FSIS response to supplemental comments on the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat, (Docket #03-005N), submitted by the American Meat Institute on January 03, 2006.

FSIS Response to Supplemental Public Comments on The 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat

by
Daniel Gallagher, Ph.D.
Virginia Polytechnic University
Under SAIC Contact 43-3A94-4-5115

and

The Risk Assessment Division
Office of Public Health Science
Food Safety and Inspection Service
U.S. Department of Agriculture

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On February 26, 2003, FSIS held a public meeting to present the draft peer-reviewed 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat. At this meeting, FSIS announced that it would like to receive additional public input and information through Docket 03-005N. In addition to having the risk assessment report on the FSIS website, the risk assessment model and supporting data were publicly available in Docket 03-0005N. As a result, FSIS received a number of comments and additional information that strengthened this final risk assessment and it was used to guide the development of the FSIS Interim Final Rule to Control *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products (9 CFR 430). FSIS published the interim final rule on June 6, 2003 and sought further public comment on both the rule and the risk assessment, with a public comment period of more than one year.

The following are eight supplemental comments on the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat received in January 2006 from the American Meat Institute (AMI). FSIS has provided a response to each of AMI's comments (see http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp for a complete text of AMI's submitted supplemental comments). References to page numbers, table numbers, figure numbers, etc. correspond to the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat provided on the FSIS web site.

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.

The model does assume that *Listeria monocytogenes* contamination comes from a reservoir. However, the commenter needs to provide a physically plausible explanation of sporadic positives. "Sporadic" *Listeria* species positives may appear because the sampling frequency is too low, because the concentrations are near the detection limit, because the duration of a contamination event is short, or due to a lag in sampling product after a *Listeria* species positive. The presence of *Listeria monocytogenes* on a food contact surface (FCS) clearly increases the risk of product contamination.

The in-plant model generates transient and sporadic positives, as well as positives clustered in time. This is not inconsistent with stochastic contamination events that move *Listeria monocytogenes* from a harborage site to FCS. The duration and frequency of the contamination events are stochastic, and thus shorter events can produce positive findings that appear transient and sporadic. Longer events together with high frequencies of sampling appear as a process no longer in control. The model produces both situations.

The current version of the model does not consider contamination at retail, and published data (Gombas et al 2003) indicate that such contamination does occur. FSIS is currently assessing recently completed research by the National Alliance for Food Safety and Security to understand more fully the degree of contamination that occurs at retail establishments versus processing plants.

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.

The 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat was designed to answer specific risk management questions. Rather than simulate each possible process configuration, a range of model input values are used that capture the variability within the industry. This eliminates the need to simulate every possible individual operation or process, while still allowing valid conclusions to be drawn. Stochastic modeling is also appropriate in cases such as this where data are limited.

FSIS is not aware of any published data which indicates large plants are actually less risky than small or very small plants. Current risk based plant sampling may eventually be able to answer this question, but for now the model assumes that plant size does not directly correlate with risk.

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.

FSIS agrees that sanitation effectiveness is one of the more uncertain parameters. However, as currently configured the model results are not very sensitive to sanitation effectiveness. Because of the range of transfer coefficients used in the model, most of the bacterial cells are transferred from the FCS to the product before the surface is sanitized at the end of the shift. This is clearly mentioned on page 29 of the report.

When additional data are made available regarding transfer coefficients, they will be evaluated for use. If the transfer coefficient is lowered, then the specific value of sanitation effectiveness becomes more important.

The routine daily sanitation effectiveness in the model is 87.5%, and this is within the range of published data.

If AMI has data to indicate 99-99.9% sanitation effectiveness is more likely, they should make this data available in the open literature. As discussed on page 14 of the report, one interpretation of the Lunden et al. 2002 paper is that it can be very difficult to sanitize harborage sites.

These efficiencies are not assumptions in the model. As shown in Figure 23, the lethality effectiveness ranged from 70 to 99%, with industry participation ranging from 50 – 100%. At no point were they tied to specific interventions. A range of values was

chosen so that risk managers could relate public health improvements to post processing efficiencies. See risk management question #2 on page 8 of the report.

This risk assessment was not asked and did not attempt to identify specific types of interventions other than general post processing lethality and use of growth inhibitors. There was no need to model specific treatments such as sodium lactate, irradiation, or steam pasteurization.

Note: the AMI comments themselves indicate the very high efficiencies suggested are not always applicable. Post processing lethality is effective only when "environmental contamination" levels exist. But in some, possibly rare, instances the process is not fully in control or the product is abused, resulting in greater than "environmental levels" of contamination. Requirements for post processing lethality treatments are provided in the Compliance Guidelines accompanying the Interim Final Rule to Control *Listeria monocytogenes* in Ready to Eat Meat and Poultry Products (9 CFR 430), available at www.fsis.usda.gov.

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.

The 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat made use of all available and appropriate data sets. The report discusses the limitations associated with a relative paucity of particular types of data. The report includes data gathered by FSIS during In-Depth Verification (IDV) reviews following a non-compliance event, such as a product sample which tested positive for *Listeria monocytogenes.* IDV data was used to estimate contamination frequency. The report clearly discusses this limitation on page 23.

FSIS disagrees with the comment that "all current relevant scientific literature and industry data have not been integrated". FSIS used both industry and published scientific data as shown in the citations of the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat report. As just one of several examples, FSIS used industry data provided by Dr. Bruce Tompkin that was published in the peer reviewed scientific literature in order to estimate the duration of a contamination event. The AMI comment cited the need for specific industry data with regards to the effectiveness of specific interventions for which the model accommodates through the use of sensitivity analyses. If specific data on the effectiveness of specific interventions is known, then users can simply use the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat model and evaluate the estimated public health impact for specific interventions.

"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?)"
This statement included in the comments does not appear in the FSIS published report. A similar statement concerning the IDV data appears on page 23-24 "Nor does the data provide sufficient sampling evidence to estimate the duration of contamination in comparison to other data (i.e., Tompkin, 2002).

With regards to the inappropriate use of the term indicator organism, as opposed to index organism, ICMSF 7 (Microbiological Testing in Food Safety Management) provides a discussion of indicators and a table describing factors to consider when selecting an indicator. The FSIS use appears consistent with this reference. The term "index" organism does not appear in the index.

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 it 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.

The suggestion that contaminant event timing should change based upon plant interventions is probably accurate. However, the Lunden et al. 2002 paper illustrates how difficult it can be to control *Listeria monocytogenes* contamination once a harborage site is established. Given the limited contamination event timing data, treating the contamination event parameters as independent of interventions is conservative in protecting public health.

With regard to plant size not being related to FCS area, the Exponent report conducted for AMI clearly shows that FCS is related to plant size. Conceptually, there may be better variables to consider such as process line configuration and packaging technology, but plant size in a stochastic model appears adequate.

With regard to product configuration (stacked, shingled, etc) affecting the transfer coefficient, the level of detail required to simulate each product configuration is not warranted. The stochastic nature of the model should account for these variations.

With regard to the assumption in the risk assessment that concentrations distributions were similar to prevalence distributions, FSIS agrees that this assumption requires further data. But this assumption is discussed in detail on Page 33-34 of the report, and further evaluated by sensitivity analysis in Table 28.

With regard to the assumption that bacteria are uniformly distributed spatially on the FCS and throughout a product lot, FSIS agrees that this is a major limitation, and is discussed as such on Page 37 of the report. From a sampling perspective however, such a limitation

could be overcome by an appropriately designed composite sampling design rather than simple random samples.

With regard to the fixed growth of 1 log from production to retail, FSIS agrees that it is a simplification. However, it is a consistent approach to the model used in the 2003 FDA USDA Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, which used 2 log growth as a constant. The limitation is clearly discussed on page 39 of the report and Appendix B is used to discuss the appropriate value.

The comment that the University of Georgia data were not considered is simply incorrect. It is referenced as Deaver (2002). These data were used as the basis of Figure 9 dealing with sequential testing and therefore heterogeneity, and an example of why this prevalence data could not be used to generate a transfer coefficient is given in Table 17. These data were carefully considered in the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat, not ignored as the comments suggested.

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.

FSIS feels these comments do not present the full benefit of food contact surface and product sampling. It is true, as discussed in the report, that sampling has limitations especially as prevalence decreases. The modeling results showed that even extensive sampling only identified lots with *Listeria monocytogenes* concentrations above the detection limit. If product abuse occurred prior to consumption, even low concentrations could grow to cause public health impacts. So sampling is limited by prevalence and detection limits. Most of the criticisms of sampling assume a binomial distribution because a sample is found to be either positive or negative. However, the binomial distribution assumes homogeneity and independence from one sample to the next. The risk assessment model does not make these assumptions. Because of contamination events and mass balance principles, there is a correlation in the *Listeria monocytogenes* concentrations from one lot to the next. Thus there is a degree of clustering in the product lots that are contaminated. In this case, something like a negative binomial distribution is more appropriate than a binomial. Even low frequency of sampling can produce public health benefits if response is taken after a *Listeria monocytogenes* positive.

With regard to the statement in the AMI comments that “In order to define sampling and testing program, it is necessary to define prevalence of pathogen, sensitivity & selectivity of assay, and number of samples from lot… These inputs will provide a probability of excluding defective lots.”

In effect the risk assessment did exactly this, but in a more physically and biologically plausible mathematical framework than a simple binomial table. The model was also designed to answer risk management questions, not merely a probability of excluding defective lots. The risk assessment simulates *Listeria monocytogenes* concentrations rather than prevalences. Note the concentrations are model outputs, not inputs. Also note that prevalences can be calculated if concentrations and detection limits are known, but not the reverse. Concentrations are also required if mortality and morbidity are to be predicted (as through a dose response curve). An example of the predicted *Listeria monocytogenes* concentrations is given in Table 20. The assay sensitivity is discussed in pages 34-36. The various sampling frequencies are discussed throughout (e.g. 4-2-1 indicates 4 FCS samples per line per month for large plants, 2 for small, and 1 for very small). An example of the probability of excluding lots is provided in Table 27.

The table from the International Commission on Microbiological Specifications for Foods (ICMSF) (Table 7-1) referenced in the AMI comments is a simple binomial table. For the use of this table to be valid, *Listeria monocytogenes* concentrations must be homogeneous and samples must be independent. In the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat, FSIS did not want sampling to be independent. Rather, the Agency approach is to trigger additional sampling (and corrective actions) whenever a positive is found.

Thus, the binomial distribution of the ICMFS table is not a valid point of comparison, and the table does not apply in the context of the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat and its associated risk management questions. If the degree of clustering was quantifiable *a priori*, a table based on a negative binomial distribution would be more appropriate. For the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat, the dynamic model generates the clustering over time, and degree of clustering does not need to be specified beforehand. (It is implied from the contamination event duration & frequency, as well as the plant production levels and sanitation effectiveness, i.e. anything that affects the mass balance.)

Because *Listeria monocytogenes* contamination is clustered over time, even limited sampling can produce public health benefits if rapid actions are taken when positive samples are found. This also suggests that waiting until a fixed number of sequential positives are found greatly reduces the effectiveness of sampling.

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.

Rather than simulate each possible intervention or technology possible, a range of input values are used that capture the variability within the industry. This eliminates the need

to simulate every possible individual operation or process, while still allowing valid conclusions to be drawn.

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 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat report and model were formally peer reviewed in accordance with the guidelines issued by the Office of Management and Budget and made publicly available through Docket 03-0005N prior to the February 2003 public meeting. Subsequently, the risk assessment report and model were updated based on public input and have been publicly available through the Docket (03-0005N) since May 2003. The 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat model and report are currently posted to the FSIS website (www.fsis.usda.gov) for increased public accessibility.

In addition, AMI's contractor Exponent requested and received the 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat model directly from FSIS in 2004. Attached to these comments from AMI was a report by Exponent that was funded by AMI evaluating the model with industry data.