Pass	Pass	Pass	Pass	Pass	Fail	Pass
21	Fail	Pass	Pass	Pass	Fail	Fail	Pass
22	Pass	Pass	Fail	Fail	Pass	Pass	Pass
23	Fail	Fail	Fail	Fail	Pass	Pass	Pass
24	Fail	Pass	Pass	Pass	Pass	Fail	Pass
25	Fail	Pass	Pass	Pass	Pass	Fail	Pass
26	Pass	Pass	Fail	Pass	Pass	Fail	Pass
27	Pass	Pass	Pass	Pass	Pass	Fail	Pass
28	Pass	Pass	Pass	Pass	Pass	Pass	Pass
29	Fail	Fail	Fail	Pass	Fail	Pass	Pass
30	Pass	Pass	Pass	Fail	Pass	Pass	Pass
31	Fail	Pass	Fail	Fail	Pass	Fail	Fail
32	Pass	Pass	Fail	Fail	Fail	Fail	Pass
33	Pass	Pass	Pass	Fail	Pass	Fail	Pass
34	Pass	Pass	Pass	Pass	Fail	Pass	Pass
35	Fail	Fail	Fail	Fail	Pass	Fail	Pass
36	Pass	Pass	Pass	Pass	Pass	Pass	Pass
37	Pass	Pass	Pass	Pass	Pass	Pass	Pass
38	Pass	Fail	Pass	Pass	Fail	Fail	Pass
39	Pass	Pass	Pass	Fail	Pass	Pass	Pass
40	Pass	Pass	Pass	Pass	Pass	Fail	Pass
41	Fail	Pass	Fail	Fail	Pass	Pass	Pass
42	Fail	Pass	Pass	Pass	Fail	Pass	Fail
43	Pass	Pass	Pass	Fail	Pass	Fail	Pass

44	Pass	Pass	Pass	Pass	Pass	Fail	Pass
45	Pass	Pass	Fail	Fail	Fail	Fail	Pass
46	Pass	Pass	Fail	Fail	Fail	Pass	Pass
47	Pass	Fail	Pass	Pass	Pass	Fail	Pass
48	Fail	Pass	Pass	Fail	Pass	Fail	Pass
49	Pass	Fail	Pass	Pass	Pass	Fail	Pass
50	Pass	Pass	Pass	Fail	Pass	Fail	Fail
51	Pass	Fail	Fail	Fail	Pass	Fail	Pass
52	Pass	Pass	Pass	Pass	Pass	Pass	Pass
53	Fail	Fail	Fail	Fail	Pass	Fail	Pass
54	Pass	Pass	Pass	Pass	Pass	Pass	Pass
55	Fail	Pass	Pass	Pass	Pass	Fail	Fail
56	Fail	Pass	Fail	Fail	Pass	Fail	Fail
57	Pass	Pass	Pass	Pass	Pass	Pass	Pass
58	Pass	Pass	Pass	Fail	Pass	Pass	Pass
59	Fail	Fail	Fail	Fail	Fail	Fail	Pass
60	Pass	Pass	Pass	Fail	Pass	Fail	Pass
61	Fail	Fail	Pass	Fail	Fail	Fail	Fail
62	Pass	Pass	Pass	Fail	Pass	Fail	Fail
63	Pass	Fail	Pass	Fail	Pass	Fail	Pass
64	Pass	Fail	Pass	Pass	Pass	Fail	Pass
65	Fail	Fail	Fail	Fail	Fail	Fail	Pass
66	Fail	Fail	Fail	Fail	Pass	Pass	Pass
67	Fail	Fail	Fail	Pass	Fail	Fail	Fail
68	Fail	Pass	Fail	Pass	Pass	Fail	Fail
69	Fail	Pass	Fail	Fail	Pass	Fail	Fail
70	Pass	Fail	Fail	Pass	Pass	Fail	Pass
71	Fail	Fail	Fail	Fail	Fail	Fail	Fail
Total Pass	43	50	40	36	54	28	57
Total Fail	28	21	31	35	17	42	14
%Pass	60.6	70.4	56.3	50.7	76.1	40.0	80.3

Table AI-4c. Univariate test results for year, quarter, and inspection system.

Stratum	U-5	B-5	NC-5	S-6	U-6	B-6	NC-6
1	Pass	Pass	Fail	Pass	Pass	Fail	Pass
2	Pass	Pass	Fail	Pass	Pass	Fail	Pass
3	Pass	Pass	Pass	Pass	Fail	Pass	Pass
4	Pass	Pass	Pass	Pass	Pass	Pass	Pass
5	Pass	Fail	Pass	Pass	Pass	Fail	Pass
6	Fail	Pass	Pass	Pass	Fail	Pass	Pass
7	Pass	Fail	Pass	Fail	Pass	Fail	Fail
8	Pass	Pass	Pass	Fail	Pass	Fail	Fail
9	Pass	Pass	Pass	Fail	Pass	Fail	Fail
10	Pass	Pass	Pass	Pass	Fail	Fail	Pass
11	Pass	Pass	Pass	Pass	Pass	Fail	Pass
12	Pass	Pass	Pass	Pass	Pass	Pass	Pass

13	Pass	Pass	Pass	Fail	Pass	Pass	Fail
14	Pass	Pass	Pass	Fail	Pass	Fail	Pass
15	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16	Pass	Fail	Pass	Fail	Fail	Pass	Pass
17	Fail	Pass	Pass	Fail	Fail	Fail	Pass
18	Fail	Pass	Pass	Pass	Pass	Fail	Fail
19	Fail	Fail	Pass	Fail	Pass	Pass	Fail
20	Pass	Pass	Pass	Pass	Pass	Pass	Pass
21	Pass	Pass	Pass	Pass	Pass	Fail	Fail
22	Pass	Pass	Fail	Pass	Fail	Pass	Pass
23	Fail	Pass	Fail	Fail	Pass	Fail	Fail
24	Pass	Pass	Fail	Fail	Pass	Pass	Fail
25	Pass	Pass	Fail	Fail	Pass	Pass	Fail
26	Pass	Fail	Fail	Fail	Pass	Fail	Fail
27	Pass	Pass	Fail	Pass	Pass	Pass	Pass
28	Pass	Pass	Pass	Fail	Pass	Pass	Pass
29	Pass	Fail	Pass	Fail	Pass	Fail	Pass
30	Pass	Pass	Pass	Pass	Pass	Pass	Pass
31	Pass	Pass	Fail	Fail	Fail	Fail	Fail
32	Pass	Pass	Pass	Pass	Pass	Fail	Pass
33	Pass	Pass	Pass	Pass	Fail	Pass	Fail
34	Pass	Pass	Pass	Pass	Pass	Fail	Pass
35	Pass	Pass	Pass	Fail	Fail	Fail	Fail
36	Pass	Pass	Pass	Pass	Pass	Pass	Pass
37	Pass	Pass	Pass	Fail	Pass	Pass	Pass
38	Pass	Fail	Pass	Fail	Pass	Fail	Fail
39	Pass	Pass	Pass	Fail	Fail	Pass	Pass
40	Pass	Pass	Pass	Pass	Pass	Pass	Pass
41	Fail	Pass	Fail	Fail	Fail	Fail	Pass
42	Pass	Pass	Pass	Pass	Fail	Fail	Fail
43	Pass	Pass	Pass	Pass	Pass	Pass	Pass
44	Pass	Pass	Fail	Pass	Pass	Pass	Pass
45	Pass	Pass	Pass	Fail	Fail	Fail	Fail
46	Pass	Fail	Fail	Pass	Fail	Fail	Pass
47	Pass	Pass	Pass	Pass	Pass	Fail	Pass
48	Fail	Pass	Fail	Fail	Fail	Fail	Pass
49	Pass	Pass	Pass	Pass	Pass	Pass	Fail
50	Pass	Pass	Pass	Fail	Fail	Fail	Pass
51	Pass	Pass	Pass	Pass	Pass	Pass	Pass
52	Pass	Pass	Pass	Pass	Pass	Pass	Pass
53	Pass	Pass	Pass	Fail	Fail	Fail	Fail
54	Pass	Pass	Pass	Pass	Pass	Pass	Pass
55	Pass	Pass	Pass	Pass	Pass	Fail	Fail
56	Pass	Pass	Pass	Fail	Pass	Fail	Pass
57	Pass	Pass	Fail	Pass	Pass	Pass	Pass
58	Fail	Pass	Fail	Pass	Fail	Pass	Pass
59	Fail	Fail	Pass	Fail	Pass	Fail	Fail
60	Pass	Pass	Pass	Pass	Pass	Fail	Fail
61	Pass	Fail	Pass	Fail	Fail	Pass	Fail
62	Pass	Pass	Fail	Pass	Fail	Fail	Fail

63	Pass	Pass	Pass	Pass	Fail	Fail	Pass
64	Pass	Pass	Pass	Fail	Pass	Fail	Pass
65	Pass	Pass	Fail	Fail	Fail	Fail	Pass
66	Fail	Pass	Pass	Pass	Fail	Fail	Fail
67	Pass	Fail	Fail	Fail	Pass	Fail	Fail
68	Pass	Fail	Pass	Fail	Fail	Pass	Pass
69	Pass	Fail	Fail	Fail	Fail	Fail	Fail
70	Pass	Pass	Pass	Fail	Fail	Fail	Fail
71	Pass	Fail	Fail	Fail	Fail	Fail	Fail
Total Pass	61	57	51	37	44	30	42
Total Fail	10	14	20	34	27	41	29
%Pass	85.9	80.3	71.8	52.1	62.0	42.3	59.2

Table AI-4d. Univariate test results for year, quarter, and inspection system.

Stratum	U-8	NC-8	volume	ON	OFF	Beta
1	Fail	Pass	Pass	Pass	Fail	Pass
2	Fail	Pass	Pass	Pass	Pass	Pass
3	Pass	Pass	Pass	Pass	Pass	Pass
4	Fail	Pass	Pass	Pass	Pass	Pass
5	Fail	Pass	Pass	Pass	Pass	Pass
6	Fail	Pass	Fail	Pass	Fail	Pass
7	Fail	Pass	Pass	Pass	Pass	Pass
8	Fail	Pass	Pass	Pass	Pass	Fail
9	Fail	Pass	Pass	Fail	Pass	Pass
10	Fail	Pass	Pass	Pass	Pass	Pass
11	Fail	Pass	Pass	Pass	Pass	Pass
12	Pass	Pass	Pass	Pass	Pass	Pass
13	Pass	Pass	Fail	Pass	Pass	Pass
14	Fail	Pass	Pass	Pass	Pass	Pass
15	Pass	Pass	Pass	Pass	Pass	Pass
16	Pass	Pass	Pass	Pass	Fail	Pass
17	Fail	Pass	Pass	Pass	Pass	Fail
18	Pass	Pass	Pass	Pass	Pass	Pass
19	Fail	Pass	Fail	Fail	Pass	Fail
20	Fail	Pass	Fail	Pass	Pass	Pass
21	Pass	Pass	Pass	Fail	Pass	Pass
22	Fail	Pass	Fail	Pass	Pass	Pass
23	Fail	Pass	Pass	Fail	Pass	Fail
24	Pass	Pass	Pass	Pass	Pass	Pass
25	Pass	Pass	Pass	Pass	Pass	Pass
26	Fail	Pass	Pass	Pass	Pass	Pass
27	Fail	Pass	Pass	Fail	Pass	Pass
28	Fail	Pass	Pass	Pass	Pass	Pass
29	Fail	Pass	Pass	Pass	Pass	Pass
30	Fail	Pass	Pass	Fail	Pass	Pass
31	Fail	Pass	Pass	Pass	Pass	Pass

32	Fail	Pass	Pass	Pass	Pass	Pass	
33	Fail	Pass	Fail	Fail	Pass	Fail	
34	Fail	Fail	Pass	Pass	Pass	Pass	
35	Fail	Pass	Pass	Pass	Pass	Pass	
36	Pass	Pass	Pass	Pass	Pass	Pass	
37	Fail	Pass	Pass	Pass	Pass	Fail	
38	Pass	Pass	Pass	Pass	Pass	Pass	
39	Pass	Pass	Pass	Fail	Pass	Pass	
40	Fail	Pass	Pass	Fail	Fail	Pass	
41	Fail	Pass	Fail	Fail	Pass	Pass	
42	Pass	Pass	Fail	Fail	Fail	Pass	
43	Fail	Pass	Pass	Pass	Pass	Pass	
44	Fail	Pass	Pass	Pass	Pass	Pass	
45	Fail	Pass	Pass	Pass	Pass	Pass	
46	Fail	Pass	Pass	Pass	Pass	Pass	
47	Fail	Pass	Pass	Pass	Pass	Pass	
48	Pass	Fail	Pass	Pass	Pass	Pass	
49	Pass	Fail	Pass	Pass	Pass	Pass	
50	Pass	Fail	Pass	Pass	Pass	Pass	
51	Pass	Fail	Pass	Pass	Pass	Pass	
52	Pass	Pass	Pass	Pass	Pass	Pass	
53	Pass	Fail	Pass	Pass	Pass	Pass	
54	Pass	Fail	Pass	Pass	Fail	Pass	
55	Fail	Fail	Pass	Pass	Pass	Pass	
56	Pass	Fail	Pass	Pass	Pass	Pass	
57	Pass	Fail	Pass	Pass	Pass	Pass	
58	Fail	Fail	Pass	Pass	Pass	Pass	
59	Pass	Fail	Pass	Fail	Pass	Pass	
60	Fail	Fail	Pass	Pass	Pass	Pass	
61	Fail	Fail	Pass	Pass	Pass	Pass	
62	Pass	Fail	Pass	Pass	Pass	Pass	
63	Fail	Fail	Pass	Pass	Pass	Pass	
64	Fail	Fail	Pass	Pass	Pass	Pass	
65	Fail	Fail	Pass	Pass	Pass	Pass	
66	Fail	Fail	Pass	Pass	Pass	Pass	
67	Fail	Fail	Pass	Pass	Pass	Fail	
68	Fail	Fail	Pass	Pass	Pass	Fail	
69	Pass	Fail	Pass	Pass	Pass	Pass	
70	Pass	Fail	Pass	Pass	Pass	Pass	
71	Fail	Fail	Pass	Pass	Pass	Fail	
Total Pass	26	47	63	59	65	62	1244
Total Fail	45	24	8	12	6	9	672
%Pass	36.6	66.2	88.7	83.1	91.5	87.3	64.9

Bivariate Joint Distribution Evaluation within Strata

The bivariate test for normality is essentially the core of the multivariate test for normality. This is rationalized because for a distribution to be multivariate normal, all the pair-wise distributions must be bivariate normal. This approach is used in calculating the test for multivariate normality. It was decided that an appropriate test for bivariate normality was Shenton and Bowman's Omnibus test.[18] The probability of passing this test is enhanced by each variable passing the univariate test. The probability level is found from the X^2 distribution with two degrees of freedom for the univariate test and with four degrees of freedom for the bivariate test. As mentioned above, because the sample size was not large and the X^2 distribution was approximated asymptotically, failing the bivariate test at the 90% level may not mean the distribution is not approximately normal. However, failing all the univariate tests and the bivariate test with alpha probabilities much less than 0.01 (a cut-off of 0.001 was used) indicated a lack of univariate and bivariate normality. Table AI-5 shows the results of 3,900 possible bivariate tests for normality with the data stratified by year and by quarter. There were 325 tests per stratum. This number of tests was arrived at because there were 25 variables analyzed for which there are 26*25/2 combinations, or 325 bivariate tests. The overall accept rate was 22.4% for this table.

Table AI-5. Results of bivariate test for normality with stratification by year and quarter - 22.4% accept rate.

Stratum	Year	Quarter	*n*	Accept	Reject	% Accept
1	2003	1	71	133	192	40.9
2	2003	2	156	69	256	21.2
3	2003	3	90	58	267	17.8
4	2003	4	137	47	278	14.5
5	2004	1	127	72	253	22.2
6	2004	2	144	41	284	12.6
7	2004	3	84	100	225	30.8
8	2004	4	106	57	268	17.5
9	2005	1	131	91	234	28.0
10	2005	2	90	101	224	31.1
11	2005	3	172	61	264	18.8
12	2005	4	211	45	280	13.8
Total			1519	875	3025	22.4

Table AI-6 shows the bivariate test results for normality using stratification by year, quarter, and three levels of combined inspection systems. This was done in hopes of finding a shorter solution involving fewer stratification levels than a possible 72. The three levels of inspection system are IS1-HIMP+MAESTRO; IS2-MIXED+NELS+NUTECH; and IS3-SIS. The overall accept rate for this table was 39%. What is shown is that increasing the levels of partitioning increases the probability of univariate and bivariate normality. This example shows that the increase is not due to a

loss in power from reducing the sample sizes within strata, since the sample sizes are adequate to estimate the distribution moments used in the tests for normality.

Table AI-6. Results of bivariate tests for normality with stratification by year, quarter, and three combined inspection system variables - 39% accept rate.

Stratum	Year	Quarter	Inspection	*n*	Accept	Reject	% Accept
1	2003	1	IS1	22	120	205	36.9
2	2003	1	IS2	27	229	96	70.5
3	2003	1	IS3	22	1	324	0.3
4	2003	2	IS1	54	228	97	70.2
5	2003	2	IS2	65	214	111	65.8
6	2003	2	IS3	37	220	105	67.7
7	2003	3	IS1	23	11	314	3.4
8	2003	3	IS2	39	87	238	26.8
9	2003	3	IS3	28	234	91	72.0
10	2003	4	IS1	49	142	183	43.7
11	2003	4	IS2	48	20	305	6.2
12	2003	4	IS3	40	16	309	4.9
13	2003	1	IS1	53	10	315	3.1
14	2004	1	IS2	36	121	204	37.2
15	2004	1	IS3	38	207	118	63.7
16	2004	2	IS1	53	175	150	53.8
17	2004	2	IS2	54	187	138	57.5
18	2004	2	IS3	37	234	91	72.0
19	2004	3	IS1	15	2	323	0.6
20	2004	3	IS2	37	226	99	69.5
21	2004	3	IS3	32	213	112	65.5
22	2004	4	IS1	32	47	278	14.5
23	2004	4	IS2	50	192	133	59.1
24	2004	4	IS3	24	3	322	0.9
25	2005	1	IS1	51	21	304	6.5
26	2005	1	IS2	49	95	230	29.2
27	2005	1	IS3	30	274	51	84.3
28	2005	2	IS1	28	6	319	1.8
29	2005	2	IS2	29	116	209	35.7
30	2005	2	IS3	34	231	94	71.1
31	2005	3	IS1	51	60	265	18.5
32	2005	3	IS2	73	120	205	36.9
33	2005	3	IS3	48	136	189	41.8
34	2005	4	IS1	78	142	183	43.7
35	2005	4	IS2	84	188	137	57.8
36	2005	4	IS3	49	31	294	9.5
Total				1519	4559	7141	39.0

Table AI-7 shows the complete stratification as implemented in the multiple regression model. Although the overall hypothesis accept rate was 47.3%, the overall distribution approximated a multivariate normal distribution; but the accept rate is not high enough to be absolutely convincing. In order to be more certain that partitioning was aiding in detecting latent distribution information in the dataset, a final partition was employed. Although portioning by months was not used in the regression model, the dataset was partitioned by year and month bringing out detail lost due to aggregation by quarter.

Table AI-7. Bivariate normal test results for complete stratification - 47.3% accept rate.

Stratum	Year	Quarter	Inspection	*n*	Accept	Reject	% Accept
1	2003	1	HIMP	13	183	142	56.3
2	2003	1	MAESTRO	9	247	78	76.0
3	2003	1	MIXED	10	259	66	79.7
4	2003	1	NELS	17	251	74	77.2
5	2003	1	SIS	22	128	197	39.4
6	2003	2	HIMP	18	150	175	46.2
7	2003	2	MAESTRO	36	109	216	33.5
8	2003	2	MIXED	26	105	220	32.3
9	2003	2	NELS	29	198	127	60.9
10	2003	2	NUTECH	10	172	153	52.9
11	2003	2	SIS	37	115	210	35.4
12	2003	3	HIMP	3	162	163	49.8
13	2003	3	MAESTRO	20	235	90	72.3
14	2003	3	MIXED	18	215	110	66.2
15	2003	3	NELS	11	236	89	72.6
16	2003	3	NUTECH	10	187	138	57.5
17	2003	3	SIS	28	100	225	30.8
18	2003	4	HIMP	20	194	131	59.7
19	2003	4	MAESTRO	29	94	231	28.9
20	2003	4	MIXED	22	199	126	61.2
21	2003	4	NELS	15	157	168	48.3
22	2003	4	NUTECH	11	170	155	52.3
23	2003	4	SIS	40	57	268	17.5
24	2003	1	HIMP	23	171	154	52.6
25	2004	1	MAESTRO	30	78	247	24.0
26	2004	1	MIXED	14	135	190	41.5
27	2004	1	NELS	15	195	130	60.0
28	2004	1	NUTECH	7	229	96	70.5
29	2004	1	SIS	38	100	225	30.8
30	2004	2	HIMP	19	183	142	56.3
31	2004	2	MAESTRO	34	81	244	24.9
32	2004	2	MIXED	24	161	164	49.5
33	2004	2	NELS	24	178	147	54.8
34	2004	2	NUTECH	6	241	84	74.2
35	2004	2	SIS	37	91	234	28.0
36	2004	3	HIMP	3	162	163	49.8

37	2004	3	MAESTRO	12	222	103	68.3
38	2004	3	MIXED	15	159	166	48.9
39	2004	3	NELS	15	219	106	67.4
40	2004	3	NUTECH	7	191	134	58.8
41	2004	3	SIS	32	84	241	25.8
42	2004	4	HIMP	5	184	141	56.6
43	2004	4	MAESTRO	27	235	90	72.3
44	2004	4	MIXED	19	266	59	81.8
45	2004	4	NELS	17	135	190	41.5
46	2004	4	NUTECH	14	132	193	40.6
47	2004	4	SIS	24	198	127	60.9
48	2005	1	HIMP	29	106	219	32.6
49	2005	1	MAESTRO	22	173	152	53.2
50	2005	1	MIXED	28	171	154	52.6
51	2005	1	NELS	19	167	158	51.4
52	2005	1	NUTECH	2	162	163	49.8
53	2005	1	SIS	30	94	231	28.9
54	2005	2	HIMP	11	265	60	81.5
55	2005	2	MAESTRO	17	132	193	40.6
56	2005	2	MIXED	13	139	186	42.8
57	2005	2	NELS	9	180	145	55.4
58	2005	2	NUTECH	7	181	144	55.7
59	2005	2	SIS	34	58	267	17.8
60	2005	3	HIMP	18	146	179	44.9
61	2005	3	MAESTRO	33	83	242	25.5
62	2005	3	MIXED	27	125	200	38.5
63	2005	3	NELS	32	145	180	44.6
64	2005	3	NUTECH	14	113	212	34.8
65	2005	3	SIS	48	36	289	11.1
66	2005	4	HIMP	29	114	211	35.1
67	2005	4	MAESTRO	49	23	302	7.1
68	2005	4	MIXED	38	122	203	37.5
69	2005	4	NELS	36	51	274	15.7
70	2005	4	NUTECH	10	165	160	50.8
71	2005	4	SIS	49	18	307	5.5
Total				1519	10922	12153	47.3

Table AI-8 shows the results of this stratification. Although some power was lost due to decrease in the sample sizes compared to stratification by year and quarter, the overall accept rate was 86.2%. This result strongly suggests that the underlying data structure is fundamentally bivariate normal for the majority of variate pairs. It also suggests that increasing the sample size to permit additional stratification by month in the regression model and increasing the number of structural parameters in the model would lead to improved estimation.

Table AI-8. Stratification by year and month - 86.2% accept rate.

Stratum	Year	Month	Samples	Accept	Reject	% Accept

1	2003	January	24	741	59	92.6
2	2003	February	15	569	231	71.1
3	2003	March	33	760	40	95.0
4	2003	April	43	775	25	96.9
5	2003	May	71	552	248	69.0
6	2003	June	73	639	161	79.9
7	2003	July	41	683	117	85.4
8	2003	August	35	740	60	92.5
9	2003	September	24	700	100	87.5
10	2003	October	33	719	81	89.9
11	2003	November	31	746	54	93.3
12	2003	December	31	715	85	89.4
13	2004	January	14	791	9	98.9
14	2004	February	68	611	189	76.4
15	2004	March	73	577	223	72.1
16	2004	April	83	572	228	71.5
17	2004	May	55	661	139	82.6
18	2004	June	39	760	40	95.0
19	2004	July	37	703	97	87.9
20	2004	August	32	742	58	92.8
21	2004	September	27	728	72	91.0
22	2004	October	8	799	1	99.9
23	2004	November	13	800	0	100.0
24	2004	December	12	789	11	98.6
25	2005	January	38	722	78	90.3
26	2005	February	48	667	133	83.4
27	2005	March	56	656	144	82.0
28	2005	April	40	694	106	86.8
29	2005	May	26	751	49	93.9
30	2005	June	24	724	76	90.5
31	2005	July	73	546	254	68.3
32	2005	August	73	525	275	65.6
33	2005	September	68	682	118	85.3
34	2005	October	87	540	260	67.5
35	2005	November	38	672	128	84.0
36	2005	December	33	772	28	96.5
Total			1519	24823	3977	86.2

Multivariate Joint Distribution Evaluation within Strata

Unfortunately, no level of partitioning or stratification permitted the multivariate omnibus test of Shenton and Bowman[18] to be passed. The maximum Chi-square possible for $2p$ degrees of freedom, where p is the number of variates, makes $2p$ equal to 50 degrees of freedom. This means that in any stratum where all pair-wise combinations of the 25 variates are computed, eliminating all cross-product sums due to the conversion of the dataset to an orthonormal basis, the result is a sum of 25 pairs of squared terms. The statistic cannot exceed a Chi-square of 67.5 (p=0.05) or 86.7 (p=0.001). This was not

achievable with the present dataset thereby ruling out definite proof of partitioned multivariate normality. However, the argument for a joint distribution approaching multivariate normality within certain partitions and demonstrating bivariate normality in many dimensions can be made with caution.

Appendix II: Analysis of Residual Distributions

The Vose simple linear regression population model assumes, in addition to a bivariate normal distribution of the input dependent and independent variables, a normal distribution of the residual errors produced by the model.[14] Due to the difficulty in demonstrating a multivariate normal distribution for the multivariate regression model, compelling evidence for model validity can be provided by residual analysis. The residual errors are calculated as the difference between the input dependent variable logit transformed beta distributed *Salmonella* prevalence and the output or predicted logit transformed beta prevalence. The tests for normality used in Appendix I were applied to the distribution of residuals of the multivariate regression model in order to determine univariate normality for the baseline input distribution of dependent and independent variables. It is sufficient to demonstrate univariate normality for the residual errors when considering model validity. It may be possible further to demonstrate multivariate joint normality if individual regressions are considered for each of the 24 independent variables, as described in Appendix I. Multivariate normality of the residual distribution may be established by applying the respective shock levels used in the core analysis, as described in the main body of this document. One variable is evaluated at a time in the multiple regression model. The residuals are evaluated for normality at each of the shock variable levels one regression model at a time to complete an n x p matrix of residuals. The matrix can then be evaluated by the Shenton and Bowman Omnibus test[18] for multivariate normality, as described in Appendix III.

Univariate Evaluation of Residuals

The baseline multiple regression model was used to calculate the regression coefficients using the complete dataset without bootstrapping. The dependent variable was the logit of the beta distributed *Salmonella* prevalence and the independent variables were: S-1, S-3, S-4, S-5, S-6, U-1, U-3, U-4, U-5, U-6, U-8, B-1, B-3, B-4, B-5, B-6, NC-1, NC-3, NC-4, NC-5, NC-6, NC-8, ON, OFF, Volume, and the structural variables for years, quarters, and inspection systems. The predicted values of the dependent variable were subtracted from the input-dependent variable to obtain the unweighted residuals. Studentized residuals proved of no advantage and were not used. The set of residuals was subjected to the seven univariate tests for normality from the NCSS software, as outlined in Appendix I. Two of the five tests could not reject the hypothesis of normally distributed residuals at the 5% probability level. Figure AII-1 shows the histogram plot of the residuals and Figure AII-2 shows the corresponding normal probability plot. It can be concluded that the population hypothesis for multiple regression model is suitable, and that it is supported by the data used. The Martinez-Inglewicz test is the most robust test for normality among the seven tests employed and is expected to pass a marginally normal distribution at the 20% level.[18] It is remarkable that the residuals pass this test at the 5% level. The failure of the other five tests can be explained due to the marginal sample size and more sensitivity in detecting slightly skewed distributions.

Table AII-1. Univariate test results for residuals normality.

Test*	Test Value	5% Critical Value	Decision at 5% Level
Shapiro-Wilk	0.9892417		Reject normality
Anderson-Darling	2.179302		Reject normality
Martinez-Iglewicz	0.9773419	1.0024	Cannot reject normality
Kolmogorov-Smirnov	2.79E-02	0.025	Reject normality
D'Agostino Skewness	4.979506	1.96	Reject normality
D'Agostino Kurtosis	-0.776	1.96	Cannot reject normality
D'Agostino Omnibus	25.3976	5.991	Reject normality

*For a description of the tests, see Shenton and Bowman.[18]

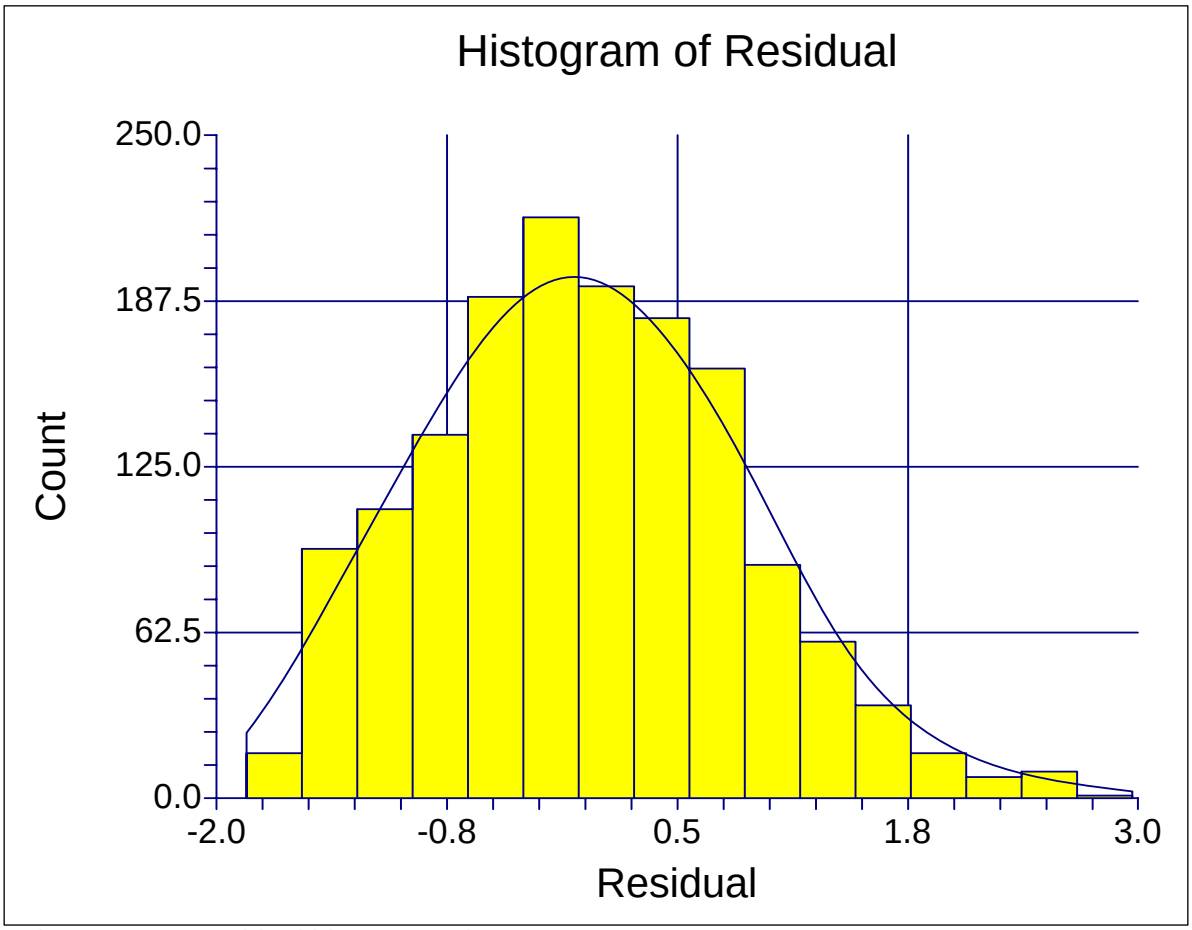

Figure AII-1. Residual histogram plot.

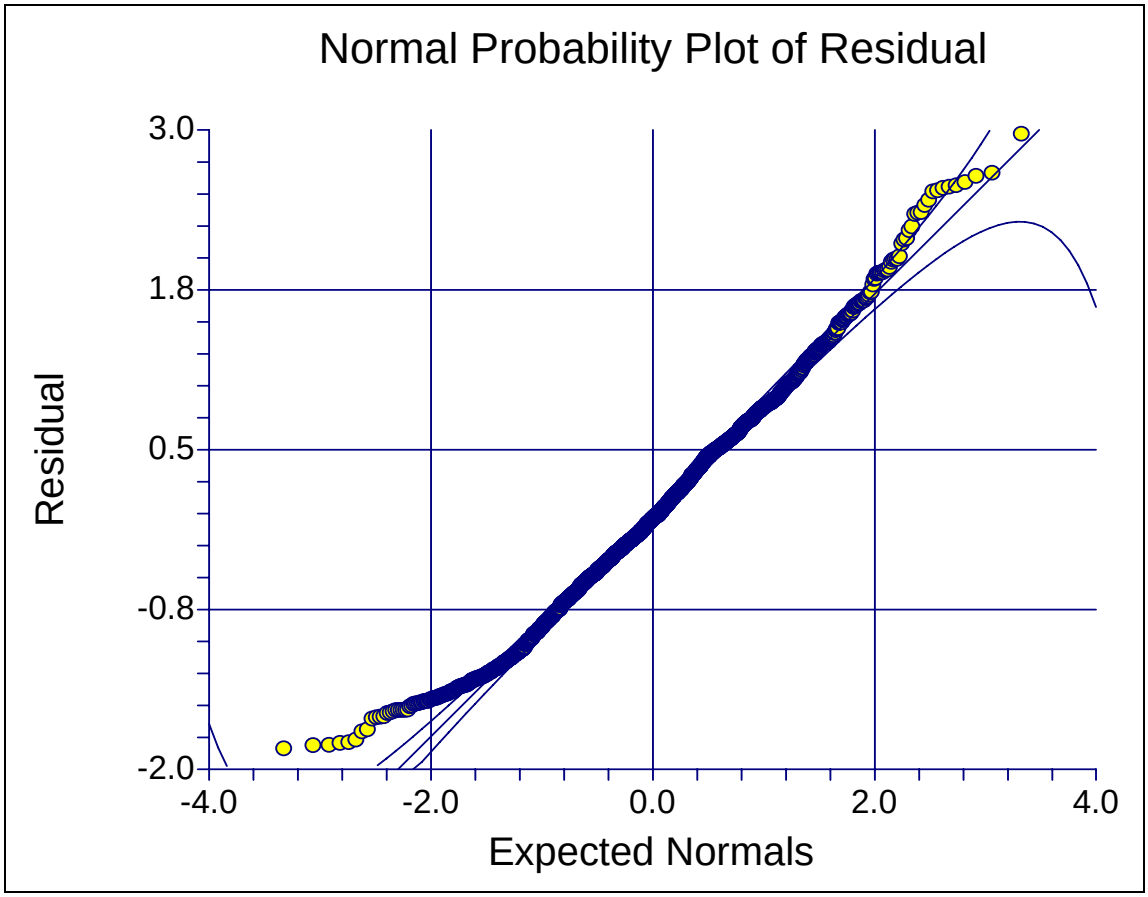

Figure AII-2. Residual normal probability plot.

Multivariate Evaluation of Residuals

It was decided to examine the multivariate properties of the residuals produced, one variable at a time, by employing the shock level used for each variable in the main body of the analysis. Twenty-five multiple regressions were evaluated for joint residual normality using sample sizes of 1,000 bootstrapped dataset points for each regression. Table AII-2 compares 50 regressions where 24 shock variables were employed. The least stringent significance level possible had only an 84% acceptance rate; it was therefore not possible to conclude absolute joint normality of the residuals. Four of the shock variable residual distributions failed to pass the Shenton and Bowman univariate test.[18] The combined Chi-square value of the 24 shock variable distributions exceeded the Chi-square critical value for joint multivariate normality. Because these tests were constructed from uncorrelated variates, the univariate Chi-squares could be combined for the joint test.

Table AII-2. Univariate uncorrelated Shenton and Bowman tests[18] for normality for bootstrapped shocked and unshocked variables.

Shock	Univariate Significance Level			No Shock	Univariate Significance Level		
Variable	**P>0.0001**	**P>0.001**	**P>0.01**	**Bootstrap**	**P>0.0001**	**P>0.001**	**P>0.01**
S1+25%	Pass	Pass	Pass	1	Fail	Fail	Fail
S3+25%	Pass	Fail	Fail	2	Fail	Fail	Fail
S4+25%	Pass	Fail	Fail	3	Fail	Fail	Fail
S5+25%	Pass	Fail	Fail	4	Fail	Fail	Fail
S6+25%	Fail	Fail	Fail	5	Fail	Fail	Fail
U1+50%	Pass	Pass	Fail	6	Fail	Fail	Fail
U3+50%	Fail	Fail	Fail	7	Pass	Fail	Fail
U4+50%	Pass	Pass	Fail	8	Pass	Fail	Fail
U5+50%	Pass	Pass	Fail	9	Pass	Fail	Fail
U6+50%	Pass	Pass	Pass	10	Pass	Pass	Fail
U8+100%	Fail	Fail	Fail	11	Pass	Pass	Fail
B1-75%	Pass	Pass	Fail	12	Pass	Pass	Fail
B3-75%	Pass	Pass	Fail	13	Pass	Pass	Fail
B4-75%	Pass	Pass	Fail	14	Pass	Pass	Fail
B5-75%	Pass	Pass	Fail	15	Pass	Pass	Fail
B6-75%	Pass	Pass	Fail	16	Pass	Pass	Fail
NC1-75%	Pass	Pass	Fail	17	Pass	Pass	Fail
NC3-75%	Pass	Fail	Fail	18	Pass	Pass	Fail
NC4-75%	Fail	Fail	Fail	19	Pass	Pass	Fail
NC5-75%	Pass	Pass	Fail	20	Pass	Pass	Fail
NC6-75%	Pass	Pass	Fail	21	Pass	Pass	Pass
NC8-75%	Pass	Pass	Pass	22	Pass	Pass	Pass
On-5%	Pass	Pass	Fail	23	Pass	Pass	Pass
OFF+25%	Pass	Fail	Fail	24	Pass	Pass	Pass
Baseline	Pass	Pass	Pass	25	Pass	Pass	Pass
Pass	21	16	4	Pass	19	16	5
Fail	4	9	21	Fail	6	9	20
Pass%	84.0	64.0	16.0	Pass%	76.0	64.0	20.0

Table AII-2 indicates that the bootstrapping employed in obtaining the regression results in the main body of the document produced at least 84% normality in the shocked variable assessment and a similar level of acceptance for non-shocked bootstrapped residual results. This is added evidence that the multiple regression population model has been appropriately applied.

Appendix III: Univariate and Joint Omnibus Test for Normality

The univariate and joint omnibus test for normality developed by Shenton and Bowman[18] uses the definition of distribution moments to define skewness and kurtosis variables termed b_1 and b_2 respectively. The moments are

$$u_1 = \Sigma x / n = \text{mean}$$

$$u_2 = \Sigma (x - \text{mean})^2 / n$$

$$u_3 = \Sigma (x - \text{mean})^3 / n$$

$$u_4 = \Sigma (x - \text{mean})^4 / n$$

where skewness is defined as

$$\sqrt{b_1} = u_3 / u_2^{3/2}$$

and kurtosis is defined as

$$b_2 = u_4 / u_2^2$$

The problem of small sample size is dealt with by using transformations for the skewness and kurtosis variables, since an approximate solution that is slowly convergent is found from the formula for *Ep*:

$$Ep = n\, b_1 / 6 + n\, (b_2 - 3)^2 / 24$$

The distribution of *Ep* is Chi-square with 2 degrees for freedom. The univariate test is achieved by computing the skewness and kurtosis parameters which are transformed by D'Agostino's method for skewness and transformation[18] from a gamma distribution to a Chi-square distribution is used for the kurtosis which is then translated to standard normal using the Wilson-Hilferty cubed root transformation.[18] This permits the conversion of $\sqrt{b_1}$ to Z_1 and b_2 to Z_2. Since the new variables are uncorrelated, a simple sum of squares of the two new variables has the required Chi-square distribution with 2 degrees of freedom.

$$Ep = Z_1^2 + Z_2^2$$

The bivariate and multivariate cases of this method proceed from the univariate case analogously. In the bivariate case is a special case of the multivariate solution. The original variables are termed *X* as an *n* x *p* matrix of *n* rows and *p* columns corresponding to the sample size *n* and the number of variates *p*. The original variables are transformed

to standard normal by subtracting the mean and dividing by the standard deviation. An orthonormal set of variates is then created easily using the matrix transformation to a dataset that has all pair-wise correlations equal to zero. The *Ep* statistic with 2p degrees of freedom will equal

$$Ep = n\,\mathbf{B_1}'\,\mathbf{B_1}/6 + n\,(\mathbf{B_2} - 3i)'\,(\mathbf{B_2} - 3i)\,/\,24$$

Where $\mathbf{B_1}'$ is the row vector of p $\sqrt{b}1$ variates and $\mathbf{B_2}$ is the column vector of p $b2$ variates. Again, since the above formula applies to only very large samples, the use of the skewness and kurtosis transformations is employed in order to arrive at

$$Ep = \mathbf{Z_1}'\mathbf{Z_1} + \mathbf{Z_2}'\mathbf{Z_2}$$

where $\mathbf{Z_1}'$ is the row vector of transformed p $\sqrt{b_1}$ variates and $\mathbf{Z_2}'$ is the row vector of transformed p b_2 variates.

In the case of the regression model, the bivariate tests involved the transformed sums of the four squares of $\sqrt{b_1}$ and b_2 for pairs of the 25 variates of concern whose sum of squares must not exceed a Chi-square with 4 degrees of freedom within any partition. In the multivariate case, the 25 x 2 sums of squares of the 25 variates of concern in any partition cannot exceed a Chi-square with 50 degrees of freedom. The overall distribution test for the completely partitioned regression model would involve *m* x 50 degrees of freedom, where *m* is the number of partitions for a final Chi-square summed over all partitions.

Appendix IV: Graphical representation of Wald Score Results from 20,000 model iterations

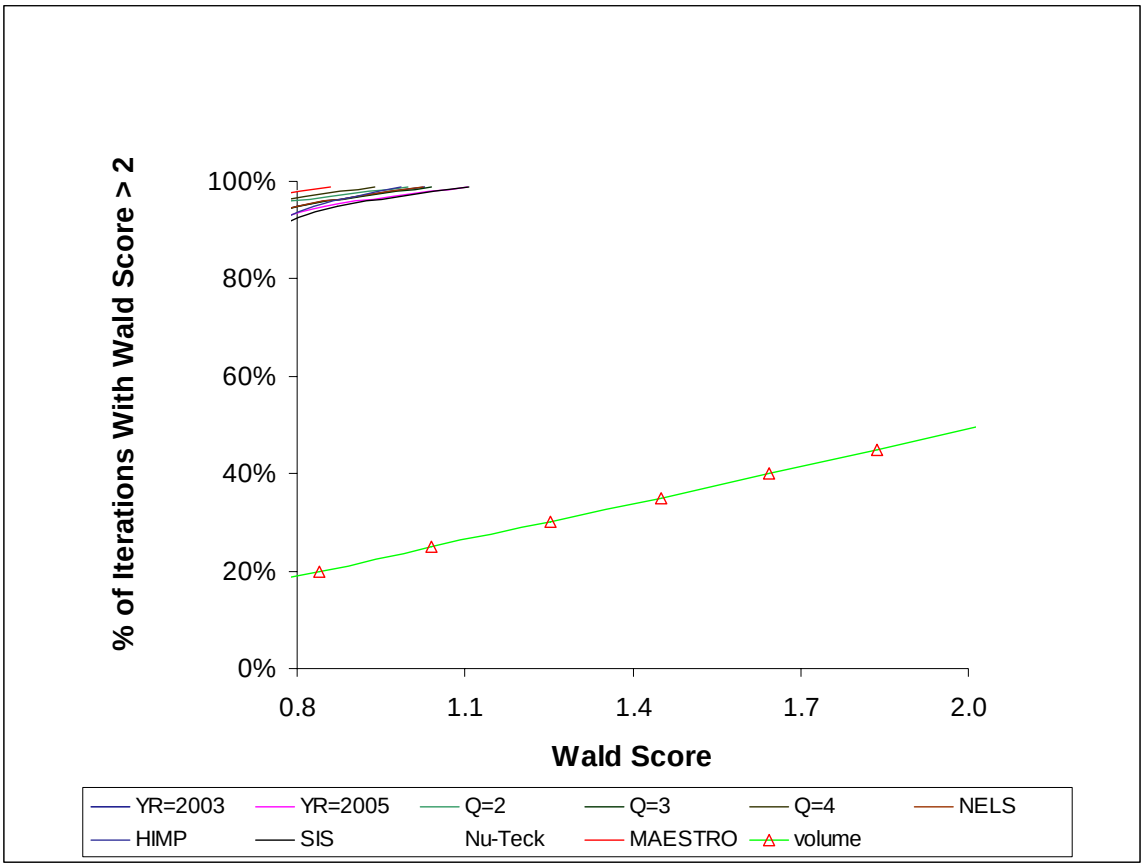

Figure AIV-1. Distribution of Wald test scores for structural parameters in the model.

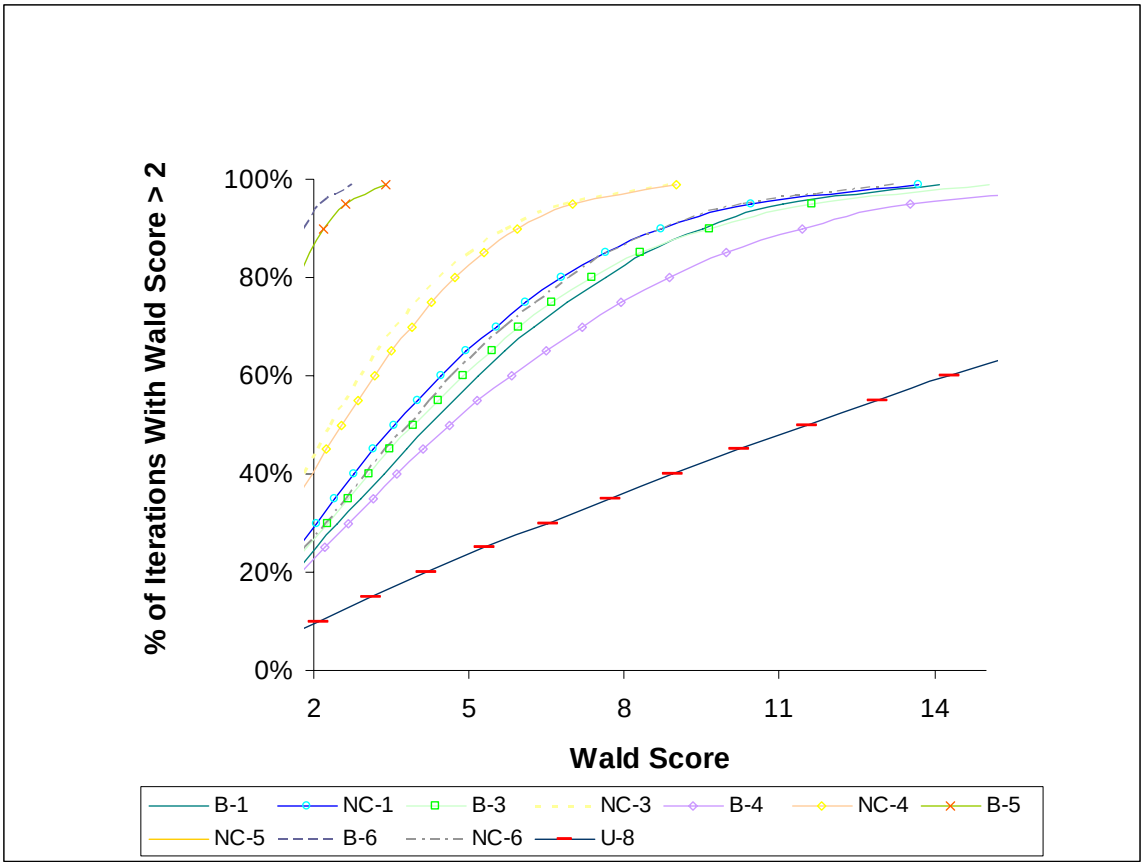

Figure AIV-2. Distribution of Wald test scores for performance tracking parameters in the model.

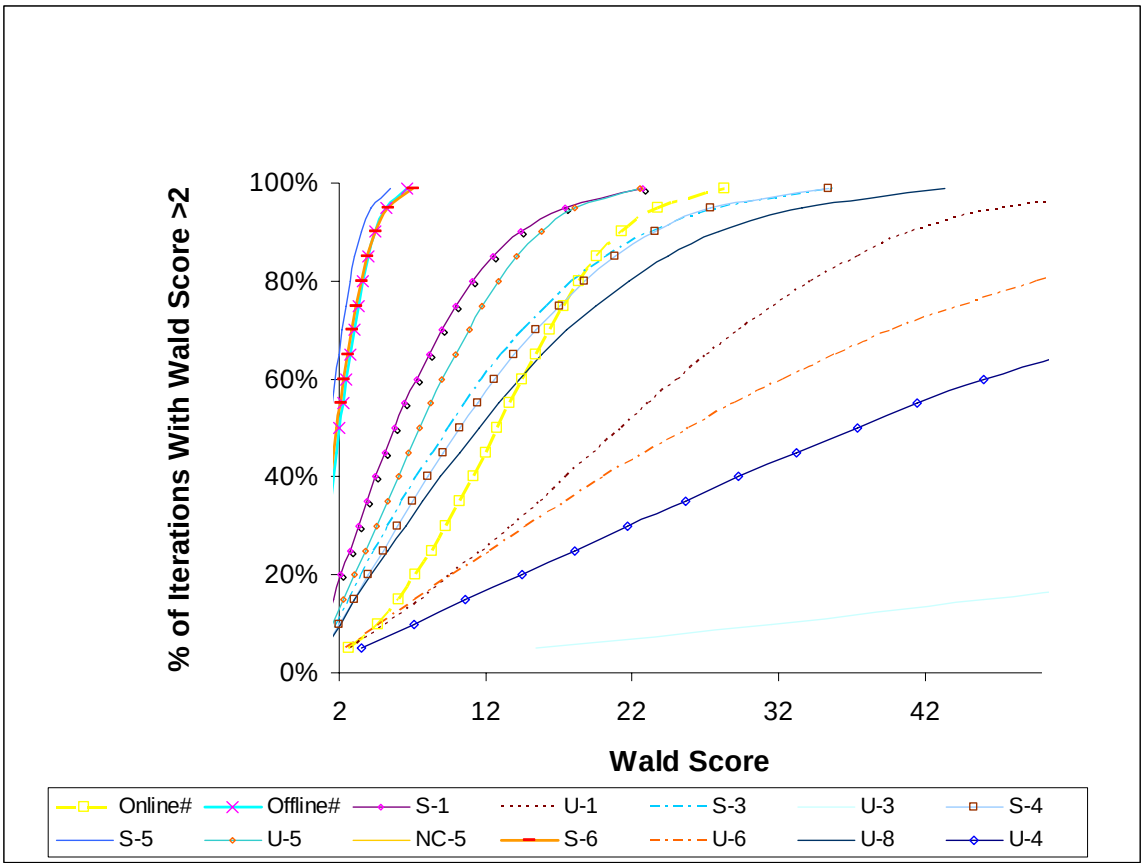

Figure AIV-3. Distribution of Wald test scores for decision parameters in the model.

References

1. National Academy of Sciences. Meat and poultry inspection: the scientific basis of the nation's program. 1985. Washington, DC, National Academy Press.

2. National Academy of Science. Poultry inspection: the basis for a risk assessment approach. 1987. Washington, DC, National Academy Press.

3. National Academy of Sciences. Ensuring safe food from production to consumption. 1998. Washington, DC, National Academy Press.

4. Cates SC, Anderson DW, Karns SA, Brown PA. Traditional versus hazard analysis and critical control point-based inspection: results from a poultry slaughter project. J Food Prot 2001;64:826-32.

5. Hong Y, Berrang ME, Liu T, Hofacre CL, Sanchez S, Wang L, *et al.* Rapid detection of *Campylobacter coli*, *C. jejuni*, and *Salmonella enterica* on poultry carcasses by using PCR-enzyme-linked immunosorbent assay. Appl Environ Microbiol 2003;69:3492-9.

6. Zhao C, Ge B, De Villena J, Sudler R, Yeh E, Zhao S *et al.* Prevalence of *Campylobacter* spp., *Escherichia coli*, and *Salmonella* serovars in retail chicken, turkey, pork, and beef from the Greater Washington, D.C., area. Appl Environ Microbiol 2001;67:5431-6.

7. Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C *et al.* Food-related illness and death in the United States. Emerg Infect Dis 1999;5:607-25.

8. Centers for Disease Control and Prevention. Preliminary FoodNet data on the incidence of infection with pathogens transmitted commonly through food--10 sites, United States, 2004. MMWR Morb Mortal Wkly Rep 2005;54:352-6.

9. Centers for Disease Control and Prevention. FoodNet Annual Report. 2003. Atlanta. Department of Health and Human Services.

10. U.S. Census Bureau. National population dataset. 2003. Washington, DC. U.S. Census Bureau.

11. Batz MB, Hoffmann SA, Krupnick AJ, Morris JG, Sherman DM, Taylor MR, and Tick JS. Identifying the most significant microbiological foodborne hazards to public health: a new risk-ranking model. 2004. Resources for the Future. Discussion Paper Series. Number 1. September. Washington, DC, Resources for the Future.

12. Hoffmann S, Krupnick A, and Fischbeck P. Expert elicitation for foodborne illness attribution. Food safety interventions and food attribution workshop. 2005. Washington, DC, Resources for the Future.

13. Economic Research Service. Food availability: spreadsheets. 2004. Washington

DC, Department of Agriculture.

14. Vose D. Risk analysis: a quantitative guide, 2nd ed. 2000. New York, John Wiley & Sons, Ltd.

15. Hosmer DW, Lemeshow S. Applied logistic regression. 1989. New York, John Wiley and Sons, Ltd.

16. Draper NR, Smith H. Applied regression analysis, 3rd ed. 1998. New York, John Wiley & Sons, Ltd.

17. Number Cruncher Statistical Systems. Statistical system for windows. 2004. Kaysville, Utah.

18. Powell, M.R., Ebel, E., Schlosser, W., Walderhaug, M., and Kause, J. Dose-Response Envelope for *Escherichia coli* 0157:H7. Quantitative Microbiology 2, 141-163, 2000.

19. Shenton LR, Bowman KO. A bivariate model for the distribution of *b*1 and *b*2. Journal of the American Statistical Association 1977;72:206-11.