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Center for Chemical Regulation and Food Safety

Risk Assessment for Thermal Inactivation of *Salmonella* in Fresh Pork

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Acronyms and Abbreviations

°C	degrees Celsius
°F	degrees Fahrenheit
ARS	Agricultural Research Service of the U.S. Department of Agriculture
BAM	Bacteriological Analytical Manual
CDC	Centers for Disease Control
CFU	Colony Forming Units
cm	centimeter
D or D-value	Decimal reduction time
DR	Dose-response
EO	Eating Occasion
FAO/WHO	Food and Agriculture Organization / World Health Organization of the United Nations
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture
FSNS	Food Safety Net Services
g	gram
GB	Green Bay, Wisconsin
GP	Grand Prairie, Texas
LOD	Limit of Detection
MLG	Microbiology Laboratory Guidebook
MPN	Most Probable Number
NPB	National Pork Board
OMB	Office of Management and Budget
P	percentile
PCE	Pork Chop Enhanced
PCUE	Pork Chop Unenhanced
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
Pr(Illness)	Probability of Illness
PRE	Pork Roast Enhanced

PRUE	Pork Roast Unenhanced
PHX	Phoenix, Arizona
RTE	Ready to Eat
RTI	Research Triangle Institute
SA	San Antonio, Texas
U.S.	United States
USDA	U.S. Department of Agriculture

Executive Summary

In establishing the scope, goals and objectives of this risk assessment, Exponent considered key factors that impinge on consumer exposure to microbiological hazards associated with cooked fresh pork. The assumptions include:

- *Salmonella* is the most relevant biological hazard;
- The most relevant scope to consider is a product pathway analysis that begins at retail and ends with home preparation and consumer consumption;
- Final end-point temperature[1] within the coldest gram of cooked meats eliminates the need to consider cooking method;
- Considering the coldest gram of cooked meat in a serving eliminates the need to consider pork consumption levels in the exposure assessment;
- Temperature end-point determinations are dynamic, not static, and result in the conservative underestimation of pathogen lethality;
- There will be some elapsed time between removal of fully cooked food from the heat source and consumption by consumers, which adds safety; and
- Consumers will reject meat if a high level of spoilage is present.

The main objective and scope of this risk assessment was to develop a retail-to-table probabilistic risk assessment to evaluate the risk of illness (salmonellosis) per serving from *Salmonella* from consumption of consumer-cooked moisture enhanced and unenhanced pork chops (bone-in) and roasts (boneless). This risk assessment considers achieving various cooking end-point temperatures (145–160ºF) at the coldest gram of the product, without regard to cooking method.

Risk assessment questions included:

[1] References to "end-point temperature" throughout this report refer to the end-point temperature within the coldest gram of cooked meat.

1. What is the risk per serving of consuming pork chops and/or roasts that are cooked to the current recommended consumer cooking end-point temperature of 160º F for both moisture enhanced and unenhanced products?
2. What is the risk per serving if the cooking end-point temperatures were reduced to 145, 150 or 155º F?

The model began with the exposure assessment, starting with an estimation of the prevalence and levels of *Salmonella* on pork meat at retail. The model captured exposures associated with four types of pork cuts, including, pork chops (bone-in) moisture enhanced and unenhanced, and pork (boneless) roast moisture enhanced and unenhanced. From the point of retail, the model evaluated the growth potential of *Salmonella* during transportation from retail stores to homes and additional growth during storage/refrigeration once the products are in consumers' homes. Subsequently, the exposure model considered the decline in *Salmonella* levels due to thermal inactivation (i.e., during cooking). As a final step, to estimate the risk of illness per serving, the model combined the exposure estimates post-cooking colony forming units per serving with the *Salmonella* dose-response model.

The initial segment of the exposure assessment model estimated the occurrence and extent of *Salmonella* contamination on raw pork chops and roasts at retail establishments. The second segment of the exposure assessment derives levels of *Salmonella* in an eating occasion. In the consumer module, the growth/decline of *Salmonella* due to transport from retail to home, storage and handling condition at home prior to cooking, the probability of survival of the bacteria, and levels in foods that are consumed after cooking, were estimated.

Because there were few data available that included the prevalence and levels of *Salmonella* on fresh enhanced and unenhanced pork roasts and chops, a 4,000-sample, four-city retail survey was conducted by the National Pork Board (NPB) prior to the conduct of this risk assessment. The purpose of the study was to get a sufficient number of positives to determine the range and distribution of *Salmonella* levels at retail for these products. The survey provided a convenience sample that yielded 28 confirmed positive samples, which is less than a 1% *Salmonella* occurrence rate. All of the confirmed positives were in enhanced pork chops (18) and roasts

(10). *Salmonella* levels on confirmed positive samples were low, ranging from 0.3-1.40 MPN/g. *Salmonella* levels on confirmed positive samples were combined with the negative results (non-detects below a limit of detection of 0.3 MPN/g) and assumed to follow a lognormal distribution.

The Agricultural Research Service of the U.S. Department of Agriculture (USDA-ARS) growth model was used to model *Salmonella* growth in pork chops and roasts. Storage times and temperatures were developed for two segments of the growth model, including transport from stores to homes, and storage and refrigeration in homes prior to cooking. In the baseline model, meat was assumed to be spoiled if there was *Salmonella* growth above 7 log CFU per gram.

A Food and Drug Administration (FDA) model was used to estimate the decline in *Salmonella* levels from cooking. A D-value was derived based on the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA-FSIS) recommendations for destruction of *Salmonella* in beef. The estimated z-value of 10ºF is based on the same guidance.

The levels of *Salmonella* being inactivated at various cooking end-point temperatures were estimated at holding times of 15 seconds and 1, 3 and 4 minutes, where holding time refers to the time held at the end-point temperature. It was estimated that *Salmonella* levels were killed at end-point temperatures of 160, 155, 150 and 145ºF. The mean log killed after a 15 second holding time were 13.9, 4.4, 1.4 and 0.4 log CFU/g at 160, 155, 150 and 145ºF, respectively. The exposure assessment model examined the cooking end-point temperature at the coldest gram, which was serving size in the exposure simulation.

Exposure simulation was carried out using Crystal Ball®. Latin Hypercube sampling and 10,000 iterations were used. The following sequence of sampling was conducted:

Step 1 - Estimation of levels of *Salmonella* in pork meat at retail.

Step 2 - Estimation of growth during transportation from retail stores to consumer homes.

Step 3 - Estimation of growth during storage in homes (refrigeration).

Step 4 - Estimation of surviving *Salmonella* levels (log CFU/g) after cooking.

Step 5 - Estimation of *Salmonella* levels and risk of salmonellosis per serving.

In the baseline scenario, the risk of salmonellosis from consumption of pork chops and roasts was estimated, assuming that product was purchased at retail, transported and stored at home, then cooked by a consumer so that the coldest gram of the meat was cooked to the current recommended consumer cooking end-point temperature of 160°F (71.1°C), and held at that temperature for 15 seconds. Based on the simulated results at a cooking end-point temperature of 160ºF, there were no surviving *Salmonella* per serving and there was no risk per serving.

In the alternative end-point temperature scenarios, cooking end-point temperatures were allowed to vary below the recommended 160ºF, to include 145 (62.8), 150 (65.6) and 155°F (68.3°C). In all cases, the simulated holding time at the end-point temperature was 15 seconds at each temperature. In all alternative cases, risk per serving was similar to the baseline scenario (zero risk per serving) at or below the 97.5th percentile.

To examine the impact of holding time on the potential surviving *Salmonella* levels, alternative holding time durations of 1, 3 and 4 minutes were incorporated into the risk assessment model. The results showed that for all four pork cuts, when a cooking end-point temperature of 145^{o}F is maintained for 4 minutes, there were no surviving levels of *Salmonella* and zero risk per serving, for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute and for 15 seconds, surviving CFU per serving and associated risk per serving were only predicted at the 99th percentiles and higher.

Sensitivity analyses were conducted for a variety of alternative scenarios including: higher retail *Salmonella* levels and different *Salmonella* distributions; several time and temperature abuse scenarios; and consideration of the risk for a human subpopulation that is especially *Salmonella* sensitive. For each sensitivity analysis, only the distributions of *Salmonella* levels at retail were redefined. The sensitivity analysis showed that for the enhanced pork meats, the estimated levels of *Salmonella* were the highest when the input distribution of levels at retail was based on carcass prevalence data. When NPB survey data were combined and a Weibull distribution was used instead of the lognormal, the estimated levels at retail were the lowest, at and below the 90th percentile. For the unenhanced pork meats, when the input distribution of levels at retail was based on carcass prevalence data, the estimated levels of *Salmonella* in pork meats at retail were higher than estimates in the baseline in the upper percentiles. However, in the lower percentiles, the predicted levels were slightly higher in the baseline model. When NPB survey data were combined and the lognormal and Weibull distributions were used, sensitivity analyses #2 and #3, respectively, the estimated levels at retail were lower than that predicted in the baseline model. At an end-point cooking temperature of 145°F for 15 seconds, the log reduction is such that the risk per serving for all cuts was essentially zero, at and below the 97.5th percentile, when alternative carcass data and model approaches were used to estimate *Salmonella* levels at retail. In the two temperature abuse scenarios, consumers were assumed to take products out of the refrigerator and leave them on the counter at room temperature for an extended amount of time before cooking. In both abuse scenarios, there were no surviving *Salmonella* and no risk per serving in all four pork cuts at the 97.5th percentile and below.

The dose-response model used in the risk assessment was derived by the Food and Agriculture Organization/World Health Organization of the United Nations (FAO/WHO), and is not specific to sensitive subpopulations. Exponent adjusted the probability of illness derived from the FAO/WHO model to a sensitive subpopulation. There was no risk per serving for all four cuts at the 97.5th percentile and below, when cooked to an end-point temperature of 145ºF for 15 seconds using the alternative dose-response model.

Uncertainty in retail *Salmonella* levels was assessed by redefining the distributions used to characterize these parameters and running alternate sets of simulations and comparing the resulting estimates to those derived using the base model. In addition, uncertainty of the fraction of unenhanced pork products likely to be contaminated with *Salmonella* was addressed by using a tolerance interval approach to estimate the highest percentile (P) of the distribution that could be estimated with 95% confidence, given the number of samples available, and assuming, conservatively, that P% of the distribution of unenhanced pork chops and roasts would have *Salmonella* levels < 0.3 CFU/g.

A key finding was that if good retail and consumer handling practices are employed prior to and during consumer cooking, enhanced and unenhanced pork chops and roasts can be cooked to 145ºF without increased risk of contracting salmonellosis. The assurance of the microbiological safety of food is a cumulative process, reflected in the product pathway analysis used in current risk assessment. Refrigerated products, such as fresh pork, need to remain clean, cold, and must be cooked properly to prevent the respective contamination, growth, and survival of harmful microorganisms, such as *Salmonella.* Inadequacies in retail and consumer handling are recognized and may pose an unnecessary but controllable risk to consumers.

This risk assessment estimated that for many such abuses, consumers' risk of developing salmonellosis remains low, even at a 145°F end-point cooking temperature. This risk assessment also demonstrated that those risks could be controlled by adherence to good pre-cooking handling practices and by continued holding of pork chops and roasts at hot temperatures after removal from the heat source, but before serving. Additional public awareness education would help consumers ensure that they are using safe and consistent food handling and proper cooking practices.

The major conclusion of this risk assessment, that consumer cooking to 145°F provides adequate protection against developing salmonellosis from the consumption of pork chops and roasts, if good retail and consumer handling practices are employed, suggests that the current FSIS consumer cooking end-point temperature guidance of 160-170°F (USDA, 2003b) yields a very conservative margin of protection.

New science presented in this risk assessment supports a re-evaluation of the current consumer recommendations for the safe cooking of fresh pork and consideration for alignment with other current meat cooking standards and guidance, including:

- Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products (FSIS, 1999). This guideline permits a minimum cooking temperature of 145°F for 4 minutes for roast beef and other fully cooked beef cuts to meet the lethality performance standards for the reduction of *Salmonella* contained in §§ 318.17(a)(1) and 381.150(a)(1) of the meat and poultry inspection regulations.
- U.S. Food Code, Section 3-401.11, is the food service and retail guidance document that is administered by FDA and endorsed by FSIS (FDA, 2005), and lists a cooking end-point temperature of 145°F for 15 seconds and 3 minutes for the cooking of fresh and injected pork, respectively.

- FSIS consumer guidance for cooking beef recommends an internal temperature end-point of 145°F for steaks and most roasts (USDA, 2003b).

The results from this risk assessment suggest that consumer cooking end-point temperature recommendations can be lowered without having an adverse impact on public health.

1 Preface: Risk Assessment Policy - Assumptions and Rationale

In establishing the scope, goals and objectives of this risk assessment, Exponent considered key factors that impinge on consumer exposure to microbiological hazards associated with fresh pork. The assumptions and their rationale used in Exponent's risk assessment are described below.

Assumption 1: ***Salmonella*** **is the most relevant biological hazard for cooked fresh pork.**

Rationale:

1. **Pathogens under consideration**

Exponent considered a variety of microbiological pathogens to incorporate into the risk assessment. This section describes those microorganisms and the rationale for their inclusion or exclusion into the risk assessment.

Listeria monocytogenes: From 2003 to 2006, *Listeria monocytogenes* accounted for 85% of the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) recalls of pork products associated with microbial contamination (USDA, 2007c). Almost all of the recalled products were processed products, such as sausages and/or ready-to-eat (RTE) products, where *L. monocytogenes* frequently contaminates after processing and before packaging. This pathogen is the leading factor associated with recalls of pork products and has been found consistently on carcasses and at retail (USDA 1996; Duffy *et al.*, 2001). However, this pathogen does not compete well against the indigenous microflora on hog carcasses and there is a lack of data linking fresh pork to listeriosis cases. Therefore, *L. monocytogenes* was not considered as a pathogen of concern for fresh pork.

Staphylococcus aureus: Of the 132 outbreaks linked to pork between 1990 and 2003, *Staphylococcus aureus* was the most common microbiological hazard (CSPI, 2006). The primary pork product associated with these outbreaks was ham (87 outbreaks), which is a processed, not fresh, meat product. The salt content of cured pork products, such as ham, creates an environmental niche where the pathogen can out-compete other microorganisms, resulting in growth and enterotoxin production. Once produced in the food, the heat stable enterotoxin survives all cooking temperatures discussed in this risk assessment. Changes in cooking temperature have no effect on the risk of illness from *S. aureus* toxin production prior to cooking. Therefore, *S. aureus* is not a pathogen of concern for cooking fresh pork.

Spore-forming pathogens: *Clostridium perfringens* is a ubiquitous spore-forming bacterium that has been traditionally associated with improperly cooled and re-heated cooked beef and poultry dishes. Pork products (non-sausage or ham) accounted for less than 3% of the outbreaks associated with *C. perfringens* from 1990 to 1999 (CSPI, 2006). *Bacillus cereus* is also a spore-forming bacterium that has traditionally caused illness from the consumption of cooked and re-heated rice and cereal dishes. Spores of both pathogens are commonly found on a multitude of foods that come into contact with soil during production. The wide distribution in nature and on foods allows for these pathogens to commonly contaminate pork dishes.

Spores of both of these pathogens survive cooking and can cause illness provided time/temperature conditions, primarily from improper cooling or failure to keep hot products at a sufficiently elevated temperature, exist to allow growth and toxin development. Like *S. aureus* enterotoxin, conventional cooking temperatures will not inactivate spores of *C. perfringens* or spores of *B. cereus* and its heat stable toxin. Therefore, the end-point temperature changes evaluated in this risk assessment will have no effect on the potential risk from these pathogens. For this reason, neither *C. perfringens* nor *B. cereus* is considered a pathogen of concern for cooking fresh pork.

Parasites: Parasites such as *Trichina* have been historically linked to the consumption of undercooked pork. The most recent surveys indicate that the seroprevalence of *Trichinella spiralis* and *Toxoplasma gondii* in carcasses is less than 1% (USDA, 2001). However, the most recent national retail meats survey for viable *T. gondii* found the parasite in pork at retail (levels below 1%) (Dubey *et al.*, 2005). Similarly, *Trichina*, although virtually absent in swine in the U.S., was the most common hazard associated with outbreaks linked to the consumption of game meat (CSPI, 2006). Clearly these parasites are prevalent in the environment and may contaminate pigs periodically. Because of this potential, *T. gondii* and *T. spiralis* must be considered when evaluating cooking of fresh pork.

Enteric viruses: Between 1998 and 2004, virus outbreaks were responsible for 30% of all foodborne illness outbreaks; of these, 88% were attributed to norovirus (CSPI, 2006). Multi-ingredient dishes (31%), produce (26%), seafood (9%), and poultry (7%) were the product categories implicated the most by outbreak reports (CSPI, 2006). Pork (grouped with luncheon and other meats) accounted for approximately 3% of the reported virus outbreaks.

Enteric viruses, such as norovirus, are shed at high numbers by their human hosts and can have low infectious doses (ICMSF, 1996). Due to these factors, virus outbreaks are reported highest in restaurant/food establishments (45%) where foods have a higher exposure to humans. Because of the human transmission of enteric viruses, all foods are susceptible to contamination before and after cooking. Therefore enteric viruses are a concern for evaluating the safety of cooking fresh pork.

Enteric bacterial pathogens: Although not implicated frequently in outbreaks or recalls, enteric bacterial pathogens that are routinely found on hog carcasses and on product at retail are persistent bacterial concerns for fresh pork. The USDA-FSIS conducts surveys for *Salmonella* on market hog carcasses as part of their Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) verification testing program. The prevalence of *Salmonella* has varied between 2.5 and 4% between 2003 and 2006 (USDA 2007d). Previous data from the 1995 to 1996 Nationwide Pork Microbiological Baseline Data Collection Program observed a *Campylobacter jejuni/coli* prevalence of 31.5% on market hogs (USDA, 1996). *Yersinia enterocolitica* primary reservoir is hogs (ICMSF 1998), where the organisms can accumulate in the tonsils. This pathogen was detected commonly (19.8%) on whole muscle pork cuts at retail (Duffy *et al*., 2001). The ability for *Salmonella* and *Campylobacter* and *Yersina enterocolitica* to contaminate pork, survive in the new environment, and compete against indigenous microflora, will influence the prevalence of these pathogens at retail.

E. coli biotype 1 was isolated on 31.5% of the pork carcasses (USDA 2007d), however the pathogenic form of this organism, *E. coli* O157:H7, was not isolated (n=1,112). This pathogen has not been considered by USDA to be a biological hazard likely to be present on fresh pork or ground pork (USDA, 1999b). Therefore *E. coli* O157:H7 is not considered a pathogen of concern for this risk assessment.

From the above considerations, parasites, enteric bacterial pathogens, and enteric viruses were considered to be of concern for fresh pork. Their heat resistance was considered and described next.

2. Heat resistance of pathogens of concern

Based on the scientific literature, *Salmonella* is the most heat resistant pathogen of concern associated with cooking fresh pork (Table 1). A recent report studying thermal resistance of foodborne pathogens over all food matrices concluded that *Salmonella* populations are more resistant than *C. jejuni* or *Y. enterocolitica* (Van Asselt *et al*., 2006). This agrees with Blankenship and Craven (1982) and Koides and Doyle (1983) who observed that cooking procedures that destroyed *Salmonella* would be expected to destroy *C. jejuni*.

Research on *Trichina* inactivation by heat in contaminated pork showed that temperatures between 130 and 140ºF completely inactivated all populations of the parasite (Carlin *et al.,* 1969). *Salmonella,* by comparison, has an estimated $D_{140ºF}$-value of 102 seconds (USDA, 1999a). Research studying the effect of high temperatures on the infectivity of *T. gondii* in pork confirmed that *Trichina* larvae are more heat resistant (Hill *et al.*, 2006; Dubey *et al.*, 1990). These data are reflected by the scientific rationale for pork-cooking temperatures in Annex 3 of the Food Code (FDA, 2005), where the Food and Drug Administration (FDA) concluded that parasites linked to pork were inactivated at temperatures below 145°F.

Published research on feline calicivirus (Duzier *et al*., 2004), an accepted surrogate for norovirus, also demonstrates that cooking temperatures that inactivate *Salmonella* will kill greater numbers of all other pathogens of concern for fresh pork.

Comparative lethalities for the various pathogens in the range of 130 to 135°F are shown in Table 1. The data demonstrate that *Salmonella* possesses greater heat resistance than all of the other pathogens that were considered for inclusion into the current risk assessment.

Table 1 Comparative Heat Resistance for Pathogens of Concern for Cooking Fresh Pork in the Range of 130-135° F

Pathogen	Lethality	Citation
Salmonella	D-value = 8.9 min at 133°F in beef roasts	USDA, 1999a
Campylobacter jejuni	D-value = 0.96 min at 133°F in ground beef	Koides and Doyle, 1983
Yersinia enterocolitica	D-value = 1.06 min at 131°F in minced beef	Bolton *et al*. 2000
Trichinella spiralis	3 to 4 log inactivation at 135°F in beef roast.	Carlin *et al*., 1969
Toxoplasma gondii	D-value = of 0.55 min at 133°F in pork meat	Dubey *et al*., 1990
Norovirus	D-value = 2.7 min at 133°F for feline calicivirus (surrogate) in broth medium	Duizer *et al*., 2004

<u>Assumption 2</u>: The most relevant scope to consider for the current risk assessment is a product pathway analysis that begins at retail and ends with home preparation and consumer consumption.

Rationale:

Data from the literature, government surveillance, and industry studies strongly suggests that pork meat is primarily contaminated at slaughter. While the prevalence of *Salmonella* on carcasses is between 2.5 and 4% (USDA, 2007d; USDA, 2007e), fabrication, and distribution do not appear to increase the prevalence of *Salmonella* in fresh pork. In fact, research has shown that prevalence decreases as product moves into retail (Zhao *et al* 2002; USDA, 2003). Therefore concentrating this risk assessment from retail to consumers' homes and through consumption is the most relevant part of the product pathway. Furthermore, beginning the risk assessment at the retail stage reduces the uncertainty of the model.

<u>Assumption 3</u>: Final end-point temperature within the coldest gram of cooked meats eliminates the need to consider cooking method.

Rationale:

Although cooking imparts esthetic sensory and food safety benefits, this process is very complex, especially to understand the integrated thermal lethality kinetics of a target microorganism, such as *Salmonella,* in pork. Considerations include: (1) cooking method, (2) heat source temperature, (3) duration of thermal treatment, (4) continued heat rise after product is removed from the heat source, (5) cooling kinetics, and (6) physico-chemical factors within food that influence heat transfer rates. These six considerations are used to estimate safe cooking practices. An integrated thermal process consists of specifying the time required to reach and maintain a given temperature at the coldest spot in the product in order to kill target microorganisms and to meet time/temperature cooling specifications to ensure that any spores will not germinate. In the case of cooking fresh pork, it is primarily the consistent and accurate delivery of the estimated *D*-value multiple to the coldest point in the food that ensures the food safety goal of killing a specified level of a microorganism of most concern.

For conventional methods, such as broiling, roasting, or pan-frying, cooking can be viewed as the direct or indirect application of heat across three dimensions of the food. As thermal energy is applied, heat and mass transfer occurs across this complex matrix. This was described by Pan *et al.* (2000), who studied the cooking of hamburger patties. They described two spatial regions, which includes the crust (i.e. meat and heating surface interface) and core portions of the food. These two regions are separated by water evaporation and fat melting boundaries that move continuously, as the cooking progresses, toward the center of the product.

Initially, at the surface and immediately inside the patty, the temperature quickly exceeds 212°F (100°C), as water evaporates. Crust is formed at the surface by dehydration and browning reactions (Zorrilla and Singh, 2003). In the early cooking stages, due to the lower melting temperature of lipids, the fat melting front moves inward, more quickly than the water evaporation boundary. The continuous heat conduction, resulting in external migration of rendered fat and water vapor, creates an inward moving heat flux interface, resulting in a core temperature rise.

During this process microorganisms die as heat conducts through the product core. Microorganisms on the food surface are quickly killed, while pathogens located in interior portions progressively die as the water vapor boundary moves inward. Microorganisms situated at the coldest spot of the product are the last to die. Even for internally located microorganisms, lethality estimates tend to be very conservative. This arises for three reasons:

1. Microbial killing increases exponentially as the product temperature progressively elevates into the microbial lethality range. This process was demonstrated by Banga *et al.* (2001) using *E. coli* 0157:H7. These investigators showed that during the ten seconds required for hamburger center temperatures to transit from approximately 50°C to 68.5°C, microbial lethality rates correspondingly increased from 1.0 to 9.3 log cycles per second.
2. The external application of thermal energy necessary to achieve a target five to seven log kill at all locations within the food, creates a heating and concomitant biocidal gradient from the product surface to the coldest gram within the product. This process yields over-heating the product and over-killing microorganisms at all locations, except the product cold spot.
3. After the food is removed from heat source, pathogen killing continues at the cold spot, until the core temperature transcends the minimum time/temperature combination necessary to achieve *Salmonella* lethality.

For the reasons described above, this risk assessment addresses the integrated thermal lethality of *Salmonella* at the coldest portion (coldest gram) within pork products, independent of cooking methods. Therefore, the total exposure is based upon the fraction of the surviving *Salmonella*, if any, within the coldest gram.

<u>Assumption 4:</u> **Considering the coldest gram of cooked meat in a serving eliminates the need to consider pork consumption levels in the exposure assessment portion of the risk assessment.**

Rationale:

Given the nature of heat penetration during the cooking of meat, as described in Assumption 3, if the coldest gram in a serving of pork reaches a temperature adequate to eliminate all *Salmonella*, the remainder of the product is rendered pathogen free. Therefore other than the coldest gram, the amount of product consumed would have no contribution to the risk of an individual developing salmonellosis.

<u>Assumption 5:</u> **Temperature end-point determinations are dynamic, not static, and result in the conservative underestimation of lethality.**

Rationale:

As heat is applied to the coldest gram within meat, higher temperatures pervade the remainder of the muscle tissue. Once the meat is removed from the heat source, the temperature at the coldest spot will increase in temperature until thermodynamic equilibrium is reached with the surrounding muscle. Because pathogen lethality at inactivation temperatures is exponential, the resulting post cooking temperature rise yields several more magnitudes of killing than that calculated by reaching end-point temperature. This adds a sizable level of conservatism to all lethality calculations of end-point temperatures.

<u>Assumption 6:</u> **There will be some elapsed time between removal of fully cooked food from the heat source and consumption by consumers, which adds greater safety due to the heat holding capacity of pork.**

Rationale:

As described above, heat rise continues after removal of the product from the heat source. While end-point temperatures not linked to a holding time are the preferred approach for consumer guidance, there is inevitably elapsed time between removal of the product from the heat source and the time that a consumer will actually eat the product. Continued temperature rise will kill greater numbers of microorganisms.

<u>Assumption 7:</u> Consumers will reject meat if a high level of spoilage is present.

Rationale:

Meats are considered spoiled if sensory changes make them unacceptable to the consumer. Populations of bacteria in muscle tissue in live healthy animals are virtually non-existent (ICMSF, 1998). As stated previously, most microbial contamination occurs during slaughter. Microorganisms on hog carcasses are reduced during processing but not completely eliminated (Grau, 1986); and are then transferred onto muscle tissue during the fabrication of meat into subprimal and retail cuts. It is generally agreed that spoilage defects in meat become evident when the spoilage bacteria at the surface reach log 7 colony-forming units (CFU) per cm^2 (ICMSF, 1998).

Pork slaughter and fabrication facilities employ rapid chilling of product after processing. Any bacteria adhering to the muscle tissue after cutting will encounter low temperatures, low relative humidity and high air velocities. These conditions favor the establishment of psychotrphic spoilage bacteria over the establishment of more mesophillic pathogens such as *Salmonella.*

This risk assessment treated meat as spoiled and rejected by the consumer (i.e. not consumed, and therefore, no risk for salmonellosis) if the coldest spot within the meat reached a population density of log 7 CFU/g of *Salmonella*. This assumption is conservative because the accepted level for spoilage on the surface of meats would need to be several magnitudes higher for the same levels (log 7 CFU) to be found within a gram of muscle at the coldest spot. Similarly, *Salmonella* would not grow as fast as spoilage bacteria, such as *Pseudomonas,* because of the conditions in which the meats are held.

2 Introduction

The main objective and scope of this risk assessment is to develop a retail-to-table probabilistic risk assessment to evaluate the risk of illness (salmonellosis) per serving from *Salmonella* from consumption of consumer-cooked moisture enhanced and unenhanced pork chops (bone-in) and roasts (boneless). This risk assessment considers achieving various cooking end-point temperatures (145 – 160ºF) at the coolest point of the product, without regard to cooking method. This encompasses the range of temperatures that USDA currently recommends for the consumer cooking of medium and well-done beef and medium pork (see Table 2).

Table 2 USDA Cooking Recommendations for Beef and Pork

Type of Red Meat	Cooking Recommendation
Beef Ground Beef Mixtures	160°F
Beef Whole Muscle Meats	145°F (medium rare) 160°F (medium) 170°F (well done)
Pork Ground Beef Mixtures	160°F
Pork Whole Muscle Meats	160°F (medium) 170°F (well-done)

Specifically, the following risk assessment questions were evaluated:

- What is the risk per serving of consuming pork chops and/or roasts that is cooked to the current recommended consumer cooking end-point temperature of 160º F for both moisture enhanced and unenhanced products?
- What is the risk per serving if the cooking end-point temperatures were to be reduced to 145, 150 or 155º F?

The risk assessment presented in this report addresses the above questions and were conducted in that manner that meets the Food and Agriculture Organization/World health Organization of the United Nations (FAO/WHO) and *Codex Alimentarius* guidelines for microbial risk assessments and Office of Management and Budget (OMB) guidelines on the conduct of risk assessments. This risk assessment report was subject to an independent peer review conducted by RTI International (RTI), according to OMB guidelines. The RTI review and Exponent's response are provided in a separate document.

3 Risk Assessment Framework

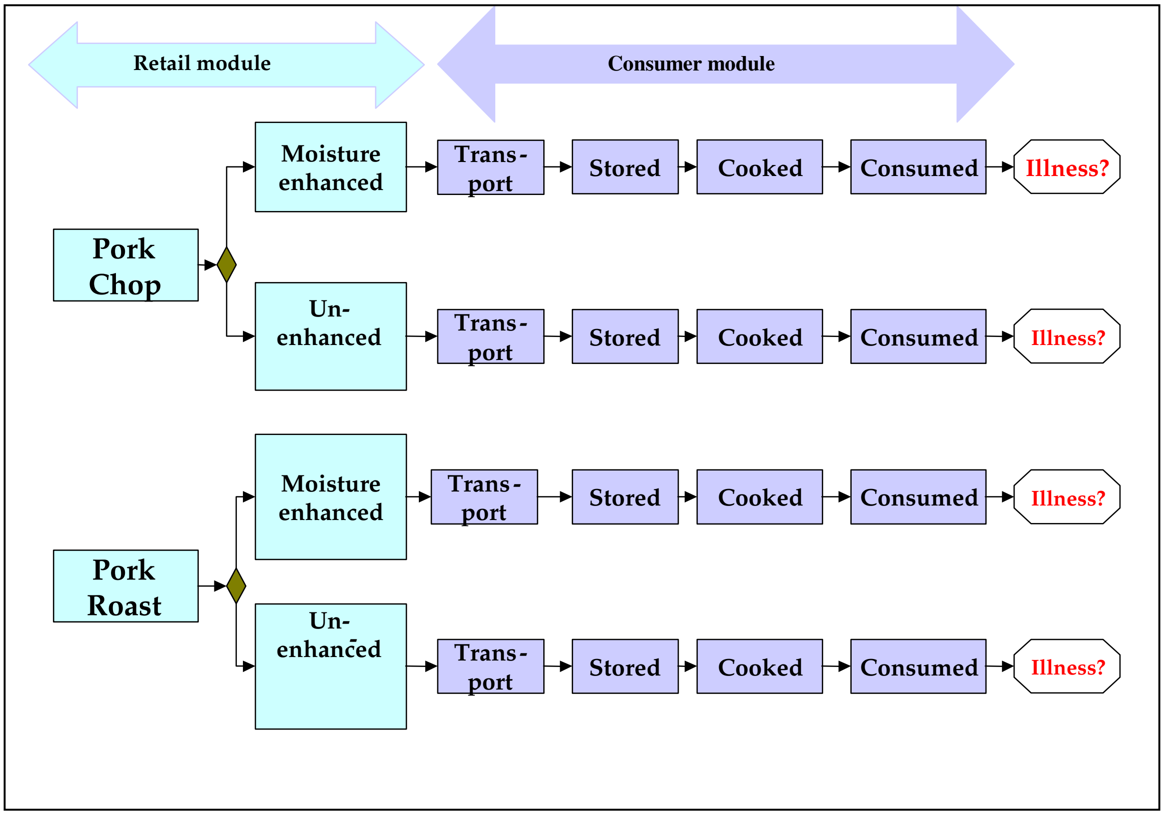
The scope of this risk assessment is from retail to consumption, with the conceptual risk assessment framework outlined in Figure 1. The model began with the exposure assessment, starting with an estimation of the prevalence and levels of *Salmonella* on pork meat at retail. The model captured exposures associated with four types of pork cuts including, pork chops (bone-in) moisture enhanced and unenhanced, and pork (boneless) roast moisture enhanced and unenhanced. From the point of retail, the model evaluated the growth potential of *Salmonella* during transportation from retail stores to homes and additional growth during storage/refrigeration once the products are in consumers' homes.

Subsequently, the exposure model considered the decline in *Salmonella* levels due to thermal inactivation (i.e., during cooking). Since the cooking "end-point" temperature is the focus of the thermal inactivation mode in this risk assessment, the predicted levels of *Salmonella* at the coldest gram of the piece of meat would represent very conservative levels in a serving. The main support for this argument is that by the time the coldest gram of the piece of meat can be measured – such as by inserting a thermometer - to verify that it reached the desired cooking end-point temperature, that location and the surrounding area would have exceeded the desired cooking end-point temperature. Thus, by determining lethality at the time the coldest gram reaches the target end-point temperature, the amount of *Salmonella* inactivation would be underestimated.

As a final step, to estimate risk of illness per serving, the model combined the exposure estimates post-cooking colony forming units per serving with the *Salmonella* dose-response (hazard characterization). The FAO/WHO dose-response curve for *Salmonella* was used to estimate risk of illness per serving.

As structured, this risk assessment has two distinct components: 1) exposure assessment and 2) illness/risk characterization. The main focus of this risk assessment was the exposure assessment model and its components, which are thoroughly described herein.

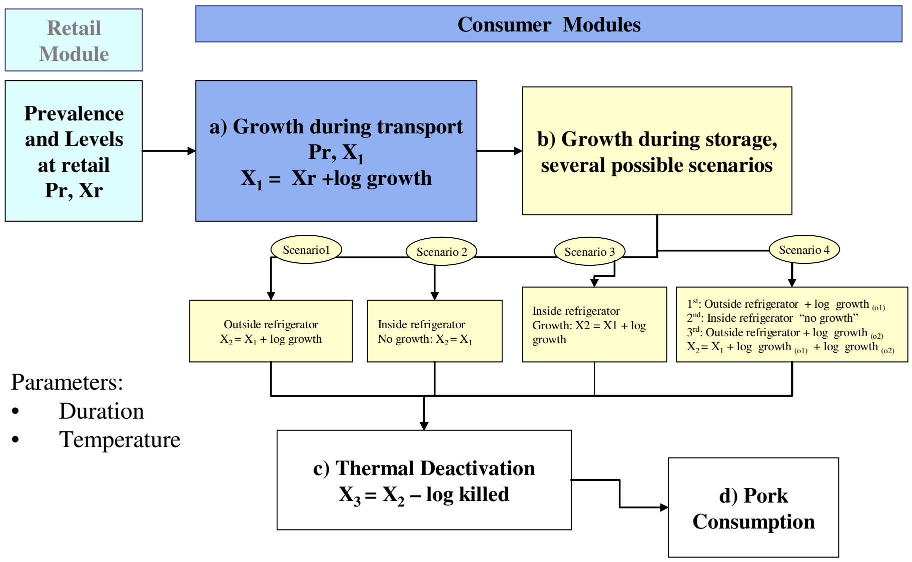
Figure 1 Conceptual Risk Assessment Framework



3.1 Exposure Assessment

The exposure assessment model begins with an estimation of the occurrence and extent of *Salmonella* contamination on raw pork chops and roasts at retail establishments. This initial segment of the exposure assessment is referred to as the "retail" module. The second part of the exposure assessment is the estimation of levels in an eating occasion. This segment of the assessment is referred to as the "consumer" module. In the consumer module, the growth/decline of *Salmonella* due to transport from retail to home, storage and handling condition at home prior to cooking, the probability of survival of the bacteria after cooking, and levels in foods that are consumed are estimated. The conceptual schematic of the exposure assessment modules is in Figure 2. Detailed descriptions of the exposure model components and data support for input parameters are provided in Section 5 of this report.

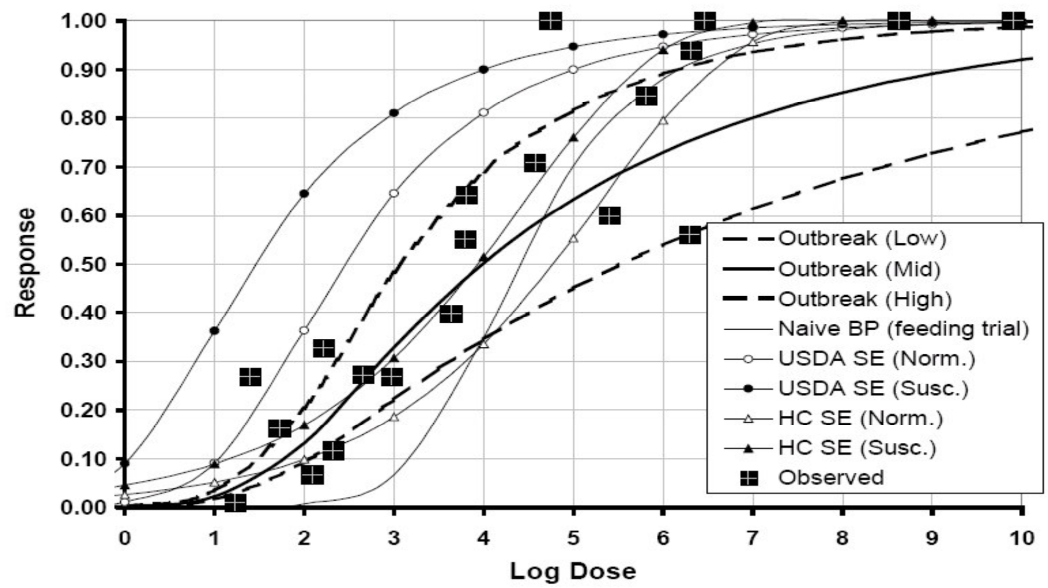
Figure 2 Conceptual Schematic of the Retail to Table Exposure Assessment



3.2 Hazard Characterization (Dose Response)

The dose-response models based on both experimental and outbreak data for *Salmonella* has been fully described in the FAO/WHO Risk Assessments of *Salmonella* in Eggs and Broiler Chickens (FAO/WHO, 2002). Figure 3 is a comparison of all dose-response models with reported outbreak data presented in the FAO/WHO report. The FAO/WHO dose-response (DR) model offers a reasonable estimate for the probability of human illness upon ingestion of a dose of *Salmonella*. The model is based on outbreaks. The FAO/WHO report concluded that the model can be used for risk assessment purposes and generates estimates that are consistent with those that have been observed in outbreaks (FAO/WHO, 2002).

Figure 3 Comparison of Dose-Response Models for *Salmonella* with Reported Outbreaks



Ref (FAO/WHO, 2002)

The FAO/WHO (2002) risk assessment used the Beta-Poisson to fit the outbreak data. Maximum likelihood method was used to generate the best-fit curve. Uncertainty in the outbreak data was incorporated into the fitting routine. To fit the DR model to the uncertain outbreak data, the data were re-sampled based on the uncertainty distribution (5,000 iterations). The resulting statistics for the alpha and beta parameters of the Beta-Poisson Model are summarized in Table 3.

$$P_{ill} = 1 - \left(1 + \frac{Dose}{\beta}\right)^{-\alpha}$$

Table 3 Beta Poisson Dose Response Parameters for *Salmonella*

Statistics	Alpha	Beta
Lower bound	0.08	38.49
2.5th percentile	0.09	43.75
Expected value	0.13	51.45
97.5th percentile	0.18	56.39
Upper bound	0.23	57.96

Ref: Risk Assessments of *Salmonella* in Eggs and Broiler Chickens, FAO/WHO 2002, page 77

For this risk assessment, a Beta-Poisson model was also used, and the distributions for alpha and beta are based on the FAO/WHO 2002 *Salmonella* risk assessment for chicken and eggs as summarized in Table 2. The distributions of alphas and betas are assumed to be two correlated (R=0.95) triangular distributions, with the following parameters:

Alpha: Minimum 0.08, Likeliest 0.13, Maximum 0.23

Beta: Minimum 38.39, Likeliest 51.45, Maximum 57.96

3.3 Risk Characterization

In this step, the exposure and hazard characterization were integrated to express the probability of developing salmonellosis per eating occasion (EO). The schematic of the inputs and output of this segment of the risk characterization is outlined in Figure 4 below. The overall summary of the risk assessment model components and data sources is presented in Table 4. Detailed descriptions of the model components are provided in Section 5 of this report.

Figure 4 Schematic of the Risk Characterization Segment

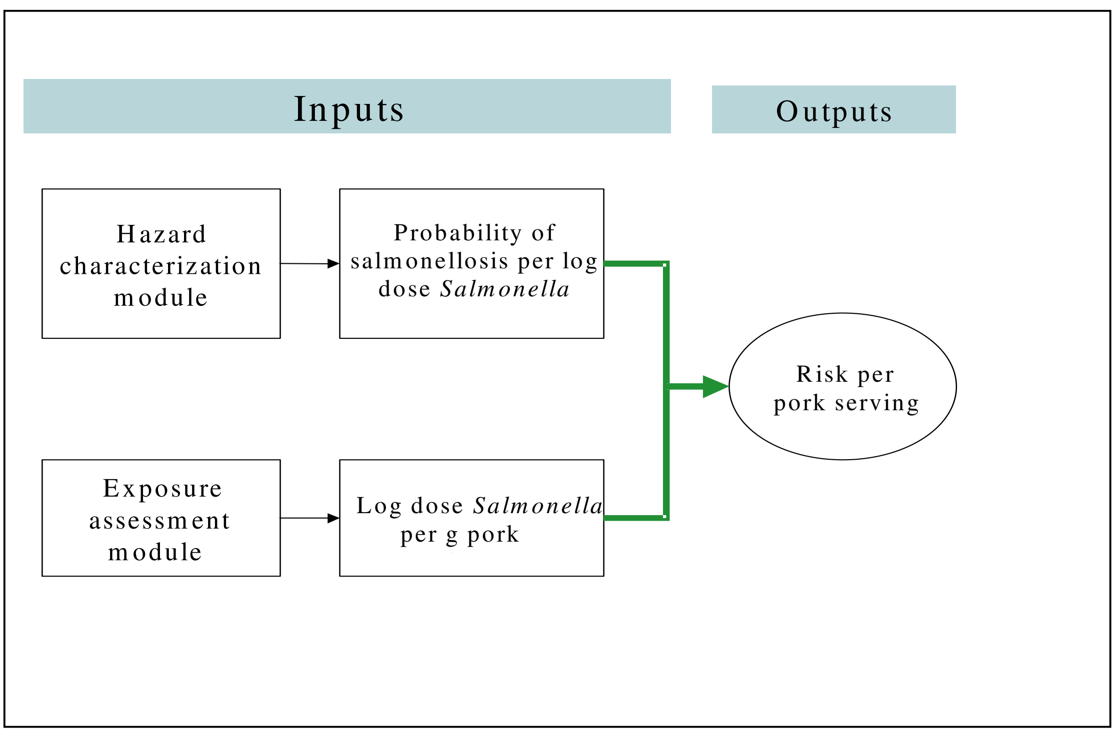


Table 4 Summary of Risk Assessment Model Components and Data Sources

Module	Model Parameters	Description	Data Sources
Retail	Prevalence and levels at retail	Lognormal distributions based on prevalence and levels found in NPB survey at retail	NPB retail survey
Consumer	**Transportation from retail to refrigeration in homes**		
	Growth model	All time/temperature conditions permissive for growth are modeled using the model used in the USDA-ARS Pathogen Modeling Program V7	Gibson et al., 1988; USDA, 2006
	Product pH	Unenhanced-One distribution for both products at all collection locations Enhanced-One distribution for PCE and PRE for the Phoenix, and one distribution for the other 3 sampling locations were created	Appendix A
	Product NaCl	Point estimates of salt content of each product type was made: Enhanced- 0.3%, Unenhanced- 0.06%	USDA, 2007a Sebranek, 2007
	Minimum growth temperature	45ºF (7ºC) was used as minimum growth temperature for *Salmonella*	ICMSF, 1996 FDA, 1992
	Temperature at retail	Custom distribution temperatures for fresh meat category of Audits International database	JIFSAN, 1999
	Time between retail and home	Custom distribution of transport times for fresh meat category of Audits International database	JIFSAN, 1999
	Temperature during transport to home	Custom distribution of temperatures for fresh meat category of Audits International database	JIFSAN, 1999
	Spoilage level	10,000,000 CFU/cm^2 (10^7)	ICMSF 1998

Module	Model Parameters	Description	Data Sources
Consumer	**Storage and refrigeration in homes**		
	Growth model	All time/temperature conditions permissive for growth was modeled using the model used in the USDA-ARS Pathogen Modeling Program V7	Gibson et al, 1988; USDA, 2006
	Home refrigeration temperature	Empirical distribution of weighted national survey	JIFSAN, 2007
	Duration of home refrigeration	Empirical distribution of national weighted survey data (fresh sliced deli meats, hotdogs, and salami)	JIFSAN 2007
	Time between refrigeration and cooking	Assumed 20% of population will remove product from fridge and will leave it on counter for 5 hours at 30ºC or 10 hours at 20ºC prior to cooking	Assumption, partially based on Novelli, 2004
	Spoilage level	10,000,000 CFU/g (10^7)	ICMSF 1998
	Thermal inactivation	FSIS lethality standards for *Salmonella* lethality in beef roasts (z=10 ºF), applied to the coldest gram in the pork products considered	USDA, 1999a
	Exposure simulation	The amount of *Salmonella* surviving cooking multiplied by amounts of pork consumed	Calculated
	Food consumption	CFU per 1g per serving was the same as CFU per g serving of pork since cooking end-point temperature (at the coldest spot) was used	
	Baseline risk of salmonellosis	Estimate risk from consuming pork chops and roasts (cooked to current end-point recommendation 160ºF) for 15 seconds	Calculated
	Hazard characterization	Dose response based on previous WHO/FAO *Salmonella* risk assessment. A Beta-Poisson model was used to fit the outbreak data	FAO/WHO, 2002
	Δ Risk of salmonellosis	Estimate risk from consuming pork chops and roasts cooked to various time/temperature recommendation and compare to baseline	Calculated

4 Hazard Identification

4.1 *Salmonella* Epidemiology

Salmonellosis is a major public health problem in the U.S., with recent estimates of 1.4 million cases of nontyphoidal infections occurring annually (Voetsch *et al.*, 2004). Although the majority of the cases do not require medical attention, an estimated 31,000 hospitalizations and 1,100 deaths occur each year due to this pathogen (Voetsch *et al.*, 2004). The costs of foodborne salmonellosis have been estimated at $2 billion annually. Recently, pork was estimated to contribute approximately 2% of the 30,000 culture-confirmed salmonellosis cases each year in the U.S. (USDA, 2007b).

4.2 *Salmonella* Pathogenicity and Infectious Dose

Salmonella infections begin when cells adhere to the lumen of the small intestine. Intestinal colonization begins when the microorganism grows at the adherence site. These cells can then penetrate the ileum and colon causing inflammatory reactions. Salmonellosis symptoms range from gastroenteritis and fever to bacteremia.

Although early feeding studies suggested that inoculum levels as high as 100,000 cells per gram were needed to cause illness, several *Salmonella* strains have been epidemiologically linked to foods which had less than 100 viable cells present (FDA, 1992; D'Aoust, 1989; Craven, 1975). The infectivity of *Salmonella* depends on several factors including, the strain, the food matrix, the population density present in the food, and the immune status of the individual.

4.3 *Salmonella* Prevalence on Hog Carcasses and At Retail

The USDA-FSIS estimated that the prevalence of *Salmonella* on carcasses has fluctuated between 2.5 and 4% between 2003 and 2006 (see Table 5).

Table 5 Percent Positive *Salmonella* Tests in the PR/HACCP Verification Testing Program in Market Hogs, 2003-2007

Year	% Positive	Reference
2003	2.5%	USDA, 2007d
2004	3.1%	
2005	3.7%	
2006	4.0%	
2007	2.7%	USDA, 2007e[2]

Although the primary focus for research involving pork contamination has been concentrated on the carcass, a few studies determined pathogen levels in pork products at retail. Duffy *et al*. (2001) reported a prevalence rate of 10% for *Salmonella* for whole muscle products and ground pork. Zhao *et al.* (2001) estimated a prevalence rate of 1.9% for *Salmonella* in retail pork. A 2003 retail

[2] First 2 quarters 2007: January 2007-June 30, 2007

study also reported levels of *Salmonella* in pork chops (FDA, 2003). None of these studies enumerated contamination levels on retail pork.

Recently, the National Pork Board completed a study on the prevalence and levels of *Salmonella* in enhanced and unenhanced pork at four different cities in the U.S. The study found that no *Salmonella* positives were found in unenhanced product (n=1,300). The *Salmonella* prevalence was 1.3% and 0.74% for enhanced pork chops (n=1350) and enhanced pork roasts (n=1350), respectively. *Salmonella* levels on these products were observed to be very low, averaging less that 0.6 MPN/g. The prevalence and enumeration data from this study are incorporated into the current exposure assessment module and are discussed in more detail in that section.

4.4 Factors Affecting *Salmonella* Contamination, Growth, Survival, and Inactivation on Fresh Pork

Most *Salmonella* serotypes are naturally occurring in the gastrointestinal tracts of food animals and may be transmitted to humans upon consumption of meat products contaminated at slaughter. The minimum growth pH and water activity for *Salmonella* has been reported as low as 3.8 and 0.94, respectively (ICMSF, 1996). Both of these levels are permissive for *Salmonella* growth on fresh pork.

The majority of *Salmonella* fails to grow at temperatures below 45ºF (7ºC) (ICMSF, 1996). Although some reports have observed *Salmonella* growth below 41ºF (5ºC), several of these reports have not been adequately confirmed (ICMSF, 1996). Despite these uncertainties, *Salmonella* can potentially grow at normal or elevated refrigeration temperatures and is a concern for products stored for long periods of time.

The *Salmonella* levels on fresh pork at the time of consumption depend on the conditions of the live pig before slaughter, the carcass during slaughter, cooling, cut-up, processing, distribution, storage, and cooking. Relevant growth factors at each step are discussed below.

4.4.1 Pre-Slaughter, Slaughter, Cut-Up and Processing

To reduce the stomach contents at slaughter, pigs are often withheld feed 24-hours prior to being transported to the slaughter facility. After arriving at the abattoir, pigs are generally rested for at least two hours to minimize stress, which can lower pH and affect meat quality. After the pig is stunned and exsanguinated, the carcass goes through several steps of production including, scalding, dehairing, head removal, evisceration, and carcass splitting, before being chilled for 24-hours prior to fabrication. At fabrication, a typical carcass weighs approximately 200 pounds. Carcasses are then cut into muscle cuts and variety meats are removed. Cuts are boxed, placed in combo bins, or packaged for case-ready sales. Boxed cuts are typically distributed through a wholesaler, while combo bins are further processed in-house or at a different facility. Case-ready products are distributed to a retail chain warehouse. Table 6 lists the wholesale cuts of pork from market hogs (National Pork Board, 1997).

Table 6 Wholesale Pork Cuts from Market Hogs

Wholesale cut	Percent of carcass
Ham	25
Loin	23
Side	14
Boston Butt	11
Picnic	11
Miscellaneous	16

4.4.2 Enhanced Product

After fabrication, a significant portion of fresh pork is transferred to another processing line for enhancement. Enhanced pork is the process of adding non-meat ingredients to fresh pork, usually by hollow needle injection, to improve the eating quality of the final product (Miller and Eilert, 1998). Table 7 lists the primary ingredients used in enhanced products and the ingredient functionality. If enhancement solutions are not evenly distributed in product, the potential of two-tone meat exists. To prevent this, processors inject solution using more closely spaced needles.

Table 7 Summary of Enhancement Ingredient Functionality (Miller and Eilert, 1998)

Ingredients	Color	Eating Quality		Flavor	Flavor	Microbial	Safety
		Juiciness	Tenderness		Shelf-life		

Water	-*	++	++	-	~	-	-
Sodium	+	++	++	-	+	~	~
Salt	-	+	+	++	~	+	+
Sodium lactate	+	+	+	++	++	+++	+++
Potassium	+	+	+	+	+	++	++
Sodium	~	~	~	-	~	+++	+++
Lemon juice	-	~	~	±	~	+	+
Flavor agents	~	~	~	+++	++	±	~

*** - = a negative effect, -- = a very negative effect, --- = an extremely negative effect, ~ = a neutral effect, + = a positive effect, ++ = a very positive effect and +++ = an extremely positive effect.**
Source: Miller, R. 1998. Functionality of non-meat ingredients used in enhanced pork. Available at: http://www.meatscience.org/Pubs/factsheets/functionalitynonmeat.pdf. Accessed 3 August 2007.

Several of the enhancement ingredients added to pork positively affect microbial shelf life and safety of fresh pork (see Table 7). For example, sodium lactate was reported to be effective in decreasing S*almonella* growth in cooked beef (Papadopulos *et al.*, 1991). Moreover, studies have also shown that the constituents used in pork enhancement also reduce the infectivity of *Toxoplasma gondii* cysts (Hill *et al.*, 2004).

Despite the antimicrobial activity of some of the constituents of enhancement solutions, the act of injecting the pork may transfer microorganisms to the center of the product. Several challenge studies in beef observed that 3 to 4% of the pathogens applied to the surface enter the center of the intact muscle (Rossman, 2006; Heller *et al.*, 2007). Greer *et al*. (2004) observed increasing *L. monocytognes* levels in enhanced pork the longer recirculating brine was used in the injection process. These reports support the results observed in the National Pork Board (NPB) retail pork study described in Section 5.1.1.

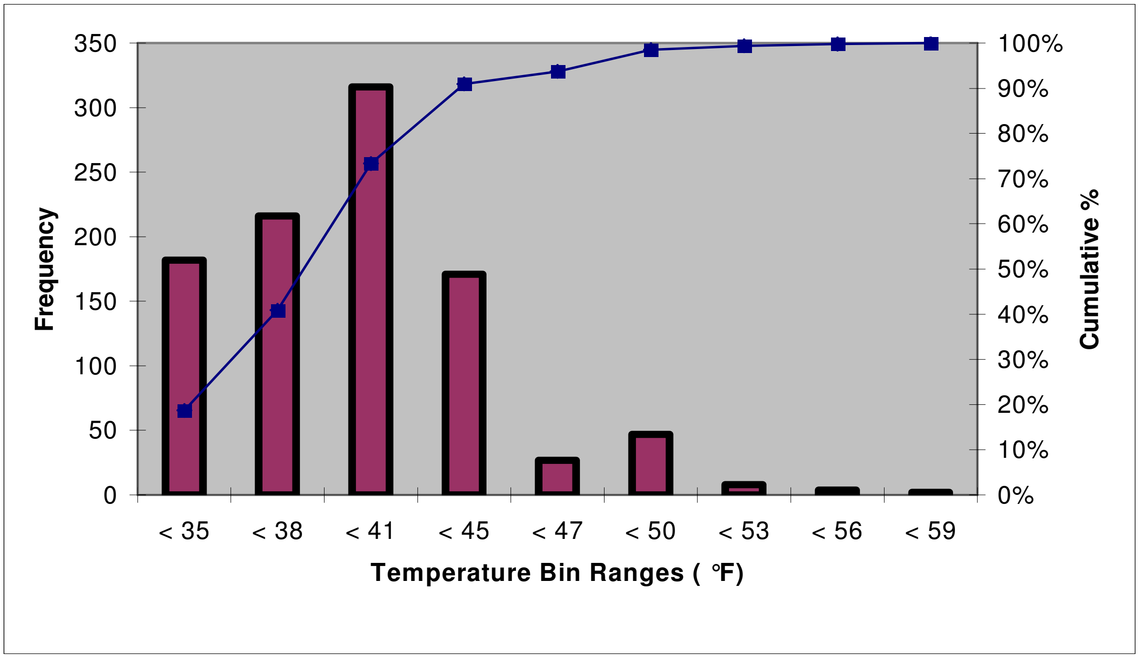
4.4.3 Retail and Consumer Handling Practices affecting *Salmonella* Growth in Fresh Pork

Consumer handling practices prior to cooking are another factor affecting levels of *Salmonella* in fresh pork, and are also the most poorly understood.

4.4.3.1 Purchasing

In 1999, the FDA purchased an Audits International study that determined the storage temperature of fresh meats at retail and the temperature of the products after transportation to the home (JIFSAN, 1999). The fresh meat data set (n=979) that included fresh pork had an average temperature of 39.2ºF (± 5.1ºF) at retail, with 9% of the samples above 45ºF and 1% above 50ºF (see Figure 5).

Figure 5 Temperature and Cumulative Distribution of Fresh Meats at Retail



In the Audits International study, the fresh meat category had the lowest percentage of temperature observations above 41, 45 or 50ºF among all refrigerated foods surveyed, indicating that retail habits with handling fresh pork are good. The most recent FDA retail compliance data (FDA, 2004) suggests that food service and supermarket cold-holding practices for fresh meats at retail has improved compared to the original 1999 study, with 17.4% of the temperature observations (n=109) above 41ºF. Both studies indicate that typical cold-holding by the retail food industry is adequate to inhibit *Salmonella* growth (min 45ºF) (ICMSF, 1996).

4.4.3.2 Temperature Change during Transport

In the Audits International study, consumers took an average of 64 (±26) minutes to transport fresh meat from refrigeration at retail to their home. During transport, the temperature of the fresh meat increased a mean of 6.7 (±5.9) ºF to yield an average temperature of 45.9ºF prior to placement in the home refrigerator. This observation indicates that on average, no significant temperature abuse is likely for fresh meat products transported to the home after purchase.

4.4.3.3 Home Refrigeration Temperature and Storage Time

There have been a few studies investigating the adequacy of home refrigeration in the U.S. The Audits International data reported that 27, 8, and 2% of refrigerators registered temperatures above 41, 45 and 50ºF, respectively (JIFSAN, 1999). Other reports found similar results (Redmond and Griffith, 2002). A recent study reported refrigeration data similar to the Audits International study, however the sample size was more than twice as large (n=2,060) and was weighted to be representative of the U.S. population. The derived weights reflect the selection probabilities of sampled units and compensate for differential non-response and under coverage (Kosa, *et al*., 2007). This data set found 72, 91, and 96% of refrigerators at 40, 46, or 50ºF or below, respectively. Because these data are more recent and representative of the entire population, they were used in the exposure assessment portion of the risk assessment. The study also collected information on refrigerator storage time for RTE foods (Cates *et al*., 2007). Storage durations of hot dogs, salami, and deli/luncheon meats were used to represent the storage durations for pork roast and chops.

4.4.4 *Salmonella* Lethality during Cooking

To estimate the total lethality for *Salmonella* in cooked pork, the following factors must be taken into account.

4.4.4.1 Surface vs. Internal Contamination

Since the interior of muscle is normally sterile, intact pork cuts should contain only surface contamination. However, when injection technologies, such as enhancement of meat products, are employed, bacterial contamination can be transferred to the interior (Heller *et al.*, 2007). A conservative approach for determining cooking lethality is to consider the contamination at the coldest interior portion to be equivalent to that at the surface of the product. Therefore, the amount of heat that is necessary to inactivate *Salmonella* at the coldest gram of the product will produce an additional margin of safety throughout the rest of the food.

4.4.4.2 Mechanisms and Uniformity of Heat Penetration

Cooking is the direct or indirect application of heat across three dimensions of a food until a temperature is reached at the coldest gram in the product that yields a safe and esthetically acceptable product. As thermal energy is applied to the food, heat and mass transfer occurs across the matrix. Crust is formed at the surface by dehydration and browning reactions (Zorrilla and Singh, 2003). Continuous heat conduction results in external migration of rendered fat and water vapor, creating an inward moving heat flux resulting in a core temperature rise.

For conventional consumer cooking methods, such as broiling, roasting, or pan-frying, heat transfer can be assumed to be the highest at the product surface and coolest at some interior spot, the location of which depends upon the nature of the heating vectors. For traditional commercial canning operations, the coldest gram is the geometric center. However, the coldest gram for some consumer cooking methods will be away from the geometric center. Therefore, *Salmonella* lethality must be considered at the coldest gram within the cooked meat, regardless of its location.

Microwave heating is employed by a small percentage of U.S. consumers to cook pork chops and roasts (Larsen, 2008). This cooking technique generally elevates the temperature of water within the food by direct absorption of alternating current. Microwave penetration is a function of the interaction and absorption of radiation by the food matrix and the accompanying transport processes due to the dissipation of electromagnetic energy into heat. The rapid cooking afforded by microwave heating can produce multiple cold spots within a food. This can be problematic for the inactivation of microbial pathogens, such as *Salmonella.* However, permitting a post-microwaving "rest" period, can more evenly distribute conductive heat throughout the food to produce a safe product.

4.4.4.3 Post-Cooking Heat Rise

Once meat is removed from the heat source at the desired end-point temperature, the surface of the product will immediately begin to cool. However, internal portions will continue to rise in temperature until thermodynamic equilibrium is reached. The temperature at the coldest gram will continue to rise by heat conduction from the surrounding muscle tissue. The time for this to occur results in a prolonged period where product is above the target end-point temperature. Therefore, using end-point temperatures to determine lethality yields an underestimation of pathogen reduction.

4.4.4.4 Product Cooling

After the heating rise at the coldest gram of a food product occurs, the temperature throughout the food will gradually begin to cool until thermodynamic equilibrium is reached with the product holding environment. *Salmonella* lethality will continue within a cooling product until the temperature at the coldest gram of the product falls below 125ºF (ICMSF 1996). Therefore, the initial cooling will impart a continued *Salmonella* lethality.

4.4.4.5 Coldest Gram Concept

Based on the above discussion about the effect of heating time and temperature on bacterial pathogen lethality, it is concluded that no *Salmonella* is expected to survive in the food once the coldest gram reaches the target time/temperature combination. The conductive heat penetration of the product during cooking would produce a greater *Salmonella* kill than the intended level throughout the surrounding portions of the food. Lethality continues at the coldest gram and much of the surrounding product after the food is removed by the heat source, as long as the product remains above 125ºF. Therefore, only the coldest gram within the meat will contribute to the exposure and resulting risk, if any, of an individual developing salmonellosis from cooked pork consumption. For this risk assessment, the coldest gram was used to model exposure.

4.4.5 Current Cooking End-point Temperature Guidance

USDA has established guidelines for meeting lethality performance standards for *Salmonella* inactivation at the coldest gram of RTE meat products that are processed in federally inspected establishments (see Table 8). The guidelines for *Salmonella* lethality are based on inactivation data in beef roasts (USDA, 1999), however the UDSA-FSIS considers the guidance appropriate for all red meat, including pork (FSIS, 2008).

Table 8 USDA Time/Temperature Recommendations to meet *Salmonella* Lethality Standards

Temperature ºF	Time (sec) for 6.5 Log CFU/g Inactivation
145	240
150	72
155	29
160	0

The USDA currently recommends that consumers cook fresh pork to a medium internal temperature of 160ºF or a well-done internal temperature of 170°F (USDA, 2003b) (see Table 2). Similarly, a Center for Disease Control (CDC) Fact Sheet on trichinosis recommends cooking pork to an internal temperature of 170°F (CDC, 2004).

The U.S. Food Code provides guidance for cooking fresh pork in institutional, food service, and retail settings. Table 9 summarizes the cooking time/temperature recommendations for fresh pork products in Section 3-401.11 of the Food Code (FDA, 2005).

Table 9 Section 3-401.11 Time/Temperature Recommendations for Fresh Pork in the Food Code

Product	Recommendation
Fresh pork	145°F for 15 sec
Injected pork	145°F for 3 min
Injected pork	150°F for 1 min
Injected pork	155°F for 15 sec
Injected pork	158°F instantaneous

5 Input Parameter Estimates for Exposure Model

The initial segment of the exposure assessment model estimates the occurrence and extent of *Salmonella* contamination on raw pork chops and roasts at retail establishments. This initial segment is referred to as the "retail" module. The second segment of the exposure assessment derives levels of *Salmonella* in an eating occasion, referred to as the "consumer" module. In the consumer module, the growth/decline of *Salmonella* due to transport from retail to home, storage and handling condition at home prior to cooking, the probability of survival of the bacteria, and levels in foods that are consumed after cooking were estimated. The evidence supporting the characterization of the model inputs is described here.

5.1 Retail Module

5.1.1 Data Collection at Retail Stores

The NPB funded a study to examine fresh retail pork products for *Salmonella* prevalence and levels as a measurement of current industry practices for effective pathogen reduction, and to provide baseline data for risk assessment purposes. The purpose of the study was to get a sufficient number of positives to determine the range and distribution of *Salmonella* levels at retail for these products. The study was not designed to be representative of the U.S.

A total of 4,000 retail pork samples in four categories were examined during this study. The categories included:

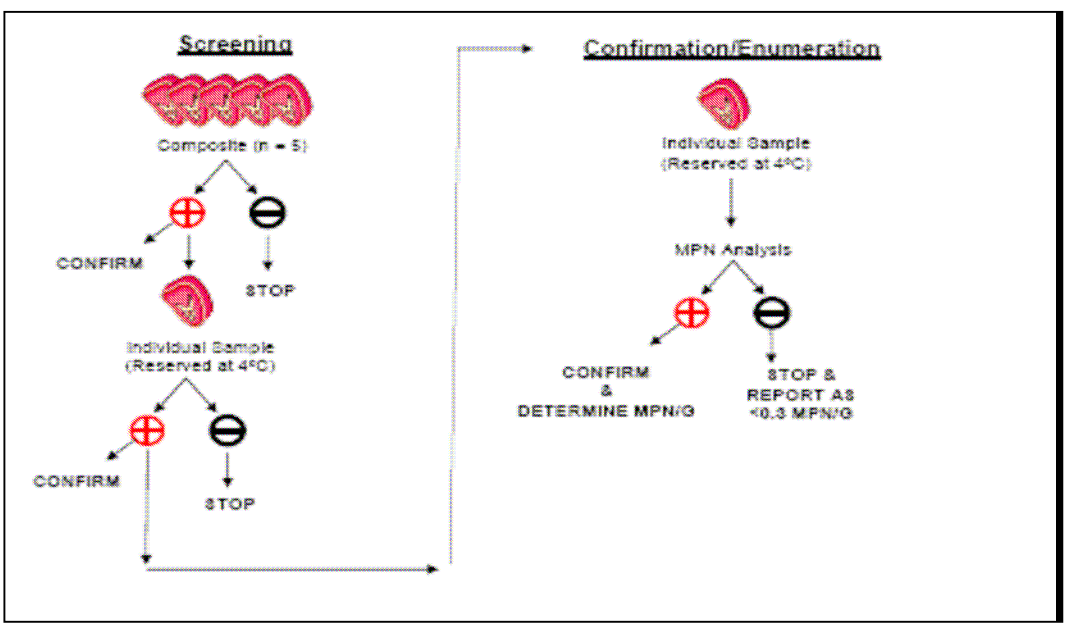
Categories	**Abbreviations**
Pork chop enhanced	PCE
Pork chop natural (unenhanced)	PCUE
Pork (boneless) roast enhanced	PRE
Pork (boneless) roast natural (unenhanced)	PRUE

Test products were purchased from grocery stores, superstores, and specialty grocery stores from January to March 2007, at various retail locations from four U.S. cities, including: Phoenix, Arizona (PHX); San Antonio, Texas (SA); Grand Prairie, Texas (GP; suburban Dallas); and Green Bay, Wisconsin (GB).

Samples were sent by overnight transport using ice packs to Food Safety Net Services (FSNS) in San Antonio, Texas, for detection and enumeration of *Salmonella*. An outline of the sample-processing scheme is shown in Figure 6. Upon receipt, all test samples were composited by product category into sets of five samples. Each composite was initially screened for the presence of *Salmonella* using a Qualicon BAX DNA-based detection system. Any presumptive positive composite was independently re-sampled from the original meat and analyzed as individual samples using the same system. Any individual sample that screened positive was again re-sampled and analyzed according to a most probable number (MPN) assay using the same detection system to estimate the associated level of *Salmonella* present on the pork sample. The MPN was based on principles outlined in the FDA Bacterial Analytical Manual (BAM) Appendix 2 and the USDA Microbiology Laboratory Guidebook (MLG) Appendix 2.02 (USDA, 2003). Full confirmation was performed following FSIS methods including Chapter 4.03 of the MLG and current FSIS baseline methodology.

A detailed description of sampling locations, test protocol and enumeration methods are described in the full report.

Figure 6 Sample Processing Scheme



5.1.1.1 Sampling Results

The initial sampling plan was designed to collect and analyze 1,000 samples per four types of pork cuts. However, the sampling scheme was modified after the sixth week to re-focus on enhanced products, as there was no confirmed *Salmonella* detected in individual unenhanced products. Further, as the *Salmonella* positive samples were clustered principally in the GB and PHX areas, sampling at the SA and GP locations was discontinued after seven weeks and sampling was reduced from four to two locations (GB and PHX). Finally, to further concentrate sampling to the area yielding the most positive samples, food collection was narrowed exclusively to PHX beginning week nine. The sampling modifications were carried out to support the detection of the highest number of confirmed individual samples. The final sample size by pork cuts and locations is summarized in Table 10.

Table 10 Sampling Size by Pork Cuts and Locations

Cut type	**Locations**				**Total Sample Size**
	Green Bay	Grand Prairie	San Antonio	Phoenix	
PCE	306	235	175	634	1,350
PCUE	173	160	152	200	685
PRE	307	235	176	632	1,350
PRUE	173	160	113	169	615

5.1.1.2 Prevalence

A total of 3.25% of all composite samples tested returned a confirmed *Salmonella* result. Composite positives by product types and locations are summarized in Table 11. However, when the individual samples that were represented in the positive composites were retested, the overall confirmed positive rate dropped to 0.70%. This is likely due to the re-sampling procedures, and the likely non-uniform distribution of *Salmonella* on the products. Table 12 provides overall prevalence for individual samples by pork meat category. A *Salmonella* prevalence of 1.33% was confirmed in the enhanced pork chops and 0.74% in the enhanced pork roasts. No *Salmonella* were found on the unenhanced chops or roasts.

Table 11 Number of Composite Positives by Locations and Product Type

Product type	Green Bay	Grand Prairie	Phoenix	Total
PCE	2	0	13	15
PRE	2	3	12	17
PRUE	1	0	0	1
Total	5	3	25	33

Table 12 Overall Prevalence for Confirmed Individual Samples

Product Group	Individual Samples	Confirmed Samples	Individual Rates
PCE	1,350	18	1.33%
PCUE	685	0	0%
PRE	1,350	10	0.74%
PRUE	615	0	0%
Total	4,000	28	0.70%

5.1.1.3 Enumeration

Levels of *Salmonella* present in individually positive samples were assessed using most MPN analysis. The limit of enumeration was 0.3 MPN of *Salmonella* per gram of sample. Overall, very low levels of *Salmonella* were isolated from individual samples. The highest level observed was 1.40 MPN/g. Over half (53.6%) of the individual positive samples were below the level of enumeration. Although there were more individual positive enhanced chop samples (n=18), the enhanced roast samples (n=10) had slightly higher MPN values (see Table 13and Table 14).

Table 13 MPN Results by Location

Location	No. (+) Individual Samples	MPN Range (MPN/g)	Avg MPN (MPN/g)
Grand Prairie, TX	1	0.30	0.30
Green Bay, WI	3	Not applicable	<0.30
Phoenix, AZ	24	0.30 – 1.40	0.54

Table 14 MPN by Product Types

Product Type	No. (+) Individual Samples	MPN Range (MPN/g)	Avg MPN (MPN/g)
PCE	18	0.30 – 0.72	0.44
PRE	10	0.30 – 1.40	0.60

5.1.2 Data Treatment for Risk Assessment

It was assumed that *Salmonella* levels (log CFU/g) in individual samples (confirmed from the positive composites) follow a normal distribution. The parameters of this distribution were derived by anchoring the probability of levels < 0.3 CFU/g, which is the limit of detection (LOD) of the method, at the proportion of negative samples, and the cumulative probabilities corresponding to the detected levels at the corresponding proportions observed in the sample. For instance, the 12 PRE composite samples collected in PHX tested positive initially, and of the 60 corresponding individual samples, 54 (90%) tested negative (< 0.3 CFU/g), and 6 (10%) tested positive (> 0.3 CFU/g). Of the individual samples that tested positive, one sample had 0.3 CFU/g, three had 0.36 CFU/g, one had 1.1 CFU/g, and one had 1.4 CFU/g. The parameters of the lognormal distributions were estimated so that 0.3, 0.36, and 1.1 CFU/g corresponded to the following cumulative probabilities: 0.92 (or 55/60), 0.97 (or 58/60), 0.98 (or 59/60), respectively. This probability "fill-in" approach assumes that all samples are contaminated at retail at some level, and is more conservative than assuming that samples without detectable *Salmonella* are uncontaminated.

5.1.2.1 Positive/Presumptive Composites and Positive Individual Samples

It was assumed that log levels (log CFU/g) in individual samples (confirmed from the positive composites) follow a normal distribution. Using Excel Solver, the mean and standard deviation of these normal distributions were estimated. Separate distributions were fitted to the different pork product category and location combinations. However, the PCE and PRE samples from GB, GP and SA were confirmed in the individual sampling as either negative or less then the detection limit (< 0.3 CFU/g), a combined distribution of positive was derived for these three cities.

5.1.2.2 Treatment of Negative Composites

For each location and product type, the highest percentile (P) that could be estimated with 95% confidence, given the number of samples available, was derived using a tolerance interval approach (Hahn and Meeker, 1991). It was then assumed that P% of the individual samples from the negative composites is below the LOD of 0.3 CFU/g. Thus, (1-P) samples were assigned values between 0.3 and 1.4 CFU/g (the highest MPN in positive PRE samples) and P samples assigned values below the limit of detection (< 0.3 CFU/g), using a probability fill-in approach, assuming lognormal distribution. The parameters of the lognormal distribution were derived using Excel Solver. The simulated distributions are summarized in the following section.

5.1.2.3 Distribution of *Salmonella* Levels in Pork

Using the distributions of levels generated from the positive/presumptive and negative composites (described above), distributions of levels of *Salmonella* in pork products were generated as follows:

Enhanced products (PCE and PRE)

Distributions of *Salmonella* in enhanced products (PCE and PRE) were developed based on random sampling from regional distributions of *Salmonella* in enhanced products (PCE and PRE). Derivation of regional and combined distributions from the retailed survey data is described below.

> <u>*Regional distributions:*</u> Since the composite samples of the enhanced products (PCE and PRE) samples from GB, GP and SA were confirmed in the individual sampling as either negative or below the detection limit of 0.3 CFU/g, a common distribution of levels of *Salmonella* was assumed for these three locations. As several positive composite samples from PHX were also confirmed positive in the individual sampling, a separate distribution was derived for this location by randomly sampling from the two distributions: one being the distribution of the samples tested positive and the other of the samples that tested negative.
>
> <u>*Combined Distribution:*</u> A combined distribution of levels of *Salmonella* is derived by randomly sampling from the regional distributions proportionately according to market shares. The combined distribution of *Salmonella* in pork meat presented in the following

tables assumed equal market share from all regions. This assumption is used in the "best case" scenario.

Figure 7 and Figure 8 summarize the simulated distributions for the enhanced products and compare these to the measured levels.

Figure 7 Distribution of Observed and Modeled *Salmonella* Levels at Retail in Individual PCE Samples

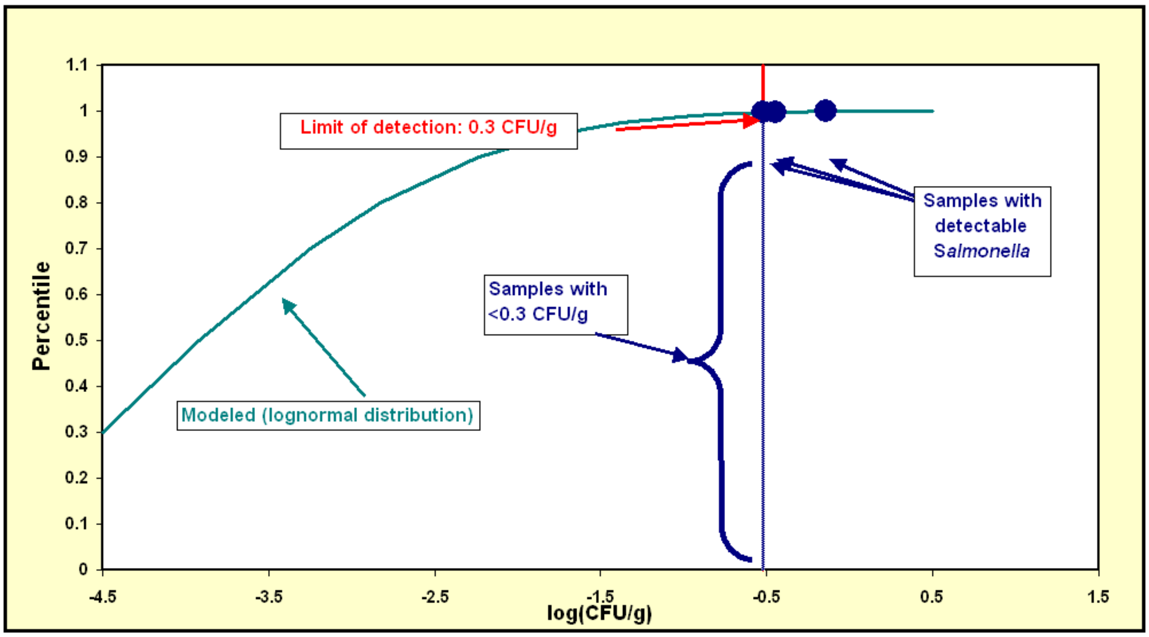
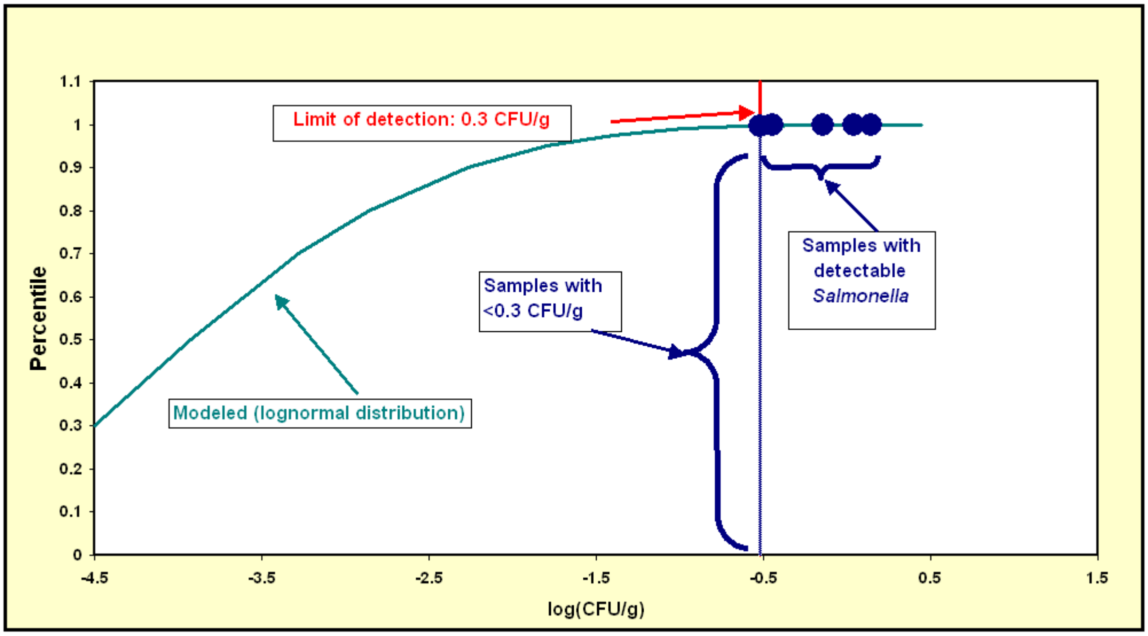


Figure 8 Distribution of Observed and Modeled *Salmonella* Levels at Retail in Individual PRE Samples



Unenhanced products (PCUE, PRUE)

Because of the small sample sizes for the unenhanced products (PCUE and PRUE), and since all samples were negative, a single distribution of levels of *Salmonella* in PCUE and PRUE for all sample locations was generated.

Summary statistics of the combined distributions of *Salmonella* levels on enhanced and unenhanced pork meat at retail (log CFU/g) based on 10,000 iterations Latin Hypercube sampling are provided in Table 15 and Figure 9.

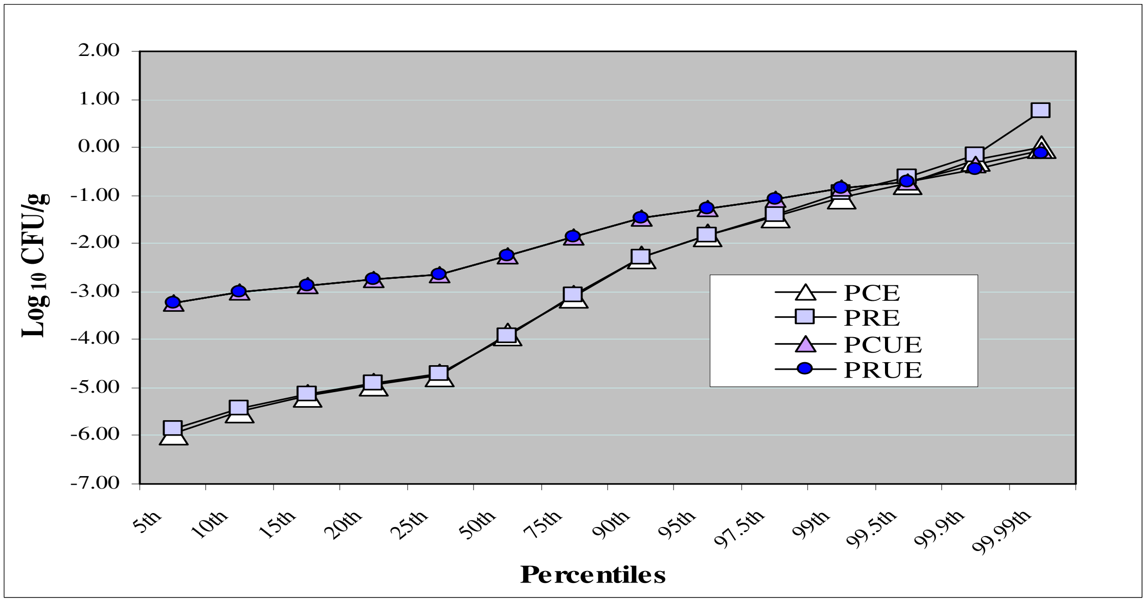
Table 15 Combined Distribution of *Salmonella* on Pork Meat at Retail, Summary Statistics (log CFU/g)

Statistics*	**Enhanced**		**Unenhanced**	
	PCE	PRE	PCUE	PRUE
Mean	-3.90	-3.88	-2.25	-2.25
SD	1.24	1.22	0.60	0.60
Percentiles				
5^{th}	-5.94	-5.85	-3.24	-3.24

10th	-5.48	-5.42	-3.02	-3.02
15th	-5.17	-5.13	-2.87	-2.87
20th	-4.93	-4.90	-2.76	-2.76
25th	-4.73	-4.70	-2.66	-2.66
50th	-3.90	-3.91	-2.25	-2.25
75th	-3.09	-3.08	-1.85	-1.85
90th	-2.30	-2.28	-1.48	-1.48
95th	-1.82	-1.82	-1.26	-1.26
97.5th	-1.43	-1.42	-1.07	-1.07
99th	-1.04	-0.96	-0.86	-0.86
99.5th	-0.75	-0.63	-0.71	-0.71
99.9th	-0.24	-0.18	-0.37	-0.45
99.99th	-0.01	0.77	-0.07	-0.13

*Based on 10,000 iteration runs

Figure 9 Distributions of *Salmonella* Levels in Pork Chop Enhanced (PCE), Pork Roast Enhanced (PRE), Pork Chop Unenhanced (PCUE) and Pork Roast Un- enhanced (PRUE) at Retail



5.2 Consumer Module

5.2.1 Growth Model

The growth model for S*almonella* in broth (Gibson et al, 1988), as referenced in the USDA Agricultural Research Service (ARS) Pathogen Modeling Program, V.7 (USDA, 2006), was used to model *Salmonella* growth in pork chops and roasts. The primary growth model is the Gompertz model:

$$L(t) = A + C \exp\{-\exp[-B(t-M)]\}$$

Where:

A: is the level of S*almonella* (log CFU/g) measured at retail (see retail module)

C: is the asymptotic amount of growth as t increases indefinitely

C is the increment from the starting point of contamination to the maximum population density, and is modeled as 9 - pre-growth level. Most of the modeling studies start with about +1,000 cells/ml (log 3) and in broth this can grow to 1 billion or log 9, yielding a C of about 6 (C = 9-3). In the case of pork chops/roasts, the max population density found at retail is 1.4 MPN/g (~ log 0). If the max population density after growth (due to time and temperature abuse) is log 9, then C = 9.

t: is time duration, and is modeled for two separate growth segments, transport to home and storage at home.

B and M: are expressed as a function of temperature (T), pH (p) and sodium chloride (s) content:

$$\ln B = -23.5 + 1.496s + 0.487t + 4.29p - 0.0608s^2 - 0.00563t^2 - 0.293p^2 - 0.01261st - 0.171sp - 0.0124tp$$

$$\ln M = 29.19 - 0.409s - 0.5518t - 6.02p + 0.0924s^2 + 0.007710t^2 + 0.448p^2 + 0.00118st + 0.0166sp + 0.01367tp$$

pH (p): A custom distribution of pH was generated based on measured pH for PCE, PRE, PCUE and PRUE samples. There was no difference in pH levels for PRUE and PCUE samples collected at different locations. Similarly, no differentiation was made for the PCE and PRE samples except for those collected in PHX. One custom distribution of pH levels was generated for PCE and PRE samples collected at GB, GP and SA locations. For samples collected at PHX, separate distributions were generated from positive and negative samples (see Table 16). Table 17 provides summary statistics for the overall pH distributions by types of pork samples.

Table 16 pH Levels in Enhanced Pork Samples by Locations

Sample Types	Locations	Median	Mean	SD	Min	Max
PCE	GB, GP, SA	6.36	6.35	0.27	3.42	7.05
	PHX negative	6.48	6.45	0.26	5.36	9.62
	PHX positive	6.58	6.52	0.15	6.21	6.7
PRE	GB, GP, SA	6.38	6.38	0.24	5.71	7.1
	PHX negative	6.46	6.44	0.21	5.61	6.94
	PHX positive	6.51	6.50	0.12	6.31	6.72

Source: NPB Baseline Study, April 30, 2007

Table 17 pH Levels in Pork Samples by Types

Statistics*	PCE	PRE	PCUE	PRUE
Mean	6.39	6.40	6.34	6.36
Standard Deviation	0.27	0.24	0.27	0.22
Minimum	3.42	5.61	5.61	5.48
Maximum	9.62	7.10	8.99	7.83
Percentile				
5th	5.94	6.01	5.92	6.01
15th	6.17	6.17	6.10	6.15
25th	6.23	6.21	6.17	6.21
50th	6.41	6.41	6.36	6.38
75th	6.56	6.56	6.52	6.52
90th	6.71	6.71	6.66	6.62
95th	6.79	6.79	6.73	6.72
99th	6.93	6.92	6.85	6.81
99.5th	6.96	6.93	6.87	6.89
99.9th	7.05	7.07	8.99	7.83
99.99th	9.62	7.10	8.99	7.83

*Based on 10,000 iteration runs

Sodium Chloride (s): Point estimates of sodium chloride content were used. The value for unenhanced pork samples were based on the USDA nutrient databank (USDA, 2007a). The values for enhanced products were based on email communication with Dr. Joseph Sebranek of Iowa State University (Sebranek, 2007).

Pork Meat	Sodium %w/v	Source
PCE, PRE	0.3%	Sebranek, 2007
PCUE, PRUE	0.06%	USDA, 2007a

Temperature (T): Temperature is modeled for two separate growth segments in this risk assessment: 1) transport to home and 2) storage at home. A detailed discussion on modeling storage temperature is provided below.

The temperature (T) below, which no growth could occur, was assumed to be 7ºC or 45ºF (ICMSF, 1996).

5.2.2 Time and Temperature Input for Growth Module

Time and temperature were developed for two segments of the growth module:

1) Transport from stores to homes; and
2) Storage and refrigeration in homes prior to cooking.

5.2.2.1 Transport from Stores to Homes

Custom distributions of transport time and temperature were developed based on the following data available from the Audits International Database (JIFSAN, 1999):

- Temperature of meat at retail,
- Temperature of meat before putting in home refrigerators, and
- Time interval between the two measurements.

It is assumed that the time interval between the two temperature measurements reported in the database corresponds to the transport time between store and home, plus any counter storage time once at home and before any refrigeration takes place. The data from Audits International included records with missing temperature or transport duration. These records were not included in the assessment. There were a few temperature pairs where the final temperature was lower than the temperature at retail (< 3% of the pairs). There were also a few temperatures (< 1.3%) where the final temperature was < 0°C. These data points are potentially indicative of measurement errors and were not excluded from the analysis. Including them in the distribution was unlikely to have a significant impact on the assessment because they represent a very small fraction of the distribution. Summary statistics for transport duration and temperature are summarized in Table 18.

Table 18 Distributions of Transport Duration from Retail to Consumers' Home and Temperature, Summary Statistics

Statistics*	Transport Durations (Minutes)	Transport Temperature (ºC)
Mean	64.69	7.73
SD	26.35	3.28
Percentiles		
5th	30.00	3.00
10th	37.00	4.00
15th	40.00	4.00
20th	44.00	6.00
25th	47.00	6.00
50th	61.00	8.00
75th	79.00	10.00
90th	95.00	11.00
95th	108.00	13.00
97.5th	119.00	15.00
99th	140.00	16.00
99.5th	150.00	17.00
99.9th	380.00	19.00
99.99th	380.00	21.00

*Based on 10,000 iteration runs

5.2.2.2 Storage and Refrigeration

The model is set up for two pork-handling scenarios:

- Best Practice Scenario: consumers purchase pork meat, transport the product home, store in refrigerators, and cook.
- Temperature Abuse Scenarios: are similar to the best practice scenario, but there is an added aspect of temperature abuse by consumers, such as leaving the meat outside the refrigerator for a period of time, thus allowing for more growth prior to cooking.

Currently, there are no available empirical data to support the parameterization for the "temperature abuse" scenarios. Therefore, these scenarios are evaluated as part of the sensitivity analysis (see Section 7).

Storage inside Refrigerator

Custom distributions of refrigerator temperature and refrigeration durations were derived from the Research Triangle Institute (RTI) study of consumer storage practices for refrigerated RTE foods (*RTI*, 2005; Cates *et al*, 2007). Table 19 provides summary statistics of these distributions.

The RTI study asked participants to record refrigeration temperatures and storage practices for several products, including hotdogs, salami and deli-meats. Participants were asked to report how long they stored the products in the refrigerator before opening them, and how long they stored products after opening. Two sets of times, the time in storage until opening the product (i.e. 1st eating occasion) and the time until last eating occasions, were used in the risk assessment. These times were kept correlated with the refrigerator temperatures. In other words, the model randomly samples a product, and then randomly samples a temperature, duration pair for that product. Note that each person in the RTI survey had a statistical weight, and the model uses these weights to sample the various pairs. Finally, the RTI survey recorded storage durations in bins and thus, the midpoints of the bins were used. For the last bin, which was > 28 days, 28-42 days were assumed. For temperature, the respondents recorded the temperatures in bins (bin width is 2ºF). The smallest and largest bins were < 20, and > 60, therefore, values of 20 and 60 were assumed. The data from the RTI study were for deli meats, salami, and hotdogs and were not specific to pork roasts or chops. Exponent used the storage distributions for these products as a surrogate for the storage distribution for pork roasts and chops. This is likely to result in conservative estimates of refrigerator storage durations (longer), since consumers typically store raw meat for a shorter time than RTE foods. Therefore, using the RTI data may represent a conservative estimate of the times that consumers store raw meat. In fact, a recent New Zealand study determined that ≤ 2 days was the most common timeframe for storing cooked or raw meat and poultry in consumer refrigerators (Gilbert, 2007).

Table 19 Distributions of Home Refrigeration of Pork Duration and Temperature, Summary Statistics

Statistics*	**Refrigerator temperature**	**Refrigeration Duration (days)**

	(ºC)	
Mean	3.62	5.47
SD	2.80	3.87
Percentiles		
5th	-1.48	0.93
10th	0.17	1.31
15th	1.00	1.68
20th	1.73	2.05
25th	2.07	2.42
50th	3.68	4.54
75th	5.18	7.63
90th	6.57	10.99
95th	8.00	13.18
97.5th	9.34	15.08
99th	12.00	17.22
99.5th	13.83	18.39
99.9th	17.86	20.66
99.99th	19.14	24.09

*Based on 10,000 iteration runs. The two distributions, shown here as independent distributions were kept correlated in the model.

Spoilage Indicator

In the baseline model, meat was assumed to be spoiled if there is *Salmonella* growth above 7 log CFU per gram. This is based on the accepted assumption that odor from spoilage organisms will become noticeable when populations on the surface of the meat reach 7 log CFU/cm^2 (ICMSF 1998). The models tag "spoiled" samples with an indicator, and in the final simulation, sampling outputs with "spoilage" indicators were excluded from the summary statistics.

5.2.3 Thermal Inactivation

This segment estimates the decline in *Salmonella* levels from thermal inactivation (cooking) using the following thermal inactivation model (FDA, 2000):

D-value

$$\mathbf{Log\ [N/N_o] = -t/D}$$

Where:

N = microbial population at any time, t

N_o = initial microbial population

t = cooking time

D = decimal reduction time, or time required for a 1-log cycle reduction in the microbial population

z-value

$$\mathbf{Log\ [D/D_R] = -(T - T_R)/z}$$

Where:

z = temperature increase for a 1-log reduction in D

D_R = reference decimal reduction time

T_R = reference temperature

T = cooking end-point temperature (at the geometric center)

Using this model, the decline in levels from heating is modeled as [-t/D] where the D-value (decimal reduction time) corresponds to the temperature at the coldest gram within the meat (i.e. cooking end-point temperature, T) and time (t) is the duration at the maximum cooking end-point temperature. This time frame was chosen to reflect the estimated amount of time between the coldest gram in the pork product reaching end-point temperature and when a thermometer registers the temperature. It should be noted that once the coldest gram of meat has reached the specified cooking end-point temperature, the temperature on the surface and areas away from the coldest gram would have exceeded the specified cooking end-point temperature. Furthermore, temperature continues to rise after the product is removed from the heat source. Hence, this approach is very conservative.

In this risk assessment, D-value was derived by solving $\{\log(D/D_R) = -(T-T_R)/z\}$, where z (ºF required for the thermal destruction curve to transverse one log cycle), T_R = 157ºF (69.4ºC) and D_R = 0.0358 minute (or 2.15 seconds for a 1-log reduction) were based on the USDA-FSIS recommendations for destruction of *Salmonella* in beef as summarized in its Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products (USDA, 1999a). The estimated z-value of 10ºF is based on the same guidance.

A literature review of the heat resistance of *Salmonella* yielded a very similar z-value of 9.5ºF (Doyle, 2000) and a thermal study of pork meat with curing additives yielded a z-value for the most heat resistant strain of 7.5°F (Quintavalla et al., 2001). The close agreement or lower z-values reported in other published studies suggests that the USDA-FSIS estimation of heat resistance is conservative and accurate for estimating the thermal resistance of *Salmonella* in fresh pork.

The levels of *Salmonella* being inactivated at various cooking end-point temperatures were estimated using the above described thermal inactivation model and USDA FSIS T_R and D_R estimates for four different holding times: 1, 3 and 4 minutes and 15 seconds. The levels of *Salmonella* estimated to be killed at end-point temperatures of 160, 155, 150 and 145ºF and for the different holding time are summarized in Table 20. The mean log killed after a 15 second holding time were 13.9, 4.4, 1.4 and 0.4 log CFU/g at 160, 155, 150 and 145ºF, respectively.

Table 20 *Salmonella* Inactivation at Various Cooking End-point Temperatures - Log Reduction

Duration (t) at Maximum Temperature	Cooking End-point Temperatures (ºF)			
	160	155	150	145
4 minutes	222.9	70.5	22.3	7.0
3 minutes	167.2	52.9	16.7	5.3
1 minutes	55.7	17.6	5.6	1.8
15 seconds	13.9	4.4	1.4	0.4

5.2.4 Pork Serving Size

Since the exposure assessment model examines the cooking end-point temperature at the coldest gram, a one-gram serving size was assumed in the exposure simulation. The rationale for this approach is that by the time the target cooking end-point temperature is reached at the coldest gram, the only levels of *Salmonella* that remain on a serving would be at that site.

5.3 Exposure Simulation

Exposure simulation was carried out using Crystal Ball® (2000.1 Standard Edition). Latin Hypercube sampling and 10,000 iterations were used. The following sequence of sampling was conducted:

Step 1- Estimation of levels of *Salmonella* in pork meat at retail:

Samples from the distributions of *Salmonella* levels on pork meats at retail were randomly selected.

Step 2 - Estimation of growth during transportation from retail stores to consumer homes:

Samples from the distributions of transport durations and temperatures were combined with pH levels that were randomly sampled from the distributions of pH levels and sodium chloride content in meat to estimate growth during transport. Growth levels were added to levels at retail (step 1) to estimate levels in meat samples post transportation and prior to refrigeration.

If the temperature during transportation was below 7.2ºC, the model assumes that there is no growth.

Step 3 - Estimation of growth during storage in homes (refrigeration):

The samples from step 2 were allowed to grow further during refrigeration storage. Samples from the distributions of refrigeration durations and temperatures were combined with pH levels that were drawn from the distributions of pH levels and sodium chloride content in meat to estimate growth during refrigeration. Growth levels were added to levels post-transportation (step 2) to estimate levels in meat samples post refrigeration and prior to cooking. As in step 2, if refrigeration temperature is below 7.2ºC, the model assumes that there is no growth.

The current model contains additional scenarios that permit further growth from temperature abuse, such as holding meats outside refrigerators prior to cooking. Two "temperature abuse" scenarios were simulated and described in the sensitivity analysis section of this report.

Step 4 - Estimation of surviving *Salmonella* levels (log CFU/g) after cooking:

In this step, the model estimated the thermal decline of *Salmonella* in meat, which corresponds to cooking end-point temperature (temperature of the coldest gram) of 160, 155, 150 and 145^{o}F. The baseline scenario assumed a 15 second exposure time at the cooking end-point temperature at 160^{o}F, while the alternative scenarios assumed the three lower cooking end-point temperatures.

In this step, decline during cooking was combined with samples of levels in step 3 to estimate the levels of *Salmonella* in pork meat (log CFU/g) post cooking.

Step 5 - Estimation of *Salmonella* levels and risk of salmonellosis per serving:

Since the levels of *Salmonella* were estimated based on the cooking end-point temperature at the coldest spot within the piece of meat, estimates of *Salmonella* levels remaining at the coldest gram would be equivalent to all viable *Salmonella* remaining in the entire serving. As such, pathogens levels in step 4 would correspond to total *Salmonella* exposure in a serving of pork. In this final step, samples of the *Salmonella* levels in step 4 were combined with samples from the dose-response distribution to estimate risk of illness per serving.

6 Model Scenarios and Outputs

6.1 Baseline

In the baseline scenario, the risks of salmonellosis from consumption of pork chops and roasts were estimated, assuming that product was purchased at retail then transported and stored at home, then cooked by a consumer so that the coldest gram of the meat was cooked to the current recommended consumer cooking end-point temperature of 160°F (71.1°C), and held at the target temperature for 15 seconds.

The simulated cumulative levels of *Salmonella* growth in pork meats at retail, after transporting from stores to consumers' homes, post refrigeration and prior to cooking, and killing and survival after cooking are summarized in the Tables 21-24. For all pork cuts (PRE, PCE, PRUE and PCUE), at the 99.9th percentile and higher, growth during storage and refrigeration lead to *Salmonella* levels greater than 6 log CFU/g (but below 7 log CFU/g, due to spoilage cutoff in the model) prior to cooking. These upper percentiles represent extreme and rare time/temperature abuse situations. However, based on the simulated results at cooking end-point temperature of 160ºF, there were no surviving *Salmonella* per serving at all percentiles, including the 99.99th, and hence within practical measurements, there was no estimated risk per serving.

Table 21 *Salmonella* Growth, Inactivation and Survival in Pork Roast Enhanced and Risk per Serving, Baseline (160° F Cooking End-point Temperature)

Statistics*	Cumulative Levels of *Salmonella* (Log CFU/g)				Surviving CFU per serving	Risk of salmonellosis per serving
	At Retail	Post Transportation	Post Refrigeration and Prior to Cooking	Post Cooking		
Mean	-3.88	-3.87	-3.69	-18.73	0.00	0.00
SD	1.22	1.22	1.56	1.93	0.00	0.00
Percentiles						
5th	-5.85	-5.84	-5.79	-21.92	0.00	0.00
10th	-5.42	-5.41	-5.37	-21.12	0.00	0.00
15th	-5.13	-5.11	-5.07	-20.55	0.00	0.00
20th	-4.90	-4.88	-4.83	-20.15	0.00	0.00
25th	-4.70	-4.68	-4.63	-19.84	0.00	0.00
50th	-3.91	-3.90	-3.82	-18.70	0.00	0.00
75th	-3.08	-3.07	-2.95	-17.66	0.00	0.00
90th	-2.28	-2.27	-2.06	-16.66	0.00	0.00
95th	-1.82	-1.81	-1.41	-15.96	0.00	0.00
97.5th	-1.42	-1.41	-0.46	-15.15	0.00	0.00
99th	-0.96	-0.94	1.86	-12.97	0.00	0.00
99.5th	-0.63	-0.62	4.47	-10.44	0.00	0.00
99.9th	-0.18	-0.17	6.43	-7.96	0.00	0.00
99.99th	0.77	0.77	6.85	-7.00	0.00	0.00

***Based on 10,000 iteration runs**

Table 22 *Salmonella* Growth, Inactivation and Survival in Pork Chop Enhanced and Risk per Serving, Baseline (160° F Cooking End-point Temperature)

Statistics*	Cumulative Levels of Salmonella (log CFU/g)				Surviving CFU per serving	Risk of salmonellosis per serving
	At Retail	Post Transportation	Post Refrigeration and Prior to Cooking	Post Cooking		
Mean	-3.90	-3.89	-3.71	-18.75	0.00	0.00
SD	1.24	1.24	1.56	1.93	0.00	0.00
Percentiles					0.00	0.00
5th	-5.94	-5.92	-5.89	-21.95	0.00	0.00
10th	-5.48	-5.46	-5.43	-21.16	0.00	0.00
15th	-5.17	-5.15	-5.11	-20.61	0.00	0.00
20th	-4.93	-4.91	-4.86	-20.19	0.00	0.00
25th	-4.73	-4.72	-4.66	-19.86	0.00	0.00
50th	-3.90	-3.89	-3.82	-18.69	0.00	0.00
75th	-3.09	-3.08	-2.95	-17.65	0.00	0.00
90th	-2.30	-2.29	-2.05	-16.67	0.00	0.00
95th	-1.82	-1.81	-1.41	-16.02	0.00	0.00
97.5th	-1.43	-1.42	-0.63	-15.19	0.00	0.00
99th	-1.04	-1.03	1.80	-12.93	0.00	0.00
99.5th	-0.75	-0.74	4.07	-10.96	0.00	0.00
99.9th	-0.24	-0.24	6.37	-8.32	0.00	0.00
99.99th	-0.01	-0.01	6.95	-7.58	0.00	0.00

***Based on 10,000 iteration runs**

Table 23 *Salmonella* Growth, Inactivation and Survival in Pork Roast Unenhanced and Risk per Serving, Baseline (160° F Cooking End-point Temperature)

Statistics*	Cumulative Levels of *Salmonella* (log CFU/g)				Surviving CFU per serving	Risk of salmonellosis per serving
	At Retail	Post Transportation	Post Refrigeration and Prior to Cooking	Post Cooking		
Mean	-2.25	-2.24	-2.10	-17.14	0.00	0.00
SD	0.60	0.60	0.97	1.49	0.00	0.00
Percentiles						
5th	-3.24	-3.22	-3.20	-19.98	0.00	0.00
10th	-3.02	-3.01	-2.98	-19.37	0.00	0.00
15th	-2.87	-2.86	-2.84	-18.59	0.00	0.00
20th	-2.76	-2.74	-2.72	-18.03	0.00	0.00
25th	-2.66	-2.64	-2.62	-17.73	0.00	0.00
50th	-2.25	-2.24	-2.19	-16.95	0.00	0.00
75th	-1.85	-1.83	-1.76	-16.35	0.00	0.00
90th	-1.48	-1.47	-1.33	-15.79	0.00	0.00
95th	-1.26	-1.25	-0.97	-15.38	0.00	0.00
97.5th	-1.07	-1.06	-0.28	-14.79	0.00	0.00
99th	-0.86	-0.85	2.10	-12.54	0.00	0.00
99.5th	-0.71	-0.70	4.20	-10.63	0.00	0.00
99.9th	-0.45	-0.44	6.25	-8.26	0.00	0.00
99.99th	-0.13	-0.13	6.70	-7.99	0.00	0.00

***Based on 10,000 iteration runs**

Table 24 *Salmonella* Growth, Inactivation and Survival in Pork Chop Unenhanced and Risk per Serving, Baseline (160° F Cooking End-point Temperature)

Statistics*	Cumulative Levels of *Salmonella* (log CFU/g)				Surviving CFU per serving	Risk of salmonellosis per serving
	At Retail	Post Transportation	Post Refrigeration and Prior to Cooking	Post Cooking		
Mean	-2.25	-2.24	-2.09	-17.13	0.00	0.00
SD	0.60	0.60	0.99	1.50	0.00	0.00
Percentiles						
5th	-3.24	-3.22	-3.20	-19.93	0.00	0.00
10th	-3.02	-3.00	-2.97	-19.38	0.00	0.00
15th	-2.87	-2.86	-2.82	-18.60	0.00	0.00
20th	-2.76	-2.74	-2.71	-18.07	0.00	0.00
25th	-2.66	-2.64	-2.61	-17.76	0.00	0.00
50th	-2.25	-2.24	-2.19	-16.95	0.00	0.00
75th	-1.85	-1.83	-1.76	-16.33	0.00	0.00
90th	-1.48	-1.47	-1.32	-15.78	0.00	0.00
95th	-1.26	-1.25	-0.98	-15.40	0.00	0.00
97.5th	-1.07	-1.06	-0.23	-14.79	0.00	0.00
99th	-0.86	-0.84	2.12	-12.52	0.00	0.00
99.5th	-0.71	-0.70	4.28	-10.40	0.00	0.00
99.9th	-0.37	-0.37	6.43	-8.14	0.00	0.00
99.99th	-0.07	-0.05	6.89	-7.13	0.00	0.00

***Based on 10,000 iteration runs**

6.2 Alternative Cooking End-Point Temperatures for Duration of 15 seconds

In the alternative scenarios, while keeping growth estimates during transportation from retail stores to homes and during storage and refrigeration the same as in the baseline scenario, cooking end-point temperatures were allowed to vary below the recommended 160ºF, to include 145 (62.8), 150 (65.6) and 155°F (68.3°C). In all cases the simulated holding time on the heat source was 15 seconds at each temperature. The conservative assumption was that temperature at the coldest gram of the product did not rise during the 15 seconds. The simulated results showed that in all alternative cases, risks per serving were similar to the baseline scenario (zero risk per serving) at or below the 97.5th percentile. Estimates of *Salmonella* levels in various pork cuts and risk per serving are summarized below.

6.2.1 Pork Roast Enhanced (PRE) Surviving Levels and Risks

Summary statistics of the surviving levels of *Salmonella* and risk of serving after cooking at various temperatures in PRE are summarized in Table 25. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling (Crystal Ball, 2000).

Similar to the baseline scenario, the predicted levels of *Salmonella* (CFU/serving) in PRE were zero for all percentiles below the 99.5th percentile when the alternative cooking end-point temperature was 155ºF. At the extreme upper tail of the distribution, 99.5th percentile and higher, the model predicted detectable levels corresponding to a risk of 1.6E-3 per serving, as compared to zero risk per serving in the baseline scenario of 160ºF.

When cooking end-point temperatures of 150 and 145ºF were used, the levels of *Salmonella* (CFU/serving) in PRE were zero for all percentiles below the 99th percentile. At 150 and 145ºF, risks predicted at the 99th percentile were 2.7E-3 and 5.1E-3 per serving, respectively.

Table 25 *Salmonella* Surviving Levels (Log CFU/serving) and Risk per Serving at Various Cooking End-point Temperatures for 15 seconds, Pork Roast Enhanced

Statistics*	Baseline 160ºF		155ºF		150ºF		145ºF	
	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving
Mean	-17.6	0.0E+00	-8.1	2.4E-05	-5.1	1.0E-04	-4.1	1.4E-04
SD	1.6	0.0E+00	1.6	3.6E-04	1.6	1.1E-03	1.6	1.3E-03
Percentiles								
5th	-19.8	0.0E+00	-10.2	0.0E+00	-7.2	0.0E+00	-6.3	0.0E+00
10th	-19.3	0.0E+00	-9.8	0.0E+00	-6.8	0.0E+00	-5.8	0.0E+00
15th	-19.0	0.0E+00	-9.5	0.0E+00	-6.5	0.0E+00	-5.5	0.0E+00
20th	-18.8	0.0E+00	-9.3	0.0E+00	-6.3	0.0E+00	-5.3	0.0E+00
25th	-18.6	0.0E+00	-9.1	0.0E+00	-6.0	0.0E+00	-5.1	0.0E+00
50th	-17.8	0.0E+00	-8.2	0.0E+00	-5.2	0.0E+00	-4.3	0.0E+00
75th	-16.9	0.0E+00	-7.3	0.0E+00	-4.3	0.0E+00	-3.4	0.0E+00
90th	-15.9	0.0E+00	-6.4	0.0E+00	-3.4	0.0E+00	-2.4	0.0E+00
95th	-15.3	0.0E+00	-5.8	0.0E+00	-2.8	0.0E+00	-1.8	0.0E+00
97.5th	-14.3	0.0E+00	-4.8	0.0E+00	-1.7	0.0E+00	-0.8	0.0E+00
99th	-11.7	0.0E+00	-2.1	0.0E+00	0.9	2.7E-03	1.8	5.1E-03
99.5th	-9.0	0.0E+00	0.6	1.6E-03	3.6	9.7E-03	4.5	1.2E-02
99.9th	-7.5	0.0E+00	2.0	6.1E-03	5.1	1.6E-02	6.0	1.8E-02
99.99th	-7.0	0.0E+00	2.5	7.8E-03	5.5	1.8E-02	6.5	2.1E-02

***Based on 10,000 iteration runs**

6.2.2 Pork Chop Enhanced (PCE) Surviving Levels and Risks

Summary statistics of the simulated surviving levels of *Salmonella* and risk per serving after cooking at various temperatures in PCE are summarized in Table 26. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

When the alternative cooking end-point temperature of 155°F was applied, the levels of *Salmonella* (CFU/serving) in PCE below the 99.5th percentile were zero, similar to that found in the baseline scenario of 160°F. At the extreme upper percentiles, 99.5th percentile and higher, the model predicted levels of *Salmonella* corresponding to a risk of 1.2E-3per serving, as compared to zero risk per serving in the baseline scenario of 160ºF.

When cooking end-point temperatures of 150 and 145ºF were evaluated, *Salmonella* levels (CFU/serving) in PRE were zero for all percentiles below the 99th percentile. At 150°F, the predicted risks were 2.3E-3, 9.4E-3, 1.6E-2 and 1.8E-2 per serving at the 99th, 99.5th, 99.9th, and 99.99th percentiles, respectively. At 145°F the predicted risks ranged from 5.2E-3 at the 99th percentile to 2.2E-2 per serving at the 99.99th percentile.

Table 26 *Salmonella spp* Surviving Levels (Log CFU/serving) and Risk per Serving at Various cooking End-point Temperatures for 15 seconds, Pork Chop Enhanced

Statistics*	**Baseline 160ºF**		**155ºF**		**150ºF**		**145ºF**	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving
Mean	-17.6	0.0E+00	-8.1	2.6E-05	-5.1	1.0E-04	-4.1	1.4E-04
SD	1.6	0.0E+00	1.6	3.8E-04	1.6	1.1E-03	1.6	1.3E-03
Percentiles								
5th	-19.8	0.0E+00	-10.2	0.0E+00	-7.2	0.0E+00	-6.3	0.0E+00
10th	-19.3	0.0E+00	-9.8	0.0E+00	-6.8	0.0E+00	-5.8	0.0E+00
15th	-19.0	0.0E+00	-9.5	0.0E+00	-6.5	0.0E+00	-5.6	0.0E+00
20th	-18.8	0.0E+00	-9.3	0.0E+00	-6.3	0.0E+00	-5.3	0.0E+00
25th	-18.6	0.0E+00	-9.1	0.0E+00	-6.1	0.0E+00	-5.1	0.0E+00
50th	-17.8	0.0E+00	-8.2	0.0E+00	-5.2	0.0E+00	-4.3	0.0E+00
75th	-16.8	0.0E+00	-7.3	0.0E+00	-4.3	0.0E+00	-3.3	0.0E+00
90th	-15.9	0.0E+00	-6.4	0.0E+00	-3.4	0.0E+00	-2.4	0.0E+00
95th	-15.2	0.0E+00	-5.7	0.0E+00	-2.7	0.0E+00	-1.8	0.0E+00
97.5th	-14.3	0.0E+00	-4.8	0.0E+00	-1.7	0.0E+00	-0.8	0.0E+00
99th	-11.7	0.0E+00	-2.2	0.0E+00	0.9	2.3E-03	1.8	5.2E-03
99.5th	-9.1	0.0E+00	0.4	1.2E-03	3.4	9.4E-03	4.4	1.2E-02
99.9th	-7.5	0.0E+00	2.1	6.6E-03	5.1	1.6E-02	6.0	1.9E-02
99.99th	-7.0	0.0E+00	2.5	8.5E-03	5.5	1.8E-02	6.5	2.2E-02

***Based on 10,000 iteration runs**

6.2.3 Pork Roast Unenhanced (PRUE) Surviving Levels and Risks

Summary statistics of the simulated surviving levels of *Salmonella* and risk per serving after cooking at various temperatures in unenhanced pork roast are summarized in Table 27. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

Similar to the baseline scenario, the levels of *Salmonella* (CFU/serving) in PRUE were zero for all percentiles, except at the upper tail (99.5th percentile and higher) when the alternative cooking end-point temperature was 155ºF. At the 99.5th percentile, the model predicted risks of 1.5E-3, as compared to zero risk per serving in the baseline scenario of 160ºF.

Similarly, when cooking end-point temperatures of 150 and 145ºF were used; the levels of *Salmonella* (CFU/serving) in PRUE were zero for all percentiles, except for the upper tail of the distribution (99th percentiles and higher). At 150ºF, the predicted risks at the 99th, 99.5th, 99.9th and

99.99th percentiles were 3.0E-3, 9.4E-3, 1.5E-2 and 1.8E-2, respectively. At 145°F, the predicted risks were 5.9E-3 at the 99th percentile and 2.1E-2 per serving at the 99.99th percentiles.

Table 27 *Salmonella spp* Surviving Levels (Log CFU/serving) and Risk per Serving at Various Cooking End-point Temperatures, for 15 seconds, Pork Roast Unenhanced

Statistics*	**Baseline 160ºF**		**155ºF**		**150ºF**		**145ºF**	
	Log CFU per Serving	Risk per Serving	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving
Mean	-16.0	0.0E+00	-6.5	2.3E-05	-3.5	1.1E-04	-2.5	1.6E-04
SD	1.0	0.0E+00	1.0	3.4E-04	1.0	1.1E-03	1.0	1.3E-03
Percentiles								
5th	-17.1	0.0E+00	-7.6	0.0E+00	-4.6	0.0E+00	-3.6	0.0E+00
10th	-16.9	0.0E+00	-7.4	0.0E+00	-4.4	0.0E+00	-3.4	0.0E+00
15th	-16.8	0.0E+00	-7.2	0.0E+00	-4.2	0.0E+00	-3.3	0.0E+00
20th	-16.6	0.0E+00	-7.1	0.0E+00	-4.1	0.0E+00	-3.2	0.0E+00
25th	-16.5	0.0E+00	-7.0	0.0E+00	-4.0	0.0E+00	-3.1	0.0E+00
50th	-16.1	0.0E+00	-6.6	0.0E+00	-3.6	0.0E+00	-2.6	0.0E+00
75th	-15.7	0.0E+00	-6.2	0.0E+00	-3.2	0.0E+00	-2.2	0.0E+00
90th	-15.2	0.0E+00	-5.7	0.0E+00	-2.7	0.0E+00	-1.8	0.0E+00
95th	-14.9	0.0E+00	-5.4	0.0E+00	-2.3	0.0E+00	-1.4	0.0E+00
97.5th	-14.0	0.0E+00	-4.5	0.0E+00	-1.4	0.0E+00	-0.5	0.0E+00
99th	-11.5	0.0E+00	-2.0	0.0E+00	1.1	3.0E-03	2.0	5.9E-03
99.5th	-9.0	0.0E+00	0.5	1.5E-03	3.5	9.4E-03	4.5	1.2E-02
99.9th	-7.5	0.0E+00	2.0	6.6E-03	5.1	1.5E-02	6.0	1.8E-02
99.99th	-7.0	0.0E+00	2.5	7.4E-03	5.5	1.8E-02	6.5	2.1E-02

***Based on 10,000 iteration runs**

6.2.4 Pork Chop Unenhanced (PCUE) Surviving Levels and Risks

Summary statistics of the simulated surviving levels of *Salmonella* and risk per serving after cooking at various temperatures in PCUE are summarized in Table 28. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

Similar to the baseline scenario, the levels of *Salmonella* (CFU/serving) in PCUE were zero for all percentiles below the 99.5th percentile when the alternative cooking end-point temperature was 155ºF. At the extreme upper tail of the distribution, 99.5th percentile and higher, the model predicted detectable *Salmonella* levels corresponding to a risk of 2.0E-3 per serving, as compared to zero risk per serving in the baseline scenario of 160ºF.

When the cooking end-point temperatures of 150 and 145°F were used, the levels of *Salmonella* (CFU/serving) surviving in PCUE were zero for all percentiles below the 99th percentile. At 150°F, the predicted risks were 3.1E-3, 9.9E-3, 1.5 E-2 and 1.7 E-2 per serving, at the 99th, 99.5th, 99.9th and 99.99th percentiles, respectively. At 145°F, risk per serving was also predicted at the extreme upper percentiles: 5.9E-3, 1.3E-2, 1.8E-2 and 2.1E-2 at the 99th, 99.5th, 99.9th and 99.99th percentiles, respectively.

Table 28 *Salmonella spp* Surviving Levels (Log CFU/serving) and Risk per Serving at Various Cooking End-point Temperatures for 15 seconds, Pork Chop Unenhanced

Statistics*	**Baseline 160ºF**		**155ºF**		**150ºF**		**145ºF**	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per serving	Risk per Serving	Log CFU per serving	Risk per Serving
Mean	-16.0	0.0E+00	-6.5	2.5E-05	-3.5	1.1E-04	-2.5	1.6E-04
SD	1.0	0.0E+00	1.0	3.5E-04	1.0	1.1E-03	1.0	1.4E-03
Percentiles								
5th	-17.1	0.0E+00	-7.6	0.0E+00	-4.6	0.0E+00	-3.6	0.0E+00
10th	-16.9	0.0E+00	-7.4	0.0E+00	-4.4	0.0E+00	-3.4	0.0E+00
15th	-16.8	0.0E+00	-7.2	0.0E+00	-4.2	0.0E+00	-3.3	0.0E+00
20th	-16.6	0.0E+00	-7.1	0.0E+00	-4.1	0.0E+00	-3.2	0.0E+00
25th	-16.5	0.0E+00	-7.0	0.0E+00	-4.0	0.0E+00	-3.0	0.0E+00
50th	-16.1	0.0E+00	-6.6	0.0E+00	-3.6	0.0E+00	-2.6	0.0E+00
75th	-15.7	0.0E+00	-6.2	0.0E+00	-3.1	0.0E+00	-2.2	0.0E+00
90th	-15.2	0.0E+00	-5.7	0.0E+00	-2.7	0.0E+00	-1.8	0.0E+00
95th	-14.9	0.0E+00	-5.4	0.0E+00	-2.3	0.0E+00	-1.4	0.0E+00
97.5th	-13.9	0.0E+00	-4.4	0.0E+00	-1.4	0.0E+00	-0.4	0.0E+00
99th	-11.3	0.0E+00	-1.8	0.0E+00	1.2	3.1E-03	2.1	5.9E-03
99.5th	-8.9	0.0E+00	0.6	2.0E-03	3.6	9.9E-03	4.6	1.3E-02
99.9th	-7.5	0.0E+00	2.1	6.3E-03	5.1	1.5E-02	6.0	1.8E-02
99.99th	-7.0	0.0E+00	2.5	7.3E-03	5.5	1.7E-02	6.5	2.1E-02

***Based on 10,000 iteration runs**

6.3 End-Point Cooking Temperature of 145˚F and Alternative Durations

To examine the impact of time on the surviving *Salmonella* levels, alternative durations of 1, 3 and 4 minutes were incorporated into the risk assessment model (see Tables 29-32). The results showed that for all four pork cuts, when a cooking end-point temperature of 145°F is maintained for 4 minutes, there were no surviving levels of *Salmonella* and zero risk per serving, for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute, *Salmonella* levels (log CFU/serving) were estimated to be less than zero for all percentiles below the 99.9th percentile (i.e. no surviving CFU and zero risk per serving). When a cooking end-point temperature of 145ºF is maintained for 1 minute and 15 seconds, surviving CFU per serving and associated risk per serving were only predicted at the 99th percentiles and higher. The following sections provide more detailed results for the four pork cuts.

6.3.1 Pork Chop Enhanced (PCE)

Summary statistics of the simulated surviving levels of *Salmonella* after cooking and achieving an end-point cooking temperature for 15 seconds, 1, 3 and 4 minutes for PCE and associated risk per serving are summarized in Table 29. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

When a cooking end-point temperature of 145ºF is maintained for 4 minutes, the surviving levels of *Salmonella* (log CFU/serving) in PCE were less than zero (or no surviving CFU and zero risk per serving) for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute and for 15 seconds, surviving CFU per serving was only predicted at the 99th percentiles and higher. The predicted risks at the cooking end-point temperature of 145ºF for 15 seconds were 5.2E-3, 1.2E-2, 1.9E-2 and 2.2E-2 per serving at the 99th, 99.5th, 99.9th, and 99.99th percentiles, respectively.

Table 29 *Salmonella* Surviving Levels (Log CFU/serving) and Risk per Serving at 145˚F for Various Durations, Pork Chop Enhanced

Statistics*	15 seconds		1 minute		3 minutes		4 minutes	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving
Mean	-4.1	1.41E-04	-5.4	8.83E-05	-9.0	1.24E-05	-10.7	0.00E+00
SD	1.6	1.33E-03	1.6	9.79E-04	1.6	2.08E-04	1.6	0.00E+00
Percentiles								
5th	-6.3	0.00E+00	-7.6	0.00E+00	-11.1	0.00E+00	-12.9	0.00E+00
10th	-5.8	0.00E+00	-7.2	0.00E+00	-10.7	0.00E+00	-12.5	0.00E+00
15th	-5.6	0.00E+00	-6.9	0.00E+00	-10.4	0.00E+00	-12.2	0.00E+00
20th	-5.3	0.00E+00	-6.6	0.00E+00	-10.2	0.00E+00	-11.9	0.00E+00
25th	-5.1	0.00E+00	-6.4	0.00E+00	-10.0	0.00E+00	-11.7	0.00E+00
50th	-4.3	0.00E+00	-5.6	0.00E+00	-9.1	0.00E+00	-10.9	0.00E+00
75th	-3.3	0.00E+00	-4.7	0.00E+00	-8.2	0.00E+00	-10.0	0.00E+00
90th	-2.4	0.00E+00	-3.7	0.00E+00	-7.3	0.00E+00	-9.0	0.00E+00
95th	-1.8	0.00E+00	-3.1	0.00E+00	-6.6	0.00E+00	-8.4	0.00E+00
97.5th	-0.8	0.00E+00	-2.1	0.00E+00	-5.6	0.00E+00	-7.4	0.00E+00
99th	1.8	5.2E-03	0.5	1.2E-03	-3.0	0.00E+00	-4.8	0.00E+00
99.5th	4.4	1.2E-02	3.0	8.6E-03	-0.5	0.00E+00	-2.2	0.00E+00
99.9th	6.0	1.9E-02	4.7	1.5E-02	1.2	3.9E-03	-0.6	0.00E+00
99.99th	6.5	2.2E-02	5.2	1.7E-02	1.6	5.4E-03	-0.1	0.00E+00

***Based on 10,000 iteration runs**

6.3.2 Pork Roast Enhanced (PRE)

Summary statistics of the simulated surviving levels of *Salmonella* after cooking and achieving an end-point cooking temperature for 15 seconds, 1, 3 and 4 minutes for enhanced pork roast and associated risk per serving are summarized in Table 30. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling. When a cooking end-point temperature of 145°F is maintained for 4 minutes, the surviving levels of *Salmonella* (log CFU/serving) in PRE were less than zero (or no surviving CFU and zero risk per serving) for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute and for 15 seconds, surviving CFU per serving were predicted at the 99th percentiles and higher. The predicted risks at a cooking end-point temperature of 145º F for 15 seconds were 5.1E-3, 1.2E-2, 1.8E-2 and 2.1E-2 per serving at the 99th, 99.5th, 99.9th, and 99.99th percentiles, respectively.

Table 30 *Salmonella* Surviving Levels (Log CFU/serving) and Risk per Serving at 145˚F for Various Durations, Pork Roast Enhanced

Statistics*	15 seconds		1 minute		3 minutes		4 minutes	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving
Mean	-4.1	1.41E-04	-5.4	8.87E-05	-9.0	1.12E-05	-10.7	0.00E+00
SD	1.6	1.32E-03	1.6	9.63E-04	1.6	1.91E-04	1.6	0.00E+00
Percentiles								
5th	-6.3	0.00E+00	-7.6	0.00E+00	-11.1	0.00E+00	-12.9	0.00E+00
10th	-5.8	0.00E+00	-7.2	0.00E+00	-10.7	0.00E+00	-12.4	0.00E+00
15th	-5.5	0.00E+00	-6.9	0.00E+00	-10.4	0.00E+00	-12.2	0.00E+00
20th	-5.3	0.00E+00	-6.6	0.00E+00	-10.1	0.00E+00	-11.9	0.00E+00
25th	-5.1	0.00E+00	-6.4	0.00E+00	-9.9	0.00E+00	-11.7	0.00E+00
50th	-4.3	0.00E+00	-5.6	0.00E+00	-9.1	0.00E+00	-10.9	0.00E+00
75th	-3.4	0.00E+00	-4.7	0.00E+00	-8.2	0.00E+00	-10.0	0.00E+00
90th	-2.4	0.00E+00	-3.8	0.00E+00	-7.3	0.00E+00	-9.0	0.00E+00
95th	-1.8	0.00E+00	-3.1	0.00E+00	-6.6	0.00E+00	-8.4	0.00E+00
97.5th	-0.8	0.00E+00	-2.1	0.00E+00	-5.6	0.00E+00	-7.4	0.00E+00
99th	1.8	5.1E-03	0.5	1.6E-03	-3.0	0.00E+00	-4.8	0.00E+00
99.5th	4.5	1.2E-02	3.2	8.7E-03	-0.3	0.00E+00	-2.1	0.00E+00
99.9th	6.0	1.8E-02	4.7	1.4E-02	1.2	3.4E-03	-0.6	0.00E+00
99.99th	6.5	2.1E-02	5.2	1.7E-02	1.6	5.1E-03	-0.1	0.00E+00

***Based on 10,000 iteration runs**

6.3.3 Pork Chop Unenhanced (PCUE)

Summary statistics of the simulated surviving levels of *Salmonella* after cooking and achieving an end-point cooking temperature for 15 seconds, 1, 3 and 4 minutes for PCUE and associated risk per serving are summarized in Table 31. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

When a cooking end-point temperature of 145^{o}F is maintained for 4 minutes, the surviving levels of *Salmonella* (log CFU/serving) in PCUE were less than zero (or no surviving CFU and zero risk per serving) for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute and for 15 seconds, surviving CFU per serving was only predicted at the 99th percentiles and higher. The predicted risks at a cooking end-point temperature of 145ºF for 15 seconds were 5.9E-3, 1.3E-2, 1.8E-2 and 2.0E-2 per serving at the 99th, 99.5th, 99.9th, and 99.99th percentiles, respectively.

Table 31 *Salmonella* Surviving Levels (Log CFU/serving) and Risk per Serving at 145˚F for Various Durations, Pork Chop Unenhanced

Statistics*	15 seconds		1 minute		3 minutes		4 minutes	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving
Mean	-2.5	1.60E-04	-3.8	9.33E-05	-7.4	1.09E-05	-9.1	0.00E+00
SD	1.0	1.35E-03	1.0	9.70E-04	1.0	1.83E-04	1.0	0.00E+00
Percentiles								
5th	-3.6	0.00E+00	-5.0	0.00E+00	-8.5	0.00E+00	-10.2	0.00E+00
10th	-3.4	0.00E+00	-4.7	0.00E+00	-8.3	0.00E+00	-10.0	0.00E+00
15th	-3.3	0.00E+00	-4.6	0.00E+00	-8.1	0.00E+00	-9.9	0.00E+00
20th	-3.2	0.00E+00	-4.5	0.00E+00	-8.0	0.00E+00	-9.8	0.00E+00
25th	-3.0	0.00E+00	-4.4	0.00E+00	-7.9	0.00E+00	-9.7	0.00E+00
50th	-2.6	0.00E+00	-4.0	0.00E+00	-7.5	0.00E+00	-9.2	0.00E+00
75th	-2.2	0.00E+00	-3.5	0.00E+00	-7.0	0.00E+00	-8.8	0.00E+00
90th	-1.8	0.00E+00	-3.1	0.00E+00	-6.6	0.00E+00	-8.4	0.00E+00
95th	-1.4	0.00E+00	-2.7	0.00E+00	-6.2	0.00E+00	-8.0	0.00E+00
97.5th	-0.4	0.00E+00	-1.7	0.00E+00	-5.3	0.00E+00	-7.0	0.00E+00
99th	2.1	5.9E-03	0.8	2.3E-03	-2.7	0.00E+00	-4.5	0.00E+00
99.5th	4.6	1.3E-02	3.3	9.0E-03	-0.3	0.00E+00	-2.0	0.00E+00
99.9th	6.0	1.8E-02	4.7	1.4E-02	1.2	3.6E-03	-0.6	0.00E+00
99.99th	6.5	2.0E-02	5.2	1.6E-02	1.6	4.6E-03	-0.1	0.00E+00

***Based on 10,000 iteration runs**

6.3.4 Pork Roast Unenhanced (PRUE)

Summary statistics of the simulated surviving levels of *Salmonella* after cooking and achieving an end-point cooking temperature for 15 seconds, 1, 3 and 4 minutes for PRUE and associated risk per serving are summarized in Table 32. These statistics were based on 10,000 iteration runs using Latin Hypercube sampling.

When a cooking end-point temperature of 145^{o}F is maintained for 4 minutes, the surviving levels of *Salmonella* (log CFU/serving) in PRUE were less than zero (or no surviving CFU and zero risk per serving) for all estimated percentiles. When a cooking end-point temperature of 145ºF is maintained for 1 minute and 15 seconds, surviving CFU per serving was predicted at the 99th percentiles and higher. The predicted risks at a cooking end-point temperature of 145ºF for 15 seconds were 6.0E-3, 1.2E-2, 1.8E-2 and 2.1E-2 per serving at the 99th, 99.5th, 99.9th, and 99.99th percentiles, respectively.

Table 32 *Salmonella* Surviving Levels (Log CFU/serving) and Risk per Serving at 145˚F for Various Durations, Pork Roast Unenhanced

Statistics*	**15 seconds**		**1 minute**		**3 minutes**		**4 minutes**	
	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving	Log CFU per Serving	Risk per Serving
Mean	-2.5	1.59E-04	-3.8	9.13E-05	-7.4	9.74E-06	-9.1	0.00E+00
SD	1.0	1.35E-03	1.0	9.59E-04	1.0	1.81E-04	1.0	0.00E+00
Percentiles								
5th	-3.6	0.00E+00	-5.0	0.00E+00	-8.5	0.00E+00	-10.2	0.00E+00
10th	-3.4	0.00E+00	-4.7	0.00E+00	-8.3	0.00E+00	-10.0	0.00E+00
15th	-3.3	0.00E+00	-4.6	0.00E+00	-8.1	0.00E+00	-9.9	0.00E+00
20th	-3.2	0.00E+00	-4.5	0.00E+00	-8.0	0.00E+00	-9.8	0.00E+00
25th	-3.1	0.00E+00	-4.4	0.00E+00	-7.9	0.00E+00	-9.7	0.00E+00
50th	-2.6	0.00E+00	-4.0	0.00E+00	-7.5	0.00E+00	-9.2	0.00E+00
75th	-2.2	0.00E+00	-3.5	0.00E+00	-7.0	0.00E+00	-8.8	0.00E+00
90th	-1.8	0.00E+00	-3.1	0.00E+00	-6.6	0.00E+00	-8.4	0.00E+00
95th	-1.4	0.00E+00	-2.7	0.00E+00	-6.2	0.00E+00	-8.0	0.00E+00
97.5th	-0.5	0.00E+00	-1.8	0.00E+00	-5.3	0.00E+00	-7.1	0.00E+00
99th	2.0	6.0E-03	0.7	1.9E-03	-2.8	0.00E+00	-4.6	0.00E+00
99.5th	4.5	1.2E-02	3.2	8.4E-03	-0.4	0.00E+00	-2.1	0.00E+00
99.9th	6.0	1.8E-02	4.7	1.4E-02	1.2	3.8E-03	-0.6	0.00E+00
99.99th	6.5	2.1E-02	5.1	1.7E-02	1.6	4.7E-03	-0.2	0.00E+00

***Based on 10,000 iteration runs**

7 Sensitivity Analysis

7.1 *Salmonella* Levels at Retail

Since the levels of *Salmonella* on pork meat at retail were the starting point for the exposure and risk model, uncertainty in this model input parameter would greatly influence the final exposure and risk estimates at the consumer level. The baseline and alternative cooking end-point temperature scenarios were based on the NPB survey data (described earlier). The NPB survey sampling is based on a convenient sampling strategy. Therefore, there is a degree of uncertainty in the national representativeness of the data. As such, the sensitivity analyses focused on alternative input data and distribution of *Salmonella* in pork meats, including the following:

Sensitivity Analysis #1: Alternative distribution of *Salmonella* levels at retail based on FSIS carcass prevalence data. In this option, a single combined distribution of *Salmonella* levels in pork meat at retail was developed assuming the highest prevalence rate in carcasses (4%) that was detected in the FSIS PR/HACCP verification program (USDA, 2007d; USDA 2007e). Enumeration of levels was based on the NPB retail sampling data. A lognormal distribution was assumed. This approach represents the worst-case scenario since it is highly unlikely that prevalence on carcasses would remain at the same rate at retail. Indeed, the prevalence rate found at retail is lower.

Sensitivity Analysis # 2: Distribution of *Salmonella* levels at retail based on combined NPB survey data. In this analysis, rather than developing distinct regional distributions based on the four sampling locations for each pork cut and then sampling from the regional distributions to develop national distribution for each pork cut, retail samples from all four sampling locations were combined and one national distribution of *Salmonella* levels for each pork cuts (PRE, PCE, PRUE and PCUE) was generated. Lognormal distributions were assumed.

Sensitivity Analysis # 3: Distribution of *Salmonella* levels at retail based on combined NPB survey data and alternative distribution shape. In this analysis, the retail samples from all NPB sampling locations were also combined to develop one national distribution of *Salmonella* levels for each type of pork cuts as in sensitivity analysis #2. However, a Weibull distribution was assumed, instead of the lognormal distribution.

For each sensitivity analysis, only the distributions of *Salmonella* levels at retail were redefined as described above. The remainders of the exposure and risk model components were kept the same as in the original model. Exposure simulation was carried out following the same sequence as in the initial model simulation:

Step 1 – Estimation of levels of *Salmonella* in pork meat at retail.

Step 2 – Estimation of growth during transportation from retail stores to consumer homes and addition to levels in step 1.

Step 3 – Estimation of growth during storage in homes (refrigeration) and addition to levels in step 2.

Step 4 – Estimation of surviving *Salmonella* levels (log CFU/g) after cooking, wherethe end-point cooking temperature was 145°F for 15 seconds. Decline in levels during cooking were combined with levels in step 3 to estimate the levels of *Salmonella* in pork meat (log CFU/g) post-cooking.

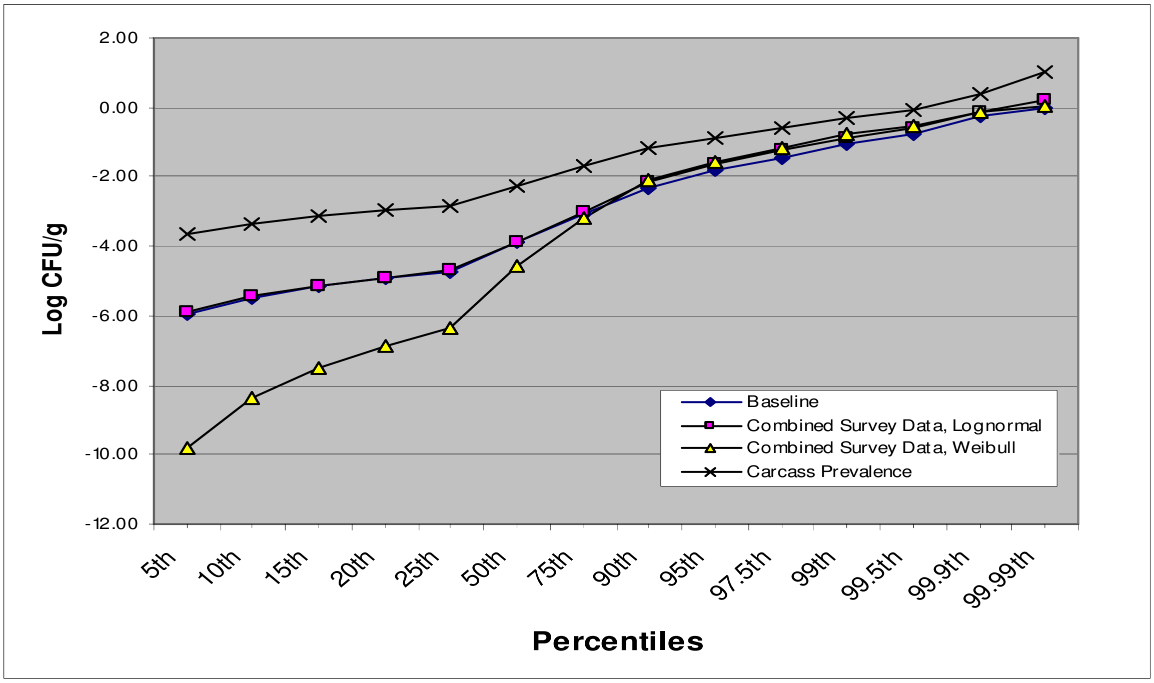
Step 5 – Combining levels in step 4 with DR data to estimate risk per serving.

7.1.1 Comparison of Alternative Distributions of *Salmonella* Levels on Pork Cuts at Retail

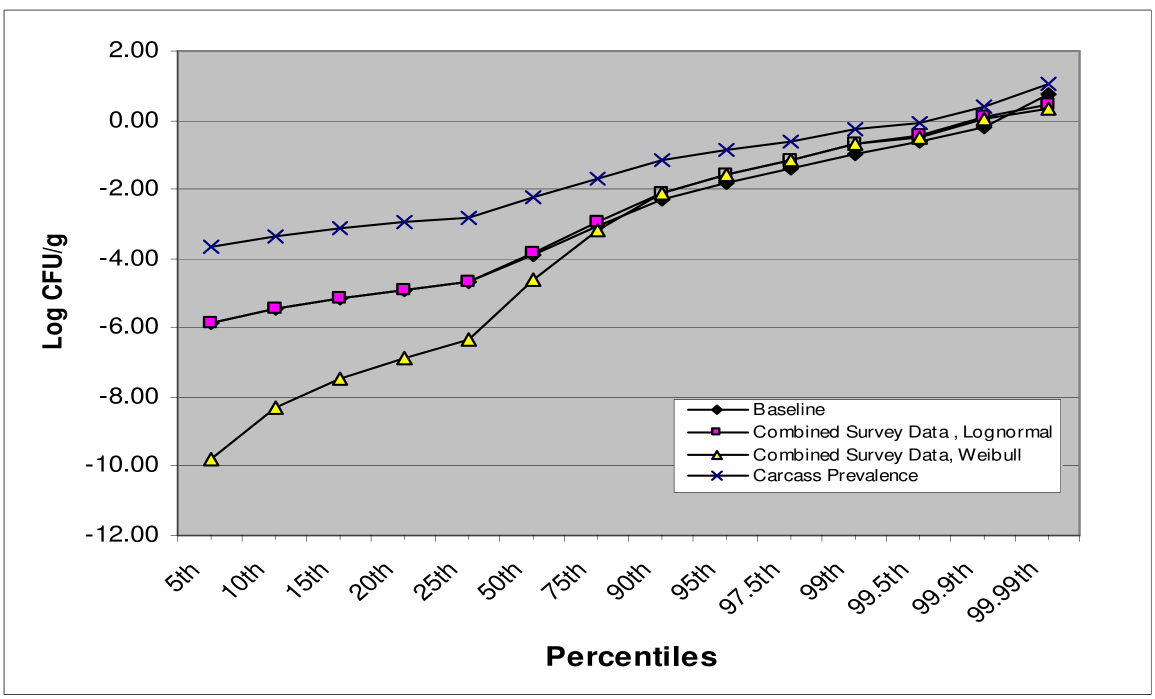
For the enhanced pork meats (PRE and PCE) the estimated levels of *Salmonella* were the highest when the input distribution of levels at retail was based on carcass prevalence data (sensitivity analysis #1), See Figure 10 below. When NPB survey data were combined and a Weibull distribution was used instead of the lognormal (sensitivity analysis # 3), the estimated levels at retail were the lowest at and below the 90th percentile. It appears that there is no real difference between the approach used to develop national distributions of levels at retail in the baseline assessment and that used in sensitivity analysis #2 (i.e. distribution of levels at retail is based on combined samples and lognormal).

Figure 10 Comparison of Levels of *Salmonella* (log CFU/g) at retail for Enhanced Pork

a) Pork Chop Enhanced



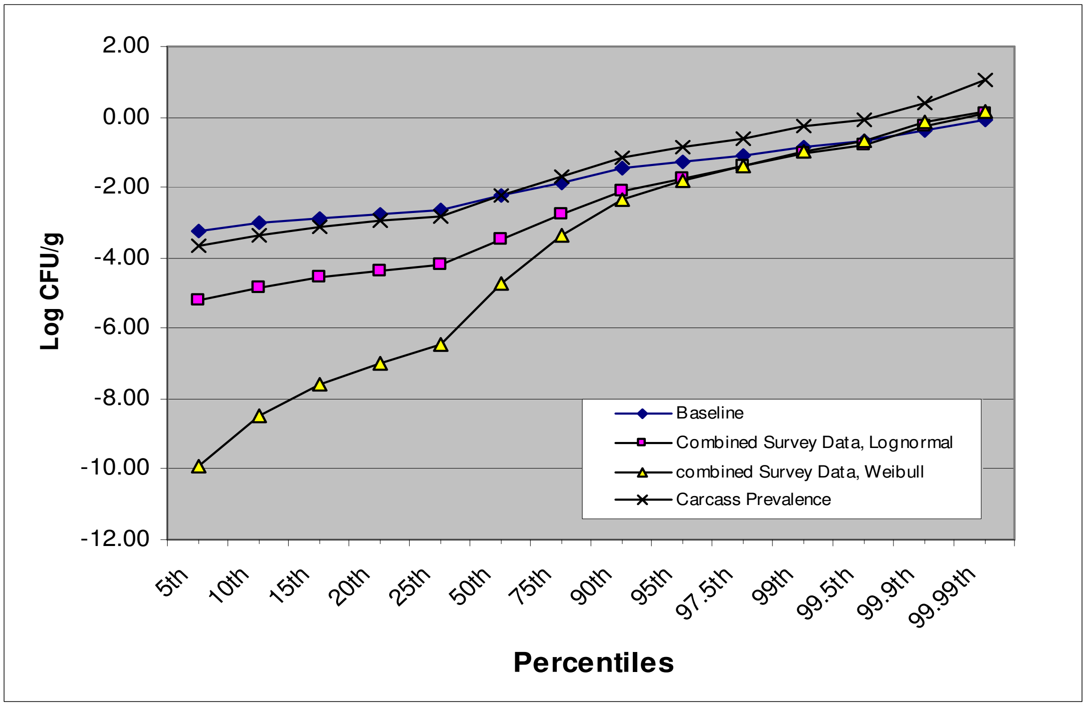
b) Pork Roast Enhanced



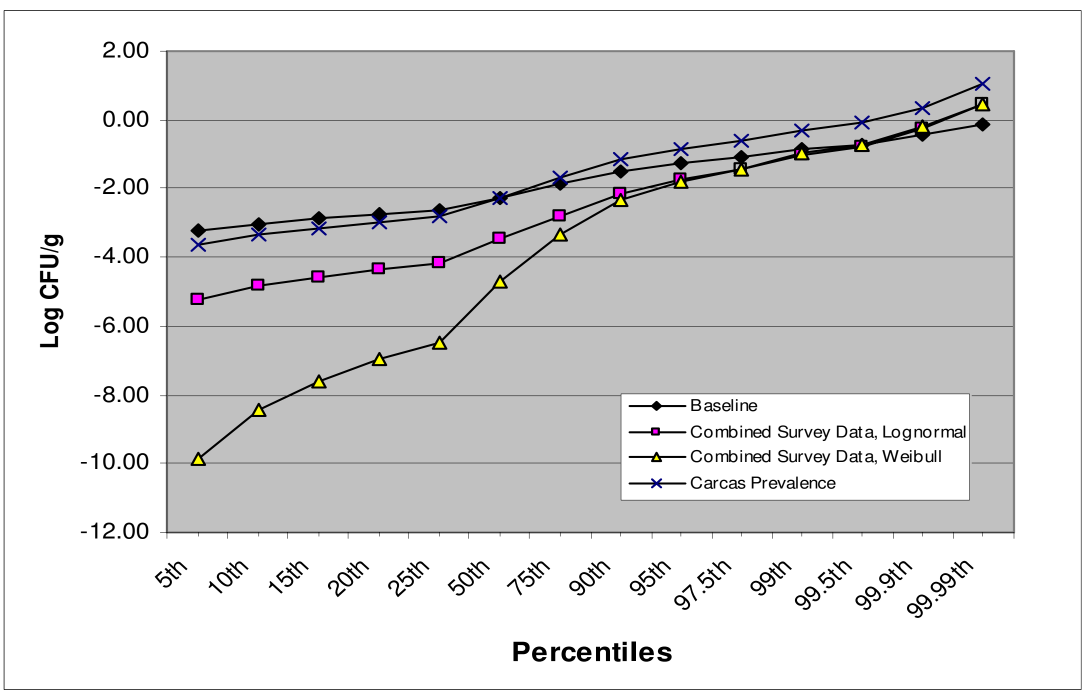
For the unenhanced pork meats (PRUE and PCUE) when the input distribution of levels at retail was based on carcass prevalence data (sensitivity analysis #1) the estimated levels of *Salmonella* in pork meats at retail were higher than estimates in the baseline in the upper percentile. However, in the lower percentiles, the predicted levels were slightly higher in the baseline model (see Figure 11 below). When NPB survey data were combined and the lognormal and Weibull distributions were used, sensitivity analyses #2 and #3, respectively, the estimated levels at retail were lower than that predicted in the baseline model.

Figure 11 Comparison of Levels of *Salmonella* (log CFU/g) at Retail for Unenhanced Pork

a) Pork Chop Unenhanced



b) Pork Roast Unenhanced



7.1.2 Comparison of Risk of Salmonellosis per Serving

At end-point cooking temperature 145°F for 15 seconds, the log reduction is such that the risk per serving for all cuts was essentially zero at and below the 97.5th percentile when alternative carcass data and model approaches were used to estimate *Salmonella* levels at retail. At the extreme percentiles 99th and higher, risk per serving ranges from 1:1000 to 1:100 for all cuts. The summaries of risk per serving for all four cuts are summarized in Table 33-36.

Table 33 Risk per Serving, Pork Chop Enhanced, at 145° F for 15 Seconds

Statistics*	**Sensitivity 1- Carcass Data**	**Sensitivity 2 - Combined Survey Data, Log Normal**	**Sensitivity 3 – Combined Survey Data, Weibull Distribution**	**Original Survey Data Treatment**
Mean	1.46E-04	1.25E-04	1.16E-04	1.41E-04
Std Deviation	1.25E-03	1.22E-03	1.17E-03	1.33E-03
Percentiles				
5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
10th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
15th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
20th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
25th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
50th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
75th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
90th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
95th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
97.5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
99th	5.84E-03	3.96E-03	3.53E-03	5.20E-03
99.5th	1.05E-02	1.10E-02	1.03E-02	1.18E-02
99.9th	1.73E-02	1.73E-02	1.73E-02	1.89E-02
99.99th	2.04E-02	2.18E-02	2.05E-02	2.15E-02

***Based on 10,000 iteration run**

Table 34 Risk per Serving, Pork Roast Enhanced, at 145° F for 15 Seconds

Statistics*	**Sensitivity 1- Carcass Data**	**Sensitivity 2 - Combined Survey Data, Log Normal**	**Sensitivity 3 – Combined Survey Data, Weibull Distribution**	**Original Survey Data Treatment**
Mean	1.46E-04	1.16E-04	1.08E-04	1.41E-04
Std Deviation	1.25E-03	1.19E-03	1.16E-03	1.32E-03
Percentiles				
5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
10th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
15th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
20th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
25th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
50th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
75th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
90th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
95th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
97.5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
99th	5.84E-03	3.15E-03	2.76E-03	5.06E-03
99.5th	1.05E-02	9.87E-03	9.83E-03	1.21E-02
99.9th	1.73E-02	1.77E-02	1.77E-02	1.83E-02
99.99th	2.04E-02	2.18E-02	2.16E-02	2.11E-02

***Based on 10,000 iteration runs**

Table 35 Risk per Serving, Pork Chop Unenhanced, at 145° F for 15 Seconds

Statistics*	Sensitivity 1- Carcass Data	Sensitivity 2 - Combined Survey Data, Log Normal	Sensitivity 3 – Combined Survey Data, Weibull Distribution	Original Survey Data Treatment
Mean	1.46E-04	9.99E-05	8.88E-05	1.60E-04
Std. Deviation	1.25E-03	1.06E-03	1.01E-03	1.35E-03
Percentiles				
5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
10th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
15th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
20th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
25th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
50th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
75th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
90th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
95th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
97.5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
99th	5.84E-03	2.34E-03	1.14E-03	5.86E-03
99.5th	1.05E-02	1.01E-02	8.35E-03	1.26E-02
99.9th	1.73E-02	1.57E-02	1.51E-02	1.77E-02
99.99th	2.04E-02	1.88E-02	1.93E-02	2.07E-02

***Based on 10,000 iteration runs**

Table 36 Risk per Serving, Pork Roast Unenhanced, at 145° F for 15 Seconds

Statistics*	Sensitivity 1- Carcass Data	Sensitivity 2 - Combined Survey Data, Log Normal	Sensitivity 3 – Combined Survey Data, Weibull Distribution	Original Survey Data Treatment
Mean	1.50E-04	1.10E-04	1.04E-04	1.59E-04
Std Deviation	1.28E-03	1.15E-03	1.13E-03	1.35E-03
Percentiles				
5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
10th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
15th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
20th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
25th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
50th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
75th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
90th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
95th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
97.5th	0.00E+00	0.00E+00	0.00E+00	0.00E+00
99th	6.12E-03	2.99E-03	2.39E-03	5.95E-03
99.5th	1.06E-02	9.73E-03	1.00E-02	1.18E-02
99.9th	1.76E-02	1.76E-02	1.72E-02	1.81E-02
99.99th	2.04E-02	2.05E-02	2.00E-02	2.10E-02

***Based on 10,000 iteration runs**

7.2 Temperature Abuse Scenarios

7.2.1 Approach

In the temperature abuse scenario, consumers were assumed to take products out of the refrigerator and leave them on the counter at room temperature for an extended amount of time before cooking. As there are no empirical data on consumers' temperature abuse behavior, as a bounding exercise, the following scenarios of temperature abuse were assumed:

- Temperature Abuse Scenario 1: Products are left on counter for 5 hours, at 30ºC (86ºF) (day time, in a hot kitchen)
- Temperature Scenario 2: Products are left on counter for 10 hours, at 20ºC (68ºF) (overnight, at "normal" temperature)

Using the same growth equations in the main model (see Section 5), the log-growth that could occur for each of the two scenarios were developed for the different cuts of pork. The average log growth for each temperature abuse scenario and pork cuts is summarized in Table 37.

Table 37 Average *Salmonella* Log-Growth for Each Temperature Abuse Scenario and Pork Cut

Pork Types	Temperature Abuse Scenarios	
	86°C, 5 hrs	68°C, 10 hrs
PCE	1.3	1.9
PRE	1.3	1.9
PCUE	0.9	1.5
PRUE	0.9	1.6

According to Novelli (2004) approximately 19% of consumers sometimes, rarely, or never safely defrost frozen meat and poultry (i.e., in the refrigerator, in cold water, or using the microwave). Based on this reference, it is assumed that 20% of the population does not use good food handling practices and 80% follow acceptable practices. The following approach was implemented to estimate the levels of *Salmonella* on pork cuts if temperature abuse occurred:

- **Acceptable practice:** *Salmonella* levels were simulated post refrigeration (10,000 iterations) using the baseline model. This distribution of levels represents the 80% of the population that follows safe food handling. No *Salmonella* levels above $\log_{10}$ 7 CFU/g (spoilage) were excluded from this scenario.

- **Abuse practices:** The growth of *Salmonella* for temperature abuse scenarios 1 and 2 in Table 37 was estimated (10,000 iterations). Distribution levels represent the 20% of the population that do not follow acceptable food handling practices.

For each pork cut, the overall distributions of *Salmonella* levels for the temperature abuse scenarios were generated by sampling 80% from the acceptable practice distribution and 20% from the abuse practice distribution. These distributions of *Salmonella* levels were then subject to thermal inactivation simulation as previously described.

7.2.2 Surviving Levels and Risk per Serving for the Temperature Abuse Scenarios

Surviving levels and risk per serving for temperature abuse scenarios 1 and 2 are summarized in Tables 38 and 39, respectively. In both temperature abuse scenarios, there were no surviving *Salmonella* and no risk per serving in all four pork cuts at the 97.5th percentile and below. In the extreme upper percentile of temperature abuse (i.e. 99th percentile and higher) there were approximately ≥ 2 log CFU surviving *Salmonella* per serving, corresponding to a risk of 1 in one thousand or greater chances of developing salmonellosis.

Table 38 Temperature Abuse Scenario 1 (30ºC (86ºF), 5 hours)

Statistics*	**Pork Chop Enhanced**		**Pork Roast Enhanced**		**Pork Chop Un-Enhanded**		**Pork Roast Unenhanced**	
	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving
Mean	-3.9	1.4E-04	-3.9	1.4E-04	-2.4	1.6E-04	-2.4	1.6E-04
Std. Deviation	1.6	1.3E-03	1.6	1.3E-03	1.1	1.3E-03	1.0	1.3E-03
Percentiles								
5th	-6.1	0.0E+00	-6.2	0.0E+00	-3.6	0.0E+00	-3.6	0.0E+00
10th	-5.7	0.0E+00	-5.7	0.0E+00	-3.4	0.0E+00	-3.4	0.0E+00
15th	-5.4	0.0E+00	-5.4	0.0E+00	-3.2	0.0E+00	-3.2	0.0E+00
20th	-5.1	0.0E+00	-5.1	0.0E+00	-3.1	0.0E+00	-3.1	0.0E+00
25th	-4.9	0.0E+00	-4.9	0.0E+00	-3.0	0.0E+00	-3.0	0.0E+00
50th	-4.0	0.0E+00	-4.0	0.0E+00	-2.5	0.0E+00	-2.5	0.0E+00
75th	-3.1	0.0E+00	-3.1	0.0E+00	-2.0	0.0E+00	-2.0	0.0E+00
90th	-2.1	0.0E+00	-2.1	0.0E+00	-1.5	0.0E+00	-1.5	0.0E+00
95th	-1.4	0.0E+00	-1.5	0.0E+00	-1.1	0.0E+00	-1.1	0.0E+00
97.5th	-0.6	0.0E+00	-0.5	0.0E+00	-0.3	0.0E+00	-0.3	0.0E+00
99th	1.8	5.2E-03	1.8	5.3E-03	2.1	5.8E-03	2.1	5.9E-03
99.5th	4.4	1.2E-02	4.5	1.2E-02	4.6	1.2E-02	4.5	1.2E-02
99.9th	6.1	1.9E-02	6.1	1.8E-02	6.1	1.8E-02	6.0	1.8E-02
99.99th	6.5	2.2E-02	6.5	2.3E-02	6.5	2.1E-02	6.5	2.1E-02

Based 10,000 iteration runs

Table 39 Temperature Scenario 2 (20ºC (68ºF), 10 hours)

Statistics*	**Pork Chop Enhanced**		**Pork Roast Enhanced**		**Pork Chop Un-Enhanded**		**Pork Roast Unenhanced**	
	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving	Log CFU per serving	Risk per serving
Mean	-3.8	1.5E-04	-3.8	1.5E-04	-2.3	1.6E-04	-2.3	1.6E-04
Std. Deviation	1.7	1.3E-03	1.7	1.3E-03	1.1	1.4E-03	1.1	1.4E-03
Percentiles								
5th	-6.1	0.0E+00	-6.1	0.0E+00	-3.6	0.0E+00	-3.6	0.0E+00
10th	-5.7	0.0E+00	-5.7	0.0E+00	-3.3	0.0E+00	-3.3	0.0E+00
15th	-5.4	0.0E+00	-5.4	0.0E+00	-3.2	0.0E+00	-3.2	0.0E+00
20th	-5.1	0.0E+00	-5.1	0.0E+00	-3.1	0.0E+00	-3.1	0.0E+00
25th	-4.9	0.0E+00	-4.9	0.0E+00	-2.9	0.0E+00	-2.9	0.0E+00
50th	-3.9	0.0E+00	-4.0	0.0E+00	-2.4	0.0E+00	-2.4	0.0E+00
75th	-2.9	0.0E+00	-2.9	0.0E+00	-1.8	0.0E+00	-1.8	0.0E+00
90th	-1.8	0.0E+00	-1.8	0.0E+00	-1.1	0.0E+00	-1.1	0.0E+00
95th	-1.1	0.0E+00	-1.2	0.0E+00	-0.7	0.0E+00	-0.7	0.0E+00
97.5th	-0.3	0.0E+00	-0.3	0.0E+00	0.0	0.0E+00	0.0	0.0E+00
99th	1.9	5.4E-03	2.0	5.6E-03	2.2	6.2E-03	2.1	6.2E-03
99.5th	4.4	1.2E-02	4.5	1.2E-02	4.6	1.3E-02	4.5	1.2E-02
99.9th	6.1	1.9E-02	6.1	1.8E-02	6.2	1.8E-02	6.0	1.8E-02
99.99th	6.5	2.2E-02	6.5	2.3E-02	6.5	2.1E-02	6.5	2.1E-02

***Based 10,000 iteration runs**

7.3 Sensitive Subpopulation

7.3.1 Approach

The DR model used in the hazard characterization of the risk assessment was derived by FAO/WHO, and is not specific to sensitive subpopulations. A recent study by Bollaerts *et al.* (2008) used epidemiologic data to estimate the probability of illness (Pr(illness)) for various food matrices and serovars for "normal" and sensitive populations (see Table 40).

Table 40 (Serovar ×Food Matrix)-Specific Estimates of Pr(ill |infection) for the Normal Population and for the Susceptible Population (Bollaerts et al., 2008)

Serovar	**Food matrix**	**Probability of illness|infection)**	
		Normal	***Sensitive***
S. cubana	Dye	0.603	<1.000
S. enteritidis	Beef	0.486	<1.000
S. enteritidis	Cake	0.553	<1.000
S. enteritidis	Chicken	0.393	<1.000
S. enteritidis	Egg	0.757	<1.000
S. enteritidis	Ice cream	0.303	<1.000
S. enteritidis	Peanut	0.881	<1.000
S. enteritidis	Sauce	0.997	<1.000
S. enteritidis	Soup	0.946	<1.000
S. heidelberg	Cheese	0.804	<1.000
S. infantis	Ham	0.97	<1.000
S. newport	Hamburger	0.873	<1.000
S. oranienburg	Soup	0.974	<1.000
S. typhimurium	Ice cream	0.704	<1.000
S. typhimurium	Water	0.333	<1.000

However, these Bollaerts *et al.* estimates were not for the probability of illness, given dose, like in the FAO/WHO model, which was used in the baseline risk assessment, but for the probability of illness, given infection. To adjust the probability of illness derived from the FAO/WHO model to a sensitive subpopulation, Exponent used the ratio of the probability of illness, given infection for sensitive subjects, to the probability of illness for "normal" subjects. Specifically, Exponent assumed that:

Pr(illness|dose, sensitive population) = Pr(illness|dose, normal population) x
[Pr(illness|infection, sensitive population) / Pr(illness|infection, normal population)]

Pork roast and pork chops were not among the food matrices considered by Bollaerts *et al.* Therefore, we used the estimates for beef, ham, and hamburgers, and assumed that Pr(illness|infection) = 1 for the sensitive population. For each of the 10,000 simulations, the model randomly selected one of the three food matrices and associated probability.

7.3.2 Risk per Serving for Sensitive Subpopulation

Risks per serving for all four cuts using the alternative dose-response, to account for a sensitive subpopulation, are summarized in Table 41 below. Since there was no surviving level of *Salmonella* at the 97.5th percentile and below when cooked to an end-point temperature of 145ºF for 15 seconds, there would be no expected risk. At the 99th percentile and higher, risks per serving of 5 to 6.5 x 10-3 were estimated for the four pork cuts.

Table 41 Risk per Serving, Sensitive Subpopulation, Cooking End-point Temperature of 145ºF for 15 Seconds

	Pork Chop Enhanced	Pork Roast Enhanced	Pork Chop Unenhanced	Pork Roast Unenhanced
Mean	1.8E-04	1.9E-04	2.0E-04	2.0E-04
SD	1.9E-03	1.9E-03	1.9E-03	1.9E-03
Percentiles				
5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
10th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
15th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
20th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
25th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
50th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
75th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
90th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
95th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
97.5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00
99th	5.9E-03	5.2E-03	6.4E-03	6.5E-03
99.5th	1.4E-02	1.4E-02	1.3E-02	1.4E-02
99.9th	3.1E-02	3.3E-02	3.4E-02	3.0E-02
99.99th	4.0E-02	4.1E-02	3.9E-02	4.1E-02

7.4 Sensitivity Analyses Summary

Using the alternative distribution of *Salmonella* levels at retail based on FSIS carcass prevalence data (4%) a predicted higher risk per serving in the upper percentile (> 99th percentile) was obtained compare to the model prediction using the NPB survey data. This should be viewed as the worst-case (upper-bound), since pork at retail is expected to have fewer *Salmonella* than carcasses based on published studies. Temperature abuse scenarios were also applied to estimate surviving levels and risk per serving. Finally, an alternative DR was evaluated to assess risk for a sensitive subpopulation. The results of all sensitivity analyses are summarized in tables 42-45. Overall, even under these worst-case, upper-bound scenarios, when cooking end-point temperature of 145ºF is held at 15 seconds, there are no surviving levels of *Salmonella* on all pork cuts considered in this risk assessment at and below the 97.5th percentile.

Table 42 Sensitivity Analyses Summary, Risk per Serving for Pork Chop Enhanced, Cooking End-point Temperature 145ºF for 15 Seconds

Statistics*	**Suscep'tle Population**	**Temp Abuse Scenario 1**	**Temp Abuse Scenario 2**	**Sensitivity 1 Carcass Data**	**Sensitivity 2 Combined Survey Data Log Normal**	**Sensitivity 3 Combined Survey Data Weibull Distribution**	**Original Survey Data Treatment**
Mean	1.8E-04	1.4E-04	1.5E-04	1.5E-04	1.3E-04	1.2E-04	1.4E-04
SD	1.9E-03	1.3E-03	1.3E-03	1.3E-03	1.2E-03	1.2E-03	1.3E-03
Percentiles							
5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
10th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
15th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
20th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
25th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
50th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
75th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
90th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
95th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
97.5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
99th	5.9E-03	5.2E-03	5.4E-03	5.8E-03	4.0E-03	3.5E-03	5.2E-03
99.5th	1.4E-02	1.2E-02	1.2E-02	1.1E-02	1.1E-02	1.0E-02	1.2E-02
99.9th	3.1E-02	1.9E-02	1.9E-02	1.7E-02	1.7E-02	1.7E-02	1.9E-02
99.99th	4.0E-02	2.2E-02	2.2E-02	2.0E-02	2.2E-02	2.0E-02	2.2E-02

***Based on 10,000 iteration runs**

Table 43 Sensitivity Analyses Summary, Risk per Serving for Pork Roast Enhanced, Cooking End-point Temperature 145ºF for 15 Seconds

Statistics*	Susceptible Population	Temp Abuse Scenario 1	Temp Abuse Scenario 2	Sensitivity 1 Carcass Data	Sensitivity 2 Combined Survey Data Log Normal	Sensitivity 3 Combined Survey Data Weibull Distribution	Original Survey Data Treatment
Mean	1.9E-04	1.4E-04	1.5E-04	1.5E-04	1.2E-04	1.1E-04	1.4E-04
SD	1.9E-03	1.3E-03	1.3E-03	1.3E-03	1.2E-03	1.2E-03	1.3E-03
Percentiles							
5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
10th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
15th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
20th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
25th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
50th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
75th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
90th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
95th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
97.5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
99th	5.2E-03	5.3E-03	5.6E-03	5.8E-03	3.2E-03	2.8E-03	5.1E-03
99.5th	1.4E-02	1.2E-02	1.2E-02	1.1E-02	9.9E-03	9.8E-03	1.2E-02
99.9th	3.3E-02	1.8E-02	1.8E-02	1.7E-02	1.8E-02	1.8E-02	1.8E-02
99.99th	4.1E-02	2.3E-02	2.3E-02	2.0E-02	2.2E-02	2.2E-02	2.1E-02

*** Based on 10,000 iteration runs**

Table 44 Sensitivity Analyses Summary, Risk per Serving for Pork Chop Unenhanced, Cooking End-point Temperature 145ºF for 15 Seconds

Statistics*	Susceptible Population	Temp Abuse Scenario 1	Temp Abuse Scenario 2	Sensitivity 1 Carcass Data	Sensitivity 2 Combined Survey Data Log Normal	Sensitivity 3 Combined Survey Data Weibull Distribution	Original Survey Data Treatment
Mean	2.0E-04	1.6E-04	1.6E-04	1.5E-04	1.0E-04	8.9E-05	1.6E-04
SD	1.9E-03	1.3E-03	1.4E-03	1.3E-03	1.1E-03	1.0E-03	1.4E-03
Percentiles		0.0E+00					
5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
10th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
15th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
20th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
25th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
50th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
75th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
90th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
95th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
97.5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
99th	6.4E-03	5.8E-03	6.2E-03	5.8E-03	2.3E-03	1.1E-03	5.9E-03
99.5th	1.3E-02	1.2E-02	1.3E-02	1.1E-02	1.0E-02	8.3E-03	1.3E-02
99.9th	3.4E-02	1.8E-02	1.8E-02	1.7E-02	1.6E-02	1.5E-02	1.8E-02
99.99th	3.9E-02	2.1E-02	2.1E-02	2.0E-02	1.9E-02	1.9E-02	2.1E-02

***Based on 10,000 iteration runs**

Table 45 Sensitivity Analyses Summary, Risk per Serving for Pork Roast Unenhanced, Cooking End-point Temperature 145ºF for 15 seconds

Statistics*	Susceptible Population	Temp Abuse Scenario 1	Temp Abuse Scenario 2	Sensitivity 1 Carcass Data	Sensitivity 2 Combined Survey Data Log Normal	Sensitivity 3 Combined Survey Data Weibull Distribution	Original Survey Data Treatment
Mean	2.0E-04	1.6E-04	1.6E-04	1.5E-04	1.1E-04	1.0E-04	1.6E-04
SD	1.9E-03	1.3E-03	1.4E-03	1.3E-03	1.1E-03	1.1E-03	1.3E-03
Percentiles							
5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
10th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
15th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
20th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
25th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
50th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
75th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
90th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
95th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
97.5th	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
99th	6.5E-03	5.9E-03	6.2E-03	6.1E-03	3.0E-03	2.4E-03	5.9E-03
99.5th	1.4E-02	1.2E-02	1.2E-02	1.1E-02	9.7E-03	1.0E-02	1.2E-02
99.9th	3.0E-02	1.8E-02	1.8E-02	1.8E-02	1.8E-02	1.7E-02	1.8E-02
99.99th	4.1E-02	2.1E-02	2.1E-02	2.0E-02	2.0E-02	2.0E-02	2.1E-02

***Based on 10,000 iteration runs**

8 Uncertainty

Uncertainty in the assessment stems from missing information to fully describe the model or its parameters. Uncertainty in retail *Salmonella* levels was assessed by redefining the distributions used to characterize these parameters and running alternate sets of simulations and comparing the resulting estimates to those derived using the base model (see the sensitivity analysis section). In addition, uncertainty of the fraction of unenhanced pork products likely to be contaminated with *Salmonella* was addressed by using a tolerance interval approach to estimate the highest percentile (P) of the distribution that could be estimated with 95% confidence, given the number of samples available, and assuming, conservatively, that P% of the distribution of unenhanced pork chops and roasts would have *Salmonella* levels < 0.3 CFU/g.

Data on refrigeration storage durations were not available for pork chops or roasts. The model used storage data for deli meats, hot dogs and salamis, and uncertainty in refrigeration storage duration was modeled by randomly selecting a distribution from the three distributions available for these three products, and randomly selecting a refrigerator temperature and storage value from that distribution.

However, other potential uncertainties in the model were not addressed in the assessment. These include:

- The potential selection of incorrect models to represent *Salmonella* growth or heat inactivation;
- Incomplete analysis due to overlooking other important pathways or excluding potentially relevant variables;
- The use of "surrogate" data (e.g., use of refrigeration storage data from other meat products, or the use of a growth model based on chicken broth instead of a model based on pork meats); and
- The potential statistical uncertainty in the approach used to estimate the parameters of the distributions, including the normal distributions used to represent the logarithms of the *Salmonella* levels at retail.

9 Discussion

The quantitative retail-to-table simulation model developed for this risk assessment was designed to estimate risk per serving of contracting salmonellosis after consumption of consumer prepared enhanced and unenhanced, bone-in and boneless fresh retail pork cuts cooked to different end-point temperatures. *Salmonella* exposure was estimated by (1) an initial evaluation of pathogen distributions on retail pork, (2) the microorganism's simulated growth during home transport and storage, and (3) predicted decreases by cooking. Results of the simulation demonstrated that no *Salmonella* survived at any cooking end-point temperature between 160 and 145ºF at 15 seconds, except after extreme pre-cooking abuse conditions. Therefore, the low predicted risk of developing salmonellosis was 1:10,000 to 1:100, after an exposure likehood of 1:100 to 1:10,000 to a cooked serving of pork that contained sufficient surviving *Salmonella*.

Prior to the development of the exposure and risk characterization models, consensus assumptions were developed to narrow the scope of the risk assessment to the most significant elements, thereby reducing uncertainty to the greatest degree possible. These assumptions included:

1. Targeting *Salmonella* as the pathogenic microorganism of concern for cooking of fresh pork; this was a decision supported by the scientific literature and by the USDA-FSIS.
2. Limiting the product pathway of the risk assessment to retail-to-table, to reduce the uncertainty of the model.
3. Focusing the thermal inactivation modeling on the coldest gram of the cooked fresh pork. This provided a number of advantages. First, it eliminated the need to consider cooking method, which is the heat inactivation delivery system. Cooking has many variables and does not address the fundamental question of identifying a safe end-point cooking temperature. The focus of the risk assessment needs to be on determining the microbiological safety at a specific temperature and time combination throughout the entire serving of food. Second, the focus on the coldest gram reduced uncertainty in the model by eliminating the distribution of serving size and conservatively focusing on the last *Salmonella* "hot spot" in the product, if present. Finally, the model was designed to be intentionally conservative by not accounting for the continued heat rise, and concomitant additional *Salmonella* lethality after the final end-point temperature was reached.

4. Lastly, it was assumed that consumers would reject raw pork if the *Salmonella* levels at the coldest gram were 10 million or above. At this level, surface spoilage microorganisms would be expected to be significantly higher, triggering a rejection by the consumer.

The risk assessment began with an estimation of *Salmonella* levels on pork cuts at retail. Because there were few data available that included both the prevalence and levels of *Salmonella* on fresh enhanced and unenhanced pork roasts and chops, a companion 4,000-sample, four-city retail survey was conducted by the NPB prior to the conduct of this risk assessment. The survey provided a convenience sample that yielded 28 confirmed positive samples, which is less than a 1% *Salmonella* occurrence rate. All of the confirmed positives were in enhanced pork chops (18) and roasts (10). *Salmonella* levels on confirmed positive samples were low, ranging from 0.3-1.40 MPN/g. *Salmonella* levels on confirmed positive samples were combined with the negative results (non-detects below a limit of detection of 0.3 MPN/g) and assumed to follow a lognormal distribution. Because this was not a nationwide retail survey, a sensitivity analysis was performed using FSIS carcass data, which simulated increased *Salmonella* prevalence to 4%. The NPB retail surveillance study accounted for episodic events, such as those resulting from processing and retail deviations from best practices. In fact, the samples collected from the Phoenix location had higher proportions of contaminated samples, suggesting that less than best practices occurred at the fabrication, distribution, or retail nodes within product intended for that city. Furthermore, the use of higher contamination rates, from the FSIS carcass data, in the alternative scenarios, can be viewed as another episodic scenario, where further processing failed to reduce *Salmonella* levels as a result of fabrication.

The exposure assessment also modeled *Salmonella* growth during transportation from the store to home, further growth during home refrigeration, then finally pathogen cooking declines. The growth model for *Salmonella* in broth (Gibson et al, 1988), as referenced in the USDA-ARS, Pathogen Modeling Program, V.7, was used to estimate *Salmonella* growth in pork chops and roasts during the transportation phase, and during storage and refrigeration in consumer's homes. Audits International data were relied upon to characterize the duration and temperature of transport from retail locations to homes. A recently published survey on consumer practices by RTI was used to estimate refrigeration duration and temperatures.

A second predictive microbiological model was used to estimate thermal inactivation at the coldest gram (FDA, 2000). The mean inactivation estimates were approximately 15, 5, 1.50 and 0.5 log CFU/g for cooking end-point temperatures of 160, 155, 150 and 145ºF, respectively. Initial modeling was performed using a 15 second holding time. *Salmonella* inactivation distal from the coldest gram can be expected to be dramatically higher, as the food surface and heat source is approached. Fifteen seconds was held constant to compare *Salmonella* inactivation of the alternative end-point temperatures. The risk assessment also considered the effect of holding product for 1, 3, and 4 minutes, at a constant 145ºF.

Sensitivity analyses were conducted for a variety of alternative scenarios including: higher retail *Salmonella* levels and different *Salmonella* distributions; several time and temperature abuse scenarios; and finally, consideration of the risk for a human subpopulation that is especially *Salmonella* sensitive.

After the exposure assessment modeling was performed simulated levels of surviving *Salmonella* in a cooked serving was combined with the *Salmonella* FAO/WHO dose-response curve (or an alternative to account for the sensitive subpopulation) to estimate risk per serving.

The risk of developing salmonellosis from consumption of enhanced and unenhanced pork chops and roasts was estimated in the baseline scenario, which assumed cooking to the current recommended end-point temperature of 160°F (71.1°C) for 15 seconds. Based on the simulated results, thermal treatment achieving a cooking end-point temperature of 160ºF resulted in zero surviving *Salmonella* per serving at all percentiles, including the 99.99th, and hence there was no risk per serving.

Alternative cooking end-point temperatures at 145 (62.8°C), 150 (65.6°C) and 155°F (68.3°C) for 15 seconds were also evaluated. In all cases, with the exception of the upper extremes (> 99th percentile), risks per serving were similar to those predicted for the baseline scenario (i.e. zero risk per serving). At the upper percentiles, levels of *Salmonella* in various pork cuts were predicted and corresponded to risks per serving in the range of 1:10,000 (at the 99th percentile for some cuts) to 1:100 (at the 99.99th percentile and at 145ºF for some pork cuts). Like above, this represents the low risks associated with rare and extreme temperature/storage abuse.

The NPB survey demonstrated that *Salmonella* was more likely to be observed in enhanced retail cuts. This is likely to result from the commingling and recycling of enhancement solutions. However, the heat inactivation model indicated that proper cooking eliminated any additional risks associated with product enhancement.

The effect of extended holding time at 145ºF was modeled and demonstrated the dramatic increase in *Salmonella* killing that was predicted to occur when cooking times are extended from 15 seconds to 4 minutes. This occurred, however, without a decrease in the risk of developing salmonellosis for any of the longer cooking times, if good pre-cooking handling practices were employed. As would be expected, at the upper percentiles (> 97.5), shorter cooking times at 145ºF were estimated to yield a higher risk; however, this represents rare abuse situations, where *Salmonella* grow to higher numbers, and some survive cooking. No *Salmonella* were predicted to survive, even at the 99.99th percentile, if product is held at 145ºF for 4 minutes, which corresponds to a mean of 9-10 logs of *Salmonella* inactivation.

Sensitivity analysis was conducted focusing on various retail *Salmonella* levels and various distributions: several temperature abuse scenarios, and consideration of the effects on a *Salmonella* sensitive human subpopulation.

The alternative distribution of *Salmonella* levels on pork at retail was based on the USDA-FSIS carcass prevalence data (rate = 4%). The model predicted higher risk per serving at the upper percentiles than the prediction using the NPB survey *Salmonella* data (rate = <1%). This approach could be viewed as worst-case (upper-bound), since it is highly unlikely that prevalence on carcasses would remain at the same rate at retail and the prevalence rate at retail is expected to be lower. Even under this worst-case upper-bound scenario, surviving *Salmonella* levels and their corresponding increased risks per serving were predicted only in the extreme percentiles (99th percentile or higher) for enhanced pork meats (PRE and PCE) at all three alternative cooking end-point temperatures (155, 150 and 145ºF). The levels in unenhanced pork meats are expected to be even lower. Similarly, room temperature abuse scenarios that included 86ºF for 5 hours and 68ºF for 10 hours (for 20% of the population) predicted that *Salmonella* survived cooking only at the extreme upper percentiles (above 97.5th).

When a sensitive subpopulation was considered, estimated risk of developing salmonellosis after consuming pork cooked at 145ºF for 15 seconds remained zero for all four cuts of pork at the 97.5th percentile and below. Estimated risk using the alternative dose-response model increased modestly compared to the baseline FAO/WHO model at upper percentiles, which represents rare and extreme abuse situations.

A key finding of this risk assessment is that if good retail and consumer handling practices are employed prior to and during consumer cooking, enhanced and unenhanced pork chops and roasts can be cooked to 145ºF without increased risk of contracting salmonellosis. The assurance of the microbiological safety of food is a cumulative process, reflected in the product pathway analysis used in current risk assessment. Refrigerated products, such as fresh pork, need to remain clean, cold, and must be cooked properly to prevent the respective contamination, growth, and survival of harmful microorganisms, such as *Salmonella.* Inadequacies in retail and consumer handling are recognized and may pose unnecessary but controllable risk to consumers. Examples include:

- Time or temperature abuse at retail stores and during home transport of foods;
- Inadequate home refrigeration temperatures or storage beyond the recommended shelf life;
- Unsanitary thawing of frozen products;
- Poor kitchen hygiene practices; and
- Cooking practices that may lead to the insufficient destruction of pathogens, including *Salmonella*, such as not using, or the improper use of, meat thermometers.

This risk assessment estimated that for many such abuses, consumers' risk of developing salmonellosis remains low, even at 145°F cooking temperature. The risk assessment also demonstrated that those risks could be controlled by adherence to good pre-cooking handling practices and by continued holding of pork chops and roasts at hot temperatures after removal from the heat source, but before serving. Additional public awareness education would help consumers ensure that they are using safe and consistent food handling and proper cooking practices.

10 Implications for Risk Management

The major conclusion of this risk assessment, that consumer cooking to 145°F provides adequate protection against developing salmonellosis from the consumption of pork chops and roasts, if good retail and consumer handling practices are employed, suggests that the current FSIS consumer cooking end-point temperature guidance of 160-170°F (USDA, 2003b) yields a very conservative margin of protection.

New science presented in this risk assessment supports a re-evaluation of the current consumer recommendations for the safe cooking of fresh pork and consideration for alignment with other current meat cooking standards and guidance, including:

- Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products (FSIS, 1999). This guideline permits a minimum cooking temperature of 145°F for 4 minutes for roast beef and other fully cooked beef cuts to meet the lethality performance standards for the reduction of *Salmonella* contained in §§ 318.17(a)(1) and 381.150(a)(1) of the meat and poultry inspection regulations.
- U.S. Food Code, Section 3-401.11, is the food service and retail guidance document that is administered by FDA and endorsed by FSIS (FDA, 2005), and lists a cooking end-point temperature of 145°F for 15 seconds and 3 minutes for the cooking of fresh and injected pork, respectively.
- FSIS consumer guidance for cooking beef recommends an internal temperature end-point of 145°F for steaks and most roasts (USDA, 2003b).

The results from the present risk assessment suggest that consumer cooking end-point temperature recommendations can be lowered without having an adverse impact on public health.

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