15

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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 80^{th} and 99^{th} percentiles and not for the 99.99^{th} 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.

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,

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cc: J. Patrick Boyle
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