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Dr. Neal Golden
Risk Analyst
Risk Assessment Division, OPHS
Food Safety and Inspection Service
US Dept of Agriculture
1400 Independence Ave. S.W.
Room 333 Aerospace Center
Washington, DC 20250-3700

[Docket No. 04-001N] Technical Meeting on Risk Assessments of *Salmonella* and of *Clostridium perfringens* in Ready-to-Eat Products; Notice of Availability and Public Meeting; 70 *FR* 15017; March 24, 2005. [*Salmonella* Risk Assessment]

Dear Dr. Golden:

This letter responds to the Food Safety and Inspection Service (FSIS or the Agency) March 2005 request for public comment regarding the "Risk Assessment of the Impact of Lethality Standards on Salmonellosis from RTE Meat and Poultry Products" (the risk assessment). These comments are being submitted jointly by the American Meat Institute, the Food Products Association, and the National Turkey Federation.

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb and veal products and 70 percent of the turkey products in the U.S. Headquartered in Washington, DC, the Institute provides legislative, regulatory, public relations, technical, scientific and educational services to the industry. Its affiliate, the AMI Foundation, is a separate 501(c)3 organization that conducts research, education and information projects for the industry.

The Food Products Association (FPA) – formerly the National Food Processors Association – is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

The National Turkey Federation (NTF) is the only national trade association exclusively representing all segments of the turkey industry. NTF represents over 98 percent of all production, processing and marketing of turkeys in the United States, representing more than $8 billion dollars in sales at the retail and food service levels.

Risk Management Question Posed to the Risk Assessment Team

- 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.

Data Gaps, Uncertainties and Assumptions

- 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.
- 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.
- 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."
- 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.
- 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.

Risk Estimates

- 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.
- 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.

Lethality Calculations

- 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.)

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.

Product Classification and Descriptive Risk Factors

- 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.
    - 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.

- 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.
- 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.
- 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.)
- 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.

- 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.

Pathogen Burden

- 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.

- 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.
- 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.

Compliance with Lethality Standards

- 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.
- 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.

- 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.
- 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.

Growth During Storage

- 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.
- 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.
- 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.
- 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)?

- 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.
- 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).

Impact of Reheating

- 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.
- 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.

- 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.

Risk Characterizations

- 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.
- 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.
- 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."

Ease of Use of the Model

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.

CONCLUSIONS

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. 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.

We appreciate the opportunity to comment on this "Risk Assessment of the Impact of Lethality Standards on Salmonellosis from RTE Meat and Poultry Products." If additional information is needed regarding these comments, please contact us.

Sincerely,

American Meat Institute
Food Products Association
National Turkey Federation

Table 1. Predicted Cases of Salmonellosis from RTE Meat and Poultry /Year Based on the Assumption that Pathogen Burden Per Serving* (In Lieu Of Per Mkg) Is More Reflective of Risk

	BASELINE			PATHOGEN BURDEN PER SERVING		
RTE Product Category	**All 5-log**	**Split**	**All 6.5/7-log**	**All 5-log**	**Split**	**All 6.5/7-log**
Roast beef, corned beef	0.01	0.0004	0.0004	5.30×10^{-9}	1.68×10^{-10}	$1.68E \times 10^{-10}$
Fully cooked beef patties	0.11	0.11	0.003	4.99×10^{-8}	4.99×10^{-8}	1.58×10^{-9}
Cooked pork	0.0046	0.0001	0.0001	2.10×10^{-9}	6.64×10^{-11}	6.64×10^{-11}
Cooked turkey	1,250	13	13	5.71×10^{-4}	5.71×10^{-6}	5.71×10^{-6}
Cooked chicken	40,740	407	407	0.01862	1.86×10^{-4}	1.86×10^{-4}
Cooked poultry deli meat	15,460	155	155	7.07×10^{-3}	7.07×10^{-5}	7.07×10^{-5}
Cooked chicken patties	3,541	35	35	1.62×10^{-3}	1.62×10^{-5}	1.62×10^{-5}
Beef/pork frankfurters	257	8	8	1.17×10^{-4}	3.71×10^{-6}	3.71×10^{-6}
Bologna, liverwurst and other cooked sausages	163	5	5	7.43×10^{-5}	2.35×10^{-6}	2.35×10^{-6}
Poultry frankfurters	3,263	33	33	1.49×10^{-3}	1.49×10^{-5}	1.49×10^{-5}
Summer sausage etc.	244	244	77	1.12×10^{-4}	1.12×10^{-4}	3.53×10^{-5}
Salami, etc.	371	371	152	1.69×10^{-4}	1.69×10^{-4}	6.96×10^{-5}
Meat sticks	373	373	147	1.71×10^{-4}	1.71×10^{-4}	6.71×10^{-5}
Beef jerky	247	247	98	1.13×10^{-4}	1.13×10^{-4}	4.49×10^{-5}
Uncooked country ham	0.14	0.14	0.01	6.20×10^{-8}	6.20×10^{-8}	6.22×10^{-9}
Prosciutto etc.	0.20	0.20	0.07	9.22×10^{-8}	9.22×10^{-8}	2.99×10^{-8}
Totals	**65,910**	**1,891**	**1,130**	**0.03013**	**0.0009**	**0.0005**

*Serving size assumed to be 454 g

Table 2. Reduction in Cases of Salmonellosis from RTE Meat and Poultry/Year Based on the Assumption that the FSIS Verification Data Are More Reflective of Current Prevalence

	BASELINE			REDUCED PREVALENCE		
RTE Product Category	**All 5-log**	**Split**	**All 6.5/7-log**	**All 5-log**	**Split**	**All 6.5/7-log**
Roast beef, corned beef	0.01	0.0004	0.0004	0.01	0.0004	0.0004
Fully cooked beef patties	0.11	0.11	0.003	0.036	0.036	0.001
Cooked pork	0.0046	0.0001	0.001	0.0014	0.00005	0.0005
Cooked turkey	1,250	13	13	989	10	10
Cooked chicken	40,740	407	407	31,230	312	312
Cooked poultry deli meat	15,460	155	155	11,890	119	119
Cooked chicken patties	3,541	35	35	2,714	27	27
Beef/pork frankfurters	257	8	8	128	4	4
Bologna, liverwurst and other cooked sausages	163	5	5	81	3	3
Poultry frankfurters	3,263	33	33	2,509	25	25
Summer sausage etc.	244	244	77	122	122	38
Salami, etc.	371	371	152	184	184	76
Meat sticks	373	373	147	123	123	48
Beef jerky	247	247	98	81	81	32
Uncooked country ham	0.14	0.14	0.01	0.04	0.04	0.004
Prosciutto etc.	0.20	0.20	0.07	0.06	0.06	0.02
Totals	**65,900**	**1,891**	**1.130**	**50,050**	**1,010**	**695**