FSIS Response to Public Comments

for

An FSIS-Contracted Risk Assessment

The Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products

September 2005

by

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and

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On March 24, 2005, FSIS held a public meeting to present the draft risk assessment for the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products, including the model, data, and underlying assumptions. At this meeting, the Agency announced that it would like to receive additional public input and information through Docket No. 04–001N. The official comment period closed on May 9th, 2005; however, it was extended to July 11, 2005. FSIS received several comments on the FSIS *Salmonella* risk assessment from industry groups (addressed below) and none from consumer groups.

Comments are given verbatim and are, as far as possible, in the order provided by the commenters. Following every paragraph of particular or grouped comments a response is provided. FSIS has attempted to respond correctly to the context of the comment, even if that context is not given here. All comments and responses are numbered but are not otherwise labeled.

1. *Risk Management Question Posed to the Risk Assessment Team*

Comment 1. The risk management question posed to the risk assessors relates to the public health impact (with respect to salmonellosis) of alternative lethality standards of 5.0-log and 6.5/7.0 log reductions of *Salmonella* (7.0-log reduction for poultry). A fundamental question not asked is whether or not differentiating between 6.5 and 7.0 log reductions is significant. It would be a benefit if the risk assessors, or FSIS, would substantiate that such a difference is measurable and practically significant as opposed to a mathematical exercise that can lead to different regulatory standards based solely on modeling.

Response 1. The question of the significance of the difference or its practical significance was not considered by the risk assessment team. Judgements regarding public health significance is a matter of risk management.

2. Data Gaps, Uncertainties and Assumptions

Comment 2. We commend the risk assessors for their open and honest approach to the data gaps, uncertainties and assumptions associated with the risk assessment. They repeatedly acknowledge the absence of, or limited availability of, data useful to the estimation of risk associated with RTE products and *Salmonella*. The authors clearly state important limitations and assumptions in Section 1.5. The list is exhaustive and should point ultimately to the limited usefulness of the conclusions from the risk assessment. There is no point is going through all of the limitations and assumptions again in these comments; but we contend that, with so many limitations and assumptions, one must view the results of the risk assessment with caution, particularly as a basis for any policy action.

Response 2. No comment required from the risk assessment team.

Comment 3. The authors make it clear (p.3) that "… providing risk estimates for a broad variety of RTE meat and poultry products requires considerable simplification of the problem to make the analysis tractable." The authors correctly note that the usefulness and accuracy of the risk assessment is limited by the many data gaps, assumptions and uncertainties acknowledged throughout the risk assessment.

Response 3. No comment required from the risk assessment team.

Comment 4. We agree with the authors' statement (p. 4) that product "categorization necessarily results in somewhat crude representations of diverse products." The groupings made to manage the data result in significant increases in the uncertainty due to the diversity within a category. The authors recognize this and state that "By considering products in broad categories there is uncertainty in the growth rates, in the storage conditions of products, and in estimating the maximum population density."

Response 4. The commenters acknowledge the lack of data on numerous occasions within the comments. This lack of data requires addressing products in such categories. The uncertainty is not caused by the categorization since the required data is not available at a finer level of detail. Rather, the categorization is a means to cope with the uncertainty and the lack of data in developing risk estimates.

Comment 5. We strongly agree with the authors' statements (p. 4) that "current estimates of the number of organisms in raw materials are not available" and that relying on the FSIS Microbiological Baseline Surveys "may not be representative of current production." Yet, these data are critical to the estimation of survival following lethality treatments. Unfortunately there were no "expert elicitations" from industry to help reduce the uncertainty of factors such as thermal process safety factors, storage times and temperatures and production volumes.

Response 5. No comment required from the risk assessment team.

Comment 6. Ultimately, the risk assessors state (p. 5) that "given the uncertainty, the relative ranking (or attribution of total risk) among products should not be considered robust." Perhaps this should be re-emphasized in the concluding remarks and in association with Tables presented in Section 6. This is particularly important, as it may limit the utility of the risk assessment as a guide to focus resources based on risk.

Response 6. Despite the uncertainty present in the risk estimates, the relative rankings have much less associated uncertainty compared to the estimates of the annual number of cases, and can be taken as directional when considering focus of risk mitigation effort. This is reinforced through the scenario analyses that have been undertaken (described in the report and within this document) to investigate the impact of some of the components of the model associated with high degrees of uncertainty. In the majority of cases, although absolute estimates of risk are sensitive to changes in these parameter values the relative rankings

appear to be much less sensitive to these areas of uncertainty. Re-considering the phrasing used in the technical document, it is felt that the term "…should not be considered robust" is too exclusive of the potential usefulness of this risk assessment, as suggested by the above comment. Therefore this section has been reworded to read

"With this in mind, risk estimates should be considered to fall within a broad range of uncertainty including the possibility that they may be orders of magnitude smaller or larger. Given this, the relative ranking (or attribution of total risk) among products is also associated with a high degree of uncertainty, although to a lesser degree than the absolute estimates of risk."

3. *Risk Estimates*

Comment 7. The authors point out correctly that the contribution of RTE meat and poultry products to the estimated one million cases of salmonellosis annually in the U.S. is unknown. Without the linkage between food products and their human health impact, it is impossible to properly develop performance standards, and furthermore, to differentiate between different lethality standards such as those under review by the risk assessment. As the Agency works with CDC to better define food attribution for foodborne illnesses, data will become available for revision of the risk assessment.

Response 7. No comment required from FSIS' Risk Assessment Division.

Comment 8. Based solely on the projected risk of illness by product category provided in Section 1.6 (p.6), one would conclude that to address 62% of the foodborne illness cases, using a 5-log reduction standard, one should focus on cooked chicken; to address 61% of the foodborne illness cases, using a "split" lethality approach, one should focus on cooked chicken and salami, uncooked pepperoni, chorizo, soudjuk and meat sticks; and to address 65% of the foodborne illnesses, using the "all 6.5/7.0" standard, one should focus on the same products identified for the "split" standard. If this is directionally correct, then FSIS could use these risk assessment data to focus their inspection and testing resources to determine whether such a characterization of risk is accurate. However, the statement on p.5 that the relative ranking (or attribution of total risk) among products should not be considered robust would appear to preclude such an approach.

Response 8. FSIS agrees with the use of the outputs of the risk assessment to facilitate the identification of areas of focus for FSIS. Despite the uncertainty present in the risk estimates, the relative rankings have much less associated uncertainty compared to the estimates of the annual number of cases. Re-considering the phrasing used in the technical document, it is felt that the term "…should not be considered robust" is too exclusive of the potential usefulness of this risk assessment, as suggested by this comment. Therefore this section has been reworded to read

"*With this in mind, risk estimates should be considered to fall within a broad range of uncertainty including the possibility that they may be orders of magnitude smaller or larger. Given this, the relative ranking (or attribution of total risk) among products should is also associated with a high degree of uncertainty, although to a lesser degree than the absolute estimates of risk*"

4. Lethality Calculations

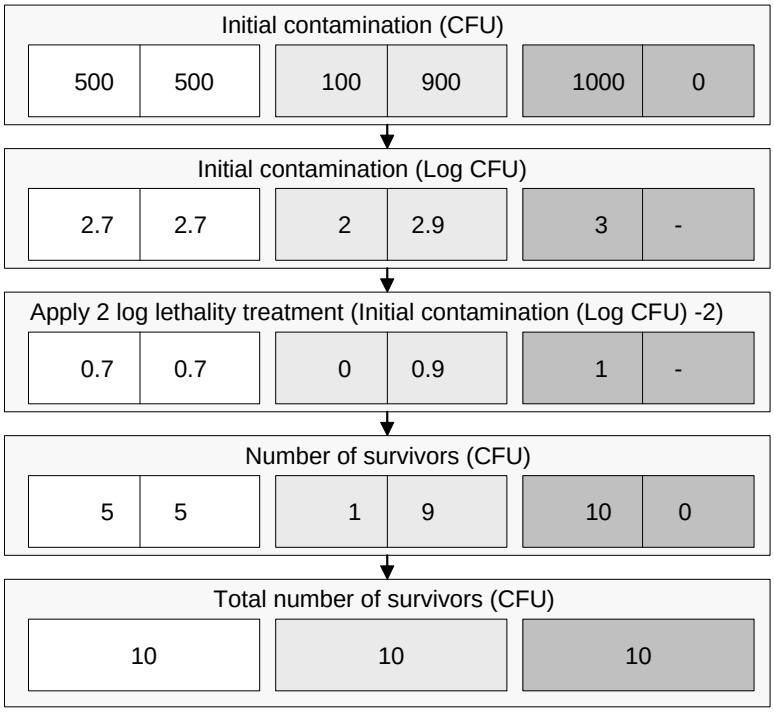
Comment 9. In the risk assessment, Sections such as 2.5 rationalize the use of contamination levels expressed as CFU/MKg and the projection of these values to servings. If the meat and poultry products were liquid or finely minced, such a generalization of contamination might be more realistic. However, there are no data to suggest that contamination of RTE meat and poultry products will be homogeneously distributed; in fact, the alternative is much more probable. Although very difficult to model such non-homogeneous contamination, the approach taken in the risk assessment appears to be one of convenience rather than one taken in an attempt to project more realistic conditions.

The 'scale up' from CFU/g to CFU/MKg was chosen "to highlight the importance of seemingly low per-gram contamination levels that might be found in RTE meat and poultry products." The risk assessors contend that "when considered in terms of mass production, these low levels can result in a non-negligible risk of illness to the population." The authors state that "although the majority of servings will not be contaminated, this level of contamination [1 CFU per 1,000,000 g of products] is sufficient to pose a non-negligible risk of illness to the consuming population." There has always been a contradiction between the theoretical risk that is derived from extending the tail of a distribution curve to millions of units of products and the reality of the application of lethality treatments. Each unit should be viewed independently with respect to the lethality treatment, which, if delivered properly, results in the practical destruction of all pathogens of concern yet leaving a theoretical probability of some small fraction surviving. Since this fraction surviving is less than one, there are no survivors in the unit of food (whether this is a can of beef stew, a chicken breast or a hamburger patty). It is not reasonable to add the fractions of survivors for X numbers of units to obtain a number greater than one and claim this presents a risk. (If this were not true, we would be seeing sporadic cases of botulism from commercially canned products from time to time.)

Response 9. The calculations used to estimate the impact of lethality are not affected by the units (e.g., g versus MKg) used in the model or whether individual servings are modeled as such, or as a total mass.

To demonstrate that the predicted impact of lethality is not affected by splitting the mass into discrete units consider a mass of product which is split into two discrete units that are contaminated with 1,000 CFU in three possible ways: 1) the organisms are equally split between the two units, 2) there is an uneven split of organisms, and 3) only one of the two units is contaminated. (note that neither the total mass of the product, nor the mass of each unit

affects the calculation as will be demonstrated later). The below figure shows the sequence of steps to estimate the impact of a 2-log lethality treatment on the contamination level of the product under each of the three contamination scenarios. Following the steps, it can be seen that the end result of the 2 log lethality in each case is survival of, on average, 10 CFU. It should be noted that this is not purely mathematical convenience but rather is an inevitable result of the appropriate application of the effect of lethality on populations of organisms.



The most common assumption applied in estimating the impact of thermal inactivation processes is that, for a given process, each organism has an individual and identical chance of survival in the process. This probability of surviving the process is directly related to the level of lethality and is given by 10^{-L} where L is the log reduction afforded by the process. The equal-chance assumption implies a Binomial survival process which is a process where there are two possible outcomes (in this case survival or inactivation by the lethality treatment) and the outcomes are governed by the probability of surviving the lethality treatment (10^{-L}, which for the above example is $10^{-2} = 0.01$). This is the probability that 1 organism will survive the process, and for the above example, **on average,** 1 in 100 CFU will survive the process. Therefore, if a log reduction is applied to 100 CFU, on average, there will be 1 survivor. As the Binomial process is inherently stochastic, and describes the variation around this average, in some instances there will be no survivors and in other instances there will be more that 1 survivor. This is an inherent characteristic of a Binomial process. In a Binomial process (and consistent with the basic biological reality) only discrete number of organisms will be

predicted to survive (i.e. 0, 1, 2,…), while the average number of survivors (taken across a number of production units) need not be a discrete number (e.g., the average number of survivors may be 0.5). This distinction may be the source of confusion.

One of the implications of a Binomial survival process applied across multiple production units is that the total number of surviving organisms in the total production volume is governed by the total number of organisms in the system and the Binomial lethality parameter. In other words, when a Binomial process applies, the exact allocation of organisms among the production units before lethality does not have an impact on the total number of survivors. Given no effect of the discretisation of contamination upon the predicted impact of lethality, the scale up in the model to Mkg is not for mathematical convenience. Rather it is in-line with current understanding of the impact of lethal processes on micro-organisms. If the model were developed on a serving size basis the effect would be compartmentalization of contamination to servings and whether this is done in a homogeneous or non-homogenous fashion does not impact the results. The results would be identical as seen in the above the example.

To demonstrate this further, consider a mass of product (note that the actual size of the production unit does not enter into the calculations below). This mass is contaminated with 10,000 CFU (4 Log CFU). This mass can be divided up into servings any number of ways, but in the event of no treatment that reduces the contamination level, no matter how this lot is divided into servings the total number of organisms summing across all servings will still be 10,000 CFU. The same applies following lethality, the splitting of the total mass into servings has no effect on the number of survivors of the process (as demonstrated above). Now consider application of a 5-Log lethality treatment to the mass of product. The probability of survival is $10^{-5} = 0.00001$. Under the assumption that the survival of organisms follows a Binomial process (that is they either survive or do not based upon some probability) the probability that the mass will remain contaminated with some number of organisms following lethality is given by $1-(1-P)^C$ where P is the probability of survival and C is the initial level of contamination. In this example the probability the mass will remain contaminated is 0.095 or approximately 1/11. This is misinterpreted in the comments as predicting the existence of 1/11th of an organism (we agree that it is not reasonable to predict the survival of a fraction of an organism). The correct interpretation is to predict that roughly one out of every 11 lots (having 4 log CFU contamination and receiving a 5 log lethality treatment) will have one or more survivors.

Implementing this logic in the risk assessment, it can be seen that in no way are fractions of organisms added together to obtain whole organisms. To suggest this in the comments is a misunderstanding of the process behind applying, and interpreting lethality calculations. As the level of lethality increasingly exceeds the level of contamination in the product, the probability of the product having survivors becomes smaller, but it is always non-zero. As this probability becomes smaller, organisms surviving lethality becomes an increasingly rare event but given sufficient production volume there will inevitably be some survival. The commenters mistakenly convert very low average concentrations in some unit of product to be

functionally or practically equivalent to zero organisms, and following this reasoning, rare low-level contamination events are inappropriately discounted to constitute zero risk. Conversion of average concentrations of less than 1 organism per unit mass to be equivalent to zero organisms is an unacceptable application of the science and inappropriately underestimates the risk of RTE products.

In summary, the risk assessment appropriately assigns a very low, but non-zero, probability to the survival of organisms. At the level of the individual serving, they are indeed rare events. However, by the same logic, at the scale of millions of servings, survival of some organisms is a certainty. The fact that the risk assessment predicts illnesses on the order of hundreds or thousands per year from millions or billions of servings per year accurately reflects the rareness of the illness in the context of any given serving, but the certainty of some number of illnesses in a population consuming billions of servings.

Comment 10. To support this notion, we ran a scenario analysis where the raw material pathogen burden per serving, rather than per Mkg, was the input. Based on the 99th percentile serving sizes reported in the 2003 FDA/FSIS *L. monocytogenes* risk assessment for various RTE meat and poultry products, 454 g (the highest 99th percentile value among frankfurters, dry/semi-dry fermented sausage, deli meats, pâté and meat spreads) was chosen as the serving size estimate for the analysis. The predicted cases of salmonellosis per year (Table 1) show that survivors in a serving (assuming the lethality is properly applied) pose a negligible level of risk to consumers – the total number of cases for the 5-log, split, and all 6.5/7 log lethality standards is 0.03, 0.0009, and 0.0005 cases per year, respectively. This is the equivalent of 1 illness every 33, 1000 or 2000 years, respectively. We believe that this is more representative of realistic risk.

Response 10. Adapting the model to run the suggested scenario (running the model based upon 'per 454g serving' rather than 'per Mkg') **does not** give the results presented here. Through investigation with the model it is suspected that the reviewers have incorrectly modified the model to run this scenario. Specifically, in modifying the model to run on a per-serving basis, the commenters neglected to update the consumption volume to account for the change in units from Mkg to 454g servings. The effect of this error is identical to reducing the amount of RTE product consumed per year (by a factor of more than a million), which will inevitably reduce the predicted number of cases per year. When the model is correctly adapted to account for the same total production volume, the risk estimates are, as expected, identical to the calculations carried out on a MKg basis. (See the previous comment for explanation of why the adjustment to serving size has no impact upon estimates of risk).

5. Product Classification and Descriptive Risk Factors

Comment 11. The authors clearly state the problems associated with dividing all RTE meat and poultry products into categories that assist with the risk assessment process. In general we agree that the product categories selected are reasonable for the purposes described in the

risk assessment. However, as noted before, by grouping products there will be increased uncertainty in several areas (e.g., growth rates, storage conditions). Moreover, it is not clear how the 16 product classes were assigned to the risk categories based on the factors of controllability, role of formulation in lethality, relative margin of safety, and re-growth of pathogens. A table is needed that shows how the risk factors were applied to each of the 16 product categories to obtain the 6 risk category assignments. We make the following observations with respect to the descriptive risk factors and assignments to a risk category, although it is unclear how the suggested changes would impact the risk category assignment for a product and, ultimately, the risk assessment.

Response 11. The assignment of the risk categories to the product classes is a result of consideration of Table 5-2 and Table 5-3.

Comment 12. We note that salami and pepperoni are assigned to a risk category "fermented, uncooked, shelf stable" (p.19) and that controllability is "low." It is not clear whether or not the risk assessors have taken account of the fact that, since an outbreak from E. coli O157:H7 in salami in 1994, processors have implemented processes validated to achieve a 5-log reduction of this organism. In many instances heat is used to achieve at least part of this reduction. Theses processes are likely to achieve appropriate reductions of *Salmonella* as well, and are much more controllable. In later parts of the risk assessment, there is reference to "cooked pepperoni" in the FCSS category (which receives a cook), and on p. 35 there is reference to product heating for the salami category, but the impact of this on risk category assignment is unclear. It is not clear how servings of pepperoni were divided between the cooked and the uncooked categories.

Response 12. The division of the amount of cooked and uncooked pepperoni between dry and semi-dry fermented sausages occurs at the consumption volume level. Due to limitations with consumption volume data, the total mass reported in the CFSII database is split equally between the two categories, as described in section 6.4.

The frequency with which a process validated to achieve a 5-log reduction will achieve a 5-log reduction, or indeed greater than 5-log reduction, is handled in the compliance section. The table presenting the risk factors (Table 5-2) is purely presented to explore the multiple facets in the production of RTE products and characterizing them in terms of risk factors that are used to facilitate the reader's understanding of the difference in the risk factors and how despite the broad variety in RTE products there are a small number of characteristics which can be used to describe them (i.e. thermal process safety factors, re-growth of pathogens, etc.). These risk factors are explicitly used in assigning thermal process safety factors, growth and reheating patterns but are not used directly to assign levels of lethality achieved or compliance. Compliance estimates are entirely based on the expert elicitation in the cited RTI report.

Comment 13. The discussions on Primary Control Mechanisms and Role of Formulation in Lethality in Section 5.2.1 suggest that temperature is more controllable than formulation.

However, under FSIS HACCP requirements, if formulation were used for control, then it would require a Critical Control Point; and the CCP must be validated and met for product to enter the marketplace. If there is a requirement for a specific lethality, regardless of whether it is provided by heat or through formulation, that lethality must be met. To suggest that one CCP is more controllable than another may be correct, however, in practice, any CCP used for pathogen control must be met for product to be released into commerce. Thus, from the standpoint of practical significance, control of temperature and formulation achieve the same end result (except for the additional margin of safety addressed by the thermal process safety factor in the risk assessment). These discussions result in what appear to be arbitrary conclusions on Controllability. The risk assessors should re-visit their conclusions based on the application of CCPs in a HACCP system.

Response 13. The controllability factors are used in the application of thermal process safety factors. Highly controllable processes (the commenters acknowledge that there will be some variability) are assumed to be more likely to have higher thermal process safety factors. The only other place where controllability is considered would be by the experts interviewed in the RTI study which leads to estimates of compliance.

Comment 14. The descriptions of risk factors for risk categories in Table 5-2 should be clarified. For FCSS and FUSS, fermentation (or direct acidification) is cited as the control mechanism; however, it is actually low pH or level of acidity that is the control mechanism with respect to *Salmonella*, not the process to achieve that pH or level of acidity. It is the final pH resulting from the fermentation (or acidification) process that is critical and must be met at the CCP; if the pH is not met, the product will not be released into commerce. Thus these products would pose no risk for the consumer. This should be factored into the risk assessment.

Response 14. The pH achieved will be associated with a specific log reduction. Whatever level of log reduction is achieved there remains a probability that some *Salmonella* will survive (albeit a very low probability for high log reductions). The percentage of producers that would not be in compliance with the rule, for example through not obtaining adequate pH in a product, is taken into account in the risk assessment in the compliance section through reliance on the expert elicitation study cited.

Comment 15. For DH, thermal processing is "critical to lethality." Water activity should be considered as inhibitory to growth more than a lethality mechanism, as *Salmonella* is relatively resistant to drying and survives well at reduced water activity. (There have been outbreaks from spray-dried milk, chocolate, cereal and other reduced water activity products.)

Response 15. The text has been clarified to read "*Thermal process provides primary lethality and water activity provides further control.*"

Comment 16. In the section titled "Margin of Safety" there is a suggestion that lethality would be less efficient with comminuted product than with intact product because of the

likely location of contamination. Unless the risk assessment models lethality based on location of organisms within the product, the assignment of a margin of safety may not be meaningful. However, once again, the discussion fails to acknowledge that the required lethality is not negotiable when executing a HACCP plan. The CCPs are designed to address the physical nature of the product such that, regardless of the product's physical nature, the likelihood of under-processing may be considered the same for any product category. For this reason, the characterizations listed *in* Table 5-2 for FUSS and DH should be modified to at least "Variable," or the risk assessment should provide a more realistic basis for the existing characterizations.

Response 16. For intact products, it is assumed that basic product considerations beyond the minimal requirements of the lethality standard will result in a product cooked more thoroughly than minimally required to inactivate organisms on the surface of the product. The low margin of safety for FUSS and DH products relates to the lack of any incentive, to 'overcook' these products (i.e., beyond what is required by the standard).

Comment 17. The risk assessment states that "… when considering a large volume of RTE meat, some survival of organisms is expected." The assessment team needs to supply some documentation to support this statement. Again, there is an inherent failure to recognize that processors of RTE meat and poultry products must produce products with validated HACCP plans where CCPs are designed, executed and verified to achieve the required lethality. To make the judgment that there is a background level of survivors in all production simply is unfounded and not supported by data. Although convenient for the mathematical calculations in predicting risk from organisms that survive the lethality process and potentially grow during subsequent storage, distribution and handling, the conclusion fails to recognize the requirements to manufacture products according to defined CCPs.

Response17. The appropriate application of lethality calculations ensures that there will always be some survivors, however rare they may be. It is entirely unscientific to convert the assertion "verified to achieve the required lethality" into a presumption that there will be no survivors. "Required lethality," by definition, specifies the acceptable proportion of survivors.

We agree that such processes are verified to achieve the required lethality. However, there is simply no basis to convert that to a statement that there will be no survivors. Although not necessary to prove the inevitability of survival, the commenters might consider data from FSIS sampling programs demonstrating consistent prevalence of *Salmonella* in finished RTE meats products from plants employing HACCP.

6. Pathogen Burden

Comment 18. The risk assessment team admittedly had little data on current pathogen levels in the numerous raw materials used for manufacturing RTE meat and poultry products and relied on outdated survey data from 1992-1997. The risk assessment recognizes this as a factor contributing to uncertainty (5.3.2), and concludes that "without a renewed and

comparable baseline study it is not possible to fully characterize this effect and the attendant uncertainty." The risk assessors consider that major changes in the industry to ensure compliance with the performance standards would imply reduced estimates of contamination levels compared to the baseline studies but that this is offset by increased test sensitivity; as a result it is assumed the baseline data serve as a "surrogate" for microbiological quality of the raw materials. We disagree and contend that better data are available for the risk assessment. FSIS has conducted more recent *Salmonella* prevalence studies for some species that have not yet been published (although some have been made available on the FSIS website). FSIS has also been conducting *Salmonella* testing of raw meat and poultry for verification tests since implementation of HACCP. While we all acknowledge that the verification test data are not appropriate to establish new performance standards, they do provide a more realistic picture of current *Salmonella* prevalence. To ignore, or discount the progress that has been made since 1997 in reducing incoming pathogen loads is a disservice to the industry and minimizes the usefulness of the risk assessment. In addition, FSIS has access to data that establishments have collected to use in their hazard analyses. Thus, while not comprehensive, industry data, in combination with FSIS verification testing data, would be more accurate in predicting incoming pathogen load than the outdated survey data.

FPA used the model to conduct an analysis in which inputs were changed to reflect the FSIS 2003 verification data for all plant sizes (A sets) for broilers, cows and bulls, steers and heifers, and hogs. The results compared to the baseline model are shown in the attached Table 2. Not surprisingly, the number of cases per year decreased and the "all 5 log" scenario produced the highest number of cases. There were also some changes in the rankings. In conducting the analysis we noted that in addition to carcass categories for broilers and turkeys there was one for poultry. Likewise there was a category called beef in addition to cows and bulls and steers and heifers. The source of input for the poultry and beef levels was not clear.

Response 18. While it is acknowledged that more recent prevalence information is available from the 2003 PR/HACCP Verification Testing Program, this does not provide all of the information required for the risk assessment. In particular, no updated enumeration data is available to estimate the level of contamination. As a result, the use of updated prevalence data in the absence of data of the associated contamination levels can still only be considered a surrogate for the actual data required.

To acknowledge the progress made since the FSIS Baseline survey implementing HACCP, we have added a section to the report that provides risk estimates generated using the estimates of prevalence reported through the PR/HACCP Verification Testing Program from 2003. (This section is provided for information in the attached appendix). Note that no data for Turkey was provided, the assumption is therefore made that the reduction in Turkey prevalence was equal to that of broilers. As there is no update to the level of *Salmonella* contamination, the assumption underpinning these risk estimates is that contamination levels for *Salmonella* positive carcasses is the same as reported in the FSIS Baseline study. Comparing the risk estimates using the PR/HACCP prevalence estimates with previous estimates form the FSIS Baseline Surveys it can be seen that the annual number of cases for each scenario is lower. For

All log 5 scenario this corresponds to a decrease from 66,000 to 50,050 cases; for the Split scenario this corresponds to a decrease from 1,900 to 1,010 cases per year and for the All 6.7/7 log scenario from 1,100 to 700 cases per year. However, the percentage contribution of the product categories to the estimates of the total number of cases per year does not change significantly with the adjustment to the input prevalence data.

The category Poultry is a pool of all the chicken and turkey data. Similarly, Beef is a pool of the Steers/Heifers and Cows/Bulls data.

Comment 19. Another limitation to the calculation of pathogen burden is in the manner in which carcass surface data were translated into CFU/kg data. Sampling for pathogens on the surfaces of carcasses has been based on surface-mapping studies demonstrating where on the carcass the pathogens are most likely to reside following slaughter. To extrapolate the carcass data uniformly for the entire carcass discounts this understanding of pathogen distribution on the carcass surface. The result is an over-estimation of pathogen load and risk.

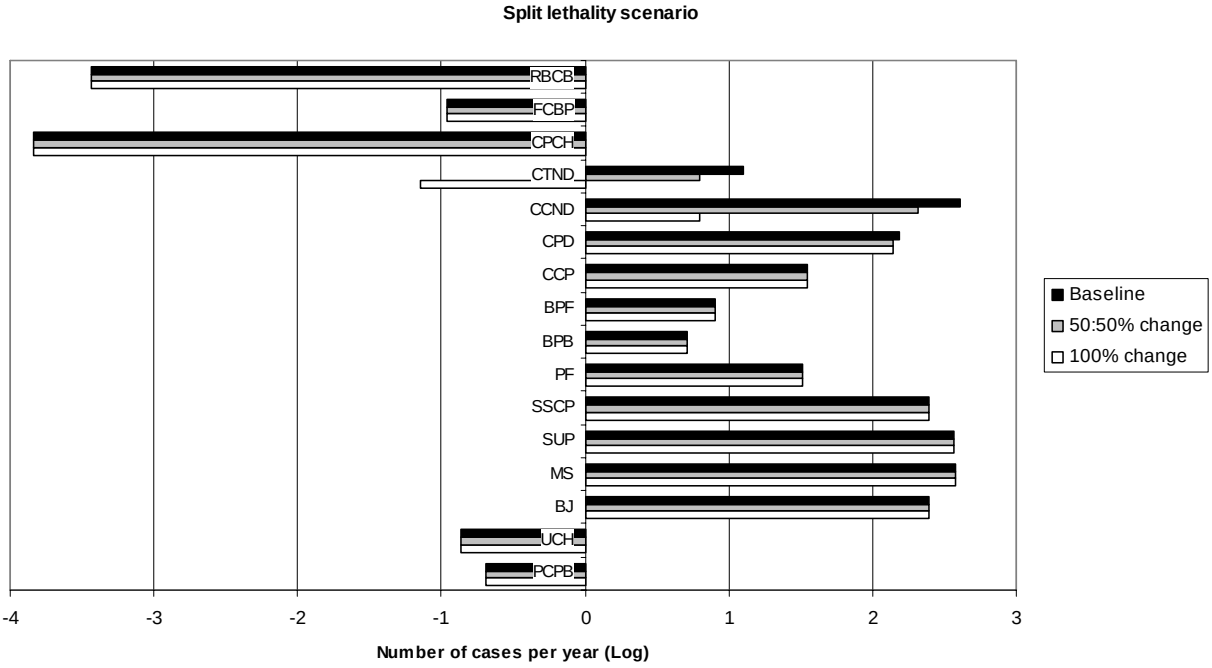
Response 19. It is agreed that assuming a uniform distribution of *Salmonella* across the surface of products where sampling was limited to a small area of the carcass (as is the case for surface swabs for beef and pork samples) may result in an overestimation of the pathogen burden. However, currently there are no readily available data that allow an alternative approach to estimating the concentration, and given the uncertainties associated with the sensitivity of experimental measures such as enumeration through surface swabs, more complex approaches to deal with total burden estimation have not been considered viable. Section 8.1 of the technical report describes a scenario where the total pathogen burden for the products was varied from half the estimate to 3 times the estimate. This can be consulted to determine the sensitivity of the overall estimates to the pathogen burden for beef and pork.

Comment 20. Table 5-6 illustrates some of the problems associated with estimating and predicting pathogen loads on RTE products. To use ground turkey data as data for cooked turkey (non-deli) would not accurately characterize the likelihood of *Salmonella* on these products since many of these products would be whole muscle in nature, not ground products. The same can be stated for cooked chicken where whole muscle portions often serve as raw materials for these products; and based on the risk assessment's conclusions, such raw materials would have a lower level of pathogen contamination than ground product.

Response 20. To investigate the impact of the assumption of non-deli meats being assigned ground versus intact meat as the product constituents, the model was run with non-deli meats assigned to 1) 100% ground meat (this is the 'baseline results'), 2) 50% ground and 50% intact, and 3) 100% intact meat. In reality the proportionate split of products between ground and intact meat is somewhere between 0 and 100% however it is not known where on this continuum the value is – to establish this would require a survey of all RTE non-deli product to establish the appropriate assignment. However, the result of the investigation would result in a risk estimate within the bounds of 1,462 to 1,891 cases per year. The impact on the

individual product types is shown in the below figure for the split scenario. The assignment of 100% turkey to intact greatly reduces the contribution of CTND to the overall risk.

	Total number of cases Salmonellosis per year		
	Baseline	50:50 Ground:Intact	100% Intact
All Log 5	65,908	43,737	23,055
Split	1,891	1,669	1,462



7. Compliance with Lethality Standards

Comment 21. The risk assessment assumes some level of non-compliance that ultimately contributes to risks for the consumer. The risk assessment fails to acknowledge that when non-compliance is noted, by the establishment or by FSIS, product does not enter the marketplace. A review of the data would point out that the number of recalls associated with *Salmonella* on RTE meat and poultry products is a very low number since such recalls are highly infrequent. Additionally, FSIS conducts verification testing for *Salmonella* in RTE meat and poultry products and finds occasional positive results. Thus, we recognize that product is produced that does not comply with lethality standards that exist or may be proposed. While it is acknowledged that some non-compliant product enters the marketplace, the risk assessment does not account for non-compliant product that is never shipped from an establishment and thus would not contribute to consumer risk.

Response 21. The actual volume of product that enters the market is used for the consumption data. Therefore, the amount of product that is not released due to recognized non-compliance is accounted for in this way.

The fact that occasional positive results would occur is not necessarily evidence of non-compliance. Compliance with lethality standards, by definition, allows for the survival of pathogens as rare events in production.

Comment 22. The risk assessors assume a set of compliance patterns based on data from an expert elicitation process used as part of data collection and economic analysis for the performance standard rule (RTI, 2004). The basis for describing and using three levels of non-compliance (and the specific levels used) is not provided, nor is it based on data analysis of recalls or end-product verification testing data. The RTI data from 2004 was not designed to provide or determine a measurable impact on lethality. There is an apparent lack of recognition of HACCP systems and verification of CCPs during manufacturing of RTE meat and poultry products, as well as the fact that USDA does not allow for release of product into the marketplace without a review of the CCP data. The data on recalls and, in particular, FSIS verification sampling for *Salmonella*, should be used to assess whether the compliance patterns are reasonable assumptions.

Response 22. The RTI data presents the percentage of producers likely to obtain "less than 5 log reduction", "Between 5.0 and 6.5/7.0 log reduction", and "Reduction of 6.7/7.0 or above". This provides an indication of the level of lethality obtained. For split scenario the lethality standard is consistent with the RTI categories. The category "less than 5 log reduction" is used for the S-1.5 to S-2.5 level of lethality, "Between 5.0 and 6.5/7.0 log reduction" is used for S to S-1.5, and "Reduction of 6.7/7.0 or above" is used for S+1 to S. For the All 5 Log scenario the total of "Between 5.0 and 6.5/7.0 log reduction", and "Reduction of 6.7/7.0 or above" is used for the S+1 to S category, and "less than 5 log reduction" is used for S to S-1.5. This is now stated in the text of the risk assessment report.

Comment 23. In assigning the level of compliance, it is not clear why under the 6.5/7.0 log standard the summer sausage, thuringer, cooked pepperoni 5.5% of product would receive between a 4.0/4.5 and 5.0/5.5 lethality but under the 5.0 log standard 5.5% would receive a 3.5 to 5.0 log lethality. The same is true for the salami category. It is highly unlikely that the fermentation process would be changed such that the lowest level of lethality would be different in the two scenarios.

Response 23. The assumption is that the plants relax the process to be compliant with the standard in the same proportion as the standard changes. The model is built with the option "maintain Higher" which allows this assumption to be circumvented – assuming that a portion of industry will not alter the processing, and hence will maintain the level of lethality, in light of a change in the standard. It is unknown what proportion of industry would maintain the previous processes.

Comment 24. In Section 5.7, the risk assessment states that "there will be some products that remain contaminated with *Salmonella* that survived the lethality treatment." The risk assessment provides no basis for this statement, e.g., FSIS testing data for RTE meat and *poultry* products. To generalize a degree of survival across the entire spectrum of RTE meat and poultry products, without a scientific basis, may be mathematically convenient, but likely fails to reflect what actually occurs in practice for the many reasons already cited herein. Throughout Section 5.7.1 there are many assumptions relative to the prevalence and number of survivors, none of which are supported by data. These are significant data gaps that should be addressed before accepting the conclusions from the risk assessment as being factual or representative of the RTE products in the marketplace today.

Response 24. This essence of this comment has been repeatedly addressed above.

8. Growth During Storage

Comment 25. Table 5-15 warrants additional explanation. It provides the mean probability of pathogen survival in servings initially containing 10^{-3} to 10^{4} CFU of *Salmonella*. It appears that p>1 represents the probability that more than one cell survived and p>2 represents the probability that more than 2 cells survived, but this is not clear. When L is at least one log higher than the actual level of *Salmonella* in a serving the initial level of *Salmonella* in the serving is reduced to <1, and there is no survival. However, since the assessment of probability of survival uses the mean number of *Salmonella* per serving, when L is one log higher than the mean level of *Salmonella* in the serving, a single CFU per contaminated serving may be a reasonable assumption, depending on the variability of the level of contamination. An assessment based on a reasonable maximum level of *Salmonella* per serving might be more informative.

Response 25. This table has been clarified and is now presented as follows:

Table 5-15: Mean probability of pathogen survival resulting from a binomial survival model, specifically the probability that more than 1 organisms per serving (p>1) and the probability that more than 2 organisms (p>2) survive the lethality process for given pathogen counts per serving (CFU). [Note: only lethalities of 5 and above are considered in this assessment.]

CFU	Lethality Value									
	2 log		3 log		4 log		5 log		6 log	
	p>1	p>2	p>1	p>2	p>1	p>2	p>1	p>2	p>1	p>2
10^{-3}	>0	>0	>0	>0	>0	>0	>0	>0	>0	>0
10^{-2}	>0	>0	>0	>0	>0	>0	>0	>0	>0	>0
10^{-1}	$2x10^{-3}$	$7x10^{-7}$	$2x10^{-4}$	$7x10^{-9}$	$2x10^{-5}$	$7x10^{-9}$	$2x10^{-6}$	$5x10^{-11}$	$2x10^{-7}$	$2x10^{-9}$
10^{0}	0.2	$4x10^{-4}$	0.02	$4x10^{-6}$	$2x10^{-3}$	$4x10^{-8}$	$2x10^{-4}$	$4x10^{-10}$	$2x10^{-5}$	$1x10^{-9}$
10^{1}	4	0.1	0.4	$1x10^{-3}$	0.04	$1x10^{-5}$	$4x10^{-3}$	$1x10^{-7}$	$4x10^{-4}$	$4x10^{-9}$
10^{2}	40	10	5	0.2	0.5	$2x10^{-3}$	0.05	$2x10^{-5}$	$5x10^{-3}$	$2x10^{-7}$
10^{3}	99.9	99.7	40	10	5	0.2	0.5	$2x10^{-3}$	0.05	$2x10^{-5}$
10^{4}	100	100	99.9	99.7	40	10	5	0.2	0.5	$2x10^{-3}$

Comment 26. The risk assessment acknowledges that given "the diversity both within and between RTE products, a complete characterization of the growth potential of products considered is beyond the scope of this analysis." The risk assessment team acknowledges the many data gaps in the list provided as part of Section 5.7.2. Clearly, filling some of these data gaps is important in providing a better assessment of risk for setting performance standards.

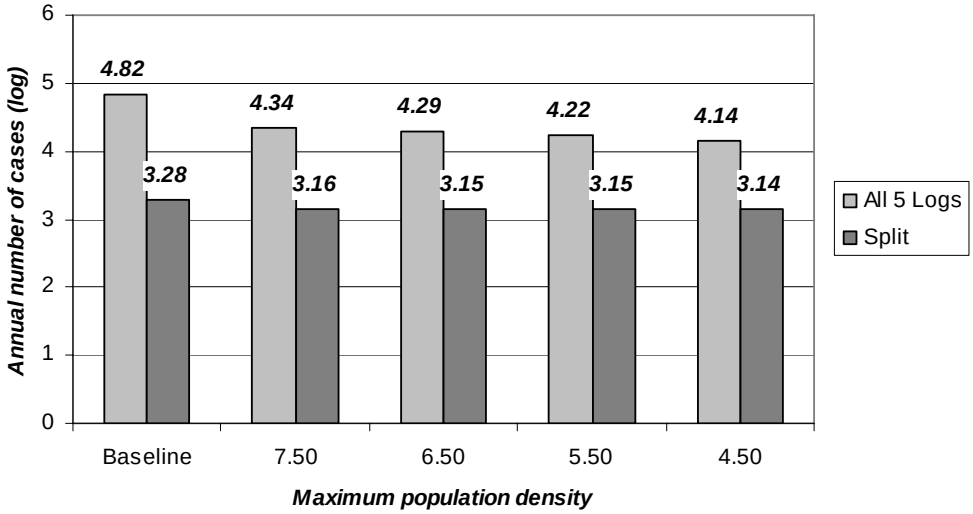
Response 26. No comment required from the risk assessment team.

Comment 27. The risk assessors assume a maximum population of 8.5 logs per serving for all products supporting growth. This is unlikely given that some products are likely to be somewhat inhibitory to growth (e.g., corned beef, ham) due to compounds such as salt. This is especially true when considering that the *Salmonella* present are assumed to have survived the process and would likely be injured.

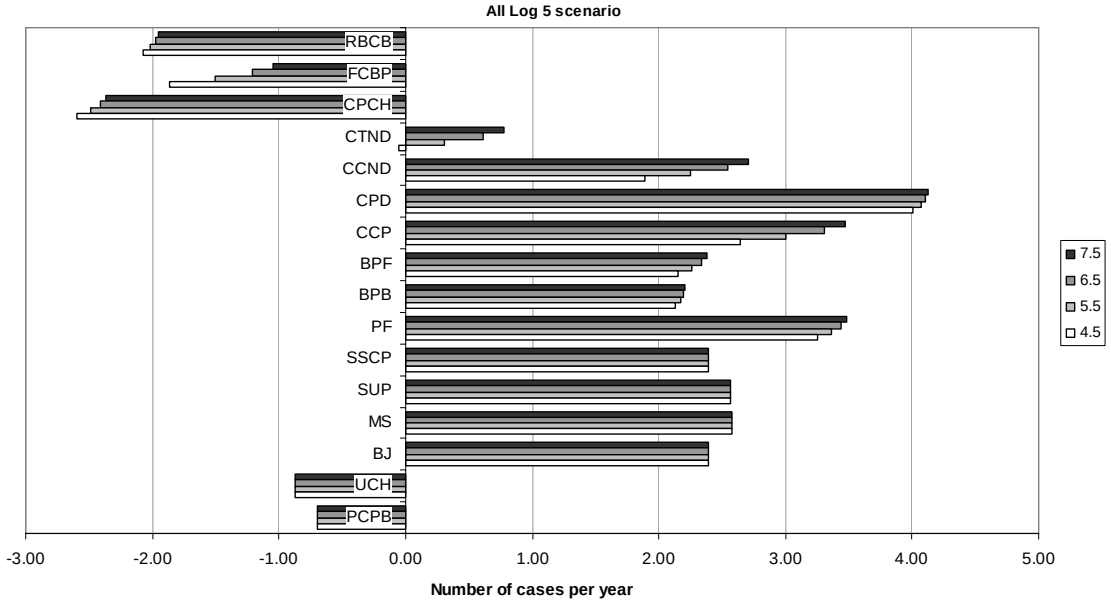
Response 27. The value used in the model is based upon available information regarding maximum population densities and taking into account other factors such as the presence of spoilage organisms that may inhibit growth. This inhibition could be extended to the compounds present in products. A value of 8.5 logs per serving is assumed. Consider a 20 gram serving of some RTE product, this would correspond to a maximum population density of approximately 7 logs per gram. Reports in the literature estimate a 9 log maximum (per gram) for other organisms (see page 5.7.2) therefore the assumption of 8.5 logs per serving is not considered to be a conservative assumption.

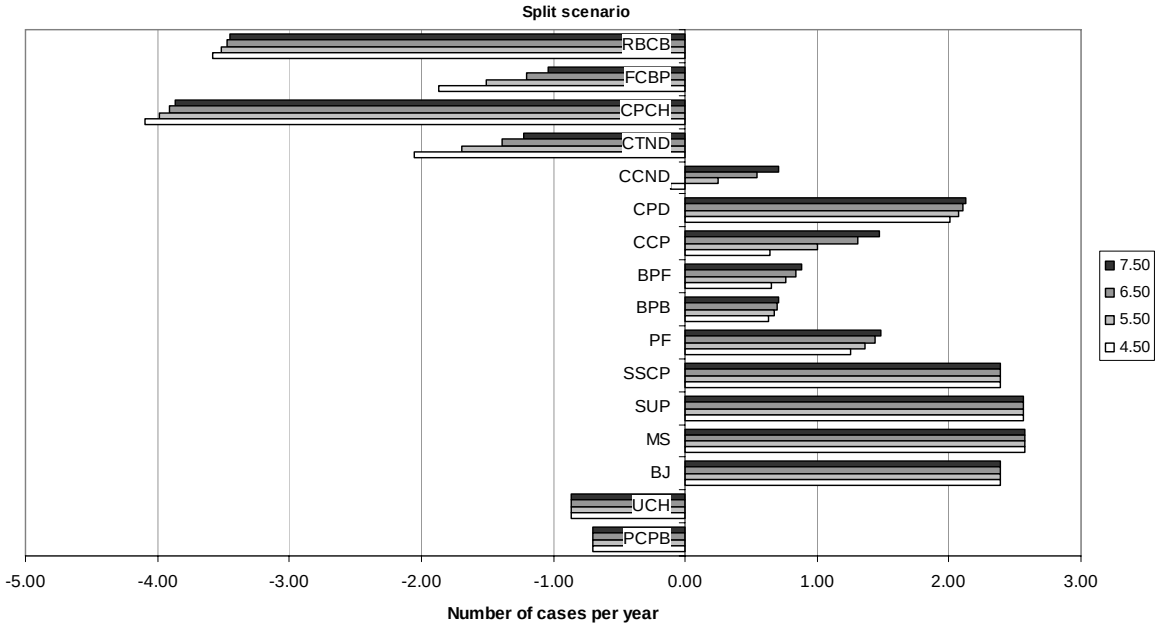
To investigate the importance of this assumption risk estimates were obtained based upon an assumed maximum population density (MPD) of 7.5, 6.5, 5.5 and 4.5 log CFU per serving.

The result are combined with the baseline estimate of risk (8.5 Log CFU per serving) in the below figure. It can be seen that in the split scenario the assumption of MPD has a small impact upon risk estimates. This impact is greater in the "All log 5" scenario.



The following figures show the breakdown of the estimates of risk by product category for the MPD scenarios. It can be seen that in both the "All log 5" scenario and the split scenario the MPD has a big impact upon the risk estimates from cooked chicken and turkey products (specifically CCND, CCP, CTND) and also beef patties (FCBP).

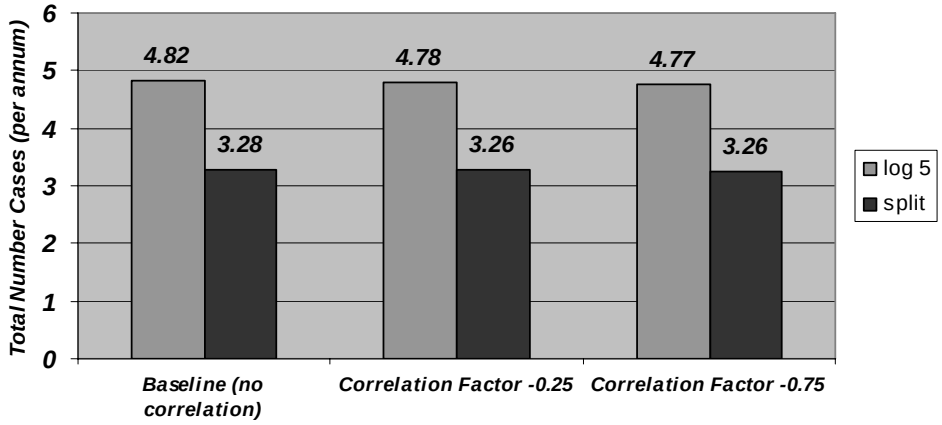




Comment 28. The retail storage temperature is derived from a survey by Audits International, but it is not clear which specific temperatures were used. (Were they temperatures for luncheon meat? For the retail case or the "back room" at retail?) Was storage time linked with temperature such that at higher temperatures longer storage times would not occur? Was the model adjusted to prevent unlikely combinations such as maximum storage time at retail (30 days) and maximum storage time by the consumer (25 days)?

Response 28. The temperatures used are those recorded for pre-packaged lunch meat at retail. This has been clarified in the text to read, "*The temperature of storage is described by an empirical distribution derived from available data recording temperatures of pre-packaged lunch meat at retail (Audits, 1999)*". The model presented did not contain correlations between time and temperature of storage. However, it is agreed that the combinations of maximum time and temperature are less likely than other combinations. Therefore, to investigate the impact of this, time and temperature were negatively correlated such that combinations are unlikely but not completely excluded from occurring.

To investigate the impact of a correlation between storage time and temperature two scenarios were implemented. Risk estimates were obtained with correlation factors of -0.25 and -0.75 between customer storage temperature and customer storage time. The results, compared to the baseline estimates (specifically no correlation modeled between customer storage temperature and customer storage time) are shown in the below figure in terms of the estimate of the total number of cases per year. It can be seen that a small decrease in the estimate occurs. The total number of cases in the All log 5 scenario decreases from approximately 65,000 cases to 59,000 cases, and for the split scenario from 1891 cases to 1825 cases per year.



Comment 29. The risk assessment relies on time and temperature considerations for products after manufacturing to estimate growth; these data are influenced by many factors that are not considered in the assessment, e.g., control of temperature by HACCP systems associated with storage at the manufacturing establishment or distribution center, and control of temperature throughout distribution and measurement of control at various points throughout product movement. The risk assessment acknowledges its limitations by stating that "there is insufficient information available to extend the growth model to take account of these factors, and it is beyond the scope of this assessment." It is not clear that if it is beyond the scope of this assessment to clearly understand and model the potential for growth following manufacturing, then why is this topic given extensive development and modeling in the risk assessment, particularly because the impact of growth following manufacturing increases the risk to the consumer according to the model. The risk assessment team needs to clarify their thought process relative to why understanding the numerous factors affecting growth is outside the scope, yet predicting growth based on numerous assumptions that are significant to the risk assessment output is within the scope.

Response 29. The prediction of the extent of growth of any contaminating organisms that survive lethality is one of the key determinants of risk to the consumer. However, as this risk assessment covers such a broad scope of products with an associated wide variation in conditions to which contaminating *Salmonella* would be exposed, it was not possible within the confinements of this project to tackle this issue. This would require the development of predictive microbiology models for each individual product type explicitly considering the characteristics of each individual product type and the associated extent of growth that may occur. Even if it were within the project boundaries, it is unlikely that data would be available which would enable such a formidable task. Despite these limitations, given the key role that growth has in predicting risk, a simplification was adopted whereby a generic model was developed which used the growth rate of *Salmonella* in a chicken product as the baseline. Chicken was chosen as the baseline medium for growth as there are published data available to develop the predictive model. The predicted level of growth is then adapted for other products, via Storage and Growth Patterns, in line with the degree of growth that would be

expected in a given product relative to that of a chicken product considering the characteristics of that product such as water content and pH.

Comment 30. The assumptions used to model growth include assumptions such as for low-growth refrigerated storage, "the exponential growth rate used in the model is assumed to be half that for normal growth." What is the basis for this assumption? Similarly, a basis for a 1-log reduction in "low-survival" foods (foods in which viability decreases) should be provided (although the number seems reasonable).

Response 30. The exponential growth assumed to be half is based upon experimental data for *Salmonella* at 25°C in cured ham. The growth rate reported is approximately half that of the data for growth in chicken at 25°C. The reference to this data has been added to the document. The reduction of 1 log in low survival foods is an assumption.

9. Impact of Reheating

Comment 31. Although the risk assessors have demonstrated a logical understanding of the variations in reheating processes used for RTE foods at retail, restaurants and in the home, the transfer of logical comparisons to a quantitative risk assessment to provide realistic estimates of risk works mathematically, but likely does not represent the real world processes involved. The risk assessment acknowledges that "… the proportion of products that fall in various categories is a rough estimate and is intended to indicate the relative shift when moving, from one category to another. The resulting level of contamination after reheating is assumed to be the level of exposure experienced by the consumer." Relative risks as mentioned in the above quote do not translate into actual risks experienced by consumers.

Response 31. It is unknown what proportion of the products will be reheated to different extents by the consumer, however, one is able to make judgments that certain products are more likely to be reheated more thoroughly than others, for example for palatable reasons or an awareness of a particular food safety issue. The values used for the percentage represent these judgments and are therefore assumed to be realistic (albeit associated with some uncertainty) estimates of the application of reheating across the spectrum of product categories. As such, output estimates can be interpreted as estimates of risk. This has been made clear in the test:

"Note that the proportion of products that fall in various categories is a rough estimate and is associated with some uncertainty. The resulting level of contamination after reheating is assumed to be the level of exposure experienced by the consumer"

Comment 32. In Table 5-17, there could be many examples of specific foods that are reheated to a greater extent than characterized in the table. For example, many of the products in the cooked chicken category typically are deep-fried before serving, a reheating pattern (thermal process) that, because of the extremely high temperatures associated with frying, could be characterized as "always reheated thoroughly" as compared to "always" as shown in the table.

It would appear that to assign appropriate re-heating patterns would require further breakdown of product categories. It is not clear whether this would change the results enough to warrant the effort.

Response 32. To examine the possible impact of assigning products to 'Always reheat thoroughly' risk estimates were obtained with 3 scenarios: 1) all chicken non-deli meat assigned to reheat thoroughly, 2) all turkey non-deli meat assigned to Reheat Thoroughly, and 3) both chicken and turkey non-deli products assigned to 'Reheat thoroughly. The results are given in the below table. It can be seem that a minimal impact on risk is observed for each scenario, in particular for the Split lethality scenario. Therefore, while it is agreed that some products may be reheated thoroughly, the intensity of effort required to reflect the proportion of products that should be assigned to 'Reheat Thoroughly' is not warranted given the low level of sensitivity of the risk estimate to this particular model variable.

Lethality Scenario	Baseline	Chicken only	Turkey Only	Chicken & Turkey
All Log 5	65,908	62,310	65,800	62,190
Split	1,891	1,855	1,890	1,854

Comment 33. In the "assumption caveat" (5.8.1), the discussion appears to display a fundamental flaw in the risk assessment. The discussion surrounding survival following the original lethality treatment, and the potential causes for the survival, is highly theoretical and without a scientific justification for both the prediction of survival itself (as discussed earlier in this document) and the reasons for survival. The "reasons for survival" of any cells in the risk assessment are strictly a function of the assumptions and mathematical calculations made, not scientifically-based on relevant data pertaining to processing of RTE meat and poultry products. The idea that "prior lethality processes will have selected for the most protected or thermally resistant organisms" is conjecture that does not add credibility to the risk assessment. The only consideration for survival is strictly a mathematical exercise as defined by the model; there are no data to support a further characterization of the survivors or the root causes for survival.

Response 33. The risk assessment applies a common Binomial process to all contaminating *Salmonella* in part because of a lack of compatible data to differentiate the proportions of *Salmonella* serotypes in the raw materials. There is no doubt that there are strains of *Salmonella* that are more thermally resistant than others (e.g., Senftenberg as an extreme example). We simply acknowledge qualitatively in this statement that, as a basic reality, surviving organisms are more likely to be, but not exclusively, those which are in some way more resistant due to inherent properties (e.g., inherent thermotolerance) or their location (from a heat transfer perspective). This has some implications for further heat treatment, even if we have not implemented a means to address these implications. FSIS disagrees that such an acknowledgement could constitute a fundamental flaw.

10. Risk Characterizations

Comment 34. The tables presented in association with risk characterization are, of course, a result of all of the other assumptions, uncertainties, predictions, estimations, and limitations discussed previously in this document and in the risk assessment itself. Thus, all of the results must be viewed with caution and regarded as directional at best.

Response 34. No comment required from the risk assessment team.

Comment 35. Table 6-10 describes the sources of the consumption data. Understandably, obtaining such information for risk assessments from databases not designed for this purpose is difficult at best. For the product class cooked pork (cooked ham, pork BBQ) the comment states "includes all references to ham, so adjustment is required to estimate the fraction that is ready-to-eat." It is not clear what type of adjustment was made. Are there references in the CSFII database to uncooked ham? Were adjustments made for shelf stable canned ham? It is not clear from this table how "cooked pepperoni" and uncooked pepperoni servings were determined.

Response 35. Table 6-10 describes the available sources available, however, Table 6-11 describes what is actually used in the model. For the category Cooked Pork, the economic census data was used on the basis that to use the CSFII data an adjustment to the figure would be required to represent RTE products. In the economic census the product description matches the required products in the risk assessment and no adjustment is necessary.

The division of the amount of cooked and uncooked pepperoni between dry and semi-dry fermented sausages occurs at the consumption volume level. Due to limitations with consumption volume data the total mass reported in the CFSII database is split equally between the two categories, as described in section 6.4

Comment 36. FSIS requires establishments producing RTE products exposed to the environment after the lethality process to fill out Form 10,240-1, which includes annual production volume for these products. This information could prove useful to the risk assessors as a "reality check" for the consumption volume estimates in Table 6-11 and may provide a better estimate for some products. The risk assessors note that the uncertainty is greatest for certain RTE products such as fully cooked beef patties and fermented sausages (p. 98), for which data should be available from form 10,240-1. We also suggest this may be an area for expert elicitation with respect to assumptions such as splitting data on dry and semi-dry sausages equally between the two categories, the volume of beef patties sold as RTE products, the volume of country ham produced, and that prosciutto represents 50% of the product class "prosciutto, cappicola, pancetta, basturma."

Response 37. No comment required from the risk assessment team.

11. Ease of Use of the Model

Comment 38. The transparency of the risk assessment was enhanced by the model being developed in Analytica, which facilitates the review of the mathematical relationships among the input variables and outputs of the risk assessment including various risk estimates. In fact, it appears that a parenthesis is missing in Equation 2 (p. 22) for the calculation of ground raw material burden, while the same error did not occur in the model. The model is reasonably easy to navigate, and it facilitates scenario analyses using different assumptions.

Response 38. We are pleased that the effort to document the model to facilitate peer and stakeholder review has been found worthwhile.

12. Conclusions

Comment 39. The risk assessment was well-documented and reasonably transparent. Nevertheless, in some instances it was difficult to follow the report and determine how some of the information fit together. It was necessary to go to the model itself, with the assistance of a trained risk assessor, to clarify some of the relationships. We appreciate the "worked example" provided by the risk assessors and the scenarios to look at the sensitivity of the model.

Response 39. It was envisaged that a very thorough understanding of the model would require access to such expertise, even with thorough documentation and a relatively user-friendly model.

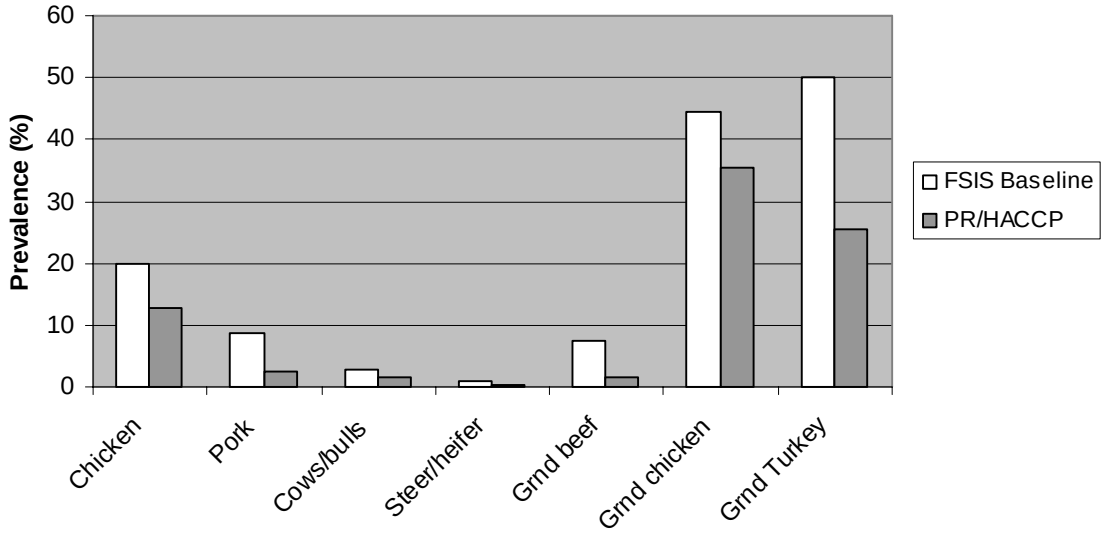
Comment 40. Ultimately, the issues we have with the risk assessment are rooted in the data gaps and uncertainties. The thermal process safety factors have the most uncertainty. We concur with the risk assessors that this can be assessed for individual products and processes but it is not feasible to do so for the industry as a whole. It is likely that even if such an analysis could be conducted, the variability would be such that it would not increase the utility of the model. Nevertheless, thermal process safety factors are widely used in industry to ensure critical limits are met. The uncertainty of this risk assessment can be reduced by obtaining new baseline data for the pathogen burden in raw materials. Likewise, the uncertainty for volume of RTE products can be reduced using FSIS data obtained in conjunction with the *L. monocytogenes* rule (as noted above). We believe that data should be obtained to reduce some of the uncertainty associated with this risk assessment and the risk assessment revised if it is to be used as a basis for setting new regulatory performance standards.

Response 40. FSIS agrees with the commenters regarding the level of uncertainty and the dominant sources. We further agree that thermal process safety factors are a reality that is largely unmeasured at the level of an entire industry. During the main period of this risk assessment, the data referred to on production volume was not available to the risk assessors.

Appendix 1. Risk Estimates Given Updated Prevalence Data

These estimates are a result of using the estimates of prevalence reported for 2003 from PR/HACCP Verification Testing Program (FSIS, 2005) in place of the prevalence estimated from the FSIS Baseline Microbiological Surveys (FSIS, 1994; FSIS, 1996a-g; FSIS, 1998). Note that as no updated enumeration data is available for the pathogen burden estimates the assumption is that the FSIS Baseline is a suitable surrogate for the raw material contamination levels in 2003 associated with the prevalence estimates.

The following graph compares the Baseline survey estimates of prevalence and the 2003 PR/HACCP Verification Testing Program estimates of prevalence. There are no data in the 2003 PR/HACCP Verification Testing Program for turkey carcasses, therefore the assumption is made that the relative change in the prevalence of chicken carcasses also applied to turkey.



Probability of Illness Per MKg RTE Product

Table 0-1: Estimates of the number of cases of salmonellosis per product class on an equal mass basis (per MKg), including reheating for the three lethality standards scenarios considered in the assessment.

RTE Product Category	Risk of Illness by product (after reheating)					
	Log Number of cases /MKg			Number of cases /MKg		
	All 5	Split	6.5/7.0	All 5	Split	6.5/7.0
Roast Beef, Corned Beef	-4.2	-5.7	-5.7	$6.4x10^{-5}$	$2.0x10^{-6}$	$2.0x10^{-6}$
Fully Cooked Beef Patties	-0.3	-0.3	-1.8	$5.0x10^{-1}$	$5.0x10^{-1}$	$1.6x10^{-2}$
Cooked Pork (Cooked Ham, Pork BBQ)	-4.8	-6.3	-6.3	$1.4x10^{-5}$	$5.0x10^{-7}$	$5.0x10^{-7}$
Cooked Turkey (non-Deli)	0.4	-1.6	-1.6	2.56	0.03	0.03
Cooked Chicken (Nuggets, Tenders, non-Deli)	1.4	-0.6	-0.6	23.2	0.2	0.2
Cooked Poultry Deli Meat	1.4	-0.6	-0.6	26.1	0.3	0.3
Cooked Chicken Patties	1.4	-0.6	-0.6	23.2	0.23	0.2
Beef / Pork Frankfurters	-0.5	-2.0	-2.0	0.3	0.01	0.01
Beef / Pork Bologna	-0.2	-1.7	-1.7	0.6	0.02	0.02
Poultry Frankfurters	0.9	-1.1	-1.1	8.2	0.08	0.08
Summer Sausage, Thuringer, Cooked Pepperoni	0.3	0.3	-0.2	2.2	2.2	0.7
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	0.5	0.5	0.1	3.4	3.4	1.4
Meat Sticks	0.8	0.8	0.4	6.7	6.7	2.7
Beef Jerky	0.9	0.9	0.5	8.0	8.0	3.2
Uncooked Country Ham	-2.9	-2.9	-3.9	$1.3x10^{-3}$	$1.3x10^{-3}$	$1.3x10^{-4}$
Prosciutto, cappicola, pancetta, basturma	-1.7	-1.7	-2.2	0.02	0.02	0.01

Relative Risk of Illness by Product Class

Table 0-1 presents the risk per year broken down by RTE product category on an equal mass basis. To ease comparison, these risk estimates are presented in purely relative terms in Table 0-2. This is a useful measure since it indicates the risk associated with the product, relative to others, while controlling for variable production volumes. Note: The value in the table is relative to the value of 1.0 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

Table 0-2: The relative risk of each product class on an equal mass basis (number of cases of salmonellosis per MKg) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

RTE Product Category	Relative Product Risk		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	$6.3x10^{-3}$	$2.0x10^{-4}$	$2.0x10^{-4}$
Fully Cooked Beef Patties	49.3	49.3	1.6
Cooked Pork (Cooked Ham, Pork BBQ)	$1.4\ x10^{-3}$	$5.0\ x10^{-5}$	$5.0\ x10^{-5}$
Cooked Turkey (non-Deli)	254.0	2.5	2.5
Cooked Chicken (Nuggets, Tenders, non-Deli)	2298.9	23.0	23.0
Cooked Poultry Deli Meat	2589.6	25.9	25.9
Cooked Chicken Patties	2298.9	23.0	23.0
Beef / Pork Frankfurters	31.6	**1**	1.0
Beef / Pork Bologna	60.6	1.9	1.9
Poultry Frankfurters	815.1	8.2	8.2
Summer Sausage, Thuringer, Cooked Pepperoni	219.0	219.0	69.2
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	332.1	332.1	136.4
Meat Sticks	667.2	667.2	262.4
Beef Jerky	790.7	790.7	315.2
Uncooked Country Ham	0.1	0.1	$1.3\ x10^{-2}$
Prosciutto, cappicola, pancetta, basturma	1.8	1.8	0.6

Number of Illnesses Per Mass of RTE Product Consumed Per Year

This risk can be interpreted as the expected number of cases of salmonellosis per year. The estimates are reported in Table 0-3, and include the impact of the thermal process safety factors and reheating.

Table 0-3: Estimate of the number of cases of salmonellosis per year that may result under differing lethality standards.

RTE Product Category	Number of Cases per year		
	All 5.0	**Split**	**All 6.5/7.0**
Roast Beef, Corned Beef	$5x10^{-3}$	$1.7x10^{-4}$	$1.7x10^{-4}$
Fully Cooked Beef Patties	$3.6x10^{-2}$	$3.6x10^{-2}$	$1.1x10^{-3}$
Cooked Pork (Cooked Ham, Pork BBQ)	$1.4x10^{-3}$	$4.5x10^{-5}$	$4.5x10^{-5}$
Cooked Turkey (non-Deli)	989	10	10
Cooked Chicken (Nuggets, Tenders, non-Deli)	31,230	312	312
Cooked Poultry Deli Meat	11,890	119	119
Cooked Chicken Patties	2,714	27	27
Beef / Pork Frankfurters	128	4	4
Beef / Pork Bologna	81	3	3
Poultry Frankfurters	2,509	25	25
Summer Sausage, Thuringer, Cooked Pepperoni	122	122	38
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	184	184	76
Meat Sticks	123	123	48
Beef Jerky	81	81	32
Uncooked Country Ham	$4.2x10^{-2}$	$4.2x10^{-2}$	$4.2x10^{-3}$
Prosciutto, cappicola, pancetta, basturma	$6.3x10^{-2}$	$6.3x10^{-2}$	$2.0x10^{-2}$
Total	50,050	1010	695

Relative Risk of Illness by Product Class

Table 0-3 presents the risk per year broken down by RTE product category. To ease comparison, these risk estimates are presented in purely relative terms in Table 0-4. Note: The value in the table is relative to the value of 1 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

Table 0-4: The relative risk of each product class (cases of salmonellosis per year) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

RTE Product Category	Relative Product Risk		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	1.3E-03	4.3E-05	4.3E-05
Fully Cooked Beef Patties	8.9E-03	8.9E-03	2.8E-04
Cooked Pork (Cooked Ham, Pork BBQ)	3.6E-04	1.1E-05	1.1E-05
Cooked Turkey (non-Deli)	245.1	2.5	2.5
Cooked Chicken (Nuggets, Tenders, non-Deli)	7,735.9	77.4	77.4
Cooked Poultry Deli Meat	2,945.3	29.5	29.5
Cooked Chicken Patties	672.3	6.7	6.7
Beef / Pork Frankfurters	31.6	1.0	1.0
Beef / Pork Bologna	20.0	0.6	0.6
Poultry Frankfurters	621.5	6.2	6.2
Summer Sausage, Thuringer, Cooked Pepperoni	30.1	30.1	9.5
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	45.7	45.7	18.8
Meat Sticks	30.5	30.5	12.0
Beef Jerky	20.2	20.2	8.0
Uncooked Country Ham	1.1E-02	1.1E-02	1.1E-03
Prosciutto, cappicola, pancetta, basturma	1.6E-02	1.6E-02	5.1E-03

Total Supply Risk Per Year From RTE Products

The total supply risk, interpreted as the total expected number of cases of salmonellosis per year, is simply the sum of the individual product risks. This risk is given in Table 0-5. For this value, we compare the results for including and excluding thermal process safety factors and reheating, as well as the baseline lethality standard scenarios of all 5-log reductions and all 6.5/7.0 log reductions. The number of significant digits has been suppressed in this presentation. Though the model calculates these numbers with more precision, the accuracy of the model does not justify presenting precise estimates.

Table 0-5: Total supply risk, interpreted as the estimated number of cases of salmonellosis per year, from RTE products under each lethality standard considered (All 5-log reduction, Split reductions and All 6.5/7-log reductions). The numbers of cases are shown with and without the inclusion of thermal process safety factors and/or reheating.

Cases per year: All 5-log Reduction		
Include Reheating	Include Thermal Process Safety Factors	
	Yes	No
Yes	50,050	4,954,000
No	92,600	9,211,000

Cases per year: Split Reductions		
Include Reheating	Include Thermal Process Safety Factors	
	Yes	No
Yes	1,010	50,500
No	1,500	93,500

Cases per year: All 6.5/7.0 Log Reduction		
Include Reheating	Include Thermal Process Safety Factors	
	Yes	No
Yes	700	50,200
No	1,100	93,000

Comparison of results

Comparing the risk estimates using the PR/HACCP prevalence estimates it can be seen that the annual number of cases for each scenario is lower. For All log 5 scenario this corresponds to a decrease from 66,000 to 50,050 cases; for the Split scenario this corresponds to a decrease from 1,900 to 1,010 cases per year and for the All 6.7/7 log scenario from 1,100 to 700 cases per year. However, ther percentage contribution of the product categories to the estimates of the total number of cases per year does not change significantly with the adjustment to the input prevalence data. The contribution to the overall estimates of risk are given in Table 0-6.

Table 0-6: The percentage contribution of each product category to the estimate of the number of cases of salmonellosis per year using the FSIS Baseline surveys and the PR/HACCP data for prevalence estimates in raw materials.

RTE Product Category	Risk of Illness by product (after reheating)					
	FSIS Basline Surveys			PR/HACCP 2003 Survey		
	All 5	Split	6.5/7.0	All 5	Split	6.5/7.0
Roast Beef, Corned Beef	$1.5x10^{-5}$	$2.1x10^{-5}$	$3.5x10^{-5}$	$1.1x10^{-5}$	$1.7x10^{-5}$	$2.5x10^{-5}$
Fully Cooked Beef Patties	$1.7x10^{-4}$	$5.8x10^{-3}$	$2.7x10^{-4}$	$7.2x10^{-5}$	$3.6x10^{-3}$	$1.6x10^{-4}$
Cooked Pork (Cooked Ham, Pork BBQ)	$7.0x10^{-6}$	$5.3x10^{-6}$	$8.8x10^{-6}$	$2.9x10^{-6}$	$4.5x10^{-6}$	$6.5x10^{-6}$
Cooked Turkey (non-Deli)	1.9	0.7	1.2	2.0	1.0	1.4
Cooked Chicken (Nuggets, Tenders, non-Deli)	61.8	21.5	36.0	62.4	30.9	44.9
Cooked Poultry Deli Meat	23.5	8.2	13.7	23.8	11.8	17.1
Cooked Chicken Patties	5.4	1.9	3.1	5.4	2.7	3.9
Beef / Pork Frankfurters	0.4	0.4	0.7	0.3	0.4	0.6
Beef / Pork Bologna	0.2	0.3	0.4	0.2	0.3	0.4
Poultry Frankfurters	5.0	1.7	2.9	5.0	2.5	3.6
Summer Sausage, Thuringer, Cooked Pepperoni	0.4	12.9	6.8	0.2	12.0	5.5
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	0.6	19.6	13.5	0.4	18.2	10.9
Meat Sticks	0.6	19.7	13.0	0.2	12.2	7.0
Beef Jerky	0.4	13.1	8.7	0.2	8.1	4.7
Uncooked Country Ham	$2.1x10^{-4}$	$7.4x10^{-3}$	$8.8x10^{-4}$	$8.5x10^{-5}$	$4.2x10^{-3}$	$6.1x10^{-4}$
Prosciutto, cappicola, pancetta, basturma	$3.0x10^{-4}$	$1.1x10^{-2}$	$6.2x10^{-3}$	$1.3x10^{-4}$	$6.2x10^{-3}$	$2.9x10^{-3}$