

**Title:** Risk Assessment for *Salmonella* spp. in Cooked Pork – **NPB #06-144**

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## II. Industry Summary

The purpose of this research was to develop a retail-to-table risk assessment to evaluate the likelihood of developing salmonellosis from consumption of a serving of enhanced or un-enhanced pork chops (bone-in) and roasts (boneless) cooked to end point temperatures of 145 – 160° F. With guidance received from USDA-FSIS, that *Salmonella* is the target organism of choice for cooking standards for fresh pork, and after NPB concurrence, Exponent did not consider *Campylobacter* in this risk assessment. *Salmonella* exposure was estimated using a statistical method that repeatedly (10,000 times) picked data points from distributions including: *Salmonella* levels in retail pork; *Salmonella* growth during home transport and storage; and *Salmonella* levels after cooking and at consumption. The report describes all databases and the rationale and approach for their use. Risk was characterized as risk of illness per serving. No *Salmonella* survived cooking to 160°F or to 145, 150 and 155° F in 99% of the simulations. However, following USDA's recommendation, a low illness risk was estimated at extreme abuse conditions (high storage and transport temperature and long storage times) at temperatures below 160°F for some cuts. Potential error and uncertainty sources of the model are described. Currently, USDA recommends consumers to cook pork to 160-170°F. However, FDA's institutional and retail establishment guidance permits 145°F. This study shows that pork cooked to 145 °F for 15 seconds does not increase salmonellosis risk, if good pre-cooking handling practices are used. Further, a greater safety margin is achieved for products cooked to Food Code recommendations.

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### III. Scientific Abstract

The objective and scope was to develop a retail-to-table probabilistic risk assessment to evaluate the risk per serving for developing salmonellosis from moisture enhanced and un-enhanced pork chops (bone-in) and roasts (boneless) that was cooked to the current USDA recommended (160°F) and alternative consumer cooking end point temperatures (145–155° F) at the geometric center of the product. Exposure simulation was carried out using Crystal Ball<sup>®</sup> and Latin Hypercube sampling for 10,000 iterations. The sequence of simulation sampling was: (1) estimation of levels of *Salmonella* in pork meat at retail; (2) estimation of growth during transportation from retail stores to consumer homes; (3) estimation of growth during storage in homes (refrigeration); (4) estimation of surviving *Salmonella* levels in product after cooking and at consumption and risk of developing illness per serving. At 160°F there were no surviving *Salmonella* per serving. In the alternative cooking scenarios risks per serving were similar to baseline at  $\leq 99^{\text{th}}$  percentile. At the extreme percentiles ( $> 99^{\text{th}}$ , representing high storage and transport temperature and long storage and transport times) at temperatures below 160°F for some cuts, a low risk of illness was estimated. Sensitivity analyses, which focused on alternative input data and distributions, show that for all pork cuts, the risk per serving for the baseline scenario (160° F cooking endpoint temperature) remained at zero. Using an alternative distribution of *Salmonella* levels at retail, based on FSIS carcass prevalence data (4%), a predicted higher risk per serving in the upper percentile ( $> 99^{\text{th}}$  percentile) was obtained at some lower end-point temperatures. Enhanced pork had higher positive rates and levels than un-enhanced pork. Uncertainty in retail levels was assessed by redefining the distributions used to characterize the model parameters and running alternate sets of simulations and comparing the resulting estimates to those derived using the base model. Currently, USDA recommends consumers to cook pork to 160-170°F. However, FDA's institutional and retail establishment guidance permits 145°F. This study shows that pork cooked to 145 °F for 15 seconds does not increase salmonellosis risk, if good pre-cooking handling practices are used. Further, a greater safety margin is achieved for products cooked to Food Code recommendations.

### IV. Introduction and Objectives

The main objective and scope of this risk assessment was to develop a retail-to-table probabilistic risk assessment to evaluate the likelihood of developing salmonellosis from the consumption of a serving of moisture enhanced and un-enhanced pork chops (bone-in) and roasts (boneless) that was cooked to the current USDA recommended and alternative (lower) consumer cooking end point temperatures (145 – 160° F) at the geometric center (coolest point) of the product, without regard to cooking method. Specifically, the following

risk assessment questions were evaluated: (1) What is the risk per serving of consuming pork chops and/or roasts that are cooked to the current recommended consumer cooking “endpoint” temperature of 160° F for both moisture enhanced and un-enhanced products, and (2) What would be the risk per serving if the cooking “endpoint” temperatures were to be reduced to 145, 150 or 155° F?

With guidance received by the USDA’s Food Safety & Inspection Service, that *Salmonella* is considered the target organism of choice for developing cooking standards for fresh pork Exponent did not consider, after concurrence by the NPB project management, *Campylobacter* in this risk assessment.

It should be noted that while swine are asymptomatic carriers of *Salmonella*, cooked pork is not a major vehicle for salmonellosis. Indeed, recently pork was estimated to contribute only 2% of the approximately 30,000 cultures confirmed salmonellosis cases each year in the U.S.

## V. Risk Assessment Model Framework and Application

The model captures exposures associated with four types of pork cuts including: pork chops (bone-in) moisture enhanced and un-enhanced, and pork roasts (boneless), moisture enhanced and un-enhanced. The model begins with the exposure assessment, starting with an estimation of the prevalence and levels of *Salmonella* spp on pork meat at retail, referred to as the “retail” module. The USDA-Food Safety and Inspection Service estimated that the prevalence of *Salmonella* on carcasses has fluctuated between 2.5 and 4% between 2003 and 2006. Recently, however, the National Pork Board completed a study on the prevalence and levels of *Salmonella* in enhanced and un-enhanced pork at four different U.S. cities. The study found no *Salmonella* in 1300 un-enhanced products. *Salmonella* prevalence was 1.3% and 0.74% for enhanced pork chops and enhanced pork roasts, respectively. *Salmonella* levels on these products were observed to be very low, averaging less than 0.6 MPN/g. National Pork Board prevalence and enumeration data were incorporated into the current exposure assessment module.

The second part of the exposure assessment, referred to as the “consumer” module, is the estimation of *Salmonella* levels at each eating occasion. In the consumer module, the growth/decline of *Salmonella* spp was estimated, due to transport from retail to home, storage and handling at home prior to cooking, and the probability of survival of the bacteria during cooking. Audits International, Inc. data were used to characterize the duration and temperature of transport from retail locations to homes, and a survey on consumer practices by the Research Triangle Institute was used to estimate refrigeration duration and temperatures. The statistical model included the USDA-ARS, Pathogen Modeling Program, V.7 growth model for *Salmonella* in broth, to estimate *Salmonella* spp growth in pork chops and roasts.

Subsequently, the exposure model considered the decline in *Salmonella* levels due to cooking using a thermal inactivation model. The population decline from cooking was modeled as the level of killing for a given temperature, at the geometric center of the product, and a standard time (15 seconds). Mean inactivation estimates were approximately 15, 5, 1.50 and 0.5 log<sub>10</sub> *Salmonella*/g pork, for cooking endpoint temperatures of 160, 155, 150 and 145° F, respectively. The values assume a 15 second holding time, and that *Salmonella* inactivation distal from the geometric center of the product is dramatically higher. Time was held constant to compare *Salmonella* inactivation at all endpoint temperatures.

Pork chop and roast consumer intakes were estimated from the National Health and Nutrition Examination Survey (NHANES 2003-2004) using Exponent's Foods and Residue Evaluation Program (FARE™ 8.03) software. Food description and codes with pork chop and/or roast components that are grilled, broiled, fried and/or other cooking methods were identified. Mean intake estimates per eating occasion was 96g and the 90<sup>th</sup> percentile estimate was 180g.

As a final step, to estimate risk, the model combined exposure estimates post-cooking with a dose-response model (hazard characterization) developed by the FAO/WHO. This dose-response curve for *Salmonella* was used to estimate risk of illness per serving. FAO/WHO concluded that the dose-response model can be used for risk assessment purposes, and generates estimates that are consistent with those that have been observed in outbreaks. In the risk characterization portion of the risk assessment, the exposure and hazard characterization are integrated to express the probability of developing salmonellosis per eating occasion.

Exposure simulation was carried out using Crystal Ball® (2000.1 Standard Edition). Latin Hypercube sampling (to insure that all segments of the input distributions were sampled) and 10,000 iterations were used. The sequence of sampling was: (1) estimation of levels of *Salmonella* in pork meat at retail; (2) estimation of growth during transportation from retail stores to consumer homes; (3) estimation of growth during storage in homes (refrigeration); (4) estimation of surviving *Salmonella* levels in product after cooking and at consumption and risk of developing illness per serving.

## VII. Results

### Baseline and Alternative Cooking Scenarios

In the baseline scenario output, risks of developing salmonellosis were estimated from the U.S. distribution of consumption of pork chops and roasts that were hypothetically cooked so that the geometric center of the meat reached the current recommended consumer cooking endpoint temperature of 160°F. Based on the simulated results, there were no surviving *Salmonella* per serving at all percentiles, including the 99.99<sup>th</sup>, and hence within

practical measurements there were no estimated risk per serving. In the alternative scenarios, theoretical cooking endpoint temperatures were lowered to 145, 150 and 155° F. In all cases the simulated holding time was 15 seconds at each temperature. 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 99<sup>th</sup> percentile. At the extreme upper percentiles, some *Salmonella* was estimated to survive cooking (at the 99.99<sup>th</sup> percentile and at 145° F for some pork cuts). However, these represent the risks associated with extreme temperature/transport and storage abuse.

Enhanced Pork Roasts Similar to the baseline scenario (160° F), the predicted levels of *Salmonella*/serving in enhanced pork roasts were zero for all percentiles below the 99.5<sup>th</sup> percentile when the alternative cooking endpoint temperature was 155° F. At the extreme upper tail of the distribution, 99.9<sup>th</sup> percentile and higher, the model predicted detectable levels corresponding to a risk of 52 in 10,000 servings, as compared to zero risk per serving in the baseline scenario of 160° F. When cooking endpoint temperatures of 150 and 145° F were used, the levels of *Salmonella*/serving were zero for all percentiles below the 99<sup>th</sup> percentile. At 150 and 145° F, risks predicted at the 99<sup>th</sup> percentile were 1 in 1,000 and 41 in 10,000 servings, respectively.

Enhanced Pork Chops When the alternative cooking endpoint temperature of 155° F was applied, the levels of *Salmonella*/serving in enhanced pork chops below the 99.9<sup>th</sup> percentile were zero, similar to that found in the baseline scenario of 160° F. At the extreme upper percentiles, 99.99<sup>th</sup> percentile and higher, the model predicted levels of *Salmonella spp.* corresponding to a risk of 45 in 10,000 servings, as compared to zero risk per serving in the baseline scenario of 160° F. When cooking endpoint temperatures of 150 and 145° F were evaluated, *Salmonella*/serving were zero for all percentiles below the 99<sup>th</sup> percentile. At 150° F, the predicted risks were 92 in 100,000; 74 in 10,000; 14 in 1,000; and 17 in 1,000 servings at the 99<sup>th</sup>, 99.5<sup>th</sup>, 99.9<sup>th</sup>, and 99.99<sup>th</sup> percentiles, respectively. At 145° F the predicted risks ranged from 39 in 10,000 servings at the 99<sup>th</sup> percentile to 21 in 1,000 servings at the 99.99<sup>th</sup> percentile.

Un-enhanced Pork Roasts Similar to the baseline scenario, the levels of *Salmonella spp* (CFU/serving) were zero for all percentiles, except at the upper tail (99.9<sup>th</sup> percentile and higher) when the alternative cooking endpoint temperature was 155° F. At the 99.9<sup>th</sup> and 99.99<sup>th</sup> percentiles, the model predicted risks of 46 in 10,000 servings and 58 in 10,000 servings respectively, as compared to zero risk per serving in the baseline scenario of 160° F. Similarly, when cooking endpoint temperatures of 150 and 145° F were used; the levels of *Salmonella*/serving were zero for all percentiles, except for the upper tail of the distribution (99<sup>th</sup> percentiles and higher). At 150° F, the predicted risks at the 99<sup>th</sup>, 99.5<sup>th</sup>, 99.9<sup>th</sup> and 99.99<sup>th</sup> percentiles were 20, 75, 130 and 160

per 10,000 servings, respectively. At 145° F, the predicted risks were 47 per 10,000 servings at the 99<sup>th</sup> percentile and 19 per 1,000 servings at the 99.99<sup>th</sup> percentile.

Un-enhanced Pork Chops Similar to the baseline scenario, the levels of *Salmonella spp* (CFU/serving) were zero for all percentiles below the 99.9<sup>th</sup> percentile when the alternative cooking endpoint temperature was 155° F. At the extreme, 99.99<sup>th</sup> percentile and higher, the model predicted detectable *Salmonella spp.* levels corresponding to a risk of 66 per 10,000 servings, as compared to zero risk per serving in the baseline scenario of 160° F. When the cooking endpoint temperatures of 150 and 145° F were used, the levels of *Salmonella*/serving surviving were zero for all percentiles below the 99<sup>th</sup> percentile. At 150° F, the predicted risks were 19, 80, 140 and 160 per 10,000 servings at the 99<sup>th</sup>, 99.5<sup>th</sup>, 99.9<sup>th</sup> and 99.99<sup>th</sup> percentiles, respectively. At 145° F, risks were also predicted at the extreme upper percentile, including: 47, 110, 170, and 190 in 10,000 servings at the 99<sup>th</sup>, 99.5<sup>th</sup>, 99.9<sup>th</sup> and 99.99<sup>th</sup> percentiles, respectively.

### 3.2 Sensitivity Analysis

Since levels of *Salmonella spp* on pork meat at retail were the starting point for the exposure and risk model, the uncertainty of this model input parameter would greatly influence the final exposure and risk estimates at the consumer level. Baseline and alternative cooking endpoint temperature scenarios were based on the National Pork Board survey data, which used a convenient sampling strategy. Therefore, there is a degree of uncertainty in the national representativeness of these data. As such, the sensitivity analyses focused on alternative input data and distribution of *Salmonella spp* in pork meats, including the following: (1) Four retail sampling locations were combined and one national distribution of *Salmonella spp* levels for each pork cut was generated; (2) Same as #1, however an alternative distribution shape was used; (3) Alternative distribution of *Salmonella spp* levels at retail based on FSIS carcass incidence (4%). The 3<sup>rd</sup> sensitivity analysis represents the worst-case scenario, since it is highly unlikely.

For enhanced pork, estimated levels of *Salmonella* were the highest when the input distribution of levels at retail was based on FSIS carcass prevalence (4%; sensitivity analysis #3). When NPB survey data were combined with an alternative distribution (sensitivity analysis # 2), the estimated levels at retail were the lowest at and below the 90<sup>th</sup> 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 #1 (i.e. distribution of levels at retail is based on combined samples and lognormal).

For un-enhanced pork meats, when the input distribution of levels at retail was based on the higher carcass prevalence data (analysis #3) the estimated levels of *Salmonella spp* 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. When NPB survey data were combined and the lognormal and alternative distributions were used, sensitivity analyses #1 and #2, respectively, the estimated levels at retail were lower than that predicted in the baseline model.

Risks from enhanced pork chops were consistently highest when the higher FSIS carcass prevalence data were used to estimate distribution of levels at retail (sensitivity analysis #3), and were lowest when combined retail data and the alternative distribution were used (sensitivity analysis #2). This is consistent with levels at retail being highest when carcass prevalence data were used (sensitivity analysis #3). When carcass prevalence data were used to estimate distribution of levels at retail (sensitivity analysis #3), risks for pork roast enhanced at the upper percentiles were consistently higher than estimates based on the combined retail data and the alternative distribution (sensitivity analysis #2), or the original model. This is consistent with the upper percentile levels at retail being the highest when carcass prevalence data were used (sensitivity analysis #3). There were no large differences in the upper percentile risk estimates between the base model and other alternative distribution of retail levels (sensitivity analysis #1 and #2).

Thus, using the alternative distribution of *Salmonella spp* levels at retail, based on FSIS carcass prevalence data (4%) a predicted higher risk per serving in the upper percentile (> 99<sup>th</sup> percentile) was obtained than the model prediction using the NPB survey data. This should be viewed as the worst-case, 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 based on published studies. It should be noted that even under this worst-case upper-bound scenario, higher risks per serving were predicted only at the extreme percentiles (99<sup>th</sup> percentile or higher) for enhanced pork meats at all three alternative cooking endpoint temperatures (155, 150 and 145° F) held at 15 seconds. Enhanced pork meats had higher positive rates and levels than un-enhanced pork (see retail sampling results discussed earlier), thus, risk per servings for unenhanced pork meats would be expected to occur very rarely.

### Uncertainty

Uncertainty in the assessment stems from missing information to fully describe the model or its parameters. Uncertainty in retail 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 un-enhanced pork products likely to be contaminated with *Salmonella* was addressed by using a tolerance interval approach to estimate the highest percentile of the distribution that could be estimated with 95% confidence, given the number of samples available, and assuming,

conservatively, that the distribution of un-enhanced pork chops and roasts would include actual *Salmonella* levels <0.3 CFU/g, which is the limit of detection.

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 3 distributions available for these three products, and randomly selecting a fridge temperature and storage value from that distribution.

Other potential uncertainties were not addressed in the assessment, including: 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; 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; 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.

## VIII. Discussion

The USDA currently recommends to consumers that fresh pork should be cooked to a medium internal temperature of 160°F or a well-done internal temperature of 170°F. However, the FDA’s U.S. Food Code guidance for cooking fresh pork is different for institutional and retail settings, which is shown below:

<b>Product</b>	<b>Recommendation</b>
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

### Conclusion:

The probabilistic quantitative risk assessment developed for this study estimated that enhanced and un-enhanced pork chops and roasts can be cooked to as low as 145 °F for 15 seconds without incurring an increased risk of developing salmonellosis, if good retail and consumer handling practices are employed prior to consumer cooking. If the products are cooked following the U.S. Food Code recommendations for enhanced pork, an even greater margin of safety would be achieved.