

Recalled food products and foodborne illnesses: Quantifying prevented illnesses
and evaluating factors influencing the amount of product recovered

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Dedication

This dissertation is dedicated to my late grandfather, Arthur Lindberg, who first steered me in the direction of higher education; to my grandmother, Alice Lindberg, my shining model of perseverance and tenacity; and to my three sons, who have taught me so much about patience, love, and what's truly important...

Abstract

In the United States, a number of government agencies are responsible for overseeing the recall of consumer products. However few agencies, such as the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), collect and publicly release recall-specific information on the amount of product recovered following a recall. Data on the amount of recalled food products recovered can be used by public health officials and researchers to analyze the effectiveness of recalls, examine the consequences of removing contaminated product from commerce, and evaluate opportunities for preventing additional exposures and illnesses.

Meat and poultry product recall data associated with Shiga toxin-producing *Escherichia coli* (STEC) O157 and *Salmonella* contamination were used to develop quantitative models to estimate the number of illnesses prevented by recalls. The number of illnesses prevented was based on the number of illnesses that occurred relative to the number of pounds consumed, then extrapolated to the number of pounds of recalled product recovered. Recalls, although reactive in nature, are an important tool for averting further exposure and illnesses.

Recall data were also examined to assess factors associated with recovery of meat and poultry products following recalls. The amount of recalled product recovered following a recall action was dependent on a number of factors including the complexity of distribution, type of distribution, type of product, reason for the recall, amount of time between production and recall dates, and the number of pounds of product recalled. Illness-related recalls were likely impacted by larger amounts of product, broader scopes,

and delays from epidemiologic and traceback investigations, which would involve unraveling distribution chains, therefore impacting the amount of time involved and number of pounds recalled.

Data and system improvements are recommended to further refine future analyses while improved traceability and investigation efficiencies are recommended to further prevent foodborne illnesses. The results further illustrate the public health benefits of recalls and provide an improved understanding of the significance of the amount of product recovered following a recall.

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Chapter 1. Introduction

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency within the United States Department of Agriculture (USDA) responsible for the safety of meat, poultry, and egg products nationwide (1). It is estimated that 9.4 million episodes of foodborne illness, including 55,961 hospitalizations and 1,351 deaths, caused by 31 known pathogens, are acquired each year in the United States (2). Due to the nature of the products regulated by FSIS, much of the agency focus is on five of those pathogens: *Campylobacter* species, *Listeria monocytogenes*, *Salmonella enterica*, Shiga toxin-producing *Escherichia coli* (STEC) O157, and non-O157 STEC. While *Campylobacter* and *Salmonella* infections account for a large number of foodborne illnesses (Tables 1.1, 1.2), STEC O157 continues to be an important pathogen targeted by agency programs and policies due in part to its association with beef products and the severity of illnesses.

When illnesses are potentially associated with FSIS-regulated products, agency investigators coordinate with the Centers for Disease Control and Prevention (CDC); local, state, or territorial public health, environmental health, or agriculture departments; and other agencies as needed to conduct a foodborne illness investigation. The general steps of an FSIS foodborne illness investigation are presented in Figure 1.1. If there is evidence from an investigation that an FSIS-regulated product contains a pathogen or is harmful to health, a recall committee is convened and agency action is considered (3). Illness-related recalls are classified as class 1 which indicates a situation where there is a “reasonable probability” that consumption of product could lead to adverse health

consequences or death (4). Class two recalls indicate a “remote probability” of adverse consequences and class three are thought to not cause adverse health consequences (4). Recalls are conducted for a number of different reasons such as illnesses, undeclared ingredients and mislabeling, extraneous materials, underprocessing, pathogen testing, and residues.

When a recall occurs, FSIS coordinates with the establishment to determine the scope of the recall, conducts effectiveness checks to ensure product is removed from commerce, and distributes public notification (4). Public notification of recalls is provided to public health and agriculture officials, media outlets, and other interested parties, and is also posted to the FSIS website. Following the recall action, the quantity of product recovered by the establishment is also obtained and posted to the FSIS website.

In the United States, a number of government agencies are responsible for overseeing the recall of consumer products, from food products to boats and motor vehicles to environmental products such as pesticides. However fewer agencies, such as FSIS, collect and publicly release recall-specific information on the amount of product recovered following the recall (4). Data on the amount of recalled food products recovered can be used by public health officials and researchers to analyze the effectiveness of recalls and examine the consequences of removing contaminated product from commerce.

Evaluations of recall effectiveness have traditionally focused on the comprehensiveness, effectiveness, and speed of removing contaminated product from commerce (5,6). However, several studies have focused on the public health benefits and

attempted to estimate the number of illnesses averted by the recall (C.W. Hedberg unpublished data). Hartnett developed a model focused on food defense examining the response to an event of intentionally-contaminated food products (7). One of three components of the model was the public health authority response which included exposures averted due to consumer compliance with advisories (7). A smaller scale economic analysis of a single state laboratory-based surveillance system has also been conducted (8). However, due to a lack of data to be used in determining the number of cases averted, researchers instead calculated threshold values to determine if the system was cost beneficial (8).

Traceback of foods suspected to be causing foodborne illness clusters is essential for identifying sources and vehicles of transmission to subsequently control affected product and prevent additional illnesses; however, increasing complexity of food supply chains can make product tracing more challenging. FSIS regulatory actions for illnesses linked to STEC-contaminated products were found to be associated with whether local, state, or federal agencies conducted traceback investigations (9). Integrating results of both the epidemiologic investigation and traceback information is critical (10). In the meat industry, many producers have developed more precise product tracing capabilities due to heightened awareness of the impact of traceability on outbreaks and food safety (11). However, limitations to effective and efficient traceback investigations of meat products still remain, such as poor recordkeeping at retail establishments that grind beef products, which may delay recalls and other mitigating factors (12).

Rapid detection of foodborne illness clusters by surveillance systems is also critical for preventing illnesses. However, resources available at the local and state levels along with staff expertise and interest, substantially impact the variability of jurisdictions' detection capabilities (13). Collaborative efforts such as FoodNet, the Foodborne Diseases Active Surveillance Network, and EHS-Net, the Environmental Health Specialists Network, have built capacity in the detection of foodborne diseases in participating sites (14). However, the majority of jurisdictions in the United States rely on other local, state, and federal funding sources. A Council to Improve Foodborne Outbreak Response (CIFOR) multidisciplinary workgroup created foodborne outbreak guidelines targeted at aiding government agencies, which specifically include outbreak detection guidelines as well as critical performance measures for public health agencies (15).

In 2010, the Council of State and Territorial Epidemiologists (CSTE) conducted a study of epidemiologic capacity in the United States (16). All respondents reported barriers to investigating foodborne illnesses with delayed notification, lack of staff, and low prioritization of foodborne illness investigations as the top three obstacles (16). CSTE has made a recommendation to increase the foodborne epidemiology and surveillance infrastructure at state and local levels (16).

The American Public Health Association is one of many organizations drawing attention to threatened funding for public health programs (17). When infrastructure is an issue, it's important to quantify the effects of public health programs, the significance of prevention, and the consequences of an eroding public health system.

Deficiencies in federal-level recall activities have been recently noted. A 2004 report by the United States Government Accountability Office (GAO) focused on the recall programs of FSIS and the Food and Drug Administration (FDA) as a result of two multi-state outbreaks in 2003 that led to large recalls (18). The GAO investigators reported that there were weaknesses in each agency's recall programs that "heighten the risk that unsafe food will remain in the food supply and ultimately be consumed" (18). Furthermore, during the investigation, staff from both agencies reported not knowing how promptly and completely companies were recalling products (18). This report followed a GAO report from 2000 with similar findings (19).

In 2009, the President's Food Safety Working Group identified three principles to guide the development of a food safety system (20). Two of those principles are relevant to this project: Principle 2: Effective food safety inspections and enforcement depend upon good data and analysis, and Principle 3: Outbreaks of foodborne illness should be identified quickly and stopped (20). These principles were used as a foundation for workgroup recommendations and a myriad of actions and deliverables, including those for STEC O157 and national traceback and response systems (20).

Table 1.1. Estimated Yearly Number of Foodborne Illnesses in the United States, Selected FSIS-focused Pathogens of Interest

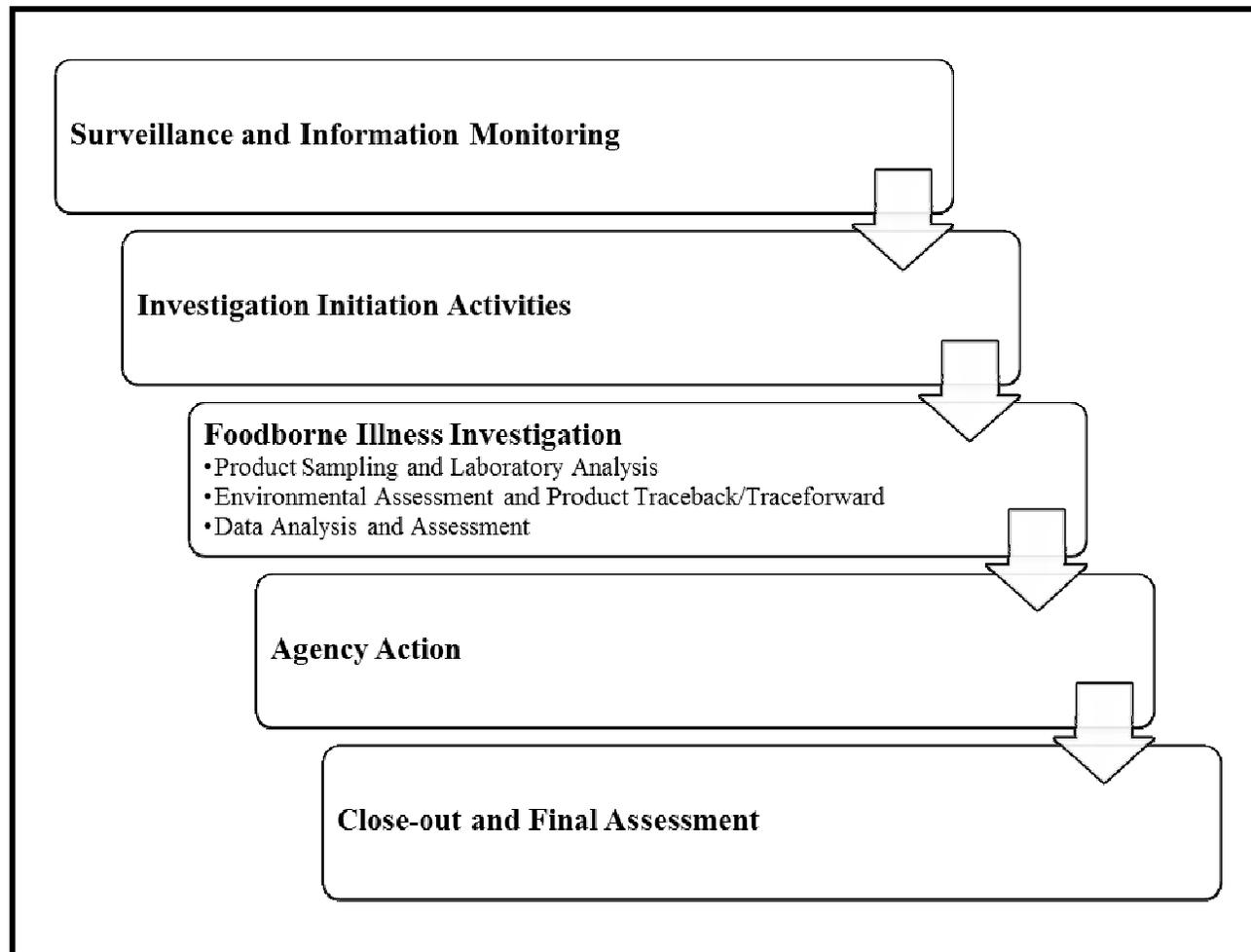
(2)

	Domestically acquired foodborne, mean	Hospitalizations, mean	Deaths, mean
<i>Campylobacter</i> spp.	845,024	8,463	76
<i>Listeria monocytogenes</i>	1,591	1,455	255
<i>Salmonella</i> spp., nontyphoidal	1,027,561	19,336	378
STEC non-O157	112,752	271	0
STEC O157	63,153	2,138	20

Table 1.2. Total Reported Foodborne Outbreaks in the United States, Selected FSIS-focused Pathogens of Interest, 2012 (21)

	Outbreaks	Illnesses	Hospitalizations
<i>Campylobacter</i> spp.	37	476	29
<i>Listeria monocytogenes</i>	5	42	38
<i>Salmonella</i> spp., nontyphoidal	113	3,394	454
STEC O157 and non-O157	29	500	98

Figure 1.1. Steps Involved in an FSIS Foodborne Illness Investigation (3)



Chapter 2. Assessment of Shiga Toxin-producing *Escherichia coli* O157 Illnesses Prevented by Recalls of Beef Products

This study aimed to develop models to quantify Shiga Toxin-producing *Escherichia coli* (STEC) O157 illnesses prevented by recalls of beef products from 2005 through 2012 incorporating methods to address the inherent uncertainty in the public health data. The results from the study will be used to evaluate the public health benefits of recalls and provide a straightforward framework for modeling of food recalls.

Materials and Methods

Recall and Illness Data

We obtained data from recalls carried out by FSIS-regulated establishments from 2005 through 2012. A spreadsheet was created to include illness-related recalls due to STEC O157 and beef products. Specific data fields included the FSIS recall number; number of pounds recalled; reason for the recall; whether the product was distributed to hotels, restaurants, or institutions (HRI); and the pounds of recalled product recovered.

CDC maintains the Foodborne Disease Outbreak Surveillance System (FDOSS) which collects data on foodborne illness outbreaks reported in the United States (22). The FSIS recall data were cross-referenced with FDOSS data from 2005 through 2011 to incorporate illness data. As FSIS may initiate an investigation for even single illnesses associated with FSIS-regulated product, we utilized FSIS data for those specific circumstances and for recalls without corresponding FDOSS data.

As shown in Figure 2.1, the number of illnesses prevented was estimated from the number of illnesses that occurred, relative to the number of pounds consumed and recovered. Loss-adjusted food availability 2012 estimates from the U.S. Department of Agriculture, Economic Research Service were used to estimate the amount of product discarded (23). For products distributed to HRI, consumers, or both HRI and consumers, we used factors of 20%, 24%, and 20% product loss, respectively, to estimate the amount of food loss.

Deterministic Model and Beta, PERT, and Expert Elicitation Simulation Models for Illness-related Recalls

For the deterministic model, we used FSIS recall data to calculate the percent of recalled product that was recovered, number of pounds of product consumed, rate of illnesses per 100,000 pounds of product consumed, and number of illnesses prevented using point estimates. The sum of the number of illnesses prevented by all illness-related recalls of beef products due to STEC O157 conducted from 2005 through 2012 was determined.

We used the Beta probability distribution to describe the uncertainty around the number of illnesses prevented from the deterministic model, relying on the foundational equation presented in Figure 2.1, but using the percent of recalled product recovered for the simulation. The Beta distribution was characterized by two shape values, α_1 and α_2 in the equation: Beta (α_1, α_2). The α_1 was defined by the number of pounds of recalled product recovered and α_2 was defined by the number of pounds recalled minus the number of pounds of recalled product recovered.

The uncertainty related to the percentage of pounds of recalled product recovered was expressed by a Program Evaluation and Review Technique (PERT) probability distribution due to the nature of the STEC O157 illness-related recall data that are bounded at zero and one, with a distribution that is skewed with a long tail to the right (Figure 2.2). We gathered descriptive information about two recalls that had a percentage of product recalled more than two standard deviations above the mean. Data on one recall reporting the highest product recovery (92%) was excluded from being the maximum value in the PERT simulation due to concerns with comingling of non-recalled beef products.

The foundational equations from Figure 2.1 were modified to estimate the number of illnesses prevented using a PERT distribution with the equation: Pert (minimum value, most likely value, maximum value). The values were defined as a minimum of zero, most likely value of 9.7% which was the overall percentage of recalled product recovered across all illness-related recalls combined, and maximum of 84.5% corresponding to the maximum product recovered in an illness-related recall, excluding the 92% outlier.

In order to compare and contrast the deterministic, Beta simulation, and PERT simulation models, we chose to elicit the opinions of experts in beef production and/or recalls of food products. Six experts were asked by email survey to estimate the most likely value and 90% credible interval for the total percentage of recalled product that is discarded and returned by consumers, retail stores, hotels, restaurants, institutions, or other establishments as a result of a recall. Using a recommended method of Vose (24), the expert opinions were combined into a single discrete distribution with the equation:

Discrete ($\{x_i\}$, $\{p_i\}$) where x_i are the PERT distributions of the expert estimates and p_i are the equal weights given each expert. The distribution from the expert elicitation was substituted as the percentage of recalled product that was recovered.

For each of the three simulations, Beta, PERT, and expert elicitation, Latin Hypercube sampling was conducted with 10,000 iterations using @RISK for Excel version 6.1.2 (Palisade Corporation, Ithaca, NY, USA). The number of illnesses was expressed as the mean and 95% credible interval.

Non-illness Recalls of Beef Products due to STEC O157

The deterministic model and simulations used data from illness-related recalls of beef products due to STEC O157. This methodology allowed us to use the number of illnesses that occurred relative to the number of pounds of product consumed and recovered following the recall action. In order to assess a more complete picture of the illnesses prevented, we used the mean and median number of illnesses per 100,000 pounds of product consumed calculated from each of the illness-related recall models to estimate the number of illnesses prevented by non-illness-related recalls. The mean and median were multiplied by the total pounds of recalled product that were reported as recovered for the non-illness recalls. Finally, we graphically examined all recalls of beef products due to STEC O157 from 2005 through 2012. We further divided the recalls into triads based on the percent of product recovered to evaluate the likelihood of illness in a recall based on the percentage of recalled product recovered using SAS for Windows version 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

A median of 64 recalls (range 34-103 recalls) of FSIS-regulated products occurred each year based on data from 2005 through 2012. Each year, from 5 to 22 (median 13) recalls were due to STEC and a total of 27 (median 3 each year, range 0 to 10) of those were STEC O157 illness-related recalls of beef products.

Among the 27 illness-related recalls, an estimated 39 million total pounds (median 154,000 pounds per recall) of beef products were recalled. An estimated 4 million total pounds (median 5,000 pounds per recall) of recalled beef products were recovered. This represents 9.7% of recalled product recovered overall for the 8-year study period.

As anticipated, there was great variability in the amount of beef product recovered following a recall. While the median percentage of beef product recovered by each recall was 5%, the mean percentage was 19% and the range was from 0% to 92%. The bounded distribution was skewed with a large number of illness-related recalls with a small amount of recovered product on the left and a long tail to the right with few recalls with a large amount of recovered product (Figure 2.2). A total of 517 STEC O157 illnesses (median 9, range 1-79) were reported as associated with the 27 recalls.

Deterministic Model and Beta, PERT, and Expert Elicitation Simulation Models for Illness-related Recalls

Table 2.1 lists the individual results of the estimated number of illnesses prevented by illness-related recalls in the 2005-2012 period. Figure 2.3 graphically illustrates the results of all four models using a modified boxplot design. The “whiskers”

for the Beta and PERT probability distribution simulations as well as for the expert elicitation model show the minimum and maximum values. The box outlines the 95% credible intervals, divided in two by the mean for the simulation.

The number of illnesses prevented by an individual recall ranged from 0 to 291 illnesses (mean 27 illnesses) for the deterministic model. Over the 27 illness-related recalls, an estimated total of 725 illnesses were prevented. Two recalls in particular, both from 2009, each contributed more than 260 prevented illnesses to the total calculation due in part to a high percentage of recalled product recovered.

Using the Beta probability distribution, we found that the total number of illnesses prevented over the 8-year study period was 726 (95% credible interval 684-774). The number of illnesses prevented by an individual recall resulted in a minimum of zero and a maximum of 291 prevented illnesses.

Using the PERT probability distribution for simulation of the percentage of product recovered, we found that the total number of illnesses prevented over the 8-year study period was 204 (95% credible interval 117-333). The number of illnesses prevented by an individual recall resulted in a minimum of zero and a maximum of 32 prevented illnesses. The two recalls from 2009 contributing the largest number of prevented illnesses in the deterministic model and Beta probability distribution simulation were much more muted, totaling 23 prevented illnesses.

Three of six individuals responded to our expert elicitation request, one representing the government sector and two representing the industry perspective. The expert values provided were minimum values of 0.5%, 1%, 5%; most likely values of

2%, 5%, 15%; and maximum values of 4%, 10%, 25%, respectively. Using expert opinion for the percent of product recovered, the total number of illnesses prevented over the 8-year study period was 56 (95% credible interval 28-99). The number of illnesses prevented by an individual recall resulted in a minimum of zero and a maximum of nine prevented illnesses.

Non-illness Recalls of Beef Products due to STEC O157

From 2005 through 2012, a total of 63 recalls of beef products due to STEC O157 occurred without reported illnesses. Of those, one recall did not have an estimated amount of product recalled and was excluded. For multiple recalls, where the amount of recalled product reported as recovered exceeded 100%, we adjusted the amounts to reflect a maximum of 100% of product recovered. The remaining 62 recalls accounting for an estimated total of 9.5 million (median 5,000) pounds of recalled product are presented in Figure 2.2 compared against the illness-related recalls of beef products due to STEC O157. While both types of recalls had a relatively large number where less than ten percent of product was recovered, the non-illness-related recalls have a strikingly dissimilar “U-shaped” distribution compared to the right-skewed distribution of illness-related recalls. Additionally, the recalls not associated with illnesses had a higher percentage of recovered product. An estimated total of 1.2 million (mean 19,000) pounds of product were recovered from all 62 recalls leading to a mean of 49% and median 46% for the percentage of product recovered.

The number of prevented illnesses estimated for the recalls not associated with illnesses varied depending on the model and whether the mean or median number of

illnesses per 100,000 pounds of product consumed were used. The largest number of prevented illnesses was estimated as 14,286 illnesses and resulted from using the mean of 1,199 illnesses per 100,000 pounds of product consumed from the Beta probability distribution simulation model. The smallest number, 71 prevented illnesses, resulted from using the median of 6 illnesses per 100,000 pounds of product consumed from the Beta probability distribution and expert elicitation simulation models. Using the median of 7 illnesses per 100,000 pounds of product consumed from the PERT probability distribution simulation model, there were an estimated 83 prevented STEC O157 illnesses.

All recalls (i.e., illness-related and non-illness-related recalls) were divided into similar triads of 29 recalls in the 0-10% product recovery range (triad 1), 32 recalls in the 10-60% range (triad 2), and 28 recalls in the 60-100% range (triad 3). The percent of all recalls that were illness-related decreased from 48% in triad 1 to 31% and 11% in triad 2 and triad 3 respectively. Conversely, the percent of recalls that were not illness-related increased from 52% in triad 1 to 69% and 89% in triad 2 and triad 3 respectively (chi-square for trend 9.4, $p=0.002$).

Discussion:

In 2000, public health prevention goals for 2010 were established to reduce the incidence of STEC O157:H7 infections from a baseline of 2.1 cases per 100,000 population to 1.0 cases per 100,000, and the number of foodborne outbreaks from 10 to 5 (25). In 2010, the Foodborne Diseases Active Surveillance Network (FoodNet) reported

the successful achievement of the goal with an incidence of 0.9 cases per 100,000 population, but 24 foodborne outbreaks were reported to FDOSS (22,26). From 2007 through 2010, beef was consistently within the top three commodities associated with outbreak-related illnesses, and STEC O157 in beef was within the top three pathogen-commodity pairs among outbreak-related illnesses (22,27,28). By 2011 and 2012, the latest years with published data, a total of 801 and 831 foodborne disease outbreaks were reported respectively, of which only 17 and 24 were caused by STEC O157 infections (21,29). Beef was associated with 11 outbreaks in each of the two years, accounting for 118 illnesses in 2011 and 232 illnesses in 2012, but STEC O157 associated with beef consumption was not within the top five pathogen-food category pairs in 2011 or 2012 (21,29).

Ground beef remains a staple of the American diet. In 2006-2007, 75% of respondents to a FoodNet survey reported consuming a ground beef product; 18% reported consuming it with a pink color, which may indicate it is undercooked (30). These behaviors demonstrate an ongoing risk of illness from sporadic contamination of ground beef.

As the number of STEC O157 illness outbreaks associated with beef products declines, the need for robust surveillance and food monitoring programs will continue. Improving the speed and effectiveness of public health investigations to identify contaminated sources and subsequently take public health actions, such as recalls, is essential. Enhancing our knowledge of the public health benefits of recalls could provide motivation to improve foodborne illness investigations and recall actions.

We used several models to estimate the number of illnesses prevented by recalls of beef products due to STEC O157. While the estimates resulting from the deterministic and Beta distribution models represented a large number of prevented illnesses, we believe the PERT estimates to be a more accurate indicator of the illnesses prevented. The number of prevented illnesses using the deterministic and Beta models was heavily influenced by the number of pounds recovered. As was documented for one recall in 2009, co-mingling of products likely impacted the number of pounds reported as recovered. Additionally, the estimates for number of illnesses prevented for illness-related recalls from the expert elicitation model overlay the data from the PERT estimates.

Our results for recalls that were not associated with illnesses strongly suggest that removing product from commerce is a key determinant of illness risk. The “U-shaped” distribution of the percentage of product recovered suggests that effectively preventing foodborne illnesses from occurring may be dependent on ensuring that contaminated product is recalled and recovered quickly. FSIS recommendations and policies for keeping contaminated product out of commerce, such as not applying the mark of inspection pending certain test results, which requires establishments to control product tested by FSIS for STEC O157 and other pathogens (31), may have more public health benefits than originally estimated.

We recognize that a small fraction of infectious diseases are diagnosed and reported to public health professionals. Scallan estimated multipliers of 1.0 for under-reporting and 26.1 for under-diagnosis for STEC O157 infections (2). We applied these

multipliers to the PERT distribution results in order to estimate the total possible illnesses prevented. From 2005 through 2012, for illness-related recalls, an estimated 5,300 STEC O157 illnesses were prevented. For non-illness-related recalls, the estimated total is 2,200 STEC O157 illnesses prevented.

In order to improve the models and increase the precision of the estimates, there are a number of steps to be taken. The amount of product recovered is reported from an establishment to FSIS. Although a certain amount of uncertainty is inherent, more accurate estimates are needed from the entirety of the reporting chain from grocers, hotels, restaurants, institutions, distributors, and establishments. Furthermore, we need to elucidate factors behind the uncertainty and learn about what leads to lower, as well as higher, amounts of recalled product being reported as recovered. More than 30% of recalls, both illness-related and non-illness-related, were categorized in the 0-10% category for the percent of recalled product recovered. In order to prevent illnesses, there needs to be focus on ensuring that a higher percentage of product is recovered following a recall. Additional studies of consumers are also needed to further quantify the percentage of consumers that take action by discarding or returning recalled product.

There are also improvements that can be made to ensure better data quality, and in particular, data connectedness between federal establishments. We would recommend a continued commitment to ensuring that databases from multiple different agencies, not only FSIS and CDC, but across federal, state, and local public health, agriculture, and environmental health entities, include fields that make data connectedness more fluid.

Time is of the essence when conducting foodborne illness investigations. Improvements within the entire system would result in larger numbers of prevented illnesses. Analysis of public health programs identified elements such as intervals between case report and interviews and submission of isolate and subtyping as critical (32). In regard to beef products and regulatory agencies, ensuring more detailed and complete records of beef grinding to improve the efficiency of traceback have been supported (12). We recommend a commitment to ensure that resources are available to quickly investigate foodborne illnesses and take preventive action to stop new illnesses from occurring.

Table 2.1. Estimated Number of Shiga Toxin-producing *Escherichia coli* O157 Illnesses Prevented by Illness-related Recalls of Beef Products, 2005-2012, by Model

Approach

	Minimum	Lower 95% credible interval	Estimate/Mean*	Upper 95% credible interval	Maximum
Deterministic Model			725		
Beta Distribution Simulation Model	642	684	726	774	828
PERT Distribution Simulation Model	70	117	204	333	601
Expert Elicitation Simulation Model	14	28	56	99	174

* Point estimates for Beta, PERT, and Expert Elicitation models are the mean value.

Figure 2.1. Foundational Equations for Model Generation

$$\begin{array}{l} \boxed{\text{Number of Illnesses Prevented}} = \boxed{\frac{\text{Number of Illnesses that Occurred}}{\text{Number of Pounds Consumed}}} * \boxed{\text{Number of Pounds Recovered}} \\ \boxed{\text{Number of Pounds Consumed}} = \boxed{\text{Number of Pounds Produced}} - \boxed{\text{Number of Pounds Recovered}} - \boxed{\text{Number of Pounds Discarded}} \end{array}$$

Figure 2.2. Percent of Recalled Product Recovered, Beef Product Recalls, 2005-2012

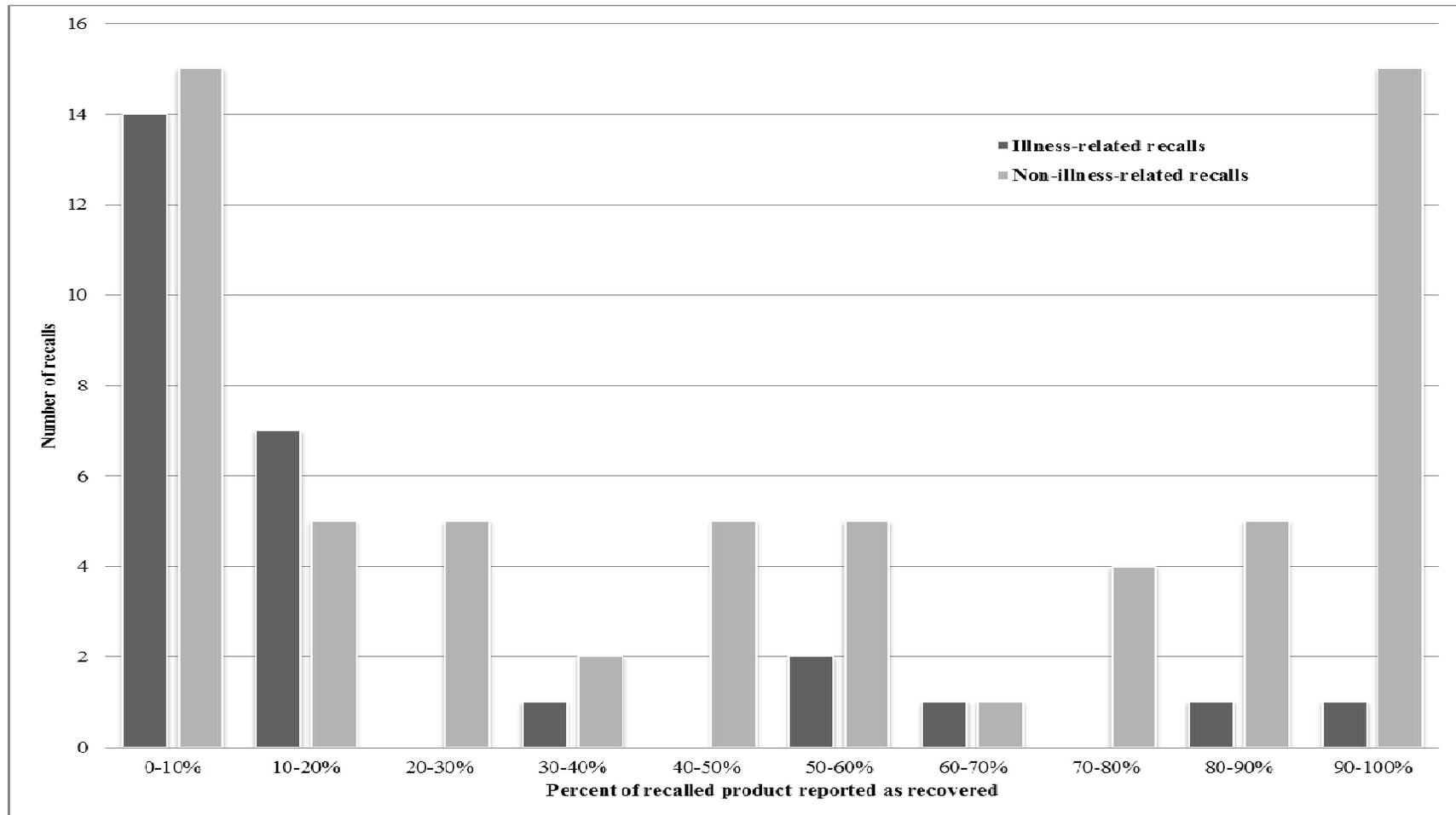


Figure 2.3. Modified Boxplot* of Illnesses Prevented, Illness-related Recalls of Beef Products, 2005-2012, by Model Approach



* Whiskers represent the minimum and maximum values for the Beta, PERT, and Expert Elicitation simulations while the box outline illustrates the 95% credible interval divided by the point estimate.

Chapter 3. Factors Associated with Recovery of Meat Products following Recalls due to Shiga Toxin-producing *Escherichia coli*

The goal of this study was to elucidate the factors affecting the amount of product recovered following a recall by an FSIS-regulated establishment, with a focus on recalls due to Shiga Toxin-producing *Escherichia coli* (STEC). STEC O157 and non-O157 together are estimated to cause approximately 176,000 domestically-acquired foodborne illnesses each year (2). Ground beef, and undercooked ground beef in particular, has been identified as a risk factor for illnesses due to STEC O157 and certain non-O157 serotypes (33-38). We also explore how the detection of foodborne illness clusters leading to recall actions vary depending on the jurisdictions involved. Our results will lead to a better understanding of the significance of the amount of product recovered following a recall. Further, they will be used to better understand improvements that are needed to more quickly respond to illnesses and more completely remove contaminated product from commerce.

Materials and Methods

Recall Data

We obtained FSIS recall data that included all recalls carried out by FSIS-regulated establishments from 2000 through 2012. A spreadsheet was edited to contain data fields including the year, FSIS recall number, date of the recall, establishment size, recall class, number of pounds recalled, number of pounds of recalled product that was recovered, type of product recalled, and the reason for the recall. Public health alerts,

retail-level recalls, and state-initiated recalls were excluded from the spreadsheet. Additionally, recalls not closed at the time of the analyses or with an unknown amount of product recalled were only used in summary statistics but not included in the analyses.

For each of the recalls listed in the spreadsheet, we obtained additional data from the FSIS website. The additional data fields included whether the recall was subsequently expanded after the initial recall; the earliest and most recent production dates of recalled product; an estimate of the extent of distribution using the number of states listed in public notifications; whether the product was distributed to hotels, restaurants, or institutions (HRI); whether the recall involved product imported into the United States or exported from the United States; and whether product was fresh, frozen, or both fresh and frozen.

Assessment of Recall Characteristics

All data were imported into SAS for Windows version 9.3 (SAS Institute Inc., Cary, NC, USA) for data manipulation and analysis. Two new continuous variables were created which represented the percent of recalled product recovered as well as the number of days between the earliest production date and the recall date. Where the percentage of recalled product reported by the recalling establishment as recovered exceeded 100%, we adjusted the amount to reflect a maximum of 100% of product recovered. The final dataset contained both continuous and categorical variables.

We used the nonparametric Wilcoxon rank-sum test to examine the association between categorical predictor variables and the principal continuous outcome variable, percent of recalled product recovered, for an analysis of all recalls and an STEC-specific

analysis. The categorical predictor variables of interest for the STEC recall analysis included the size of the establishment, whether the recall included product imported into or exported from the United States, whether the recalled product was distributed to HRI, whether illnesses were associated with the recall, whether recalled product was fresh or frozen, whether the recall was expanded, and whether the recalled product was distributed on a local (e.g., distributed to a single metropolitan area) or national (i.e., distributed to more than 13 states or reported in the public notifications as national distribution by FSIS) basis. An additional categorical predictor variable was created to reflect recalled product distributed on a limited basis, which was defined as two or fewer states as reported on the FSIS website. Specific to an analysis of the extent of distribution, we analyzed three levels of distribution for two variables (local, regional/sporadic, national distribution; HRI, both HRI and retail, retail distribution) using Mantel's test for trend. A P value of less than or equal to 0.05 was considered indicative of a statistically significant trend. For the analysis of all recalls, we additionally used the Wilcoxon rank-sum test to examine the association between percent of product recovered and whether the recall was due to STEC versus another reason, recall class, and type of product (i.e., beef, pork, poultry, mixed) recalled. If the two-sided P value was less than or equal to 0.05, the association in the univariable analysis was considered to be statistically significant.

Two continuous variables, the number of days between the earliest production date and the recall date as well as total pounds of product recalled, were used in two separate approaches to the analysis. First, they were analyzed as continuous variables

against the categorical predictor variables of interest using the Wilcoxon rank-sum test to examine illness-related versus non-illness-related STEC recalls. They were also dichotomized at the median values for an analysis of all recalls and an STEC-specific analysis. They were evaluated against the percent of product recovered, also dichotomized using the median value, using a Pearson chi-square test. Statistical significance was determined using a P of less than or equal to 0.05 as the two-sided value.

Assessment of Foodborne Illness Detection

In order to assess the detection of foodborne illness clusters, we created two categorical predictor variables representing whether the state distribution noted in the FSIS public notification included states receiving FoodNet or EHS-Net funding. Additionally, using foodborne outbreak surveillance data from 1998 through 2012 (21,22,29,39) we created a categorical state tier variable. This predictor variable indicated whether the product distribution included states that were ever represented in the lowest tier of outbreak reporting rates from 1998-2012 versus at least one state never represented in that lowest tier (i.e., higher tier stats). For recalled product distribution on a nationwide basis, individual states are often not named in the recall public notification. Therefore, for product distributed on a nationwide basis, it was assumed that recalled product was distributed to at least one FoodNet, EHS-Net, and higher tiered state. These three categorical variables were evaluated against whether STEC recalls were illness-related versus not illness-related using a Pearson chi-square test. If the P value was less than or

equal to 0.05, the association of the univariable analysis was considered to be statistically significant.

Results

Among the 911 total recalls by FSIS-regulated establishments over the 13-year period, an estimated total of 518 million pounds (median 7,000 pounds per recall) of product were recalled. Of the recalled product, an estimated 146 million pounds (28%) were reported as recovered. A median of 68 recalls (range 34-113 recalls) of FSIS-regulated products occurred each year based on data from 2000 through 2012. Recalls were conducted due to a number of reasons including extraneous materials, illnesses, mislabeling, pathogens, residues, underprocessing, and multiple other less common causes.

From 2000 through 2012, a total of 172 recalls by FSIS-regulated establishments occurred due to STEC, principally STEC O157, and were associated predominantly with beef products, with a median of 12 recalls (range 5-22 recalls) each year. Among the recalls, an estimated 84 million pounds (median 21,000 pounds per recall) of beef, pork, and bison products were recalled. An estimated 27 million pounds (median 2,000 pounds per recall) of recalled product were recovered. Overall, for the 13-year study period, approximately 33% of product recalled due to STEC was reported as recovered.

Evaluating all recalls from 2000 through 2012, we excluded 27 because they were not closed at the time of analysis or had an undetermined amount of product recalled. A total of 884 recalls, of which 171 were related to STEC, were included in the analyses.

Figure 3.1 graphically depicts the percent of product recovered for both the STEC-related and all other recalls. The extreme categories of 0-10% and 90-100% of recalled product recovered account for over 45% of the recalls.

Assessment of Recall Characteristics

As shown in Table 3.1, among the STEC recalls, a higher percentage of recalled product recovered was associated with product distributed to HRI and conversely, a lower percentage with product distributed to retail facilities. When directly comparing HRI only to retail only distribution, and not including recalls with distribution to both HRI and retail combined, the percent of recalled product recovered was significantly higher for HRI only distribution ($P=0.01$ by Wilcoxon rank-sum test). Similarly, we found that recalled products distributed locally and on a more limited basis positively affected the percentage of product recovered following a recall due to STEC in contrast to nationwide distribution (Table 3.1).

Analyzing the amount of product recalled due to STEC, products distributed locally ($P<0.0001$ by Wilcoxon rank-sum test), on a more limited basis ($P<0.0001$ by Wilcoxon rank-sum test), and to HRI ($P<0.0001$ by Wilcoxon rank-sum test) were associated with a lower amount of product recalled while products distributed nationally ($P<0.0001$ by Wilcoxon rank-sum test) and to retail ($P=0.003$ by Wilcoxon rank-sum test) were associated with a higher amount of product recalled. There were no statistically significant associations found with recalled product recovered in the STEC recall analyses for establishment size, involvement of imported product, fresh versus frozen product, international distribution, or recall expansions.

Not limiting our analyses to STEC recalls only, but using all recalls in the database, there were no statistically significant associations found between recalled product recovered for HRI and retail, local, more limited, or nationwide distribution of product. Further, similar to the STEC recall analysis, there were no statistically significant associations found with recalled product recovered for establishment size, recall class, involvement of imported product, fresh versus frozen product, international distribution, or recall expansions.

As shown in Table 3.2, for both STEC and all recalls, there were statistically significant trends when we looked at the association between the amount of recalled product recovered and local, regional/sporadic, and national distribution (test statistic=16.4, $P < 0.0001$ for STEC recalls; test statistic=4.2, $P = 0.04$ for all recalls). For STEC recalls, progressively less recalled product was recovered as you moved from HRI to combined HRI and retail to retail distribution (test statistic=10.8, $p < 0.001$). The HRI trend was not statistically significant across all recalls.

When we analyzed the number of days between the earliest production date of recalled product and the recall date, there was an association with more days having less recovered product for both STEC and all recalls (Table 3.3). Also for both STEC and all recalls, a higher amount of product recalled was associated with a lesser amount of product recovered (Table 3.3).

Assessment of Illness-related Recall Characteristics

Whether an STEC recall was illness-related or not was also associated with the percentage of recalled product recovered (Table 3.1). STEC recalls that were not illness-

related had a higher percentage of beef products recovered (median of 23% recovered compared with 6% recovered). The statistically significant association was also documented across all recalls (Table 3.4). Further, Table 3.4 shows both STEC and beef products recalls, compared with non-STEC and other types of product recalls respectively, were associated with a smaller percentage of recalled product recovered.

Directly comparing illness-related STEC recalls to STEC recalls not related to illnesses, we found that illness-related STEC recalls were associated with larger amounts of products recalled ($P < 0.0001$ by Wilcoxon rank-sum test) and a greater number of days between the earliest production date and recall date ($P < 0.0001$ by Wilcoxon rank-sum test). Illness-related STEC recalls were less likely than non-illness-related STEC recalls to be associated with HRI distribution (chi square=5.6, $p=0.02$) and distribution on a local (chi square=12.8, $p=0.0003$) and more limited (chi square=23.8, $p < 0.0001$) basis. Illness-related STEC recalls were more likely than non-illness-related STEC recalls to be associated with nationwide distribution (chi square=20.7, $p < 0.0001$).

Assessment of Foodborne Illness Detection

FoodNet states were more likely than non-FoodNet states to be listed for recalled product distribution for illness-related STEC recalls compared against non-illness-related STEC recalls (chi square=10.8, $p=0.001$) as were EHS-Net sites (chi square=8.1, $p=0.004$). Using the tiered approach a similar trend was observed. States never listed in the lowest tier of foodborne outbreak reporting rates from 1998-2012 were more likely to be listed for recalled product distribution for illness-related STEC recalls (chi square=8.3, $p=0.004$).

Discussion

Our analyses suggest that the complexity of product distribution is a central predictor of the amount of recalled product recovered following an STEC recall by an FSIS-regulated establishment. HRI, local, and more limited distribution patterns were all associated with higher recovery of recalled product and would likely have a more straightforward distribution chain. This would make it less complicated to recover product more rapidly and more completely than retail and national distribution which are associated with a lower recovery of recalled product. However, this association is not observed when taking all recalls into account. It is possible that product recovery for recalls not related to STEC may be less dependent on the distribution patterns and complexity of the supply chain. Our analyses would also suggest that illness-related STEC recalls, which are less likely to have straightforward distribution, may be influencing the observed associations with complexity of distribution and product recovery.

The association involving the number of days between the earliest production date for contaminated product and the recall action is noteworthy. Delays in initiating a recall would correspond with more product being consumed and product being distributed further through the supply chain, both of which would correspond to less recalled product being recovered. In order to maximize recall effectiveness, and prevention of foodborne illnesses, robust systems need to be in place to facilitate early detection of foodborne illness clusters as well as a timely response.

The association between illness-related recalls and a smaller amount of recovered products likely results from a number of factors. The majority of non-illness, pathogen-related recalls in the dataset are due to positive results of FSIS or establishment pathogen testing programs at the establishment. This type of recall would tend to be more timely and therefore product would not be as thoroughly distributed, have a more straightforward recall scope, and therefore a smaller quantity when compared against illness-related pathogen recalls. Quickly removing pathogen-positive product from commerce could also further prevent illnesses. Further, traceback is more difficult when product has been more thoroughly dispersed into the food chain, especially when enough product has been disseminated to result in a cluster of illnesses, versus reacting to a positive pathogen test from an establishment. In 2013, FSIS required establishments to begin controlling products tested by FSIS for adulterants, such as STEC O157, until all test results are received (31). Subsequent analyses of delays between production and recall as well as illness-related recalls using data after the requirement was in effect will be of interest.

Our results highlight that improvements within the entire system could lead to larger quantities of recalled product being recovered or discarded, therefore limiting the amount of contaminated product reaching consumers. The association between FoodNet, EHS-Net, and higher tier states with illness-related STEC recalls suggests that improvements in detection of foodborne illness clusters, and additional resources for local and state public health agencies, are needed. As for illness-related recalls, more efficient foodborne illness investigations would lead to a more rapid recall action,

reducing the amount of time between production and recall dates. Agile investigations encompassing coordinated, rapid, and innovative product tracing are needed (10,40-43) along with investments in resources, training, and expertise.

To support future studies, there are also improvements to data quality that should be considered. The amount of product recovered is reported from the recalling establishment to FSIS. Although a certain amount of uncertainty is inherent, more accurate and complete reporting is recommended. While not directly addressed in our analysis, we noted that for a number of recalls, the amount of product recovered was greater than the amount of product recalled. A mechanism is needed for scrutinizing these occurrences more closely, collecting descriptive data, and indicating why the discrepancy occurred (e.g., commingling of both recalled and non-recalled products). To assess early detection and surveillance, we were limited to using the states initially highlighted in FSIS public notifications available online. These states could consist only of known distributors and may not represent the entire distribution chain of recalled product. Preserving the full distribution by state once it has been uncovered would be beneficial for future studies of this nature. More systematic and completed collection and maintenance of descriptive recall data are also needed. Additionally, we would hypothesize that recalled products, especially ground meat products, produced at the establishment as case-ready products (e.g., in the final consumer package) would have a higher percentage of product recovered compared to products that are subsequently re-processed or relabeled. Those data are currently not readily available.

Table 3.1. Characteristics associated with Recovery of Recalled Products for Shiga Toxin-producing *Escherichia coli* Recalls, Categorical Predictor Variables, 2000-2012

Recall Characteristic	Number (%) of Recalls	Median Percent of Product Recovered	Recall Characteristics of Comparison Group	Median Percent of Product Recovered	Wilcoxon Rank-Sum Test	
					Z	p-value
HRI Distribution	53 (31%)	30%	Retail Distribution and Combined HRI and Retail Distribution	11%	2.9	<0.005
Retail Distribution	67 (39%)	10%	HRI Distribution and Combined HRI and Retail Distribution	23%	-2.2	0.03
Local Distribution	45 (26%)	45%	All Non-Local Distribution	13%	1.9	0.06
Distribution to ≤ 2 States	83 (49%)	35%	Distribution to >2 States	10%	3.3	<0.005
National Distribution	40 (23%)	10%	All Non-National Distribution	23%	-2.2	0.03
Illness-Related	41 (24%)	6%	Not Illness-Related	23%	-2.4	0.02

Table 3.2. Trends associated with Recovery of Recalled Products for Both Shiga Toxin-producing *Escherichia coli* and All Recalls, 2000-2012

Recall Characteristic Levels	Shiga Toxin-producing <i>Escherichia coli</i> Recalls		All Recalls*	
	0-18% Recalled Product Recovered	18-100% Recalled Product Recovered	0-31.5% Recalled Product Recovered	31.5-100% Product Recovered
Local Distribution	30 (Row 35%)	56 (Row 65%)	186 (Row 47%)	212 (Row 53%)
Regional/Sporadic Distribution	27 (Row 60%)	18 (Row 40%)	136 (Row 50%)	134 (Row 50%)
National Distribution	28 (Row 72%)	11 (Row 28%)	114 (Row 56%)	91 (Row 44%)
	Mantel's Test for Trend: 16.4, P <0.0001		Mantel's Test for Trend: 4.2, P =0.04	
Recall Characteristic Levels	Shiga Toxin-producing <i>Escherichia coli</i> Recalls		All Recalls*	
	0-18% Recalled Product Recovered	18-100% Recalled Product Recovered	0-31.5% Recalled Product Recovered	31.5-100% Product Recovered
HRI Distribution	16 (Row 30%)	37 (Row 70%)	92 (Row 49%)	97 (Row 51%)
Combined HRI and Retail Distribution	21 (Row 60%)	14 (Row 40%)	74 (Row 58%)	53 (Row 42%)
Retail Distribution	41 (Row 61%)	26 (Row 39%)	243 (Row 50%)	244 (Row 50%)
	Mantel's Test for Trend: 10.8, P <0.0001		Mantel's Test for Trend: 0.004, P =0.9	

* The “All Recalls” category includes recalls from FSIS-regulated establishments for all causes between 2000 and 2012.

Table 3.3. Characteristics associated with Recovery of Recalled Products for Both Shiga Toxin-producing *Escherichia coli* and All Recalls, Continuous Predictor Variables, 2000-2012

Recall Characteristic (STEC Recalls)	Median	Chi-square	p-value
Days from Earliest Production to Recall Date	17 days	27.9	<0.0001
Number of Pounds Recalled	22,000 pounds	15.2	<0.0001
Recall Characteristic (All Recalls)	Median	Chi-square	p-value
Days from Earliest Production to Recall Date	36 days	44.5	<0.0001
Number of Pounds Recalled	7,000 pounds	29.9	<0.0001

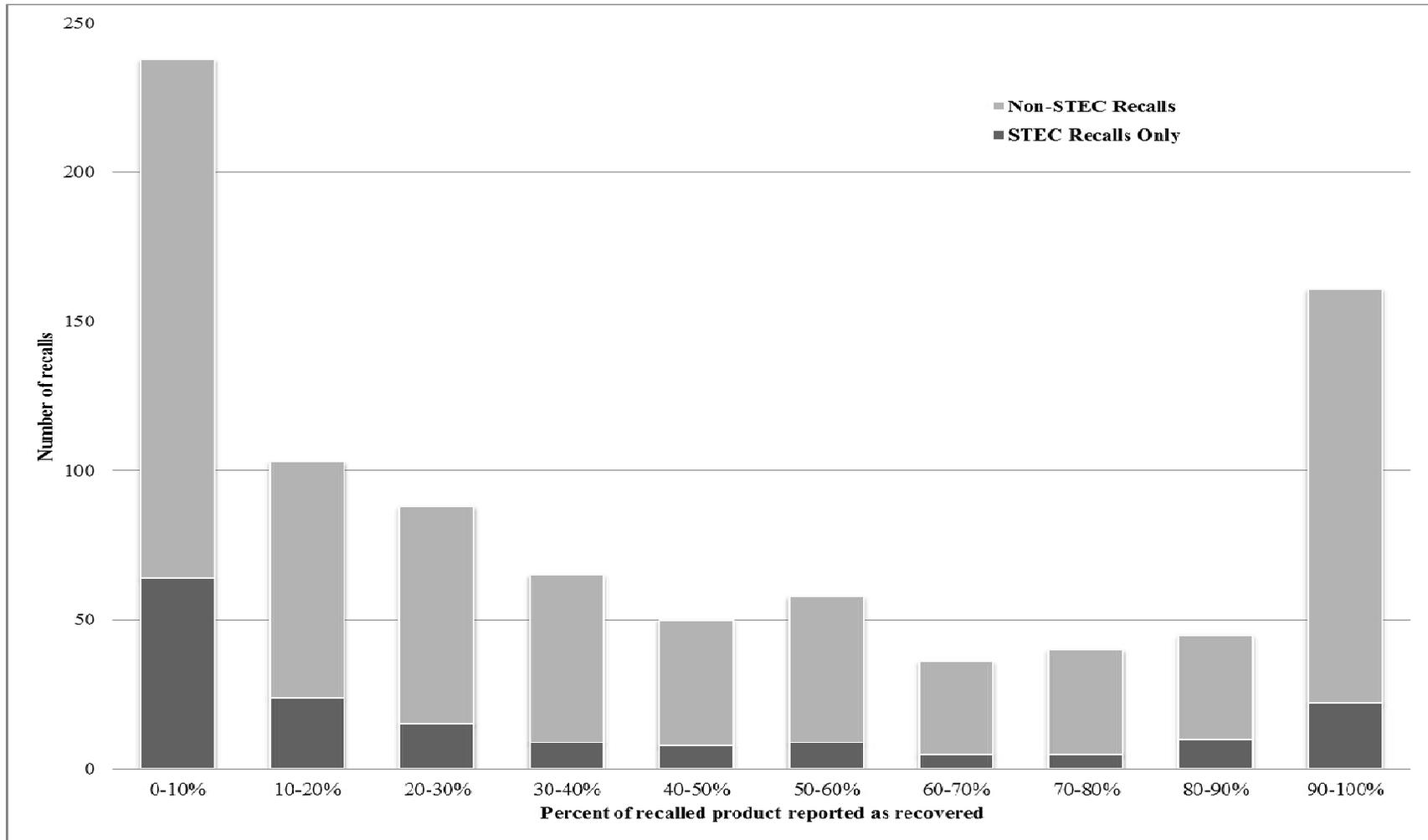
* The “All Recalls” category includes recalls from FSIS-regulated establishments for all causes between 2000 and 2012.

Table 3.4. Characteristics associated with Recovery of Recalled Products for All Recalls, Categorical Predictor Variables, 2000-2012

Recall Characteristic	Number (%) of Recalls	Median Percent of Product Recovered	Recall Characteristics of Comparison Group	Median Percent of Product Recovered	Wilcoxon Rank-Sum Test	
					Z	p-value
Illness-Related	58 (7%)	6%	Not Illness-Related	34%	-5.0	<0.0001
STEC-Related	171 (19%)	19%	Not STEC-Related	35%	-3.8	<0.005
Beef-Associated	336 (38%)	26%	Not Beef-Associated	34%	-2.6	0.01

* The “All Recalls” category includes recalls from FSIS-regulated establishments for all causes between 2000 and 2012.

Figure 3.1. Percent of Recalled Product Recovered, Shiga Toxin-producing *Escherichia coli* and All Other Recalls, 2000-2012



Chapter 4. Beyond Shiga Toxin-producing *Escherichia coli*: Recovery of Meat and Poultry Products Recalled due to Illnesses, Pathogen Testing, and Undeclared Ingredients

The emphases of this study were twofold and the results were intended to inform and be compared against previous studies involving Shiga Toxin-producing *Escherichia coli* (STEC). While STEC is a focus of the Food Safety and Inspection Service (FSIS) given its jurisdiction over meat, poultry, and egg products, *Listeria* and *Salmonella* are also pathogens of concern (1). *Listeria* is estimated to cause 1,591 domestically-acquired foodborne illnesses, 1,455 hospitalizations, and 255 deaths annually in the United States while nontyphoidal *Salmonella* estimates are 1,027,561 foodborne illnesses, 19,336 hospitalizations, and 378 deaths (2). Since 2008, there has been a sustained increase in the number of FSIS-regulated establishments conducting recalls due to undeclared ingredients (44).

For the first component of the study, with a focus on recalls due to illnesses, *Listeria*, *Salmonella*, and undeclared ingredients, we planned to describe and examine the factors affecting the amount of product recovered. This additionally included methodology to assess the detection and surveillance of *Salmonella* infections by states receiving distribution of recalled FSIS-regulated products. Secondly, we modified a model used previously for STEC O157 to quantify the number of *Salmonella* infections prevented by *Salmonella*-related recalls from 2003-2012. Additionally, we extrapolated the results of the simulation to recalls due to *Salmonella* that were not associated with illnesses from 2000-2012.

The results from the study will be used to further illustrate the public health benefits of recalls and provide an improved understanding of the significance of the amount of product recovered following a recall.

Materials and Methods

We utilized an FSIS recall database that included all recalls carried out by FSIS-regulated establishments from 2000 through 2012. The database contained data fields required for the analyses including the date of the recall, size of the recalling establishment, number of pounds recalled, number of pounds of recalled product that were recovered, type of product recalled, whether the recalls were associated with illnesses, and the reason for the recall. Additional data fields in the database had been gathered from the FSIS website and included whether the recall was subsequently expanded after the initial recall; the earliest and most recent production dates of recalled product; an estimate of the extent of distribution using the number of states listed in FSIS public notifications; whether the product was distributed to hotels, restaurants, or institutions (HRI); whether the recall involved product imported into the United States or exported from the United States; and whether product was fresh, frozen, or both fresh and frozen.

Two continuous variables represented the percent of recalled product recovered and the number of days between the earliest production and recall dates. Where the percentage of recalled product reported as recovered exceeded 100%, we adjusted the amounts to reflect a maximum of 100% of product recovered. Public health alerts, retail-

level recalls, and state-initiated recalls were excluded from the database along with recalls not closed at the time of the analyses or with an unknown amount of product recalled. The final dataset used for the assessment of recall characteristics contained both continuous and categorical predictor variables and the principal continuous outcome variable, percent of recalled product recovered.

Assessment of Illness-related, *Listeria*, *Salmonella*, and Undeclared Ingredient Recall Characteristics

The database was imported into SAS for Windows version 9.3 (SAS Institute Inc., Cary, NC, USA) for data manipulation and analysis. We used the nonparametric Wilcoxon rank-sum test to examine the association between categorical predictor variables and the continuous outcome variable, percent of recalled product recovered, for analyses of recalls due to illnesses, *Listeria*, *Salmonella*, and undeclared ingredients. The categorical predictor variables of interest for the recall analyses included the size of the establishment, type of product recalled, whether the recall included product imported into or exported from the United States, whether the recalled product was distributed to HRI, whether illnesses were associated with the recall, whether recalled product was fresh or frozen, whether the recall was expanded, and whether the recalled product was distributed on a local (e.g., distributed to a single metropolitan area) or national (i.e., distributed to more than 13 states or reported as national distribution by FSIS) basis. An additional categorical predictor variable was used to reflect recalled product distributed on a limited basis, which was defined as two or fewer states as reported in recall public notifications on the FSIS website.

A two-sided P value of less than or equal to 0.05 was used to determine statistical significance in the univariable analysis. Where analyses involved cells with expected values less than five, a two-sided P value of less than or equal to 0.05 was used utilizing Fisher's exact methods. Specific to an analysis of the extent of distribution, we analyzed three levels of distribution for two variables (local, regional/sporadic, national; HRI, both HRI and retail, retail) using Mantel's test for trend. A P value of less than or equal to 0.05 was considered indicative of a statistically significant trend.

Two continuous variables, number of days between the earliest production date and the recall date as well as total pounds of product recalled, were dichotomized using the median values for illness, *Listeria*, *Salmonella*, and undeclared ingredient specific analyses. The variables were evaluated against the percent of product recovered, also dichotomized using the median value, using a Pearson chi-square test. Statistical significance was determined using less than or equal to 0.05 for a two-sided P value.

Assessment of *Salmonella* Illness Detection

In order to assess the detection of foodborne illness clusters related to recalls due to *Salmonella*, we created two categorical predictor variables representing whether the state distribution noted in the FSIS public notifications posted online included states receiving FoodNet or EHS-Net funding. Additionally, using foodborne outbreak surveillance data from 1998 through 2012 (21,22,29,39) we created a state tier variable. This categorical predictor variable indicated whether the product distribution included states that were ever represented in the lowest tier of outbreak reporting rates versus at least one state never represented in that lower tier (i.e., higher tiered state). For recalled

product distribution on a nationwide basis, individual states are often not named in the recall media release. Therefore, for product distributed on a nationwide basis, it was assumed to be distributed to at least one FoodNet, EHS-Net, and higher tiered state. These three categorical variables were evaluated against whether *Salmonella* recalls were illness-related versus not illness-related using a Pearson chi-square test. A two-sided P value of less than or equal to 0.05 was used to determine statistical significance. Where analysis involved cells with expected values less than five, we utilized a two-sided P value less than or equal to 0.05 as a cut-off point using Fisher's exact methods.

PERT Simulation Model for Illness-related *Salmonella* Recalls

A separate spreadsheet was created specifically for illness-related *Salmonella* recalls carried out by FSIS-regulated establishments in the ten years from 2003 through 2012. Specific data fields included the FSIS recall number; number of pounds recalled; whether the product was distributed to hotels, restaurants, or institutions (HRI); and the pounds of recalled product recovered. FSIS conducts and collects data on foodborne illness investigations possibly related to meat, poultry and egg products (3). Recall data from the spreadsheet were cross-referenced to FSIS illness data in order to incorporate critical, recall-specific illness data into the spreadsheet.

As shown in figure 4.1, the number of illnesses due to *Salmonella* infection prevented by a given recall was estimated from the number of illnesses that occurred, relative to the number of pounds consumed and recovered. Loss-adjusted food availability 2012 estimates from the USDA, Economic Research Service were used to estimate the amount of product discarded (23). All products recalled due to *Salmonella*

and associated with illnesses were distributed to retail, therefore we used a factor of 24% product loss to estimate the amount of food loss.

The uncertainty related to the percentage of pounds of recalled product recovered was expressed by a Program Evaluation and Review Technique (PERT) probability distribution due to the nature of the *Salmonella* illness-related recall data that are bounded at zero and one, with a distribution that is skewed with a long tail to the right (Figure 4.2).

The foundational equations shown in Figure 4.1 were modified to estimate the number of illnesses prevented using a PERT distribution with the equation: Pert (minimum value, most likely value, maximum value). The values were defined as a minimum of zero, most likely value of 15.4%, which was the overall percentage of recalled product recovered across all illness-related *Salmonella* recalls combined, and maximum of 95.5% corresponding to the maximum product recovered in an illness-related *Salmonella* recall. Latin Hypercube sampling was conducted with 10,000 iterations using @RISK for Excel version 6.1.2 (Palisade Corporation, Ithaca, NY, USA). The number of illnesses was expressed as the mean with a 95% credible interval.

Non-illness Related Recalls due to *Salmonella*

The PERT simulation model used data from illness-related recalls due to *Salmonella*. This methodology allowed us to use the number of illnesses that occurred relative to the number of pounds of product consumed and recovered following the recall action. In order to assess a more complete picture of the illnesses prevented, we used the median number of illnesses per 100,000 pounds of product consumed calculated from the

PERT simulation model to estimate the number of illnesses prevented by non-illness-related recalls. The median was multiplied by the total pounds of recalled product that were reported as recovered for the non-illness *Salmonella* recalls from 2000-2012.

Finally, we graphically examined all recalls due to *Salmonella* from 2000 through 2012 (Figure 4.2). We dichotomized all *Salmonella* recalls at the median percentage of product recovered to evaluate the likelihood of illness in a recall using SAS for Windows version 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

Over the 13-year period from 2000-2012, an estimated total of 518 million pounds (median 7,000 pounds per recall) of product were recalled among 911 total recalls by FSIS-regulated establishments. A total of 884 recalls were included in the analyses after 27 were excluded because they were not closed at the time of the analyses or had an undetermined amount of product recalled.

Table 4.1 summarizes the number of illness-related, *Listeria*, *Salmonella*, and undeclared ingredient recalls, estimated amount of product recalled and product recovered, and median and mean amount of product recalled and recovered. A median of four (range 1-13) illness-related recalls occurred each year from 2000-2012. The illness-related recalls were due to STEC (n=41, 71%), *Salmonella* (n=12, 21%), *Listeria* (n=3, 5%), and *Clostridium botulinum* (n=2, 3%). A median of two (range 0-8) *Salmonella*, 14 (range 6-40) *Listeria*, and 14 (range 8-45) undeclared ingredient recalls occurred each year. Figure 4.3 graphically depicts the percent of product recovered for recalls due to

Listeria, *Salmonella*, and undeclared ingredients. The extreme categories of 0-10% and 90-100% of recalled product recovered account for approximately 44% of the recalls.

Assessment of *Listeria*, *Salmonella*, and Undeclared Ingredient Recall Characteristics

Although there was not a statistically significant association for *Salmonella* and undeclared ingredient recalls, *Listeria* recalls were associated with a larger percentage of recalled product recovered compared to all other recalls ($P < 0.0001$ by Wilcoxon rank-sum test). Among recalls related to *Listeria*, *Salmonella*, and undeclared ingredients there were not statistically significant association between the percentage of product recovered and HRI, retail, local, or nationwide distribution. Further, there were no statistically significant trends when we looked at the association between the amount of recalled product recovered and the progression from HRI to combined HRI and retail to retail distribution. Products recalled due to undeclared ingredients and distributed on a more limited basis however, were associated with a lower percentage of product recovered ($P = 0.006$ by Wilcoxon rank-sum test). Further, with undeclared ingredients only, there was a statistically significant trend with progressively more product recovered from local to regional/sporadic and national distribution (test statistic=3.7, $P = 0.05$).

Recalls of *Listeria*-related frozen products were associated with a higher percentage of recovered product ($P = 0.02$ by Wilcoxon rank-sum test). Recalls due to undeclared ingredients by large establishments were associated with a higher percentage of recovered product ($P = 0.002$ by Wilcoxon rank-sum test) while small and very small establishments were associated with a lower percentage ($P = 0.002$ by Wilcoxon rank-sum test). There were no statistically significant associations found with recalled product

recovered for involvement of imported product, international distribution, recall expansions, or type of product (i.e. beef, pork, poultry, or mixed).

For undeclared ingredient recalls, when we analyzed the number of days between the earliest production date of recalled product and the recall date, there was an association with more days having less recovered product (chi-square=14.2, P=0.0002). There was no statistically significant association for *Listeria* and *Salmonella* recalls. We did not find a higher amount of product recalled being associated with the amount of product recovered for *Listeria*, *Salmonella*, or undeclared ingredient recalls.

Assessment of Illness-related Recall Characteristics

Overall, among all illness-related recalls, a larger amount of recalled product was recovered when it was distributed to HRI only (P=0.05 by Wilcoxon rank-sum test). Alternatively, a smaller amount of product was recovered when distributed to retail only (P=0.01 by Wilcoxon rank-sum test). When directly comparing HRI only to retail only distribution, and not including recalls with distribution to both HRI and retail combined, the percent of recalled product recovered was significantly higher for HRI only distribution (P=0.02 by Wilcoxon rank-sum test). For illness-related recalls, a smaller amount of product distributed fresh was recovered compared with fresh and frozen combined, and only frozen (P=0.004, P=0.01 respectively by Wilcoxon rank-sum test).

As shown in Table 4.2, whether a *Salmonella* recall was illness-related or not illness-related was associated with the amount of recalled product recovered. *Salmonella* recalls that were not illness-related had a higher percentage of recalled products recovered (median of 36% recovered compared with 6% recovered). *Listeria*-related

recalls show a similar trend (median of 52% recovered for non-illness-related compared with 12% recovered for illness-related), however, with only three illness-related recalls in the study period, the results only approached statistical significance.

Directly comparing both *Listeria* and *Salmonella* recalls related and not related to illnesses, we found that illness-related recalls were associated with larger amounts of products recalled and a greater number of days between the earliest production date and recall date (Table 4.2). Illness-related *Salmonella* recalls were less likely than non-illness-related *Salmonella* recalls to be associated with more limited distribution (chi square=9.3, P=0.004 by Fisher's exact methods). Illness-related *Salmonella* recalls were more likely than non-illness-related *Salmonella* recalls to be associated with nationwide (chi square=7.6, P=0.01 by Fisher's exact methods) and retail (chi square=6.0, P=0.02 by Fisher's exact methods) distribution. All three *Listeria*-related recalls were distributed to both HRI and retail on a nationwide basis.

Assessment of *Salmonella* Illness Detection

FoodNet states were no more likely than non-FoodNet states to be listed for recalled product distribution for illness-related *Salmonella* recalls compared against non-illness-related *Salmonella* recalls, which is the same as EHS-Net states. However, using the tiered approach, the higher tiered states, that is the states never listed in the lowest tier of foodborne outbreak reporting rates, were more likely to be listed for recalled product distribution for illness-related *Salmonella* recalls (chi square=6.2, P=0.02 by Fisher's exact methods) as an indicator for cluster detection.

PERT Simulation Model for Illness-related *Salmonella* Recalls

Among the 11 illness-related *Salmonella* recalls analyzed, an estimated 129 million total pounds (median 470,000 pounds per recall) of FSIS-regulated products were recalled. An estimated 20 million total pounds (median 10,000 pounds per recall) of recalled products were recovered. This represents 15.4% of recalled product recovered overall for the ten year study period from 2003-2012.

As anticipated, there was great variability in the amount of product recovered following a recall. While the median percentage of product recovered by each recall was 6%, the mean percentage was 19% and the range was from 0% to 96%. The bounded distribution was skewed with a majority of illness-related recalls with a small amount of recovered product on the left and a long tail to the right with few recalls with a large amount of recovered product (Figure 4.2). A total of 1,100 illnesses (median 42, range 15-396 per recall) were reported as associated with the 11 *Salmonella* recalls.

Using the PERT probability distribution for simulation of the percentage of product recovered, we found that the total number of illnesses prevented over the 10-year study period was 649 (minimum, 122; 95% credible interval, 255-1,465; maximum 4,589). The number of illnesses prevented by an individual recall resulted in a minimum of nine and a maximum of 234 prevented illnesses.

Non-illness-related Recalls due to *Salmonella*

From 2000 through 2012, a total of 31 recalls of FSIS-regulated products due to *Salmonella* occurred without reported illnesses. Of those, two recalls did not have an estimated amount of product recalled and were excluded. For two recalls, where the amount of recalled product reported as recovered exceeded 100%, we adjusted the

amounts to reflect a maximum of 100% of product recovered. The remaining 29 recalls accounting for an estimated total of 3 million (median 1,600) pounds of recalled product are presented in figure 4.2 compared against the illness-related recalls of products due to *Salmonella*. While both types of recalls had a high number of recalls with less than ten percent of product recovered, the non-illness-related recalls also have a large number of recalls with 80-100% of recalled product recovered. Additionally, the recalls not associated with illnesses had a higher percentage of recovered product. An estimated total of 790,000 (median 500) pounds of product were recovered from the 29 recalls leading to a mean of 43% and median 30% for the percentage of product recovered.

The number of prevented illnesses estimated for the recalls not associated with illnesses, using the median of 36 illnesses per 100,000 pounds of product consumed from the PERT probability distribution simulation model, was an estimated 283 prevented *Salmonella* illnesses.

All recalls (i.e. illness-related and non-illness-related recalls) were dichotomized at the overall median of percentage of recalled product recovered for *Salmonella* recalls resulting in 24 recalls in the 0-30% product recovery range and 16 recalls in the 30-100% range. The percent of all recalls that were illness-related decreased from 38% in the 0-30% range to 13% in the 30-100% range. Conversely, the percent of recalls that were not illness-related overall increased from 63% to 88% (chi-square 16.3, $P < 0.0001$).

Discussion

Our analyses provided valuable information about the factors that affect the amount of recalled product recovered for illness-related, *Listeria*, *Salmonella*, and undeclared ingredient recalls. They were also instrumental in quantifying the number of foodborne illnesses due to *Salmonella* that were prevented by recalls. Importantly however, the results of our analyses were also notable as a comparison against previous analyses of STEC recalls.

The evaluation of illness-related and *Listeria* recalls suggests that the type of product may be relevant to the amount of product recovered following a recall. While no associations were found for beef, pork, poultry, or mixed products, among illness-related recalls, a lower amount of product distributed fresh was recovered. Conversely, among *Listeria* recalls, a higher amount of product distributed frozen was recovered. With previous analyses of STEC recalls, no association was found between the amount of product recovered and fresh or frozen product. Among *Listeria* and *Salmonella*, as well as the previous analyses of STEC, illness-related recalls were associated with a higher number of days between the earliest production and recall dates compared to recalls not related to illnesses. It is reasonable that fresh product would be more difficult to recover compared to frozen which presents a challenge to the speed of epidemiologic, laboratory, and environmental health investigations of foodborne illness clusters. The impact of delays with investigations of foodborne illness clusters becomes apparent as they would correspond with more product being consumed and product being distributed further through the supply chain, both of which correspond to less recalled product being recovered.

As with previous analyses involving STEC recalls, we found that complexity of product distribution was also a factor for the amount of product recovered for illness-related recalls. This was not consistent however among *Listeria* and *Salmonella* recalls. While it is possible that recovery of products recalled due to *Listeria* and *Salmonella* may be less dependent on distribution patterns and the complexity of the supply chain, it is also possible that the small number of *Salmonella* recalls and small number of illness-related *Listeria* recalls may have impacted the results. However, the results for illness-related recalls provide additional evidence that illness-related recalls may be influencing the associations seen between lower amounts of recovered products with increasing complexity of distribution for STEC-related recalls.

Undeclared ingredient recalls provided an intriguing comparison group for illness-related, *Listeria*, and *Salmonella* recalls. It is interesting to note the results of the analyses showing a trend for more recalled product being recovered moving from local to regional/sporadic to national distribution. Additionally, a higher percentage of recovered product was associated with large establishments and a lower percentage with small and very small establishments. In our analysis, nearly 79% of establishments conducting recalls for undeclared ingredients were small and very small establishments. Increases in the number and proportion of undeclared ingredient recalls from 2008 through 2012 have been attributed to new ingredients, new suppliers, misprinted labels, products in the wrong packaging, and product and ingredient reformulation (44). It is possible that large establishments, who would likely have more national distribution, have an increased understanding of the intricacies of preventing and controlling undeclared ingredients in

their HACCP system, impacting the number of recalls but also their interaction with customers.

Our results for *Salmonella* recalls again highlight that improvements with surveillance of foodborne illness clusters and early detection are needed. The association between higher tier states with illness-related *Salmonella* recalls supports previous STEC recall findings. These findings suggest that states with historical experience conducting large numbers of outbreaks may better detect localized illness clusters. Investments in resources, training, and expertise to ensure that less widespread foodborne illness clusters (i.e., those that may not impact resource-heavy states) are detected and investigated, with control measure implemented, are essential.

We used a PERT distribution model to estimate the number of illnesses prevented by *Salmonella* recalls. In a previous STEC analysis, we found the PERT model to be a more accurate indicator of the illnesses prevented. The number of prevented STEC illnesses using deterministic and Beta models was heavily influenced by outliers and the number of pounds recovered. Since a small fraction of infectious diseases are diagnosed and reported to public health professionals, we utilized multipliers estimated by Scallan of 1.0 for under-reporting and 29.3 for under-diagnosis for nontyphoidal *Salmonella* infections (2). We applied these multipliers to the results in order to estimate the total possible illnesses prevented. From 2003 through 2012, for illness-related recalls, an estimated 19,000 *Salmonella* infections were prevented. For non-illness-related recalls, from 2000 through 2012, the estimated total is 8,300 *Salmonella* infections prevented.

To support similar studies in the future, there are limitations and improvements that should be considered. The amount of product recovered is reported from the recalling establishment to FSIS. More accurate and complete reporting is recommended along with a thorough understanding of the logistics of calculating the amount of product recalled and recovered. Observations of a variety of establishments conducting recalls of various FSIS-regulated products would be valuable. For a number of recalls in this and previous analyses, the amount of product recovered was greater than the amount of product recalled. There needs to be a mechanism for scrutinizing and describing these occurrences more closely. To assess early detection and surveillance, we were limited to using the states initially highlighted in FSIS public notifications available online. More descriptive studies of states using other measures of resources would be appealing. Improving the data and systems used to maintain the data is also critical. We found that certain data points were not readily available and others were often unclear or inconsistent.

Table 4.1. Number of Recalls, Amount of Product Recalled, Amount of Product Recovered, and Percent of Product Recovered, 2000-2012

Recall Characteristic	Number of Recalls	Total Amount of Product Recalled	Median Amount of Product Recalled	Total Amount of Product Recovered	Median Amount of Product Recovered	Total Percent of Product Recovered
Illness-related	58	248,000,000	186,000	61,000,000	10,000	25%
<i>Listeria</i>	231	74,000,000	1,000	16,000,000	500	22%
<i>Salmonella</i>	40	133,000,000	14,000	21,000,000	800	16%
Undeclared Ingredient	240	25,000,000	9,000	5,000,000	3,000	21%

Table 4.2. Characteristics associated with Recovery of Recalled Products for *Listeria* and *Salmonella* Recalls, Continuous Predictor Variables, 2000-2012

Recall Characteristic (<i>Listeria</i>)	Illness-Related Median	Non-illness-related Median	Wilcoxon Rank-Sum Test	
			Z	P value
Percentage of Product Recovered	12%	52%	-1.7	0.1
Days from Earliest Production to Recall Date	161 days	11 days	2.9	0.004
Number of Pounds Recalled	17,000,000 pounds	1,000 pounds	3.0	0.003
Recall Characteristic (<i>Salmonella</i>)	Illness-Related Median	Non-illness-related Median	Wilcoxon Rank-Sum Test	
			Z	P value
Percentage of Recalled Product Recovered	6%	36%	-2.2	0.04
Days from Earliest Production to Recall Date	83 days	14 days	3.5	0.0004
Number of Pounds Recalled	271,000 pounds	3,000 pounds	3.6	0.0003

Figure 4.1. Foundational Equations for Model Generation

$$\begin{array}{l} \boxed{\text{Number of Illnesses Prevented}} = \frac{\boxed{\text{Number of Illnesses that Occurred}}}{\boxed{\text{Number of Pounds Consumed}}} * \boxed{\text{Number of Pounds Recovered}} \\ \boxed{\text{Number of Pounds Consumed}} = \boxed{\text{Number of Pounds Produced}} - \boxed{\text{Number of Pounds Recovered}} - \boxed{\text{Number of Pounds Discarded}} \end{array}$$

Figure 4.2. Percent of Recalled Product Recovered, Recalls due to *Salmonella*, 2000-2012

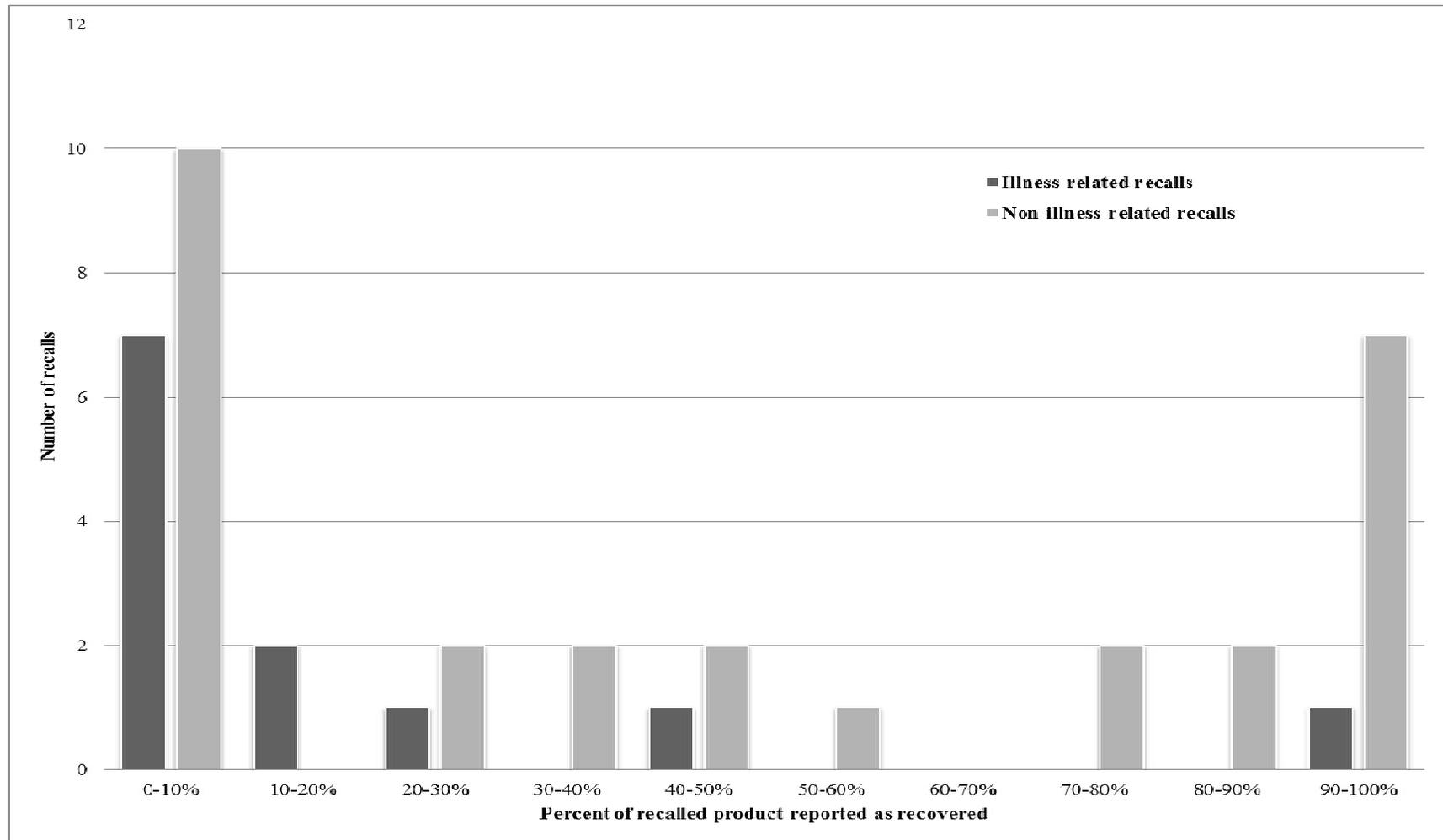
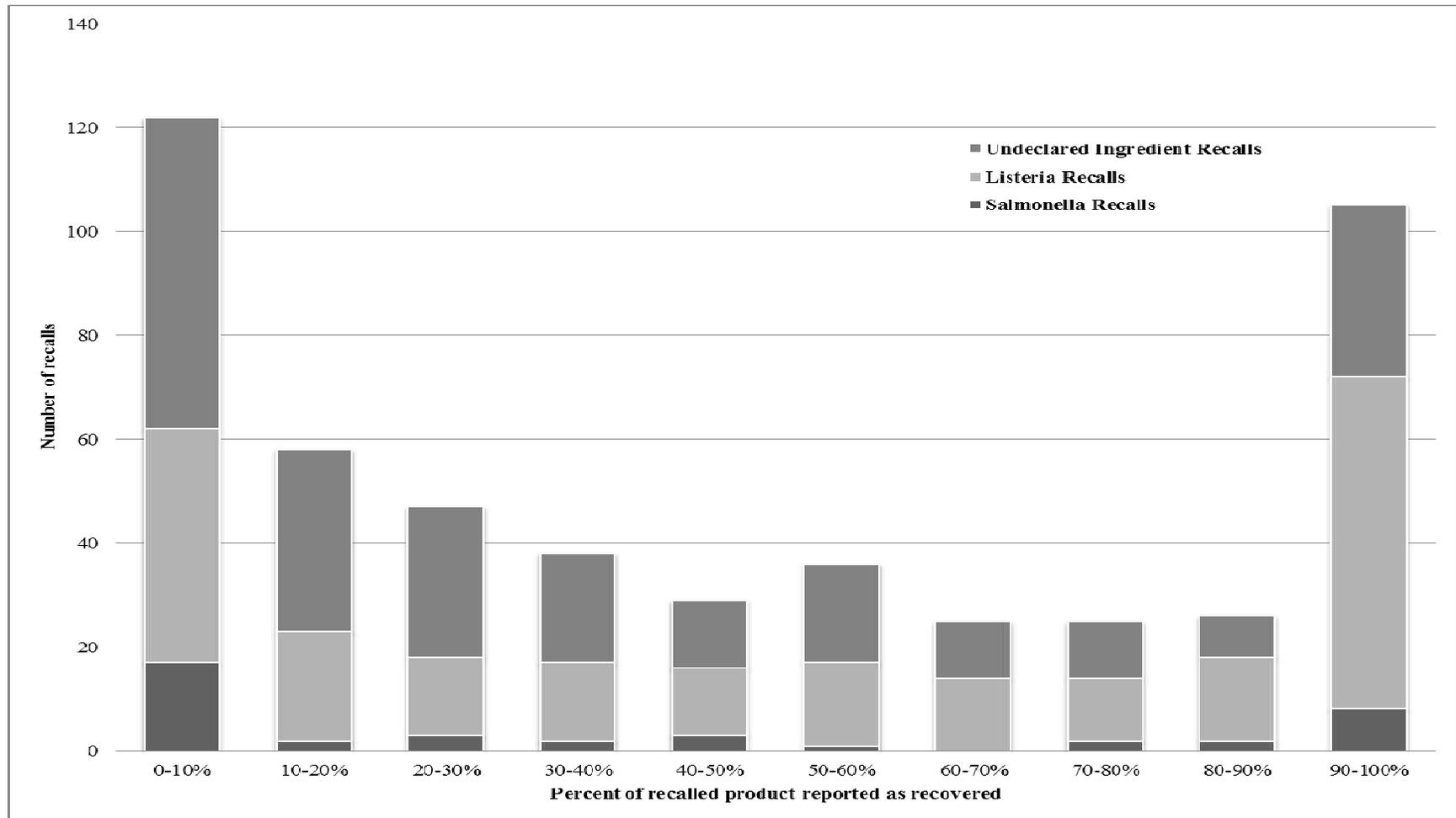


Figure 4.3. Percent of Recalled Product Recovered, Recalls due to *Listeria*, *Salmonella*, and Undeclared Ingredients, 2000-2012



Chapter 5. Conclusions

The analyses that were conducted demonstrate that recalls, although typically considered reactive in nature, are also an important tool to prevent further exposure and illnesses.

The first study was an assessment of Shiga Toxin-producing *Escherichia coli* (STEC) O157 illnesses prevented by recalls of beef products. Examining the results from several types of models, we found the Program Evaluation and Review Technique (PERT) model to be the most accurate indicator of the illnesses prevented. The number of prevented STEC illnesses using the deterministic and Beta models was heavily influenced by outliers and the number of pounds recovered. The simulation using a PERT distribution resulted in an estimated 204 illnesses prevented by recalls for FSIS-regulated beef products recalled due to STEC O157 illnesses from 2005 through 2012. Including an under-diagnosis multiplier increases the estimate to a total of 5,300 illnesses prevented. Furthermore, for recalls not related to illnesses, our results suggest that removing product from commerce is a key determinant of illness risk. These recalls are estimated to have prevented an additional 83 STEC O157 illnesses, approximately 2,200 using the under-diagnosis multiplier. Estimates from the first study are summarized in Table 5.1. Although improvements to data quality and further study of the factors contributing to the amount of product recovered following a recall would allow for further refinement of the model, the data and results of this study can drive improvements to prevent additional illnesses.

In the second study, we examined the factors associated with recovery of meat products following STEC recalls. The amount of recalled product recovered following a recall action due to STEC was dependent on the complexity of distribution, type of distribution, amount of time between production and recall dates, and the number of pounds of product recalled. Illness-related STEC recalls were associated with a lower percentage of product recovery, likely impacted by larger amounts of product, broader scopes, and delays from epidemiologic and traceback investigations, which would involve unraveling distribution chains, therefore impacting the amount of time involved and number of pounds recalled. Further, detection of illnesses related to STEC recalls appears to be enhanced in states with additional resources and a history of successful foodborne investigations (Table 5.2). This makes an argument for additional resources dedicated to public health agencies specifically for the detection and surveillance of foodborne illnesses. Finally, data and system improvements are recommended to further refine future analyses while improved traceability and investigation efficiencies are recommended to further prevent foodborne illnesses.

Moving to the third study, we pushed beyond STEC to examine the recovery of meat and poultry products recalled due to illnesses, pathogen testing, and undeclared ingredients. The results were intended to inform and be compared against previous studies involving STEC but additionally provide critical information concerning illness-related, *Listeria*, *Salmonella*, and undeclared ingredient recalls. The amount of recalled product recovered following a recall action was dependent on the reason for the recall, type of product, complexity of distribution, type of distribution, amount of time between

production and recall dates, and the number of pounds of product recalled. Illness-related *Listeria* and *Salmonella* recalls were associated with a lower percentage of product recovery, an increased number of days between the earliest production and recall dates, and a higher number of pounds of product recalled. Epidemiologic and traceback investigations impact the amount of time involved and the number of pounds recalled. Detection of illnesses related to *Salmonella* recalls appears to be enhanced in states with a higher level of performance on historical foodborne illness investigations (Table 5.2). Additional resources dedicated to public health agencies specifically for the detection and surveillance of foodborne illnesses are needed. The simulation using a PERT distribution resulted in an estimated 649 illnesses prevented by recalls for FSIS-regulated products recalled due to *Salmonella* illnesses from 2003 through 2012. Including an under-diagnosis multiplier increases the estimate to a total of 19,000 illnesses prevented. Examining recalls not related to illnesses, our results suggest that removing product from commerce is a key determinant of the risk of illness. These recalls are estimated to have prevented an additional 283 salmonellosis illnesses from 2000 through 2012, approximately 8,300 using the under-diagnosis multiplier. *Salmonella*-related estimates from the third study are presented in Table 5.1 in comparison with STEC O157 estimates from study one. The results from the study further illustrate the public health benefits of recalls and provide an improved understanding of the significance of the amount of product recovered following a recall.

Table 5.3 outlines a number of improvements that could be used to address the limitations of the three studies. Many of the improvements are targeted at improving the

quality of the data used for simulations and analysis of recovery factors. Additionally presented in Table 5.3 are a number of future studies that could be conducted to build on the foundational results of these analyses.

Table 5.1. Estimated Number of Illnesses Prevented by Recalls of FSIS-regulated Products

Pathogen	Illness-related	Years	Model	Estimate	95% Credible Interval	Estimate Based on Multipliers*
STEC [^] O157	Illness-related	2005-2012	PERT Distribution Simulation Model	204	117-333	5,300
STEC [^] O157	Not Illness-related	2005-2012	Application of PERT Model Results	83		2,200
<i>Salmonella</i>	Illness-related	2003-2012	PERT Distribution Simulation Model	649	255-1,465	19,000
<i>Salmonella</i>	Not Illness-related	2000-2012	Application of PERT Model Results	283		8,300

[^] Shiga Toxin-producing *Escherichia coli*

* Multipliers used for calculation were 26.1 for STEC O157 and 29.3 for *Salmonella* under-diagnosis (2)

Table 5.2. Association between FoodNet, EHS-Net, and Higher Tier* States and Illness-related Recalls due to Shiga Toxin-producing *Escherichia coli* and *Salmonella*, 2000-2012

Recall Characteristic (States)	Shiga Toxin-producing <i>Escherichia coli</i> Recalls, 2000-2012			<i>Salmonella</i> Recalls, 2000-2012		
	Illness-related	Not Illness-related	Chi-Square, P	Illness-related	Not illness-related	Chi-Square, P
FoodNet States (at least one)	36/41	78/130	10.8, P=0.001	11/12	22/28	1.0, P=0.3
EHS-Net States (at least one)	34/41	76/130	8.1, P=0.004	10/12	20/28	0.6, P=0.4
Higher Tier States* (at least one)	38/41	91/129	8.3, P=0.004	11/12	14/28	6.2, P=0.01

* Higher Tier States: Whether the product distribution included states that were ever represented in the lowest tier of outbreak reporting rates of foodborne outbreak surveillance summaries from 1998-2012 versus at least one state never represented (i.e., higher tier state) in that lowest tier.

Note: For product distributed on a nationwide basis, FSIS often does not list all states for distribution. It was assumed that recalled product was distributed to at least one FoodNet, EHS-Net, and higher tiered state for “nationwide” distribution. States are based on distribution listed in the public notification on the FSIS website, which may be preliminary.

Table 5.3. Recommendations to Improve Ability to Perform Assessment

Category	Recommendation
Data Quality	More accurate estimates are needed for amount of recalled product recovered from the entirety of the reporting chain (i.e. grocers, hotels, restaurants, institutions, distributors, establishments).
Data Quality	When a larger amount of recalled product is recovered than expected (e.g. greater than 100% of recalled product recovered) there needs to be further scrutiny and description of the reasons for the discrepancy.
Data Quality	Enhanced data connectedness is needed between public health entities to ensure that databases contain identifiers to link illness, recall, and other applicable data.
Data Quality	Preservation of data on the full distribution of recalled product is essential for future studies of detection of illness clusters.
Data Quality	As the factors for the amount of recalled product recovered may differ based on the specific type of product recalled, improved precision for the type of product recalled is necessary.
Future Analysis	Additional studies of consumers are needed to further quantify the amount of recalled product discarded or returned to the point of purchase.
Future Analysis	Case studies of FSIS-regulated product recalls from the establishment and retail perspective and analysis of recall practices would be desired to better enhance simulation and data utilization.
Future Analysis	The analyses of cluster detection by states could be expanded utilizing additional data sources such as the amount of resources received by public health entities.
Future Analysis	A comparison study of federal-level investigation timelines would be appealing to compare against existing state-level timeliness data.
Future Analysis	More complex simulation could be undertaken that would incorporate both the data from the recall prevention studies as well as the studies of factors influencing the amount of recalled product recovered.

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Appendix. Illness-related Recalls of Beef Products due to Shiga Toxin-producing *Escherichia coli* O157

Recall Number	Date	Expansion	Number of Pounds Recalled	Number of Pounds Recovered	Percent Recovered	Species	Reason for the Recall	Specific Reason
026-2005	06/09/05	No	63,850	259	0.41%	Beef	E. COLI O157:H7	Illness
040-2005	09/23/05	No	184,000	4,634	2.52%	Beef	E. COLI O157:H7	Illness
046-2005	11/01/05	No	94,400	12,096	12.81%	Beef	E. COLI O157:H7	Illness
019-2007	04/19/07	Yes	259,230	42,798	16.51%	Beef	E. COLI O157:H7	Illness
020-2007	04/20/07	No	107,943	0	0.00%	Beef	E. COLI O157:H7	Illness
022-2007	05/09/07	No	117,500	1,195	1.02%	Beef	E. COLI O157:H7	Illness
023-2007	05/11/07	No	129,000	85,500	66.28%	Beef	E. COLI O157:H7	Illness
025-2007	06/03/07	Yes	5,700,000	95,641	1.68%	Beef	E. COLI O157:H7	Illness
035-2007	07/25/07	No	5,920	188	3.18%	Beef	E. COLI O157:H7	Illness
040-2007	09/25/07	Yes	21,700,000	2,244,436	10.34%	Beef	E. COLI O157:H7	Illness
042-2007	10/06/07	No	845,000	42,070	4.98%	Beef	E. COLI O157:H7	Illness
045-2007	10/13/07	No	173,554	3,808	2.19%	Beef	E. COLI O157:H7	Illness
054-2007	11/24/07	No	95,927	11	0.01%	Beef	E. COLI O157:H7	Illness
002-2008	01/11/08	No	188,000	21,732	11.56%	Beef	E. COLI O157:H7	Illness
022-2008	06/29/08	Yes	5,300,000	612,408	11.55%	Beef	E. COLI O157:H7	Illness
027-2008	08/06/08	No	153,630	59,160	38.51%	Beef	E. COLI O157:H7	Illness
029-2008	08/08/08	Yes	1,360,000	7,736	0.57%	Beef	E. COLI O157:H7	Illness
039-2008	10/16/08	No	2,758	480	17.40%	Beef	E. COLI O157:H7	Illness
022-2009	05/20/09	No	95,898	4,717	4.92%	Beef	E. COLI O157:H7	Illness
034-2009	06/24/09	Yes	421,280	386,217	91.68%	Beef	E. COLI O157:H7	Illness

057-2009	10/25/09	No	1,039	878	84.50%	Beef	E. COLI O157:H7	Illness
059-2009	10/29/09	No	545,699	795	0.15%	Beef	E. COLI O157:H7	Illness
067-2009	12/24/09	No	248,000	141,636	57.11%	Beef	E. COLI O157:H7	Illness
002-2010	01/11/10	No	2,574	1,391	54.04%	Beef	E. COLI O157:H7	Illness
048-2010	08/04/10	No	1,000,000	10,121	1.01%	Beef	E. COLI O157:H7	Illness
062-2011	08/09/11	Yes	2,200	423	19.23%	Beef	E. COLI O157:NM	Illness
077-2011	09/27/11	No	131,300	18	0.01%	Beef	E. COLI O157:H7	Illness