



December 29, 2005

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street S.W.
Washington, DC 20250-3700

Re: Docket No. 03-005N: Draft FSIS Risk Assessment for *Listeria* in Ready-to-Eat Meat and Poultry Products

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. Our members slaughter and process over 90 percent of the nation's beef, pork, lamb, veal and nearly 75 percent of the turkey produced in the United States. Headquartered in Washington DC, the Institute provides legislative, public affairs, regulatory, scientific and educational services to the industry. Its affiliate, the American Meat Institute Foundation (AMIF), is a separate 501(c) 3 organization that conducts research, education and information projects on behalf of industry. AMI supports the use of risk analysis as a foundation for decision-making on regulatory policy at FSIS. Underlying this support is our belief that a scientifically-based risk assessment is paramount to development of sound inspection programs for the U.S. meat and poultry supply. We strongly believe that this process must be rigorous, credible, transparent and based upon the most reliable, current and accurate information available regarding the hazard of concern.

We appreciate the agency's willingness to accept these supplemental comments to the FSIS Risk Assessment for *Listeria* in Ready-to-Eat Meat and Poultry Products (FSIS *Listeria* Risk Assessment or *Lm* risk assessment) after the formal closure of the comment period. In communication with agency officials, we were informed that FSIS would ***"...consider any comments submitted on this risk assessment regardless of the closing of the comment period."***

AMI previously submitted comments to Docket No. 03-005N, along with several other food industry trade associations, concerning the FSIS *Listeria* Risk Assessment (attachment #1). In those comments the following statement was included:

*“AMI, NCC, NFPA and NTF (the associations) support the use of risk assessments to help provide risk estimates, and to better assess control options. A well-done risk assessment can provide useful scientific advice to risk managers. A desired level of consumer protection can be sought using risk management options. This is a very interactive process where all stakeholders should be involved to gain consensus and create benefits for everyone involved to optimize success. A key to the success of improvements in public health is a thorough and adequate risk assessment. When one considers the multitude of RTE meat and poultry products, the diverse processing operations used to produce these products, and the different interventions used along the production and distribution pathways, the complexity of the risk assessment becomes apparent. The FSIS risk assessors have done a phenomenal job in a short time frame of putting together a model to assess a very complex scenario – the transfer of *L. monocytogenes* in the environment to deli meats. This should be considered the beginning of an interactive process of peer review, submission of additional data, revision and re-review.”*

AMI continues to maintain that this *Lm* risk assessment is a complex document and that FSIS has done a good job in attempting to model a complicated and multifaceted process. Furthermore, AMI believes the concerns expressed and topics raised in the previously submitted comments remain valid, and this supplemental submission is not meant to supersede, but rather to augment previously submitted comments.

As part of the comments previously submitted, AMI and the other food trade associations made the following point as one of the primary concerns:

8. *“The draft risk assessment was not released for “use and experimentation” by interested stakeholders, providing no opportunity for further, “hands-on” analysis of the draft risk assessment before the comment period was over. The FSIS draft risk assessment needs to be reviewed by an independent, expert third-party.”*

Based on our belief that a third party review of the document was warranted, AMIF embarked upon a research project to further evaluate the technical basis of the FSIS *Listeria* Risk Assessment model. AMIF established the following general objectives for this research project:

1. Review the FSIS *Listeria* Risk Assessment document and appendices to identify the model and algorithms used, and determine what level of detail is available for the algorithms, data treatment and assumptions.

2. Review the model and assumptions for accuracy and conduct a sensitivity analysis to identify influential assumptions;
 - a. Review the algorithms in the document for mathematical accuracy,
 - b. Determine whether the algorithms reflect what the document “says” the models does,
 - c. Review the computer code in the FSIS .pdf file to see if it matches the algorithms or model described in the text,
 - d. If possible, assess the impact of assumptions and data gaps, either by setting up a simplified program, by setting up subsections of the program, or by what is known about the statistical properties of the distributions used.
3. Run “what if” assessments with the software to determine mathematical accuracy of algorithms and identify influential assumptions.

AMIF contracted with Dr. Barbara Petersen and the staff at Exponent, Inc. to conduct this technical review. Exponent is renowned and well-respected for their expertise in the field of food-based risk assessments. The final report of the Exponent technical review is attached for your review (Attachment #2). As part of the process of conducting this review, several companies have anonymously submitted data to further inform assumptions that were made in the *Lm* risk assessment. Exponent scientists were able to recreate the computer models provided by FSIS; however, it should be pointed out that the process of obtaining and eventually operating the computer code was rather arduous and very time-consuming. As AMI suggested in previous comments (Attachment #3) to the agency regarding the Risk Analysis Standard Operating Procedures, (Docket No. 03-032N, December 29, 2003), the transparency of the risk assessment can be enhanced by sharing of the computer models developed to conduct the risk assessment:

“AMI requests that FSIS provide risk assessment models in an electronic format that is accessible to the public and may be run on computers and software that is commonly available to the public. Simply providing printed computer code is not sufficient and does not meet the public expectation of transparency in the scientific process. Further, AMI requests that these models be provided well in advance of the process step whereby the agency begins to evaluate risk management options. This will provide the public with an opportunity to fairly evaluate the risk management options using the risk assessment models that have been developed by the agency. This provides the greatest opportunity for true transparency in the entire risk analysis process”.

In brief summary, the Exponent technical review made the following conclusions:

- ❖ In general, the FSIS model works as described in the FSIS report. The formulas used to model the mass balance approach are correctly implemented. The distribution used in the calibration to represent *Listeria* concentrations in deli meats at retail correctly simulates the data in the FDA/FSIS Risk Assessment. The number of iterations used in the risk assessment (1,000,000 iterations) is sufficient for the model output to stabilize. However, the distribution used by FSIS to represent the amount of *Listeria* added during a contamination event is not necessarily the distribution that resulted in the best fit when compared to that based on the data in FDA/FSIS Risk Assessment.
- ❖ Estimates of several model input variables, *i.e.* transfer coefficient, interval between contamination event, event duration, and food contact surface areas can be modified with industry data. These revised parameters can impact the calibrated values of mean and standard deviation for the *L. monocytogenes* added variable. In particular, when industry reported data are used to parameterize the interval between contamination events, the model cannot be calibrated to the FDA estimates of *L. monocytogenes* concentration at retail. This suggests that an alternative parametric distribution for this specific variable may be needed, or there may be other model construct limitations, *i.e.* inability to correlate various input variables (see below)
- ❖ Assessment using the FSIS in-plant model with several revised input variables, generally showed modest decline in the *L. monocytogenes* concentration for RTE products at retail as the food contact surface testing and sanitation effort increases. This trend was observed for the 80th and 99th percentiles and not for the 99.99th percentile. However, the decreases in *L. monocytogenes* concentrations at retail when compared with the base values were only significant for the 60-60-60, 60-60-60 lot, PP, GIP and PP&GIP tested scenarios.
- ❖ Correlation between the duration of a contamination event, the interval between contamination events, or the number of *Listeria* organisms transferred to the FCS is not allowed in the FSIS in-plant model. If such correlations are allowed, intervention such as enhanced cleaning once contamination is detected via FCS sampling to get rid of *L. monocytogenes* niches would reduce the level of *L. monocytogenes* added (now held constant in model) and the duration of a contamination event, and would lengthen the duration between events (as shown with industry reported data). Thus, FSIS's conclusions about the relative effectiveness of various intervention scenarios remain questionable.

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We appreciate the opportunity to comment on this important initiative within the agency. The concept of risk analysis is aligned with industry's desire to have science-based regulations for the meat and poultry industry.

Respectfully submitted,

A handwritten signature in black ink that reads "Randall D. Huffman". The signature is written in a cursive style with a long horizontal flourish at the end.

Randall D. Huffman, Ph.D.
Vice President, Scientific Affairs
American Meat Institute Foundation

cc: J. Patrick Boyle
Mark Dopp
Jim Hodges
Skip Seward
Lynn Morrissette

ATTACHMENT #1

March 5, 2003

Docket No. 03-005N
Department of Agriculture
Food Safety and Inspection Service
Room 102
Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

Re: Docket No. 03-005N: Draft FSIS Risk Assessment for Listeria in Ready-to-eat Meat and Poultry Products

To Whom It May Concern:

The American Meat Institute (AMI), the National Chicken Council (NCC), The National Food Processors Association (NFPA), and the National Turkey Federation (NTF) are submitting these comments on behalf of the meat and poultry products industries. The Food Safety and Inspection Service (FSIS; the Agency) draft risk assessment on *Listeria* in ready-to-eat (RTE) foods (the draft risk assessment) directly affects our members.

AMI, NCC, NFPA and NTF (the associations) support the use of risk assessments to help provide risk estimates, and to better assess control options. A well-done risk assessment can provide useful scientific advice to risk managers. A desired level of consumer protection can be sought using risk management options. This is a very interactive process where all stakeholders should be involved to gain consensus and create benefits for everyone involved to optimize success. A key to the success of improvements in public health is a thorough and adequate risk assessment. When one considers the multitude of RTE meat and poultry products, the diverse processing operations used to produce these products, and the different interventions used along the production and distribution pathways, the complexity of the risk assessment becomes apparent. The FSIS risk assessors have done a phenomenal job in a short time frame of putting together a model to assess a very complex scenario – the transfer of *L. monocytogenes* in the

environment to deli meats. This should be considered the beginning of an interactive process of peer review, submission of additional data, revision and re-review.

The risk assessment has two components, an in-plant model that links to the updated FDA/FSIS risk-ranking model, which will not be released until this summer. Information on the in-plant model was released on February 14 and more specific risk assessment results were presented at a public meeting February 26 and made available in hard copy. Even with this presentation, there is a lack of transparency in how this risk assessment arrives at its findings, in part because the revised FDA/FSIS risk-ranking model is not yet available and because there has been no external use of the models. There has been very limited time for any review of these complex models and the data and results on which FSIS is basing its findings and, presumably, rulemaking activity. Our members have looked at the in-plant model and have identified a number of problem areas with respect to its assumptions and its application.

We recognize that in all risk assessments there must be assumptions made, especially when data are limited, and there are always alternative assumptions that can be applied. Caution should be taken in extending extrapolations from single events or single scientific studies to such a complex universe of RTE meat and poultry products. The model focuses on deli meat, but the risk management questions, the findings and, presumably, the application of these are for all RTE meat and poultry products. If data are appropriate for a single class of products, e.g., deli meats, then the focus of the risk assessment should be on that class, understanding that future research and risk assessments can be directed toward another class of products, as well as closing the data gaps for the draft deli meat risk assessment. Throughout this document there is reference to RTE meat and poultry products. We urge FSIS to revise the language to clarify when a statement appropriately applies to all RTE products and when it should be limited to deli meats. In particular, the title should refer to deli meats and not RTE meat and poultry products. When applying the findings, the Agency should carefully consider whether the risk assessment supports application to the product in question or whether they should be limited to certain classes of products such as those that support growth of *L. monocytogenes*.

Ultimately there should be more focus on how the risk assessment applies to the risk from products that do not support growth of *L. monocytogenes* as a result of reduced pH, water activity, or frozen storage, in addition to inhibitors.

The associations believe that environmental monitoring to find *Listeria* and, when a positive result is found, taking immediate diagnostic and corrective actions followed by verifying efficacy is the best means of controlling *Listeria*. The success of the corrective action will determine many events, such as the duration of the problem, the concentration of any contamination, the type of sampling and testing protocols needed, and the actions needed to ensure that the source of contamination does not reoccur. The key is having programs that aggressively look for *Listeria* in the environment and preventing the establishment of *L. monocytogenes* in niches by taking action on these positives.

Whether or not the contamination is from a niche or other similar harborage point or from a transient source, the contamination may or may not have the potential to directly impact food contact surfaces or product. These considerations should be taken into account during the development of any risk assessment involving RTE meat and poultry products.

PROBLEMATIC ISSUES IN THE DRAFT FSIS RISK ASSESSMENT

The associations find the following general issues problematic in the draft risk assessment, and strongly urge FSIS to revisit these issues before using the draft risk assessment for any policy or regulatory action. These issues are described in some detail in the following discussions.

1. The model assumes that the *L. monocytogenes* contamination comes from a reservoir (a niche, or harborage site) in the plant, without consideration for contamination from sporadic positives or contamination arising at retail.
2. The draft risk assessment fails to consider the operational parameters associated with processing deli meats and other RTE meat and poultry products. These factors are significant to the discussions of product contact surfaces and other such issues raised as major considerations in the draft risk assessment. Failure to examine the operational

factors in detail greatly reduces the value of the draft risk assessment in delivering an appropriate and useful risk estimate.

3. The draft risk assessment makes unrealistic estimates of the efficacy of sanitation and corrective actions that are critical to the success of on-going control of *Listeria* in processing environments. The efficacy of post-packaging treatments is also unrealistically low.
4. All current, relevant scientific literature and industry data have not been integrated into the draft risk assessment. There is an over-reliance on single sets of data to develop the draft risk assessment when, in some cases, additional data were available. The draft risk assessment does not provide all references cited in the document.
5. In many cases the draft risk assessment fails to provide adequate support for the assumptions, variability and uncertainty for the model parameters. In some cases the draft risk assessment appears to use unrelated and inappropriate data as bases for its mathematical calculations, greatly decreasing the potential validity of the draft risk assessment, particularly in relation to the transfer coefficient. Furthermore, data and opinions unrelated to the scope of the draft risk assessment are included.
6. The draft risk assessment should describe in more detail the limitations of sampling and testing programs to detect low level prevalence of *Listeria*, whether on food contact surfaces or in RTE products. Oversimplification leads to unscientific conclusions relative to sampling and testing as a means to control *Listeria*, particularly in operations where *Listeria* control programs are very effective in reducing the likelihood of *Listeria* being present, or persisting, in the processing environment.
7. The draft risk assessment should provide more consideration to the numerous intervention technologies in use to help control *Listeria*, particularly where *L. monocytogenes* is not a hazard reasonably likely to occur because of control procedures addressed in the Sanitation SOPs and other programs, as acknowledged in the draft risk assessment by FSIS.
8. The draft risk assessment was not released for “use and experimentation” by interested stakeholders, providing no opportunity for further, “hands-on” analysis of the draft risk assessment before the comment period was over. The FSIS draft risk assessment needs to be reviewed by an independent, expert third-party.

The model assumes that the *L. monocytogenes* contamination comes from a reservoir (a niche, or harborage site) in the plant, without consideration for contamination from sporadic positives or contamination arising at retail.

While the scenario of an in-plant reservoir presents the highest risk of listeriosis if the strain is virulent, it must be recognized that most findings of *Listeria* in a plant represent transient, sporadic positives. Rarely do these positives for *Listeria* spp. or *Listeria*-like organisms (even on food contact surfaces) lead to detectable *L. monocytogenes* in product. In addition, the risk assessment assumes that all contamination at retail arose from contamination at the manufacturing plant. Data submitted to this docket (dated February 24, 2003) in a pre-publication galley (Gombas, et al., 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Protection*, in press) demonstrates this is not the case.

The draft risk assessment fails to consider the operational parameters associated with processing deli meats and other RTE meat and poultry products. These factors are significant to the discussions of product contact surfaces and other such issues raised as major considerations in the draft risk assessment. Failure to examine the operational factors in detail greatly reduces the value of the draft risk assessment in delivering an appropriate and useful risk estimate.

The issues surrounding the impact of operational parameters on the draft risk assessment are discussed elsewhere in this document; however these are significant enough to state them collectively here. Operational parameters will affect the following elements of the draft risk assessment and should be developed more completely, in partnership with industry, before the risk assessment is used for policy decisions or regulatory action.

- Duration of contamination persistence,
- Time between contamination events,
- Risk reduction through interventions,

- Extent of transfer between food contact surfaces and products,
- The potential for harborage in an establishment,
- The area of product contact surface,
- The potential for growth of contamination on products,
- The amount of product produced in a lot,
- Effectiveness of corrective actions,
- Effectiveness of sanitation,
- The likelihood of contamination in a plant, regardless of size, and
- The sampling and testing program implemented in the establishment.

Furthermore, the model assumes that, for most of these operational parameters, they apply to all plants equally regardless of plant size. We believe the model can be improved by using different approaches and assumptions for different size plants (large, small and very small). The assumptions need to reflect the different practices that take place in plants, which are often more stringent in large establishments than in less sophisticated plants, including sanitation practices and their efficiency, testing protocols for the environment and product, food contact surface area tested, frequency of positives, and interventions, including the use of inhibitors and post-packaging pasteurization. With the new Directive in place and the increased sharing of data, much of this information will be available for use in a revised risk assessment.

The draft risk assessment makes unrealistic estimates of the efficacy of sanitation and corrective actions that are critical to the success of on-going control of *Listeria* in processing environments. The efficacy of post-packaging treatments is also unrealistically low.

The draft risk assessment states on page 21 that there is “limited data on the effectiveness of sanitation in reducing the level of *Listeria* species on food contact surfaces.” The proposed assumptions of 75% for daily sanitation, obtained by expert elicitation within FSIS, would seem to be out of step with FSIS inspection data on the number of production lines that are acceptable for daily operations every production day. The basis for the 75% efficiency does not appear to

be as well grounded in available data as possible. If the end of the day sanitation were only 75% effective, there would be major spoilage problems in meat and poultry products and much shorter shelf lives. It would not be unrealistic to assume, based on industry experience, 99 to 99.9% efficiency for base sanitation. Likewise, setting 95% as the effectiveness of the “enhanced cleaning” needs supporting data or better expert elicitation. It would be more likely that the efficacy would be closer to 100% since establishments verify the efficacy of their enhanced cleaning and sanitation before production resumes, or before product is released. FSIS could improve their understanding of the efficacy of sanitation by participating with industry in the evaluation of the sanitation and corrective actions.

The 90 to 95% efficiency for interventions such as high pressure processing and post-packaging heat treatments are also low. These processes are designed to kill levels of *L. monocytogenes* that would arise from environmental contamination. If the organism is not there, there is no risk. The model should reflect close to 100% effectiveness for this parameter.

The model should be revised and re-run using these more realistic parameter inputs.

All current, relevant scientific literature and industry data have not been integrated into the draft risk assessment. There is an over-reliance on single sets of data to develop the draft risk assessment when, in some cases, additional data were available. The draft risk assessment does not provide all references cited in the document.

On pages 12 and 13, FSIS appears to use a single in-depth verification review to predict the frequency of a contamination event. This is an unpublished report, and thus, likely has not been peer-reviewed, yet it appears to be accepted as the sole basis for estimating the time between contamination events. Moreover, since this information is not publicly available, it is not clear how the data were obtained or how representative these data are for other establishments, even those with a harborage event. In fact, the risk assessment notes that it is not known how representative the data are compared to other plants. The data are fit to a lognormal probability

plot, as are the data for duration. We would like to see all distributions as cumulative frequency distributions such as in Figure 10, as these are more readily interpretable than Figures 2 and 3.

It is important that FSIS not use these data in isolation to predict the frequency of a contamination event. The data has not been reviewed, and represents a single event where it was possible that *Listeria* control was not adequately practiced. Data are needed for the frequency of contamination events from establishments where an effective *Listeria* control program is in place; these data should be more readily available under Directive 10,240.3, where establishments share their *Listeria* control programs with FSIS.

A statement on page 14 indicates that the data from this IDV do not tend to exhibit the duration seen in other data, but it is not clear what these other data are (the Tompkin data?). If the data from the IDV are not consistent with other data, then the assumption that they accurately represent frequency may also be in question.

The use of single data sets to generate conclusions occurs in the prediction of the duration of an event as well (page 15). The data in the model for duration of an event are based on published data by Tompkin. The data in the publication indicate that 4.9% of the data sets represent three consecutive positives. Industry has presented additional data showing this percentage can be much lower (a fraction of a percent), but the data were not included. Moreover, without subtyping data (e.g., PFGE, ribotyping) the questions as to whether or not the same *Listeria* strain was isolated in all situations and how representative the data used are of contamination persistence remain to be addressed before these data should be considered as sufficient to establish a timeframe for duration. It is very likely that different operational and sanitation practices, product type, corrective actions and other factors greatly influence duration.

Footnote #9 on page 4 provides what seems to be an FSIS opinion, i.e., “may indicate that the establishment has a serious sanitation problem,” without a scientific, published report used as a reference. This type of speculation seems inappropriate in a risk assessment document, particularly if the data supporting such a claim are not provided for review. The NFPA citation in footnote #11 on page 5 refers to comments submitted to the Agency; it is not included in the

list of references nor is a complete citation given in the footnote. Similarly, footnotes 7 and 12 refer to submitted comments. Comment dates and docket number should be provided.

In the first paragraph in the section entitled “Model Overview” on page 6, there is a statement that “...the fraction of *Listeria* that transfer from the food contact surface to the lot varied from lot to lot, but fell within a limited range and matched the probability distribution of the available data.” The data referenced is not specified, nor is there a discussion of how representative these data are for all RTE meat and poultry products, establishments, and operating systems.

The model assumes there are two shifts per day for 30 days per month. FSIS conducted a survey of RTE plants that should provide more accurate data on shifts per day and production days per month by plant size. It is not clear why these data were not used, since production volumes by plant size were apparently used in the model.

It is important that a draft risk assessment is transparent; and part of this transparency means having all data used properly referenced. Where the risk assessors have relied on expert elicitation, this should be explicitly stated. The Midelet and Carpentier (2002) reference is not provided in the reference list at the end of the document. Relevant data from Dr. John Luchansky, ARS, while perhaps used in part, is not referenced; although it is our understanding that the peer-reviewed article is now in-press. Furthermore, data on interventions, such as the use of lactate and diacetate to prevent growth during distribution, which has been published (Seman et al., 2002. Modeling the growth of *Listeria monocytogenes* in cured ready-to-eat processed meat products by manipulation of sodium chloride, sodium diacetate, potassium lactate and product moisture content. *J. Food Protection* 65: 651-658), is not included. Attached to this document is an example of the use of a commercial formula of lactate and diacetate to control the growth of *Listeria* at 40 °F, with a second attachment demonstrating the benefits to public health of reducing the concentration of *L. monocytogenes* in product consumed by the consumer.

The footnote (#8) on page 4 of the draft risk assessment that defines indicator organisms uses a definition that seems out-of-step with current accepted definitions for indicator organisms; the

National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2002)¹ defines indicator organisms as those organisms that define a state or condition, in contrast to index organisms that correlate with the frequency or concentration of another organism of concern.

In many cases the draft risk assessment fails to provide adequate support for the assumptions, variability and uncertainty for the model parameters. In some cases the draft risk assessment appears to use unrelated and inappropriate data as bases for its mathematical calculations, greatly decreasing the potential validity of the draft risk assessment, particularly in relation to the transfer coefficient. Furthermore, data and opinions unrelated to the scope of the draft risk assessment are included.

Although it is recognized that assumptions may be necessary in risk assessments, it is a standard practice that the effects of the assumptions on the final risk estimate need to be stated clearly. The draft risk assessment does not clearly define the effects of the many assumptions made throughout the draft. We recommend that whenever assumptions are being made full disclosure and analysis of the effects of such assumptions be presented in the draft risk assessment. The draft risk assessment could do more to identify, describe and, where possible, quantify sources of variability and uncertainty that will affect the validity of the outputs of the draft risk assessment.

In a technical draft risk assessment such as the one under discussion, it would be advisable to prepare a table of all of the assumptions being made in the risk assessment. Table 1 does do this to a limited extent, but does not provide adequate description of the effect of these assumptions on any final risk estimate. Some of the assumptions for which the associations believe it is necessary to conduct a more in-depth analysis include the following:

- The assumptions that interventions do not change the time between contamination events, the duration of an event or the amount of contamination transferred from a food contact surface do not appear to be valid, and would appear to have a

¹ NACMCF. 2002. Response to Questions posed by FSIS regarding performance standards for ground beef products.

significant effect on any risk estimate. Interventions (as described by FSIS in the draft risk assessment) may include routine operations and corrective actions such as routine and focused sanitation, respectively, that would greatly impact time, duration and concentration. Focused sanitation and other interventions can eliminate the harborage, thereby ending the contamination event. Even in instances where the harborage is not eliminated, depending on the nature of the harborage the intervention could reduce the numbers of *L. monocytogenes* in the niche, delaying contamination of food contact surfaces, thereby increasing the time between events.

- The assumption that plant size affects food contact surface area, and thus contamination events, fails to consider that plant size is much less relevant than factors such as process line configuration, *Listeria* control program implementation, and packaging technology.
- There are no assumptions provided for transfer from food contact surfaces, even though product configuration (e.g., stacked, shingled) and surface physical characteristics could affect transfer. On page 7, it is stated that the model assumes *Listeria* species are evenly distributed across food contact surfaces, and that *L. monocytogenes* is evenly distributed within product, i.e., “the variability across a food contact surface or across a lot is not accounted for in this model.” While such assumptions and dismissal of variability may simplify the model, these assumptions are clearly not valid, based on operational parameters, food product design and formulation, product packaging processes, and the process of contamination, e.g., from niches or other harborage sites or from transient contamination. The risk assessors stated that they have no data to model a different assumption, yet in other instances where data were lacking, they used expert elicitation. We urge the Agency to similarly model alternatives to uniform distribution on food contact surfaces and in product.
- The assumption that prevalence distribution is similar to concentration distribution needs additional validation. Industry experience has shown that contamination, when it occurs, may be sporadic, in clumps and not routinely occurring at some consistent frequency.

- The assumption that the growth multiplier should be fixed at one log for all lots is an oversimplification and will have an effect on the risk estimate. Cold chain management, distribution time, product formulation, microbiological species and other considerations need to be integrated into the assumption of growth, with full understanding of how each of these impacts any potential growth during transportation to retail.
- The model uses an average transfer coefficient based on data in the literature for three different product surfaces but does not include some critical data provided by industry. Transfer coefficient is discussed in more detail below.

One of the weaknesses of the draft risk assessment is the use of unrelated and inappropriate data for determination and estimation of the transfer coefficient. A review of the references cited in this section indicates that the transfer data from these citations are based on vehicles or vectors, and products unrelated to the risk assessment under development. In particular, the Midelet and Carpentier study apparently used raw beef, clearly different from RTE product. The standard deviation for the transfer coefficient was derived from a study using a Gram-negative organism and may not be applicable for *L. monocytogenes*. The study also modeled transfer in food service operations. There are no data to demonstrate that raw meat transfer is similar to RTE meat, that food service operations parallel production of RTE meat and poultry products, and that gloved hands are similar to food contact equipment surfaces. In the food-processing environment, there are many factors that would impact transfer including the type of point source contamination (e.g., niche in equipment or gloved hand), the type and physical nature of the RTE food product, and the type of product assembly, if any, necessary before packaging. An example of articles that may be of value for assessing transfer of contamination is that of Lunden, Autio and Hannu (Transfer of persistent *Listeria monocytogenes* contamination between food-processing plants associated with a dicing machine. *J. Food Protection* 65 (7): 1129-1133, 2002). Moreover, the model apparently ignores data provided to the Agency from a study on transfer sponsored by industry and conducted by the University of Georgia showing that there is no transfer to finished product at low levels found on product contact surfaces. The rationale for this was that the data were presence/absence data, rather than quantitative. However the data

provide very useful sequence of contamination information and demonstrates that where there is no continuing source of contamination the duration of the contamination event is limited.

Although the risk management questions do not relate to non-food contact surfaces, as stated on page 5, the footnote #13 on this page, discusses non-food contact surfaces such as air, floors, machine parts and walls. This section does not seem relevant to the draft risk assessment or the specific risk management questions. If it is to be included, the data from the in-depth verifications should be provided; and it should be clear as to whether these data have been published and are peer-reviewed.

The draft risk assessment should describe in more detail the limitations of sampling and testing programs to detect low level prevalence of *Listeria*, whether on food contact surfaces or in RTE products. Oversimplification leads to unscientific conclusions relative to sampling and testing as a means to control *Listeria*, particularly in operations where *Listeria* control programs are very effective in reducing the likelihood of *Listeria* being present, or persisting, in the processing environment.

In the discussion of the model parameters (pages 7 and 8), the conceptual model (pages 9 and 10, Figure 1), and the sources of data and assumptions (pages 12 and 13, Table 1), microbiological testing is presented as a tool to accept or reject product, and to establish the acceptability of food contact surfaces. In the outputs given on page 26, testing is given as an example of an intervention. It has become well established that microbiological testing is not an intervention, as is the use of chemical inhibitors, for example. In order to define sampling and testing programs, it is necessary to define the prevalence of the pathogen, the sensitivity and selectivity of the assay, and the number of samples being taken from a lot. With several underlying assumptions (e.g., homogeneous distribution of the pathogen), these inputs will provide a probability of excluding defective lots. These analyses should be incorporated into the draft risk assessment, clarifying the expected level of control with a sampling and testing protocol given in the draft risk assessment model.

Evidence should be given to support the assumption of 75% efficacy of finding one cell, given its presence in the sample. Furthermore, we recommend that a comparison be made between model results and sampling statistics published by ICMSF (*Microorganisms in Foods 7*, 2002). For example, published tables and statistical sampling curves show that with a lot containing 2% positives if three samples are taken there is a 94% chance on not detecting a positive and there is a 30% chance of missing a positive even when 60 samples are taken. It is not clear whether the model generates results consistent with these published statistics.

The draft risk assessment should provide more consideration to the numerous intervention technologies in use to help control *Listeria*, particularly where *Listeria monocytogenes* is not a hazard reasonably likely to occur because of control procedures addressed in the Sanitation SOPs and other programs, as acknowledged in the draft risk assessment by FSIS.

The draft risk assessment states “FSIS acknowledges that there may certain processing operations in which *L. monocytogenes* is not a hazard reasonably likely to occur.” It continues to state that verification testing of food contact surfaces may be appropriate. Although there is FSIS recognition of operations where *L. monocytogenes* is not a hazard reasonably likely to occur, it is not clear how this consideration integrates into the model, since it impacts the total volume of RTE meat and poultry products that potentially could contain *L. monocytogenes*.

The draft risk assessment was not released for “use and experimentation” by interested stakeholders, providing no opportunity for further, “hands-on” analysis of the draft risk assessment before the comment period was over. The FSIS draft risk assessment needs to be reviewed by an independent, expert third-party.

It would be advantageous to share the draft risk assessment model with all stakeholders in order to obtain a more complete review of the draft risk assessment. Requests for the model to date

have been denied, although the in-plant model is apparently designed to be user friendly, allowing users to easily change data required to run the model (page 19).

CONCERNS REGARDING OUTPUTS AND FINDINGS

The model was developed to address specific risk management questions that were based in part on a rule proposed in February 2001. We are concerned that the findings from the risk assessment may be inaccurate and misleading given the concerns about assumptions in the risk assessment. Moreover, companies may be required to change practices that have been shown to be effective in addressing contamination from *L. monocytogenes* in their facilities because their practices were not considered in the model. The model does not consider the impact of environmental (non-food contact) testing on preventing contamination of food contact surfaces and product. The risk assessment could be interpreted as suggesting that testing one food contact surface or testing one product sample for each lot produced could be an effective approach for reducing *L. monocytogenes* concentrations at retail (Figure 15, page 32), when industry experience, and many published papers on microbiological sampling and testing, would not support this.

We would not disagree with the findings that post-packaging interventions or formulations with growth inhibitors can significantly reduce levels of *L. monocytogenes* at retail – the risk assessment, even with inaccurate assumptions simply reinforces industry’s belief that where such interventions are available, practical, have been validated, and can be applied to a specific product, they should be used. The model predicts greater public health impact when post-packaging treatments and growth inhibiting formulations are used together. We believe this is a result of improper assumptions during the modeling (the 90 to 95% efficiency of each of these interventions) and recommend re-addressing this issue after revising the inputs as we have suggested in our comments. This is critical, since this combination was the only scenario tested where the estimated total number of deaths fell below 100 per year (page 33), and could result in the Agency implementing overly stringent requirements. In fact, the risk assessors did run one scenario in which they assumed post-packaging treatments were 99% effective in comparison to

95% effective, with a significant increase in lives saved, approaching that of the combination of post-packaging intervention and growth inhibitors.

The risk assessment conclusion that the likelihood of finding RTE product positive for *L. monocytogenes* greatly increases when food contact surfaces test positive for *Listeria* spp. is not consistent with industry experience. This conclusion may follow from the assumptions that there is a reservoir in the plant and that the contamination event is ongoing, along with the assumptions of 75% efficiency in finding a positive food contact surface and product sample (given uniform distribution); however, it is not clear that this would hold true when contamination is a transient event with low numbers of organisms, resulting in limited contamination unlikely to be detected.

The summary statement that the frequency of contamination of food contact surfaces with *Listeria* spp. encompasses a broad timeframe with a one-week duration is erroneous in most contamination events. It may be a reasonable assumption in a harborage situation; however, a number of companies have presented data to FSIS that indicate harborage events are rare occurrences when an establishment follows a validated *Listeria* control program. In fact, this statement does not belong in the summary, as it represents inputs to the risk assessment, not outputs.

It is interesting to note that the frequency of testing in the proposed rule would have resulted in only a small reduction of risk, according to this risk assessment. Clearly the recent criticism of the Agency for not implementing the rule, thereby preventing recent illnesses and deaths, is unfounded. This underscores the importance of conducting risk assessments to support policy decisions.

While industry supports the need to conduct environmental and food contact surface testing and take action when positives are found, we do not believe the summary statement that increased frequency of food contact surface testing and sanitation leads to a proportionally lower risk of listeriosis is completely accurate, given the issues we have with some of the assumptions made in the risk assessment.

The risk assessment conclusion about combinations of interventions being much more effective than single interventions may be partially correct; however, we have already noted concerns about this conclusion with respect to combining post-packaging treatments (e.g., heat, irradiation) with growth inhibiting formulations. We agree that combining environmental testing with other interventions such as post-packaging lethality treatments, inhibitors or freezing products, whose effectiveness is generally predicated on low levels of *L. monocytogenes*, can enhance our efforts to reduce the risk of illness or death from *L. monocytogenes*.

FINAL COMMENTS

The associations believe that the draft FSIS risk assessment model is a beginning, not an end. The draft illustrates the many deficiencies in the data available for an accurate and useful risk assessment. The associations support the continued development of data to achieve useful and defensible risk estimates that would allow appropriate risk management options to be proposed. The associations believe that the most effective means to achieving the public health goals for RTE meat and poultry products is to involve all of the stakeholders in the discussion of risk assessments and risk management, and welcome the opportunity to participate even more actively in the effort. Thank you for the opportunity to comment on this important draft risk assessment.

Sincerely,

American Meat Institute
National Chicken Council
National Food Processors Association
National Turkey Federation

Food and Chemicals

Exponent[®]

**Review of FSIS Risk Assessment
for *Listeria monocytogenes*
in Deli Meats**

**Review of FSIS Risk Assessment
for *Listeria monocytogenes*
in Deli Meats
Project No. WD00822.000**

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Acronyms and Abbreviations

AMI	The American Meat Institute
FSIS	Food Safety and Inspection Services
LM	<i>Listeria monocytogenes</i>

1 Introduction

At the request of the American Meat Institute (AMI), Exponent conducted a review of the FSIS Risk Assessment for *Listeria monocytogenes* (LM) in Deli Meats. As described in the FSIS report,¹ the model is a dynamic in-plant Monte Carlo model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and LM in deli meats at retail.

The in-plant model incorporates several parameters, such as plant size, interval between contamination events, duration of contamination events, transfer coefficient, cleaning efficiency, contamination event levels, food contact surface testing, product testing, sanitation, pre- and post-packaging interventions, and the effect of growth inhibitors etc. and generates a distribution of concentrations of LM in deli meats at retail. Data from the literature or information provided by industry or expert opinion were used to estimate the parameters of the model, except for the number of LM transferred to food contact surface during each lot production. This parameter was estimated in the calibration of the base model. Specifically, the distribution used to represent the variable LM concentration (cfu/cm²) added to the food contact surface (during a contamination event) was changed until the model provided a distribution of LM concentration that is similar to the distribution of LM at retail that was used in FDA's risk assessment. The following assumptions were made in the calibration of the FSIS in-plant model:

- All distributions for the model input variables (except for the LM added variable) were held constant, hence assumed as having been correctly parameterized.
- None of the plants have in place post-processing interventions, which can reduce the concentration of *L. monocytogenes* in the RTE lot or use growth inhibition product formulation and packaging.

¹ Gallagher, D.L., Ebel, E.D, and Kause, J.R. FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats, May 2003.

In subsequent “what if” and “sensitive analyses,” the distribution of LM concentration added that were derived from the calibration step was used. Conclusions based on these subsequent analyses could be misleading if any of the input variables were incorrectly parameterized. Thus, if some of the assumptions used in the base model were incorrect then the estimated distribution of LM concentration added to the food contact surface would be biased. The direction of bias would be dependent the direction of bias of the input variables. Further, if inaccurately calibrated, the LM concentration variable could have an impact on the results of subsequent assessments.

In the review of the FSIS in-plant model, Exponent conducted analyses aiming at:

1. Determining if the model works as described
2. Examining the impact of alternative model input assumptions on:
 - a. Model calibration, and
 - b. Intervention options and conclusions

2 Model/Algorithm Checks

Exponent checked the following model/algorithm:

1. Whether the model incorporates correlations between plant size, lot produced and FCS area, as stated in the report
2. Whether the mass balance approach indeed functions as described in the report
3. Whether the distribution of listeria contamination at retail used in the model is indeed similar to that summarized in FDA's assessment
4. What minimum number of runs is needed to stabilize estimates
5. Whether the distribution of added listeria contamination used by FSIS is the "best" distribution

Based on our examination, the following was found:

2.1 Correlations between plant size, lot produced and FCS area

The model assumes that 48% of all ready-to-eat deli meats and frankfurters are produced by "Large" plants, 48% by "Small" plants, and the remaining 4% by "Very small" plants. These three categories of plants are assumed to have different distributions of lot sizes (i.e., amounts produced per shift), and food contact surface area sizes. The model does not explicitly incorporate a correlation between plant size, lot produced and FCS area. However, the parameters of the uniform distribution used to represent the FCS area for "small" and medium" plants are proportionally smaller than those used for the large plants. The values used for the smaller plants are derived by multiplying the values used for large plants by the ratio of the mean values used for the distribution of lot sizes. Figure 1 illustrates the resulting distributions for the three size plants, while Figure 2 displays the distributions for very small plants. Figure 1 indicates that the parameters used to represent the distributions of lot size and FCS are correlated to the plant size, however, Figure 2 indicates that there is no correlation between lot size and FCS within plant size category, for instance the model assumes that it is possible to have plants with

FCS of about 23,000 cm² and 140,000 cm², respectively, produce lots of size 20,000 lbs and 2,000 lbs, respectively.

Figure 1: Distribution of food contact surface area and lot size for all plants

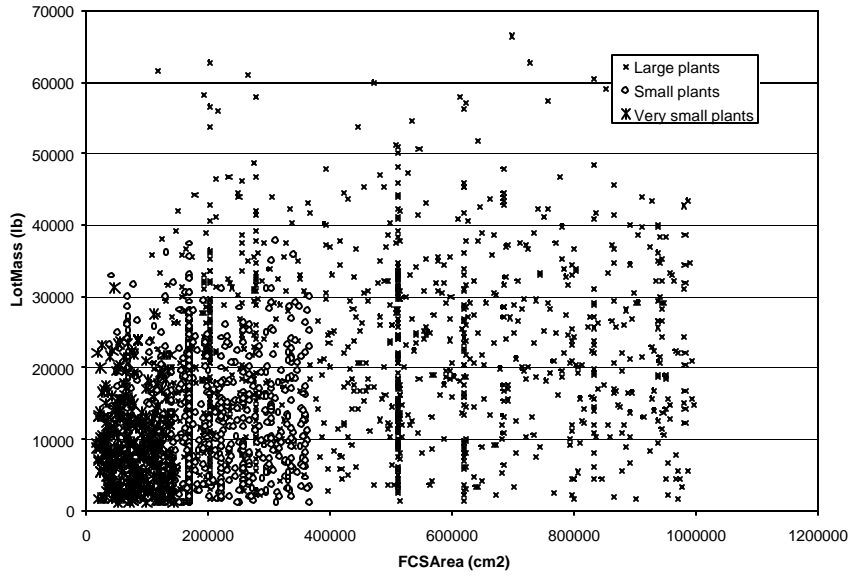
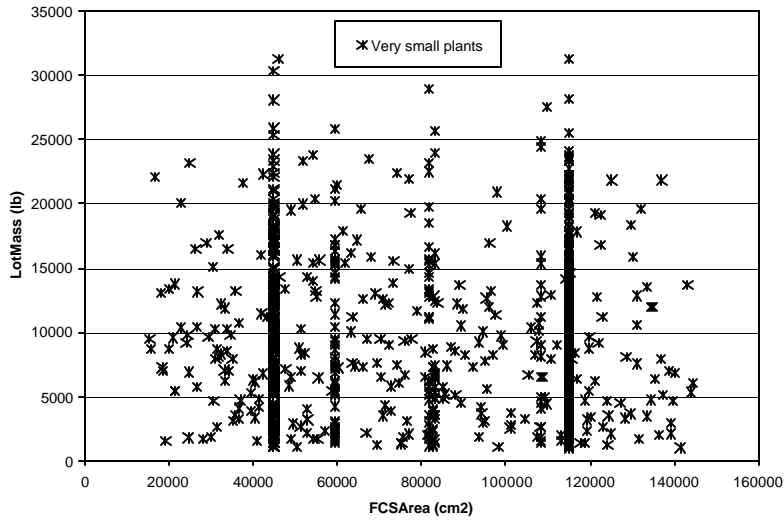


Figure 2: Distribution of food contact surface area and lot size for very small plants



2.2 The mass balance approach is correctly implemented in the model

Exponent ran the model and “dumped” the data from that run and independently verified that the total number of organisms can change due to growth of new organisms, die-off from sanitation, or transfer from external sources such as harborage sites. Specifically, the formulas presented for calculating the level of contamination at the end of a lot (page 18), for calculating the amount transferred to the product (page 19), and for adjusting for post processing interventions (page 20) and growth inhibition (page 21) appear to be correctly implemented in the program.

2.3 The distribution of *Listeria* contamination at retail used in the model is similar to that summarized in FDA’s assessment

As mentioned above, the FSIS model generates a distribution of concentrations of LM in deli meats at retail. In the calibration of the base model, the updated FDA/FSIS exposure assessment for deli meats for LM in RTE products are used as calibration values for *Listeria* added during contamination event. Thus, it is important to confirm that the distribution used by the model accurately represents the data that were used in FDA’s risk assessment.

In the case of deli meats, the FDA risk assessment used data from 61 studies conducted in the US as well as other countries. Data from the various studies were assigned different weights depending on when they were conducted and in which geographical region. Three hundred contamination curves were generated based on these data, each following a lognormal distribution.

In FSIS’s model, a single set of parameters was estimated by calculating the average of the means and standard deviations of the 300 sets of parameters generated by FDA. Thus, a lognormal with mean: -8 and standard deviation of 3.5 was used by FSIS (page 75 of FSIS report).

Exponent used the data from the 61 studies and the same weighting scheme and estimation approach as that used by FDA/FSIS assessment to generate 300 contamination curves, and confirmed that these distributions were similar to those generated by FDA/FSIS. We then confirmed that the average mean and standard deviation for these 300 distributions were similar to the parameters assumed in FSIS model, and that the estimated percentiles used in the FSIS model do indeed come from a lognormal distribution using these parameters.

2.4 Minimum number of runs needed to stabilize estimates

The FSIS model uses Monte Carlo simulation to generate estimated distributions of listeria concentrations in deli meat products. The report states that results were based on runs of 1,000,000 lots, although early calibration runs were based on fewer lots.

The “log SSR” statistics, which is defined as:

$$\sum [\text{Log}_{10}\text{FDA}(i) - \text{Log}_{10} \text{Generated}(i)]^2 ,$$

where (i) indexes 8 upper percentiles (80th, 85th, 90th, 95th, 99th, 99.5th, 99.9th and 99.99th) is used by the FSIS model to compare the “fit” of FSIS simulated distribution of LM in deli meat at retail relative to the updated FDA/FSIS distribution of LM in deli meat at retail. Hence the Log SSR was used to confirm the number of iterations needed for the model to stabilize.

Exponent ran multiple sets of simulations of sizes 50000, 100000, 500000 and 1000000 iterations to assess the minimum number of runs needed to stabilize estimates and to confirm that the 1000000 iterations used by FSIS are sufficient. The results of these runs showed little changes in estimates derived from multiple simulations of size 500,000 each, indicating that the 1,000,000 iterations used by FSIS are indeed sufficient.

2.5 The distribution of added listeria contamination used by FSIS is not necessarily the “best” distribution

The Log SSR (as described above) was used to describe how well the distribution of LM concentration on deli meat at retail characterizes that based on the FDA/FSIS revised exposure assessment as the result of a given combination of mean and standard deviation for the LM added variable.

The FSIS calibration run resulted in final estimates of the LM species added to FCS with a mean on \log_{10} scale of -6cfu/cm^2 and a standard deviation on the log scale of 3.5 cfu/cm^2 , as having the best “fit.” We conducted similar calibrations by holding all other model input variables at their base values and changing the mean and standard deviation of the added LM variable. We used the Log SSR to assess how well the fitted distribution of LM concentration compare to that based on the FDA/FSIS revised exposure assessment. The following log SSR’s were obtained for runs using various combinations of mean and standard deviation values for the added LM parameter based on 500,000 iterations runs:

Table 1. Log SSR for various combinations of mean and standard deviation (on \log_{10} scale) for the add LM variable, FSIS Base Values

Log SSR	CEAddStdDev								
CEAddMean	2.5	2.7	2.9	3.1	3.3	3.5	3.7	3.9	4.1
-8	118	93.4	75.4	59.7	41.7	31.4	22.3	15.9	11.8
-7.5	91.1	69.9	53.4	39.9	27	17.9	12.2	8.45	9.15
-7	64.7	47.8	34.6	24.2	16	9.03	4.46	4.48	8.05
-6.5	45.7	29.3	18.4	11.5	5.11	3.13	2.76	5.23	11.4
-6	29.5	17.7	8.81	4.08	1.26	1.16	5.21	11.3	20.3
-5.5	16	9.85	3.65	0.495	0.854	3.29	9.88	20.5	30.3
-5	8.74	3.05	0.621	0.79	4.45	9.02	20.6	27.5	44.3
-4.5	4.27	1.86	1.99	5.83	11.5	21	34.5	42.1	67.6

The FSIS final estimates of the LM species added to FCS is a lognormal distribution with a mean and standard deviation on \log_{10} scale of -6 and 3.5 cfu/cm^2 , has a log SSR of 1.16 in our runs (in FSIS’s report, the log SSR value is 1.02). However, other combinations of mean and standard deviation (e.g., mean = -5.5 and SD = 3.1; mean = -5.5 and SD =

3.3; mean = -5.0 and SD = 2.9; and mean = -5.0 and SD=3.1) resulted in a smaller log SSR, and a better fit. As such, the FSIS calibrated values for the LM added to FCS are not necessarily the best estimates.

3 Alternative Model Input Assumptions

3.1 Impact on Model Calibration

The values for the mean and standard deviation of the number of LM species added to food contact surfaces (FCS) at the beginning of lot production are unknown. The FSIS model assumed that the distribution of this input variable is lognormal. In the calibration of the model, the mean and standard deviation of this input variable were changed until the resulting simulated distribution of LM in deli meat at retail were deemed sufficiently close to the updated FDA/FSIS exposure assessment values for the concentration of LM in deli meat at retail. All other model input variables were kept at their base values during the calibration. The FSIS final distribution estimate of the LM species added to FCS had a mean on \log_{10} scale of -6cfu/cm^2 and a standard deviation on the log scale of 3.5 cfu/cm^2 .

The purpose of this assessment is to determine whether distribution of LM concentration added to the food contact surface developed based on the FSIS base is the “best” distribution. Based on limited “what if” assessments by changing the sanitation effectiveness parameter, and increase/decrease the number of iteration runs, the distribution of added *Listeria* contamination based on the FSIS base run does not appear to be the “best” baseline distribution. Further, in the calibration, no pre- or post-packaging processing is assumed. Thus, estimates of number of *Listeria* organisms added in the calibration model could be underestimated, if some of the plants use these practices.

To examine the validity of the distribution of added LM in the FSIS model, the reasonableness of various model input assumptions were evaluated and what-if assessments were carried out. Specifically, we re-calibrated the base model by replacing several FSIS model input assumptions with alternative distribution assumptions to examine the impact on the calibrated distribution of the added LM concentration. The

following sections describe the variables examined in these analyses and associated results.

3.1.1 Variables Examined

3.1.1.1 Distribution of Food Contact Surface (FCS) Area

The FSIS in-plant model assumes that 48% of all ready-to-eat deli meats and frankfurters are produced by “Large” plants, 48% by “Small” plants, and the remaining 4% by “Very small” plants. These three categories of plants are assumed to have different distributions of lot sizes (i.e., amounts produced per shift), and food contact surface area sizes. The food contact surface area is modeled as a uniform distribution ranging from 100,000 to 1,000,000 cm² (15,500 to 155,000 square inches) for large plants. For the other size plants, that range was modified proportionately to reflect the lower average amount produced per lot. Table 2 summarizes the distribution used for FCS area.

Table 2: Food contact surface area distribution (cm²)

Plant size	Large plants	Small plants	Very small plants
Distribution	Uniform	Uniform	Uniform
Minimum	100,000	36,653	14,455
Maximum	1,000,000	366,527	144,546
Percentiles			
25	325,000	119,121	46,977
50	550,000	201,590	79,500
75	775,000	284,059	112,023
90	910,000	333,540	131,537
95	955,000	350,034	138,041
99	991,000	363,229	143,245

Discussion with AMI company members indicated that food contact surface areas can be much larger than the upper limit of the uniform distribution for a large plant that is used in the FSIS model. Industry information on type of surface and food contact areas for a typical large plant is summarized in Table 3.

Table 3. Industry Data on Food Contact Surface Areas for a Large Plant

Type of Surface	Contact Surface Area	Total FCS (cm ²)
Line 10 Fully Cooked Belts	cm²	3,250,200
1-FUJI COOKER	1,210,836	
2-TRANSFER BETWEEN FUJI AND SPIRAL	4,168	
3-SPIRAL BELT	1,288,255	
4-INCLINE TO URSHEL	49,548	
5-URSCHEL BELT	5,574	
6-FLIGHTED INFEED BELT	46,452	
7-FLIGHTED FREEZER BELTS	441,289	
8-FLIGHTED EXIT BELT	33,445	
9-BELT FEEDING BUCKETS	33,445	
10-BELT FEEDING TRIANGLE	61,935	
11-BELT FEEDING HOPPER	5,574	
12-HOPPER BELT	27,871	
13-BULK METAL DETECTOR BELT	41,806	
Line 20 Fully Cooked Belts		1,383,017
1-JSO EXIT CONVEYOR	29,729	
2-PRECHILL FREEZER	147,096	
3-URSCHEL INCLINE BELT	23,226	
4-URSCHEL BELT	66,890	
5-FLIGHTED FREEZER BELTS	441,289	
6-FLIGHTED EXIT BELT	16,723	
7- BUCKET ELEVATOR	23,226	
8-BELT FEEDING # 25 TRIANGLE	46,452	
9-BELT FEEDING REV. CONVEYOR	55,742	
10-REV. CONVEYOR TO #20 TRIANGLE	501,676	
11- HOPPER BELT	30,968	
Line 30 Fully Cooked Belts		2,338,679
1- JSO EXIT CONVEYOR	19,819	
2- SPIRAL FREEZER BELT	1,189,159	
3-SHUTTLE CONVEYOR EXIT OF SPIRAL	16,723	
4-BRIDGE CHOPPER BELT	18,581	
5-BRIDGE SLICER BELT	37,161	
6-BRIDGE SLICER EXIT BELT TO FLIGHTED	29,729	
7-URSCHEL INFEED CONVEYOR	5,574	
8-URSCHEL BELT	5,574	
9-FLIGHTED FREEZER BELTS	441,289	
10-FLIGHTED EXIT BELT	16,723	
11-LONG WIRE BELT INCLINE	74,322	
12-LONG INTRALOX INCLINE BELT	74,322	
13-CROSS CONVEYOR TO BULK DECLINE	200,671	
14-BULK DECLINE BELT	74,322	
15-BULK METAL DETECTOR	11,148	
16-REV. CONVEYOR FOR TRIANGLES	33,445	
17-INFEED CONVEYOR TO #30 TRIANGLE	33,445	
18-INFEED CONVEYOR TO # 35 TRIANGLE	33,445	
19- BUCKET ELEVATOR	23,226	

Data provided by industry for the surface contact area in 2 smaller plants ranged from about 39,000 to 322,500 cm² per line, and thus are similar to those assumed in the FSIS model for the smaller plants.

Based on the surface contact area data provided by industry for large plants, a more reasonable assumption for the food contact surface area than what is currently used in the FSIS model would be a uniform distribution ranging from 100,000 to 3,500,000 cm² for large plants. As described above (section 2), the FSIS model assumes that the parameters defining the FCS area distribution for small and very small plants, are proportionately smaller than those used to define the distribution for large plants. Using the modified food contact surface area for large plants results in a uniform distribution ranging from 36,653 to 1,282,845 cm² for small plants and 14,455 to 505,911 cm² for very small plants. Table 4 compares the FCS area distributions used by FSIS to those derived based on industry data.

Table 4: FCS area distributions used by FSIS v. derived from industry data

Plant size	Large plants		Small plants		Very small plants	
	FSIS	Industry Data	FSIS	Industry Data	FSIS	Industry Data
Distribution	Uniform	Uniform	Uniform	Uniform	Uniform	Uniform
Minimum	100,000	100,000	36,653	36,653	14,455	14,455
Maximum	1,000,000	3,500,000	366,527	1,282,845	144,546	505,911
Resulting Distribution						
Mean	550,000	1,800,000	201,590	659,749	79,500	260,183
25th	325,000	950,000	119,121	348,201	46,977	137,319
50th	550,000	1,800,000	201,590	659,749	79,500	260,183
75th	775,000	2,650,000	284,059	971,297	112,023	383,047
80th	820,000	2,820,000	300,552	1,033,607	118,528	407,620
90th	910,000	3,160,000	333,540	1,158,226	131,537	456,765
95th	955,000	3,330,000	350,034	1,220,536	138,041	481,338
99th	991,000	3,466,000	363,229	1,270,384	143,245	500,996

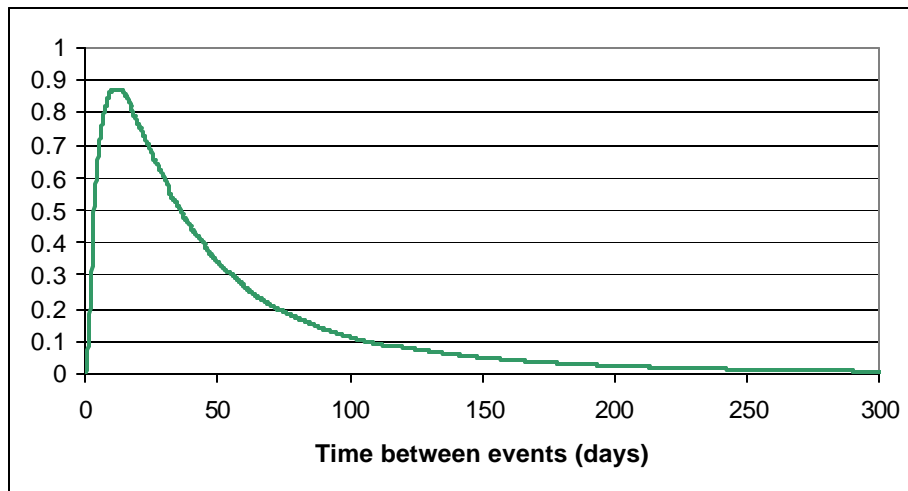
3.1.1.2 Distributions of interval between contamination events

Data on the interval between contaminations events used in the FSIS model come from a plant associated with an outbreak and not representative of other plants (p23-24). Thus, intervals between events may be underestimated. A potential impact of this bias is that number of *Listeria* organisms added during a contamination event may be underestimated in the calibration model. The current FSIS assumption for this variable is summarized in Table 5 and Figure 3

Table 5: Time between events (days)

Log ₁₀ Normal Distribution	
Mean	1.08
Standard deviation	0.46
Percentiles	days
25	6
50	12
75	24
90	46
95	67
99	138

Figure 3: Time between events (days)



Industry data of surface contamination event reported for the period of 7/7/2004 and 6/3/2005 were made available to Exponent (see Appendix A). In analyzing this dataset,

a plant/line was assumed to be contamination free during the sampling period if it had no reporting event. Similarly, it is assumed that no contamination occurred the latest reported event and 6/3/2005. It is also assumed that no contamination occurred between the beginning of the reporting period (7/7/2004) and the earliest reported date. The following three options were considered in estimating the distribution of time between contamination events:

1. Use all intervals that ended up with a contamination (i.e. intervals that correspond to a failure)
2. Use all the “data” (i.e., assume that the censored intervals were actually not censored), or
3. Use all non-censored (left or right) data (i.e., do not make any assumptions about starting and ended dates, and only use the intervals between reported events).

The FSIS model requires a \log_{10} normal distribution be used for this variable, however, for all 3 options, the \log_{10} normal distribution did not provide a good fit, and tended to underestimate the time between events (i.e., the modeled percentiles tended to be lower than the ones derived from the data). The resulting parameter estimates for all three options, assuming the \log_{10} normal distribution are summarized below:

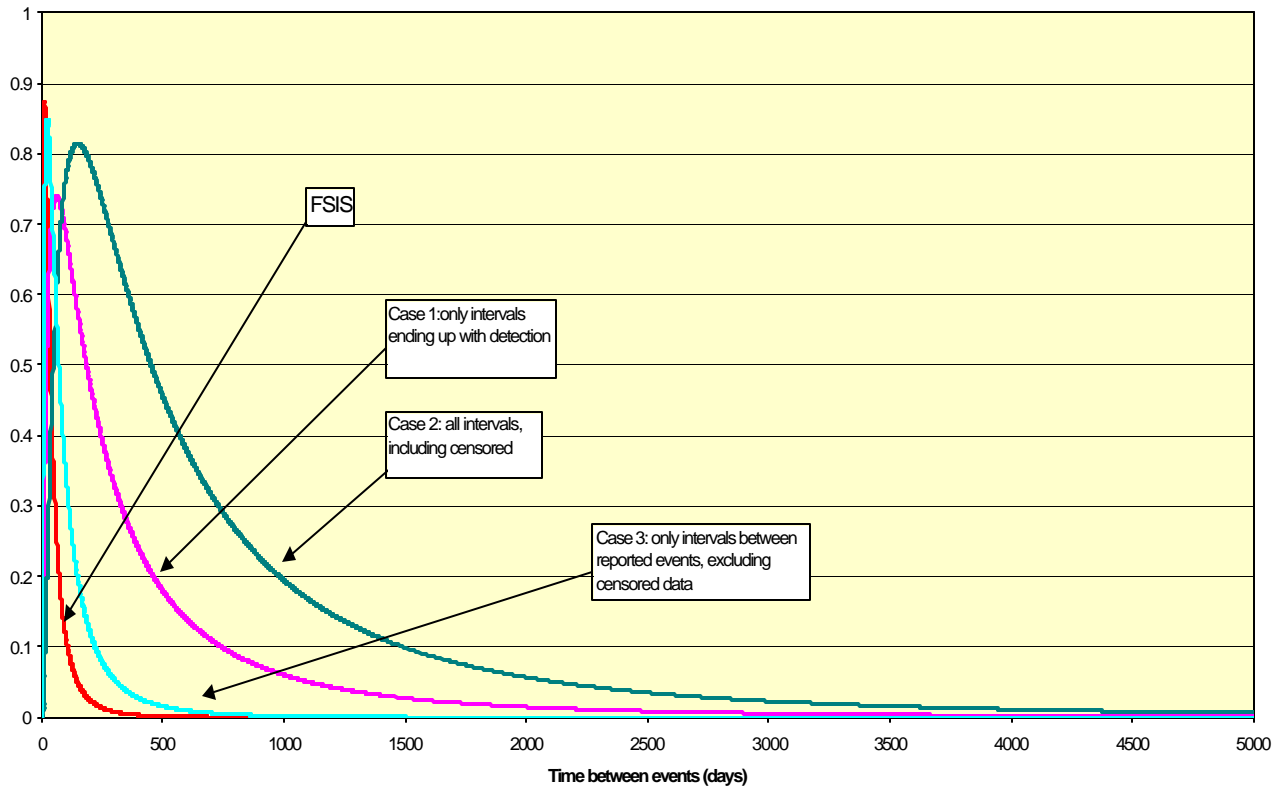
- ❖ Option 1 -- only intervals ending up with detection: mean = 1.79, sd = 0.54.
- ❖ Option 2 -- all intervals, including censored: mean = 2.17, sd = 0.49.
- ❖ Option 3 -- only intervals between reported events, so no left or right censored data: mean = 1.37, sd = 0.47

The percentile estimates of the number of days between contamination events based on FSIS assumption were consistently below the estimates based on the three distributions that were derived from industry reported data, with Option 3 distribution being the closest to FSIS estimates. These comparisons are provided in Table 6 and Figure 4.

Table 6: Days between contamination events – a comparison of FSIS assumption and industry reported data

Percentile	FSIS mean=1.08, sd=0.46	Case 1 mean=1.79, sd=0.54	Case 2 mean=2.17, sd =0.49	Case 3 mean=1.37, sd=0.47
0.1	3	13	35	6
0.2	5	22	57	9
0.3	7	32	82	13
0.4	9	45	111	18
0.5	12	62	148	23
0.6	16	84	197	31
0.7	21	118	267	41
0.8	29	176	382	58
0.9	46	303	628	94
0.95	67	477	946	139
0.99	138	1112	2041	291

Figure 4: Days between contamination events – a comparison of FSIS assumption and industry reported data



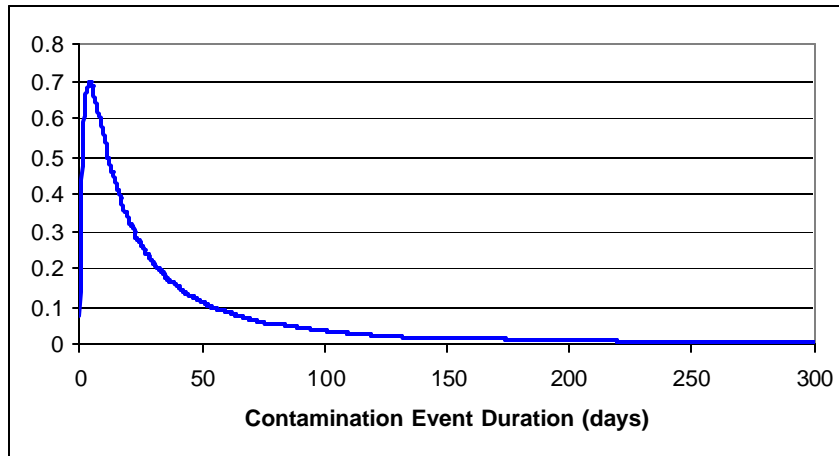
3.1.1.3 Distribution of Duration of a Contamination Event

The distribution for the duration of a contamination event variable in the FSIS base model was based on Tompkin’s 2002 data. The current FSIS assumption for this variable is summarized in Table 7 and Figure 5.

Table 7: Duration of a contamination event (days)

Log ₁₀ normal Distribution	
Mean	0.60
Standard deviation	0.57
Percentiles	days
25	2
50	4
75	10
90	22
95	35
99	86

Figure 5: Duration of a contamination event (days)



According to industry information, data from Tompkin (2002) were based on small plants and possibly not applicable to conditions at large plants. Also, there have been many operational changes since the study was conducted such that the duration of a contamination event would not be allowed to last over 10-15 days (above the 90th

percentile estimate, see table 7). To reflect a more realistic duration of a contamination event, and for purpose of “what if” analyses, the standard deviation was reduced by 20% (Log10 normal, Mean = 0.602 and Standard Deviation = 0.458.)

3.1.1.4 Distribution of transfer coefficients

The transfer of *Listeria* species from food contact surface to RTE product is described as transfer coefficients. FSIS used a “truncated” lognormal distribution for transfer coefficient. The model assumes a lognormal distribution (-0.14, 1) with the mean value based on Midelet and Carpentier (2002) data but the standard deviation based on two other articles (Montville et al, 2001 and Chen et al, 2001) that examined the transfer of *Listeria spp.* from hands and spigots to chicken and lettuce. Table 8 summarizes the distribution used by FSIS.

Table 8: FSIS Transfer Coefficients

Distribution	Lognormal values >1, set at 1
Mean	-0.14
Standard deviation	1
Percentiles	
25	15%
50	72%
75	100%
90	100%
95	100%
99	100%

However, Chen et al (2001) found that mean transfer rates differ from one pair of surfaces to another and the standard deviation associated with the means also differ considerably between different surfaces. The differences between the surfaces involved in the studies and those assumed in the FSIS in-plant model thus suggest that alternative and more appropriate values/distribution should be considered. A technical presentation at the IAFP 2003 conference by Vorst, Todd, and Ryser of Michigan State University provided additional data on the contamination of commercial slicers by *Listeria*.² In this

² Silliker’s Summary of the IAFP 2003 technical presentation by Vorst, Todd, and Ryser of Michigan State University

study retail blocks of Cheddar cheese (36.1% moisture, 25.5% fat) and smoked turkey breast (99% fat free) were inoculated ($\sim 10^6$ CFU/cm²) with *L. monocytogenes* Scott A and a 6-strain cocktail containing weak, medium, and strong biofilm formers. The inoculated product (3 replicates) was sliced (5 slices/replicate) at 4-7C on a modified commercial delicatessen slicer while applying 2 and 10 lbs of force. Five product contact areas on the slicer were identified based on Glo-Germ ®: the table, back plate, metal guard, blade, and product collection area. Using an application force of 2 lbs on turkey breast, greatest transfer was found on the metal guard ($\sim 10^3$ CFU/cm²) and blade ($\sim 10^2$ CFU/cm²) with *Listeria* transfer 10-fold higher using an application force of 10 lbs. Unlike turkey breast, Cheddar cheese transfer levels were highest on the collection area (10^2 CFU/cm²) and blade ($\sim 10^3$ CFU/cm²) with the table yielding little or no transfer. A summary of the Transfer Coefficients that can be derived from this study is summarized in Table 9. Given the type of surfaces tested in this study and the Midlet and Carpenter (2002) study, pooled TC data from these two studies would be appropriate for use in characterizing the lognormal distribution of Transfer Coefficient. The parameter estimates for the log₁₀ normal distribution of TC based on these two studies as compared with FSIS estimates are provided in Table 10.

Table 9: Transfer Coefficient by types of Food and Surface Areas

Study	Food	Surface	%TC
Vorst et al (2005)	Cheese	Table*	0.000001
	Smoked Turkey Breast	Table*	0.000001
	Cheese	Blade	0.001
	Smoked Turkey Breast	Metal guard	0.001
	Cheese	Collect area	0.0001
	Smoked Turkey Breast	Blade	0.0001
Midlet & Carpenter (2002)		Stainless steel	1
		PU	0.45
	Meat exudates	PVC	0.71

* No transfer was observed to table,. We used 0.00001 for modeling purposes.

Table 10: Comparison of revised distribution of TC and FSIS assumption

	Pooled Data From Vorst et al (2003) & Midelet & Carpentier (2002)	FSIS Assumption
Log ₁₀ Normal Distribution	Mean = -2.94, sd = 2.35	Mean = -0,14, sd = 1
Percentiles		
5%	0	0.02
10%	0.000001	0.04
15%	0.000004	0.07
20%	0.000012	0.11
25%	0.000029	0.17
30%	0.000072	0.23
35%	0.000138	0.32
40%	0.000297	0.43
45%	0.000698	0.57
50%	0.001252	0.73
55%	0.002146	0.95
60%	0.004073	1.00
65%	0.009598	1.00
70%	0.019223	1.00
75%	0.051072	1.00
80%	0.124854	1.00
85%	0.303350	1.00
90%	1.00	1.00
95%	1.00	1.00
100%	1.00	1.00

3.1.2 Findings

3.1.2.1 Calibration with Alternative Time Between Contamination Events

The model was run with the three alternative distributions for the interval between events parameters described above (Section 3.1.1.2) and a series of alternative listeria added distributions, while keeping all other parameters as in FSIS bases model. However, irrespective of what listeria added distribution used, distributions derived under Options 1 and 2 did not result in a distribution of listeria levels in retail deli meats that was similar to that based on the data summarized in FDA/FSIS report. Thus, if the lognormal distributions that were used for time between contamination events are good

representations of the distribution of actual time between events, one or more of the other assumptions and distributions used by the model are not adequate representations of what really occurs in processing plants.

The distribution derived under Option 3 yielded estimates of days between contamination events that were the closest to those estimated by FSIS, and thus was used in the re-calibration. All other model input variables were similar to those used in FSIS base runs. Table 11 is a summary of the log SSR given a combination of mean and standard deviation for the LM added variable. When using estimates of time between contamination events based on industry reported data rather than the FSIS base value for this variable, the FSIS final estimates of the mean and standard deviation for the LM added variable (in its calibration run) do not result in simulated distribution of LM in deli meat at retail that are “close” to those estimated in the revised FDA/FSIS exposure assessment (the log SSR = 30.9 when mean = -6.0 and SD = 3.5, see Table 11).

Table 11: Log SSR for various combinations of mean and standard deviation (on log₁₀ scale) for the add LM variable, alternative time between contamination events

Mean	Standard Deviation								
	2.5	2.7	2.9	3.1	3.3	3.5	3.7	3.9	4.1
-6	82.6	58.9	50.1	35	38.7	30.9	42.1	35.9	32.9
-5.5	49.7	34.2	26.9	43.1	23.4	22.2	24.5	34.5	45.9
-5	27.4	30.3	15	15.3	16.9	32.6	23.3	38.1	37.1
-4.5	28.2	15.6	6.33	10.4	17	16.3	18.1	44.4	46.9
-4	9.67	6.77	6.98	12	10.6	18.4	27.1	43.4	56.8
-3.5	5.61	4.1	6.22	9.7	16.8	25.7	46.9	51.1	63.3
-3	4.57	4.45	9.23	15.6	24.2	34.9	50.2	74.2	82.8

Note: 300K runs

In fact, with the revised time between contamination events, the combination of the mean value at -3.5 (on log 10 scale) and standard deviation at 2.7 (on log 10 scale) for the LM added variable had the lowest log SSR of 4.1 (See Table 11). However, none of the mean and standard deviation combinations resulted in log SSR ≤ 1, i.e. none would yield distribution of LM in deli meat at retail that are close to estimates in the FDA/FSIS revised exposure assessment. As discussed above, if the lognormal distribution that was

used for time between contamination events is a good representation of the distribution of actual time between events, one or more of the other assumptions and distributions used by the model are not adequate representations of what really occurs in processing plants.

3.1.2.2 Calibration with alternative values for food contact surface areas, transfer coefficients, and duration of contamination events

Alternative values for food contact surface areas, transfer coefficients, and duration of contamination event, as previously described were used to recalibrate the values of mean and standard deviation for the LM added to FCS variable. The recalibration was done by changing each variable one at a time and by changing all three variables together. The re-calibrated values of the mean and standard deviation (on log₁₀ scale) of the LM added to FCS variable that results in a distribution of LM concentration in deli meat at retail close to the revised FDA/FSIS LM concentration in deli meat at retail (based on logSSR ≤ 1, approximately equal to the Goodness of Fit value that was deemed acceptable by FSIS in baseline calibration runs) are summarized below. None of these “best fit” combinations are the same as the FSIS final values of mean and SD for LM added variable (-6, 3.5). When all three variables are modified, a mean of -4.8 and a standard deviation of 3.2 for the LM added variable appear to provide the best fit. (See Table 12)

Table 12: Recalibrated mean and standard deviation of LM added to FCS variable

Revised model input variable	LM Added to FCS (on log ₁₀ scale)		LogSSR
	Mean	Standard Deviation	
Transfer Coefficient Mean = -0.26, SD = -0.64	-5.4	3.5	0.722
	-5.2	3.3	0.726
	-5.2	3.4	0.962
	-5.2	3.5	0.868
Event Duration Mean = 0.601 SD = 0.58	-5.0	3.1	0.600
	-4.5	2.9	0.600
FCS area (cm ²) Min = 100,000 Max = 3,250,000	-6	3.1	0.800
	-6	3.3	0.500
	-5.5	2.9	1
Revised TC, Event Duration and FCS area	-5.0	3.3	1.05
	-4.8	3.1	1.15
	-4.8	3.2	1.01

Note: 300K iterations run

3.2 Impact on FSIS Conclusions

The FSIS model assumes that intervention does not affect the duration of a contamination event, the interval between contamination events, or the number of *Listeria* organisms transferred to the FCS. Food contact surface areas can act as long-term harborage sites over a long period of time (as indicated on page 14 of the FSIS report). According to industry sources, findings of contamination would typically trigger intense sampling to find niches and rigorous cleanup conducted to rid of niches. So implementation of sanitation interventions should affect the duration and interval between contamination events as well as the amount transferred from these areas. Since the FSIS in-plant model does not allow for this relationship (correlations) between these model input variables, it is not surprising that improved sanitation is found to have a limited effect based on analysis using this FSIS in-plant model (see conclusions on page 66 of the FSIS report). To appropriately address this fundamental model flaw, the FSIS in-plant model would need to be revised. This is beyond the scope of Exponent's review of the FSIS model.

The purpose of this evaluation is thus limited to determining if FSIS conclusions about the relative effectiveness of various intervention options based on the current model construct remain valid when different values for several model input variables were used, including the re-calibrated mean and standard deviation for the LM added variable. Based on available information and as discussed in previous sections, the following model inputs were changed in this evaluation:

<i>Variable</i>	<i>FSIS Values</i>	<i>Revised Values</i>
Transfer Coefficient	Mean = -0.14; SD = 1	Mean = -2.94; SD = 2.35
Event Duration	Mean = 0.602; SD = 0.573	Mean = 0.602; SD = 0.458
Food Contact Surface Area for large plants ³	Min = 100,000 cm ² Max = 1,000,000 cm ²	Min = 100,000 cm ² Max = 3,250,000 cm ²
LM Added	Mean = -6.0; SD = 3.5	Mean = 4.8; SD = 3.2

In the FSIS report, LM concentrations on deli meat at retail were predicted for various scenarios of FCS and/or product testing using the FSIS Risk Assessment in-plant model.

The scenarios were given as triplet numbers, e.g. 4-2-1, and represent the number of monthly FCS samples per line for large, small, and very small plants. FSIS assumed test and hold for all FCS testing scenarios and if a lot tested positive for LM it was assumed not to be sold for retail. In addition to FCS testing scenarios, FSIS also provided scenarios of lot testing rather than FCS testing (i.e. 60-60-60 lot scenario), post-processing intervention/control (PP), growth inhibiting packaging (GIP), and combined PP and GIP scenarios. For the PP and GIP scenarios, FSIS assumed that 100% of industry implements these practices. Outputs of LM concentration at retail at the 80th, 99th and 99.99th percentiles were compared against the FDA estimates and FSIS baseline estimates in Figure 20 and Table 20 of the FSIS report.

Exponent conducted analyses for several intervention scenarios that are similar to those described in the FSIS report. However, based on the description in the FSIS report, it is unclear what intervention was incorporated in the FSIS baseline scenario (i.e. 0-0-0 or 4-2-1 FCS sampling schemes). We assumed that when the 4-2-1 scenario is implemented without enhanced cleaning (i.e. when the “enhance cleaning” check box is not checked), the output would be similar to when the 0-0-0 scenario is implemented. The outputs of LM concentration on deli meat based on our revised input parameters for various scenarios are summarized below in Table 13. Figure 6 below shows 3 quantiles (80th, 99th, and 99.99th percentiles) concentrations of LM in deli meats at retail for the various tested scenarios. In general, similar to the FSIS result, the data generally showed modest decline in the LM concentration at RTE product at retail as the food contact surface testing and sanitation effort increases. However, this trend is better observed for the 80th and 99th percentiles and not for the 99.99th percentile. While the FSIS output showed a decline at the 99.99th percentile for the 60-60-60 FCS testing and enhanced sanitation scenario, our analysis showed minimal decline from both the base values and Exponent revised base values. Most noticeable are the drop in LM concentrations at retail that were observed for both the 60-60-60 lot, PP, GIP and PP&GIP scenarios for all three quantiles when compared with the base values. Based on the Log SSR (Log SSR > 2), the predicted LM concentrations at retail are different from the FDA estimates or baseline

³ Distributions for FCS area for small and very small plants are assumed to proportionately smaller

values (prior to intervention) only for the 60-60-60, 60-60-60 lot, PP, GIP and PP&GIP tested scenarios. (See Table 14)

Figure 6: Quantiles of LM at retail for tested intervention scenarios

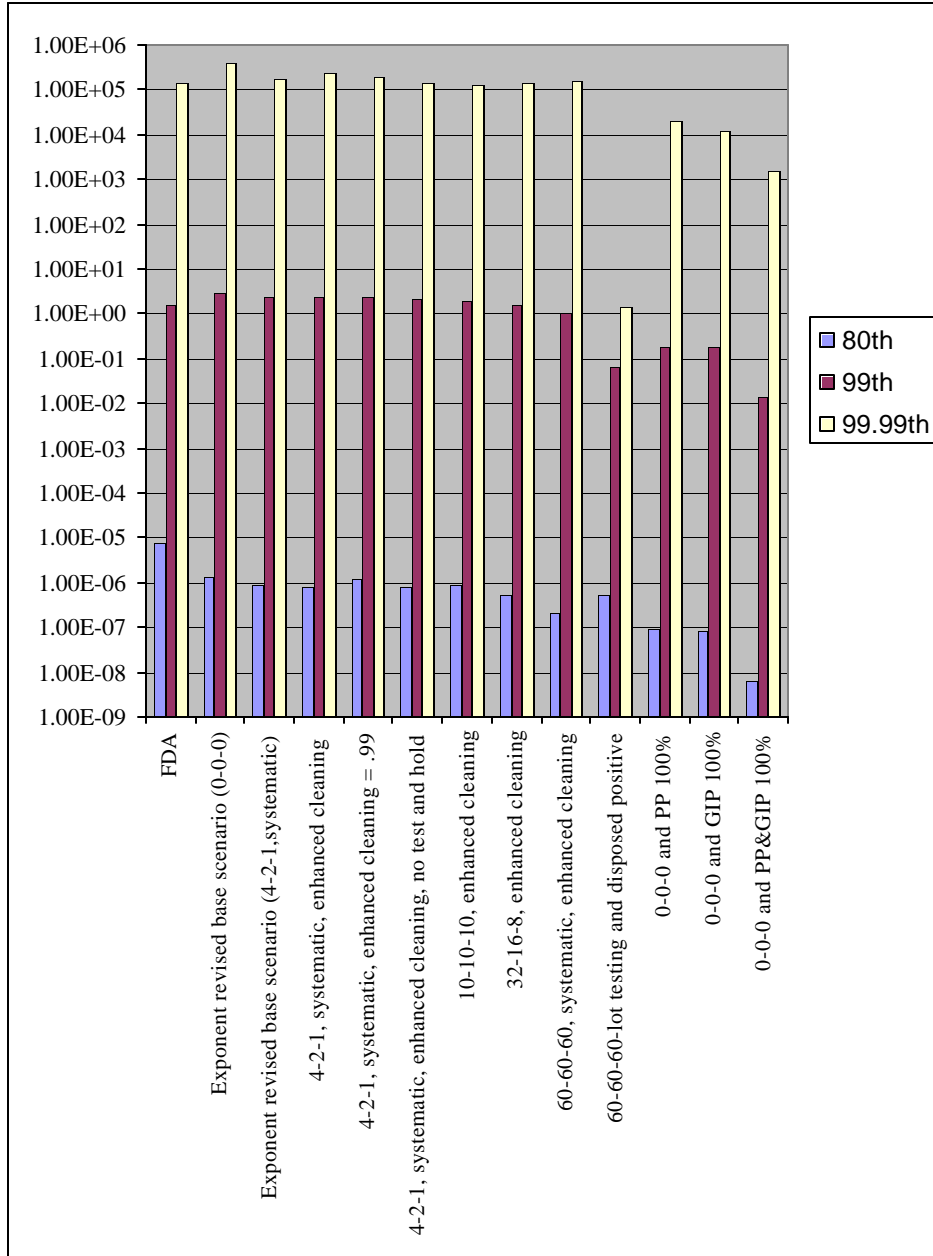


Table 13: Quantiles of *L. monocytogenes* concentrations in deli meat at retail for tested intervention scenarios and with revised model input parameters

	FDA	Exponent Revised Base (0-0-0)	Exponent parameters (4-2-1, systematic) cleaning	4-2-1 FCS, systematic, enhanced cleaning = .99	4-2-1 FCS, systematic, enhanced cleaning, no test and hold	10-10-10, enhanced cleaning	32-16-8, enhanced cleaning	60-60-60 FCS, systematic, enhanced cleaning	60-60-60 lot testing and disposed positive	0-0-0 and 100% PP	0-0-0 and 100% GIP	0-0-0 and 100% PP&GIP	
80th	7.40E-06	1.34E-06	8.76E-07	7.71E-07	1.17E-06	8.33E-07	9.02E-07	5.36E-07	2.04E-07	5.21E-07	8.93E-08	8.69E-08	6.57E-09
85th	3.70E-05	1.64E-05	1.13E-05	1.05E-05	1.43E-05	1.10E-05	1.10E-05	7.26E-06	3.16E-06	6.04E-06	1.11E-06	1.06E-06	8.37E-08
90th	2.70E-04	2.40E-04	1.82E-04	1.74E-04	2.24E-04	1.74E-04	1.69E-04	1.20E-04	5.65E-05	7.81E-05	1.70E-05	1.67E-05	1.27E-06
95th	5.50E-03	8.09E-03	6.34E-03	6.48E-03	7.35E-03	6.10E-03	5.72E-03	4.44E-03	2.32E-03	1.65E-03	5.79E-04	5.38E-04	4.24E-05
99th	1.50E+00	2.80E+00	2.38E+00	2.40E+00	2.44E+00	2.25E+00	1.84E+00	1.61E+00	1.05E+00	6.75E-02	1.90E-01	1.83E-01	1.45E-02
99.5th	1.10E+01	2.35E+01	1.83E+01	1.89E+01	1.90E+01	1.71E+01	1.37E+01	1.27E+01	8.49E+00	1.53E-01	1.54E+00	1.33E+00	1.12E-01
99.9th	7.90E+02	1.60E+03	1.31E+03	1.12E+03	1.34E+03	9.70E+02	8.61E+02	7.55E+02	5.58E+02	5.04E-01	1.06E+02	8.16E+01	7.35E+00
99.99th	1.40E+05	3.94E+05	1.82E+05	2.49E+05	2.01E+05	1.44E+05	1.26E+05	1.43E+05	1.53E+05	1.35E+00	2.10E+04	1.24E+04	1.61E+03

Notes: 500K Iterations

Table 14: Log SSR

<i>Scenarios</i>	<i>Log SSR</i>	
	<i>vs. FDA</i>	<i>vs. Exponent Revised Base</i>
FDA	NA	NA
Exponent revised base scenario (0-0-0)	1.18	NA
Exponent revised base scenario (4-2-1,systematic)	1.31	0.22
4-2-1, systematic, enhanced cleaning	1.49	0.20
4-2-1, systematic, enhanced cleaning = .99	1.01	0.11
4-2-1, systematic, enhanced cleaning, no test and hold	1.29	0.37
10-10-10, enhanced cleaning	1.18	0.51
32-16-8, enhanced cleaning	1.94	0.87
60-60-60, systematic, enhanced cleaning	4.24	2.62
60-60-60-lot testing and disposed positive	43.10	50.60
0-0-0 and PP 100%	11.40	11.16
0-0-0 and GIP 100%	12.30	12.44
0-0-0 and PP&GIP 100%	42.10	42.76

4 Conclusions

- ❖ In general, the FSIS model works as described in the FSIS report. The formulas used to model the mass balance approach are correctly implemented. The distribution used in the calibration to represent listeria concentrations in deli meats at retail correctly simulates the data in FDA/FSIS risk assessment. The number of iterations used in the risk assessment (1,000,000 iterations) is sufficient for the model output to stabilize. However, the distribution used by FSIS to represent the amount of listeria added during a contamination event is not necessarily the distribution that resulted in the best fit when compared to that based on the data in FDA/FSIS risk assessment.
- ❖ Estimates of several model input variables, i.e. transfer coefficient, interval between contamination event, event duration, food contact surface areas can be modified with industry data. These revised parameters can impact the calibrated values of mean and standard deviation for the LM added variable. In particular, when industry reported data are used to parameterize the interval between contamination events, the model cannot be calibrated to the FDA estimates of LM concentration at retail. This suggests that alternative parametric distribution for this specific variable may be needed, or there may be other model construct limitations, i.e. inability to correlate various input variables (see below)
- ❖ Assessment using the FSIS in-plant model with several revised input variables, generally showed modest decline in the LM concentration for RTE products at retail as the food contact surface testing and sanitation effort increases. This trend was observed for the 80th and 99th percentiles and not for the 99.99th percentile. However, the decreases in LM concentrations at retail when compared with the base values were only significant for the 60-60-60, 60-60-60 lot, PP, GIP and PP&GIP tested scenarios.

- ❖ Correlation between the duration of a contamination event, the interval between contamination events, or the number of *Listeria* organisms transferred to the FCS is not allowed in the FSIS in-plant model. If such correlations are allowed, intervention such as enhanced cleaning once contamination is detected via FCS sampling to get rid of LM niches would reduce the level of LM added (now held constant in model) and the duration of a contamination event and would lengthen the duration between events (as shown with industry reported data). Thus, FSIS's conclusions about the relative effectiveness of various intervention scenarios remain questionable.

Appendix A: Time between event data

Plant #	Line	Number of samples	Date with Reported Positive Event			
			1st	2nd	3rd	4th
A	Precooked line A	727				
	Precooked line B	765	8/23/2004			
	Precooked line C	801	2/2/2005	5/26/2005		
	Precooked line Bits	652				
B	Prepared Saus. Pack	438				
	Prepared saus. Bulk	370				
	RTE Bacon line 1	134				
	RTE bacon Line 2	272				
	Bacon Bits	103				
C	Belt Grill Line 1	609				
	Belt Grill Line 2	502				
	CIB Line 1	484				
	CIB Line 2	501	20-Aug			
	CIB Line 3	537				
	CIB Line 4 & Dicer (add-ons)	534				
	Ham Pack Line 3	233				
	Ham Pack Line 4 (BNLS Spiral)	583	7/7/2004	7/27/2004	8/6/2004	
	Ham Pack Line 5(BI Spiral)	1736	8/25/2004	9/15/2004	9/23/2004	
	Ham Pack Line 6	523				
Ham Pack Line 7	531	10/7/2004				
Ham Pack Line 8	527					
Ham Pack Line 9 Grd Ham	492					
D	Formax	569				
	Cocktails/Franks	479				
	Ham Pack Line	563				
	Bulk Sausage Pack	544				
	Slider Zipper Line	393				
	Toby Line	605				
	Ross Pack Chop line	570				
	Dicer	460	1/19/2005	6/3/2005		
	West Formax	590				
	Multivac Line	460				
	Crax Packaging	559				
E	Prepared Sausage Pack SLW	551				
	Canadian Bacon	572				

	West Ham RWO	637	10/13/2004			
	Belt Grill Bacon	320				
	Zipper Pack DS	666	9/1/2004	9/14/2004	9/14/2004	
	DS Pillow pack	562				
	DS Deli Line	598	11/8/2004			
	DS Chubb Line	430	5/19/2005			
	Prepared Saus. North (Bulk)	441				
	VSP	572				
	East Ham Line	562				
	DS Cry-O-Vac	585				
	DS Tote	315				
	DS Bulk	386	3/16/2005			
	F&E Bacon West	563				
	F&E Bacon East	576				
	F&E Bacon North	854	1/19/2005			
	F&E Bacon South	752				
	DS Ishida Zipper Line	690	10/20/2004	10/26/2004	11/17/2004	
	Bacon Bits	551				
	Ham Dice/Grind Pack	572				
	SM- 8610 Ham Pack	595				
F	Pillow Pack 1	579				
	A&B Bulk Line	567				
	C&D Bulk Line	622				
	Flex Vac 1	540				
	Flex Vac 2	593	4/6/2005			
	Pillow Pack 2	553				
	Dice	333	3/2/2005	3/9/2005		
G	Cryovac	532				
	Slice area	772	12/21/2004	3/29/2005	5/9/2005	
	Multivac Line	568	1/31/2005			
	Bulk Tote	553	11/1/2004			
	Pillow Pack	585	3/30/2005			
H	Room A LP	781	10/18/2004	11/30/2004		
	Room B LP	709				
	Room C LP	810	3/22/2005	3/29/2005		
	Room D LP	756				
	Browerville	554				
	Ends & Pieces	484				
	Slicing	626	3/3/2005	3/9/2005		
I	Belt Grill	1768	8/13/2004	9/7/2004	2/11/2005	3/9/2005
	Boneless Hams	209				
	Bone-In Hams	326				



December 29, 2003

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street S.W.
Washington, DC 20250-3700

RE: Docket No. 03-032N: “Risk Analysis Standard Operating Procedures at the U.S. Department of Agriculture Food Safety and Inspection Service”

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. Our members slaughter and process over 90 percent of the nation's beef, pork, lamb, veal and nearly 75 percent of the turkey produced in the United States. AMI appreciates the opportunity to comment on development of Standard Operating Procedures (SOP) at the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS or the agency). AMI supports the use of Risk Analysis as a foundation for decision-making on regulatory policy at FSIS. Underlying this support is our belief that a scientifically-based risk assessment is paramount to development of sound inspection programs for the U.S. meat and poultry supply.

AMI has long held a position supporting the use of science-based risk analysis in establishing public policy related to the processing of meat and poultry products. We are pleased that FSIS has made the decision to establish a written protocol that will guide the agency in implementing the risk analysis process. We believe strongly that this process must be rigorous, credible, transparent, and based upon the most reliable, current and accurate information available regarding the hazard of concern. We offer the following comments and suggestions for consideration by the agency as it works to finalize the SOP process.

Early Engagement of Industry Experts is Critical to Achieving Transparency.

The SOP establishes the importance of transparency with the following quote: “*Transparency is critical for credibility and scientific accountability.*” AMI agrees that it is absolutely critical to achieve the highest degree of transparency possible, very early in the process. For example, in the step that outlines *The Development of a Proposal to Address the Risk Management Options* (pages 5 - 6 of the SOP) the agency should seek input and guidance from industry experts in the formulation of the conceptual model. Industry experts are most likely to have the knowledge to complete this task, as described in the SOP, since the task will require a working knowledge of the day-to-day operations of processing, distributing, and selling products to consumers. To develop the best and most current conceptual models, the agency should engage in informal discussions with specific industry experts or groups. In this regard, the American Meat Institute is willing to assist in any way possible.

We recognize that all stakeholders provide unique and important viewpoints on food safety and other critical issues that involve the inspection of meat and poultry. We strongly encourage the agency to recognize the value of early interaction with the most knowledgeable technical experts within the industry to gain their perspective on issues and procedures. In most cases, leading industry scientists are the most knowledgeable and have the greatest awareness of the food safety issues, because they are the technical experts responsible for designing and implementing food safety control programs, including HACCP and pre-requisite programs that ensure that safe products are produced every day. The risk analysis process will be greatly enhanced by early interaction with those who have the greatest understanding of the day-to-day operations and the interactions of these processes with potential risks.

Furthermore, AMI recommends that the agency use this SOP to establish a framework for how industry may share data to help inform the risk assessment process. Under Secretary for Food Safety Dr. Elsa Murano has publicly recognized that data from industry has significant value in helping the agency conduct risk assessments and evaluate risk management options, and she has requested publicly that industry strive to share that information with the agency. However, experience has shown that in some cases, when data has been offered by industry, the agency has refused to use the data or recognize its value. The SOP provides an opportunity for the agency to describe and define the parameters that are expected for data submission.

Public Announcement of the Risk Analysis Agenda Should be Defined.

Stakeholders need to be made aware of the risk analysis agenda on a regular basis. The SOP states that public access to the agency risk analysis agenda will be afforded through the FSIS web site; however, the SOP does not establish a routine method by which stakeholders will be apprised of the agenda and the agencies current efforts to realign priorities. AMI suggests that the agency establish a set timeframe for announcing the risk analysis agenda, much like the semi-annual regulatory agenda that is required via

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Executive Order 12866 "Regulatory Planning and Review." We recognize that priorities may change during the course of the year; however, this routine announcement process will enhance transparency and will provide stakeholders with ample time to plan for providing input to the process.

The SOP Should Provide Guidance on the Timeliness of Completion.

Undoubtedly, the agency will be under pressure to quickly complete the risk analysis process for a given hazard or process, once the hazard has been identified and the risk analysis process has commenced. AMI recognizes that efficiency and timeliness of completing tasks are critical. However, we recommend that the agency clearly establish, through this SOP, the process for establishing a realistic timeline for completion. This should be done as early as possible in the process. In many cases, the risk assessment will uncover the need to fill major data gaps and to address those areas where uncertainty can be significantly reduced through additional data collection and/or targeted research. In these cases, a modification of the timeline may be most appropriate to achieve an acceptable outcome.

AMI recognizes that, on very rare occasions, an issue may arise that poses a unique and new public health threat of significant consequence, and in this circumstance, timeliness of completion of the risk analysis process may override the desire for a complete treatment of scientific issues. However, we strongly believe that these are highly unique circumstances that are less likely to occur in today's modern food processing environments. For the vast majority of food safety issues that FSIS will encounter, we do not believe that urgency of completion exceeds the priority of adequately addressing major data gaps that will result in significant scientific uncertainty. As stated by one of the afternoon panelists during the FSIS public meeting on Risk Analysis on November 13, 2003;

“Efficiency and timeliness of risk assessment completion should never be more important than getting the science right.”

This quote should be considered seriously by the agency, and AMI would suggest that this concept is an inherent part of the agency's practice in the conduct of risk assessments. There must be a very well defined process for ensuring the risk assessment portion of the process is not “rushed” due to political or other pressures. The consequences of not using the best data available or allowing a risk assessment to be finalized with major data deficiencies can be enormous. The unintended consequences on industry, and society as a whole, are significant when risk assessments are finalized with known major data deficiencies.

Use of the Risk Assessment Models.

AMI recommends that the agency take full advantage of the risk assessment model as it provides the scientific basis for risk management decisions, both now and in the future. When political or other pressures result in risk management decisions being made in the absence of sound science, and through the use of assumptions that have a high likelihood of being superseded by facts at a later date, everyone loses. AMI

recommends that the agency establish a mechanism within the SOP that will provide for ongoing incorporation of enhanced knowledge in the risk assessment output. The SOP should also recognize that when the enhanced knowledge significantly affects the risk management outcomes, a mechanism must be in place to change the risk management strategies. This action will be in keeping with the desire by FSIS to have scientifically sound regulations for meat and poultry inspection.

Furthermore, AMI recommends that the agency use the risk assessment models as a tool to retrospectively evaluate the effectiveness of pre-existing regulations implemented prior to the establishment of the formal risk analysis process within the agency.

Sharing of Mathematical Algorithms.

AMI understands that development of a risk assessment is a complex endeavor. One of the central concepts of transparency is identical to that long employed in other areas of science. Scientific publications are transparent in that they are to contain a description of how an experiment was conducted to the extent that an informed reader should be able to reproduce the study. As risk assessments are essentially a scientific and mathematical endeavor, it is expected, for the sake of complete transparency, that the models developed should also be available for those that wish to reproduce the risk estimates.

AMI requests that FSIS provide risk assessment models in an electronic format that is accessible to the public and may be run on computers and software that is commonly available to the public. Simply providing printed computer code is not sufficient and does not meet the public expectation of transparency in the scientific process. Further, AMI requests that these models be provided well in advance of the process step whereby the agency begins to evaluate risk management options. This will provide the public with an opportunity to fairly evaluate the risk management options using the risk assessment models that have been developed by the agency. This provides the greatest opportunity for true transparency in the entire risk analysis process.

Selection of Risk Management Options Must be Transparent.

The SOP describes the process and issues that the agency will consider when selecting risk management options. At this point in the SOP, however, the agency seems to lose perspective on transparency by its position that the public will be informed only on the risk management decision made, and only after the decision is made. The risk management selection step (page 10 of the SOP) should be as transparent as the other steps of the risk analysis process. The agency should establish a procedure for informing

the public about proposed risk management options and the factors that were influential in the selection of the preferred options.

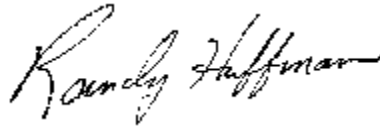
AMI agrees that it is the Office of Policy and Program Development's responsibility to develop and recommend risk management options (mitigation strategies) for Agency approval (or at least consideration). However, in our view it is imperative that this part of the risk analysis process be as transparent as the other steps in the process. The SOP lists the following as factors that Risk Managers will consider:

- risk assessment output;
- Agency's public health goals;
- societal values;
- costs of regulatory action or inaction;
- international issues;
- technical feasibility/ monitoring or enforcement capabilities;
- unintended risks associated with the management strategies;
- practicality of implementation; and
- statutory mandates.

As each of these factors will be considered for each risk management strategy, the agency should share a summary of these considerations in an open and transparent way. This should be done through a public forum. An explanation of how the agency intends to measure the various impacts that the mitigation strategy will have on the regulated industry should be included in this discussion. By embracing transparency in the risk management option selection step, the agency will increase the credibility and effectiveness of any final regulatory actions that may come of the risk analysis process.

We appreciate the opportunity to comment on this important initiative within the agency. AMI and its member companies stand ready to assist the agency in the process of implementing the Risk Analysis SOP. The concepts of risk analysis are aligned with industry's desire to have science-based regulations for the meat and poultry industry.

Respectfully submitted,



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cc: J. Patrick Boyle
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