Response to Public Comments on the
FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Deli Meats,
May 27, 2010

INTRODUCTION

On April 9, 2009, the Food Safety and Inspection Service (FSIS) announced that it would like to receive public review and input on the "Draft FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Deli Meats." [Docket No. FSIS-2009-0003]. This risk assessment compared the risk of listeriosis from consumption of prepackaged ready-to-eat (RTE) deli meat versus RTE deli meat that is sliced and packaged at retail. The risk assessment report, peer review comments, and models were made publicly available. The comment period on this risk assessment closed on June 8, 2009.

FSIS received several substantive comments, addressed below, from eight organizations which include academia, industry and consumer groups on the "Draft FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Deli Meats." FSIS responses are the result of a comprehensive review and evaluation of all the public comments received on this risk assessment. The responses are grouped into five major categories, which are: model assumptions; data quality; modeling techniques; clarity; and other comments that do not fit into the first four major categories.

FSIS revised the risk assessment report and model as part of the response to these comments, and details are provided in the document titled "FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Deli meats *Response to Public Comments"* which can be found in the FSIS docket (Docket # FSIS-2010-0000) and on the FSIS website[1]. Additionally, the risk assessment report titled, "FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Deli Meats" (hereafter the LM Comparative Risk Assessment) has been updated after due consideration of the public comments received. This final risk assessment report also can be found at the website address provided below.

[1] http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp

(A) **Model Assumptions**

Comment A-1: *The draft risk assessment uses the baseline assumption that 1,600 listeriosis cases per year are attributable to deli meats. This result is from the risk assessment for Listeria monocytogenes (Lm) that was developed by the Food and Drug Administration (FDA) and the FSIS completed in 2003. This ranked relative risk among 23 ready-to-eat (RTE) food categories and was based on data collected prior to 2003. Using this "old" data neglects to consider the considerable strides made by the industry since that time.*

Response: The draft risk assessment and the final report did incorporate the most recent available data on RTE meat and poultry products. Also, the 2003 FDA-FSIS risk assessment model was adapted to include current estimates of growth inhibitor usage by the industry and measured data at retail stores from the Draughon (2006) study. Because retail data were available, the risk assessment did not need to start the model at the processing plant. Thus the reductions in *Listeria monocytogenes* prevalence at federally inspected plants that have occurred over the last several years were not directly incorporated. These improvements are instead realized through current retail *Listeria monocytogenes* contamination data, i.e. the Draughon (2006) study.

The risk assessment did not assume that 1,600 listeriosis cases are attributable to deli meats. The number of listeriosis cases and deaths is an output of the comparative risk assessment model, not an assumption. The predicted number of listeriosis cases attributable to deli meats was about 1,100 (see Table 10 in the LM Comparative Risk Assessment).[2] This value incorporates industry changes through 2006, when the retail data were collected.

The risk assessment kept the total number of deaths in each age group across all food categories the same as the 2003 FDA-FSIS risk assessment. FSIS acknowledges that this value may well have changed since 2003. However, the total number of deaths applies to all food categories combined, and FSIS was able to determine that the percent of deaths attributed to any specific food category is not impacted by the specific value used for the total number of deaths, i.e. the relative contribution of each food category to the overall number of deaths associated with *Listeria monocytogenes* would not be expected to have changed. As part of an expanded sensitivity analysis included in the final report, FSIS ran a version of the model that arbitrarily reduced the number of deaths in each age group across all 26 food categories[3] by 50%. While, as expected, the predicted mean total

[2] http://www.fsis.usda.gov/Science/risk_assessments/index.asp#RTE

[3] In the 2003 FDA-FSIS risk assessment, 23 food categories were ranked according to their inherent risk. In that risk assessment, deli meat was considered as one category. However, for the purpose of this risk

number of deaths dropped, the percent breakdown among the four deli meat categories (prepackaged with growth inhibitor, retail-sliced with growth inhibitor, prepackaged without growth inhibitor and retail-sliced without growth inhibitor) remained largely unchanged – 83% of deaths attributed to deli meats are from retail-sliced product. Thus the results are not sensitive to assumptions concerning the total number of deaths.

Table 1 - Fraction of predicted annual listeriosis deaths from deli meat per annum.

	Pre-packaged	Retail-sliced	TOTAL
Used growth inhibitor	5.2%	13.2%	18.4%
Did not use growth inhibitor	11.8%	69.8%	81.6%
TOTAL	17.0%	83.0%	100.0%

One of the outcomes of this LM Comparative Risk Assessment is the development of an interagency risk assessment (FSIS and FDA) to evaluate *Listeria monocytogenes* cross-contamination at retail. The purpose of this subsequent risk assessment is to determine the effect on public health of current retail practices and identify potential interventions to reduce or prevent *Listeria monocytogenes* contamination in ready-to-eat foods (hereafter, the Interagency Retail Risk Assessment).

Comment A-2: *Indeed, it is believed that a new risk assessment, which once again compares the various RTE categories, would find that deli meat no longer causes most cases of listeriosis. The data appears to support this as, while the incidence of listeriosis has remained almost constant from 2001-2007, the Listeria monocytogenes contamination rate on deli meats has decreased substantially. In addition, the overall prevalence and levels of Lm in deli meats has apparently decreased. These strongly suggest that the assessment must develop better attribution data.*

Response: The prevalence of *Listeria monocytogenes* at both federally inspected processing plants and at retail has decreased. The evidence for the former can be seen from FSIS' ALLRTE monitoring program results[4], which indicate a continuous decline in prevalence since 1990 (see Figure 2 on page 22 of this document or Figure 1 in the LM Comparative Risk Assessment). The evidence for the latter can be seen from comparison of the then National Food Processors Association (NFPA) data and the National Alliance for Food Safety and Security (NAFSS) data (see Table 14 in the LM Comparative Risk

assessment, deli meat was split into 4 categories based on slicing location and whether it contained growth inhibitor or not. Therefore, this risk assessment considered 26 food categories rather than 23.

[4] http://www.fsis.usda.gov/Science/Micro_Testing_RTE/

Assessment). However, the incidence of listeriosis reported by CDC FoodNet surveillance[5] has been relatively constant since 2001. Thus, strides to reduce *Listeria monocytogenes* contamination in RTE meat and poultry products have not translated into public health improvements, and the findings of the LM Comparative Risk Assessment indicate that cross-contamination at retail may be a key reason.

As noted in the response to Comment A-1, a reduction in the contamination rate for *Listeria monocytogenes* was incorporated through the retail data measurements. Although a full risk-ranking analysis of multiple food categories (as done for the 2003 FDA-FSIS risk assessment) was beyond the scope of this project, section 3.2 in the LM Comparative Risk Assessment analyzes results across the 23 or 26 food categories (depending on whether deli meats were considered as a single category or stratified into four categories). Because only data for deli meats in the 2003 FDA-FSIS risk assessment was updated, this may impact on the results. Improvements by other industries, e.g. changes in milk pasteurization processes, were not evaluated. So the analysis, in effect, compares the *Listeria monocytogenes* contamination in deli meat associated with industry practices in place around 2006 with the other RTE foods reflecting industry practices prior to 2003. The results show that, when treating deli meat as four categories, the greatest number of deaths per annum and the greatest risk per serving is attributed to retail-sliced deli meat without growth inhibitors. Treating deli meat as one combined category indicates that deli meats are associated with the greatest number of deaths per annum, and rank third for the highest risk per serving behind raw frankfurters and pâté (Figure 1).

[5] http://www.cdc.gov/foodnet/factsandfigures/AllSites19962008_Incidence.pdf

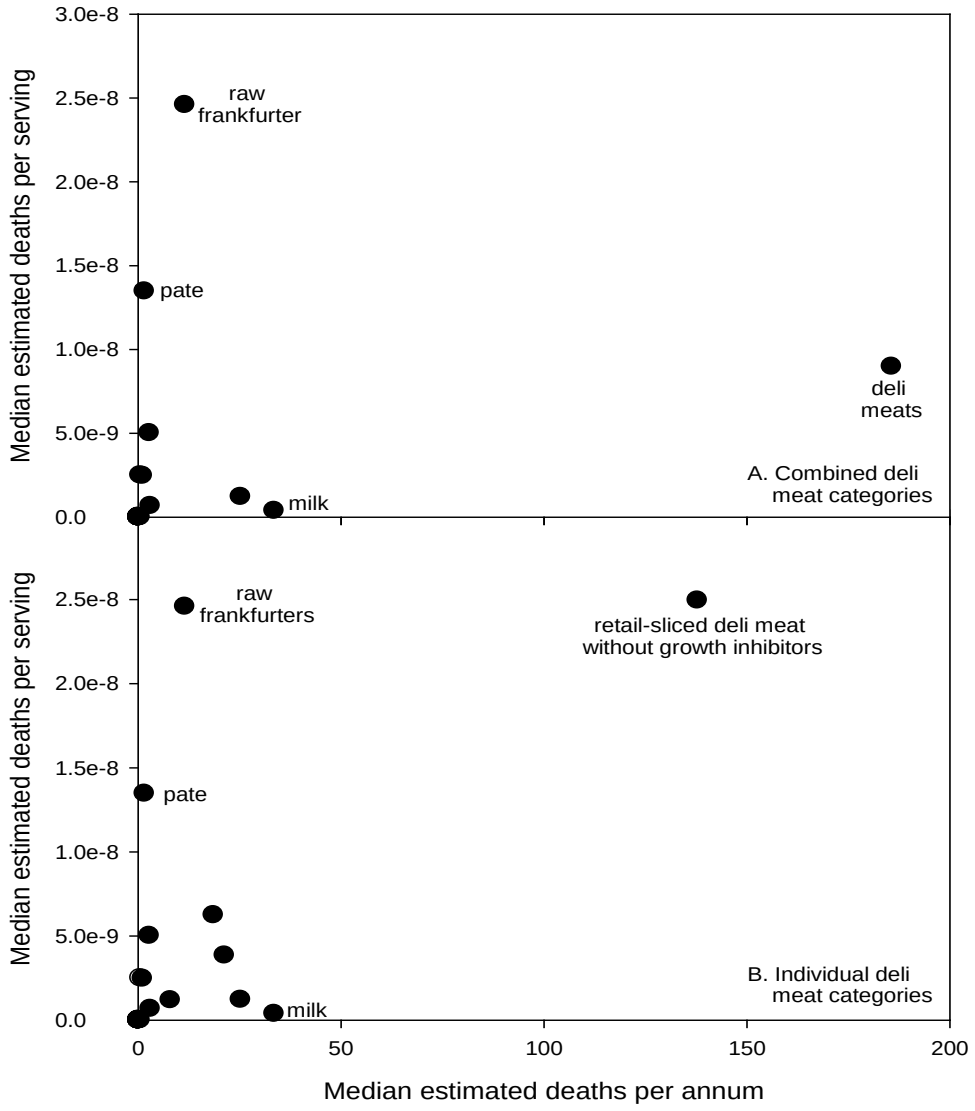

Figure 1. Comparison of estimated listeriosis deaths per annum and deaths per serving across the various food groups.

This graph is a replicate of Figure 12 in the LM Comparative Risk Assessment. (A) deli meat categories combined into one category. (B) deli meat treated as 4 separate categories.

Note: All data are from the 2003 FDA-FSIS risk assessment except those of deli meats.

Comment A-3: *The validity of the baseline assumption (1,600 listeriosis cases per year are attributable to deli meats) may be affected by a large increase in the number of deli products with growth inhibitors (from an estimated 17.5% to 58.9%). This large increase in the usage of inhibitors would be expected to lower levels of Lm consumption and would certainly be a factor in why there has been no outbreak attributable to deli meats since 2002.*

Response: As noted in the response to Comment A-1, the LM Comparative Risk Assessment model did not assume that 1,600 listeriosis cases are attributable to deli meats. The risk assessment model predicted that approximately 1,100 listeriosis cases are attributable to deli meats using the current estimate of growth inhibitor usage (46.6% for prepackaged product and 53.4% for retail-sliced product based on industry reporting in 2007 as required by 9 CFR 430.4(d)).

According to the Centers for Disease Control and Prevention (CDC), between 1998 and 2007, 7 out of 21 *Listeria monocytogenes* outbreaks were linked with deli meats. In 2002 and 2005, deli meats were implicated in outbreaks while in 2008, deli-type salad was implicated in another outbreak (Angulo, 2009). This suggests that even though the use of growth inhibitors increased in federally inspected establishments, this may not have prevented recontamination of RTE products when handled, sliced and packaged in retail facilities.

Comment A-4: *The assumption that 2-log growth occurred during the shelf life of deli meats with growth inhibitors should be re-examined. In the FSIS Listeria Guidance issued in May 2006, there are two levels of expected control: ≤1 -log growth and 1-to 2-log growth. In reality, most products with growth inhibitors show much less than 2-log growth. It would be useful to determine among deli meats with growth inhibitors, the fractions that achieve ≤1 -log and 1-to2-log growth respectively to improve the accuracy of the risk assessment. In the absence of data, "what if" scenarios should be used to demonstrate the impact of different levels of inhibition on risk.*

Response: The report did conduct a sensitivity analysis of growth during the shelf life and has expanded the analysis in the revised document (See Figure 14 in the LM Comparative Risk Assessment). However, the results were not sensitive to this assumption, presumably because approximately half of prepackaged (46.6%) and retail-sliced (53.4%) product use growth inhibitor. Thus, changes in growth inhibitor effectiveness impact both categories almost equally.

The LM Comparative Risk Assessment model did use a regulatory definition of growth inhibitor effectiveness (no more than 2-log growth during shelf life) as provided by 9

CFR 430 because the fraction of product with growth inhibitors was calculated from production volume across the alternatives as self reported by industry using the regulatory definition specified in 9 CFR 430.

The lack of industry data on the concentrations of growth inhibitors used and how their effectiveness is verified, i.e. the resulting lag phase and growth rate, does increase the uncertainty in model estimates. For an establishment to claim credit under 9 CFR 430 for growth inhibitor usage, it must support such a claim with validation studies and provide a description of the verification process in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan. These data would be useful for future FSIS risk assessment efforts.

Comment A-5: *The assumption of a 14-day shelf life for products with inhibitors packaged at manufacturing should be re-examined because it may have resulted in inaccurate calculations for growth rates for these products. In reality, most products formulated with inhibitors have at least a 40-day shelf life, and some have a shelf life up to 80 days. Furthermore, many products of this type remain very stable (no growth) over the product shelf life. Therefore, growth rates for products with inhibitors would be much lower than those calculated in the draft risk assessment because the amount of growth would be much less than 2-log overall and the shelf life would be much longer than 14 or 21 days. The number of cases or deaths attributed to products with inhibitors was likely over-estimated in the draft risk assessment. We suggest that more plausible assumptions be used when the risk assessment is finalized.*

Response: FSIS analyses indicated that shelf life did not significantly affect the results. According to an American Meat Institute (AMI) consumer survey, 96% of product is stored for less than 14 days; therefore the assumption of a 14-day shelf life seems reasonable. Regarding shelf stability, the Federal Register Volume 66, No. 39 (Docket No. 97-013P) published February 27, 2001 titled, "Performance standards for the production of processed meat and poultry products; proposed rule" states that "Shelf-stable products remain ready-to-eat under ordinary temperature and humidity conditions and, if the package integrity is maintained during holding, shipping, storage, display at retail, and in the home throughout the manufacturer's shelf-life determination." There is no mention of shelf life duration in the Federal Register or the FSIS *Listeria monocytogenes* Compliance Guidelines released May 2006. The compliance guidelines stipulate a product to be 'shelf stable' if it achieves a water activity of 0.80 or less. This is critical for controlling the growth of pathogenic microorganisms and mold over the course of the product's shelf life.

FSIS has included risk assessment model simulations based on 40- and 80-day shelf life in the LM Comparative Risk Assessment as part of an extended sensitivity analysis. Note that this assumes consistent and effective use of growth inhibitors throughout the industry, which is yet to be verified. The results indicate that for a 40-day shelf life, an estimated mean of 188.9 deaths are attributable to the 4 categories of deli meats. The percentage breakdown is shown below. Thus for a 40-day shelf life, 85.9% of deaths from deli meats are attributable to retail-sliced product and retail-sliced products are 6.07 times riskier than prepackaged.

Table 2 - Fraction of predicted listeriosis deaths per year – 40 day shelf life

	Pre-packaged	Retail-sliced	TOTAL
Used growth inhibitor	0.1%	0.4%	0.5%
Did not use growth inhibitor	14.1%	85.5%	99.5%
TOTAL	14.1%	85.9%	100.0%

For an 80-day shelf life, an estimated mean of 189.9 deaths are attributable to the four categories of deli meats. The percent breakdown is shown below.

Table 3 - Fraction of predicted listeriosis deaths per year – 80 day shelf life

	Pre-packaged	Retail-sliced	TOTAL
Used growth inhibitor	0.0%	0.0%	0.0%
Did not use growth inhibitor	14.0%	86.0%	100.0%
TOTAL	14.0%	86.0%	100.0%

Thus for an 80-day shelf-life, 86% of deaths from deli meats are attributable to retail-sliced product and retail-sliced products are 6.16 times riskier than prepackaged.

The 14-day shelf life assumption found that 83% of *Listeria monocytogenes* related deaths from deli meats are attributable to retail-sliced product and retail-sliced products are 4.88 times riskier than prepackaged. From these calculations, it is apparent that the shelf life is not a sensitive variable influencing the findings in this risk assessment.

Comment A-6: *The draft references the assumption that the use of antimicrobial growth inhibitors in prepackaged deli meat and retail-sliced deli meat are the same. This assumption was based on the usage of antimicrobial growth inhibitors prior to the*

implementation of the Interim Final Rule. This assumption likely underestimates the use of antimicrobial growth inhibitors in prepackaged deli meat as it excludes the use and importance of cook-in packages on retail deli products.

Response: The model did not assume that the use of antimicrobial growth inhibitors in prepackaged deli meat and retail-sliced deli meat are the same. FSIS data collected as part of 9 CFR 430.4(d) industry reporting in 2007 indicated that, based on total RTE deli meat production, 32.2% was prepackaged and used growth inhibitors, 26.7% was retail-sliced and used growth inhibitors, 14.4% was prepackaged and did not use growth inhibitors, and 26.7% was retail-sliced and did not use growth inhibitors. These values were used for modeling purposes (see Table 8 in the LM Comparative Risk Assessment). None of the results reported were based on data from before the Interim Final Rule.[6] Prior to the Interim Final Rule, much less growth inhibitor was used – approximately 17.5% of product. (Data from both before and after the Interim Final Rule was used to estimate the effective growth rates for product with and without growth inhibitor. See Section 2.2 in the LM Comparative Risk Assessment).

Cook-in package products are not exposed to the environment after the lethality treatment in federally inspected establishments, and therefore are not regulated under 9 CFR 430, but may be subject to cross-contamination in a retail setting if handled, prepared, sliced and repackaged there.

Comment A-7: *The use of antimicrobial growth inhibitors has changed since the 2003 data was applied to estimate usages for the Alternative categories. It would be beneficial to the meat industry, and would strengthen the finalized risk assessment if current antimicrobial growth inhibitor data was included.*

Response: The risk assessment model used July 2007 data to estimate the fraction of product with and without growth inhibitors (see Table 8 in the LM Comparative Risk Assessment). This time period is after the implementation of the Interim Final Rule.

Comment A-8: *The assumption that prepackaged and retail-sliced deli meat having the same microbial growth rate of 2 log_{10}/gram/14 day at 3°C shelf -life length may not accurately depict the shelf-life of deli meats. The 2003 assumption that the lag phase of microbial growth should not be calculated is supported but extending the microbial stationary phase is realistic in today's commercial meat processing modus operandi. Prepackaged RTE deli meats that are formulated with antimicrobial growth inhibitors*

[6] "Interim Final Rule for *Listeria monocytogenes* in ready-to-eat meat and poultry products" (9 CFR 430, 68FR 3422; June 6, 2003 at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F.pdf).

typically are designed to limit growth of Listeria monocytogenes (L. monocytogenes) to less than 1 log per gram increase over the entirẽC5labeled shelf -life which extends beyond 50 days from the point of packaging. The use of cook-in packaging creates a pasteurized product with no L. monocytogenes present. Recontamination and growth of L. monocytogenes of these types of products after package opening can result in L. monocytogenes levels of 6-8 log_{10}/gram in 14-28 days at˚C5 unless effective antimicrobial growth inhibitors are used within the product formulation. Consideration should be given to the role of cook-in packaging and the before and after package opening of shelf life in deli products, particularly for retail-sliced deli meat products.

Response: Lag phase was not included in the model, and its lack may have impacted the results. However, the major difference in lag phase appears to be whether growth inhibitor is used or not (Pradhan *et al.,* 2009). As mentioned previously, prepackaged and retail sliced product had similar percentages of growth inhibitor use. Lag phase is explicitly included in the subsequent risk assessment (Interagency Retail Risk Assessment) developed to evaluate retail practices and *Listeria monocytogenes* cross-contamination. Note: Cook-in package products are not exposed after the lethality treatment and are therefore not regulated under 9 CFR 430.

Comment A-9: *It is recognized that there is difficulty in determining the exponential growth rate for retail-sliced deli products as it is dependent on a variety of factors including, but not limited to, product temperature, when the product was opened, length of storage within the retail deli, retail store environment, and consumer behavior. But these factors need to be considered when determining public health risk for the consumption of retail-sliced deli meats. The draft conclusions support the need to gather such data.*

Response: FSIS agrees that these factors are important to consider in determining bacterial growth. Because data on *Listeria monocytogenes* concentrations as the product was sold were available (Draughon, 2006) the model did not need to include storage time/temperature conditions in retail. The concentration data served as a measure of retail conditions. Consumer storage time and temperature were included in the model. In fact, two different data sources were used to generate different storage time/temperature distributions as part of a sensitivity analysis. The second-order Monte Carlo modeling approach treats the exponential growth rate as a variable parameter. In other words, even at the same temperature different growth rates would be used for different model runs. This is done to incorporate the range of different products where growth can occur, without having to simulate each specific type of product.

Comment A-10: *FSIS should be cautious of its assumptions of sanitary conditions within the retail store. The logic of selecting retail stores for sampling is supported; the sampling protocol had the researchers sampling each store only once. This visit and the data collected should not be used to categorize the sanitary conditions of the retail store and the implied cross-contamination with positive samples, as it only measures the condition of the retail store during time of sampling. The data collected reports on "snapshots" of time and the draft should clarify and report this data to reflect conditions of sampling. Additional retail sampling over an extended period of time would allow for a clearer definition of retail store conditions and should be considered.*

Response: The report did note that *Listeria monocytogenes* positives were sometimes clustered by store. In other words, several servings from the same store were found to be positive (Draughon, 2006). While one sampling occasion was insufficient to characterize the long term sanitary conditions of stores where clustering was noted, this finding alone was sufficient to raise concerns about sanitary conditions within those stores. It should also be noted that sampling data was blinded and no regulatory actions taken.

The experimental design used to collect the retail data was a standard cross-sectional study. As noted by the comment, each store was only visited once and results were not sufficient to describe the long term sanitary conditions of any particular store. However, a sufficiently large number of cross-sectional results can describe the sanitary conditions of the retail industry as a whole (Kleinbaum *et al*., 2007). Thus the cumulative density function plots of *Listeria monocytogenes* concentrations (See Figure 5 in the LM Comparative Risk Assessment) are considered representative of prepackaged and of retail-sliced product.

As part of a subsequent risk assessment to this one, FSIS with its partners is conducting a study of *Listeria monocytogenes* contamination in retail facilities that handle, slice and prepare RTE products. This longitudinal study will provide information on *Listeria monocytogenes* levels and subtypes found in the retail setting over time and before and after implementation of interventions to control environmental sources of *Listeria monocytogenes*.

Comment A-11: *The terms retail and retail deli are very vast. Most likely they encompass some USDA inspected establishments that operate a portion of their business under the retail exemption, or as a retail deli. Follow-up to ensure that these types of facilities are not over scrutinized simply because USDA personnel are already in their facilities on a regular basis will be embarked upon. It is important that equal evaluation be given to all establishments that fall under the retail umbrella in order to accurately understand the risks for slicing deli meat in a retail setting.*

Response: The Interagency Retail Risk Assessment will assess the effect on public health of current practices and potential interventions that reduce or prevent *Listeria monocytogenes* contamination in ready-to-eat foods. This risk assessment will be used to inform any decision or action that FSIS and FDA may take to address *Listeria monocytogenes* contamination at retail.

Comment A-12: *In 2006, researchers with the National Alliance for Food Safety and Security (NAFSS) completed a study of Listeria monocytogenes contamination in prepackaged RTE meat and poultry deli meats and those sliced and packaged at retail. Reanalyzing the FSIS-FDA 2003 quantitative risk assessment of listeriosis from prepackaged meat versus RTE deli meat sliced and packaged at retail provided more data to support the original assumptions made. Thus, the assumptions made in the Draft Risk Assessment are quite reasonable.*

Response: FSIS appreciates this comment.

Comment A-13: *One important side issue for consideration within the draft assessment concerns the apparent emphasis on antimicrobials and growth inhibitors as the primary control for Listeria monocytogenes. One point in desperate need of study within the retail deli environment is a measure of the ongoing effectiveness of antimicrobials once a product is handled and sliced. Currently, using a growth inhibitor allows a product into Alternative 2. Listeria monocytogenes can still be present on the product, however. What happens when this deli product is exposed to the retail environment? Can it actually become the vector for Listeria monocytogenes? For example, does the Listeria monocytogenes rub off onto other products within the deli case or onto the slicer? Can it then propagate? This is a point worth serious consideration, one that again argues for a minimum segregating Alternative 1 and 2 products from those in Alternative 3 within the retail deli environment.*

Response: FSIS appreciates this comment and believes that some of these concerns may be adequately addressed by the Interagency Retail Risk Assessment.

Comment A-14: *The emphasis on growth inhibitors, particularly those containing sodium, seems to trade short-term risk reduction for a potentially devastating long-term hazard. Sodium is a proven health risk for diseases such as hypertension, diseases which kill millions and cost society billions. Why emphasize sodium-based products, in the face of the proven benefits of thermal and mechanical approaches to pathogen reduction? Ultimately, chemical additives may have their place, but the present myopic view precludes the evaluation and wider adoption of less invasive, proven pathogen killers.*

Response: FSIS recognizes that there are public health hazards potentially associated with excessive sodium consumption. The LM Comparative Risk Assessment makes no recommendations for specific growth inhibitors. There is always the option for cations other than sodium, e.g. potassium, to be used in growth inhibitors. The analyses indicate that when effective, growth inhibitors reduce the number of deaths caused by *Listeria monocytogenes* {Endrikat *et al*. (2010); Pradhan *et al*. (2010)}. The advantage of growth inhibitors over pathogen reduction alone is, of course, that growth inhibitors are effective if the product becomes contaminated after the pathogen reduction step. Pathogen reduction is effective at the food processing facility, which is why a post-processing pathogen lethality step can be used to qualify for Alternative 2 and is part of the requirement to qualify for Alternative 1 as in 9 CFR 430. But the data indicate that cross-contamination can occur at retail where further pathogen reduction is not feasible. Growth inhibitors can still be an effective control for bacterial growth for cross-contaminated product. The multi-barrier concept of pathogen reduction at production, use of growth inhibitor, proper sanitation and storage both at retail and by the consumer represents the most effective protection for public health.

(B) Modeling Methodology

Comment B-1: *As presented, the model is very difficult to use since there are no general instructions provided with the spreadsheets. Additionally, the model depends on inputs of growth rates from the 2003 Food and Drug Administration risk assessment which must be obtained separately, and again that model is also not particularly "user friendly". FSIS is encouraged to improve the usability of the model for stakeholders as it would be appreciated and increase the overall understanding of the impact of various factors involved in the risk assessment predictions. This would enable companies to efficiently evaluate potential strategies that could further improve food safety.*

Response: FSIS has developed a user manual to accompany the risk assessment model and report.[7]

Comment B-2: *In particular, the model used assumes that L. monocytogenes, upon contamination of RTE deli meats at retail, immediately resumes exponential growth (i.e. the model does not consider the lag phase). Contamination at retail can occur from a variety of sources though, including environmental sources, where L. monocytogenes may be exposed to different conditions (e.g., different temperatures); L. monocytogenes may thus experience a considerable lag phase once it contaminates RTE deli meats at retail. Not including a lag phase in the model may thus overestimate growth between*

[7] http://www.fsis.usda.gov/Science/risk_assessments/index.asp#RTE

contamination at retail and consumption and may also underestimate the effect of growth inhibitors (which prolong lag phase, in addition to reducing exponential growth rate).

Response: FSIS acknowledges that lag phase is not included in the LM Comparative Risk Assessment model, and that this may lead to overestimation of the public health risk of cross-contaminated retail-sliced product. The 2003 FDA-FSIS risk assessment model implicitly assumes that the bacteria at retail are already adapted to the food environment, and thus have passed their lag phase. Some authors (Pradhan *et al*., 2009) have argued that this may not be the case for product with growth inhibitors, where the lag phase may be extended. See the response to Comment A-8. FSIS and FDA have initiated an Interagency Retail Risk Assessment, which does consider the lag phase for *Listeria monocytogenes*.

Comment B-3: *The modeling techniques were developed as part of the 2003 FDA-FSIS risk assessment. As the draft risk assessment is independently peer-reviewed using a science-based analytical approach to collate and incorporate available data into a mathematical model, it was once again effective to produce similar results as the 2003 study. Overall, the modeling techniques were effective.*

Response: FSIS appreciates this comment.

(C) Data Quality

Comment C-1: *The draft risk assessment uses illness data from a paper published by P.S. Mead in 1999. And this paper was based on illness data collected prior to that time. It is believed that new FoodNet data should be used in this risk assessment and may well affect the overall numbers.*

Response: As discussed in the response to comment A-1, the number of illness and deaths may well have changed from the CDC foodborne illness estimates (Mead *et al*., 1999) which serves as the basis for the 2003 FDA-FSIS risk assessment model. However, the percent of deaths and illnesses attributable to a given food category is not affected by the number of deaths. See the table included in the response to comment A-1.

Comment C-2: *Of the twelve references for the 51 page risk assessment, only four were scientific papers published in peer-reviewed journals. It is suggested that, FSIS perform an updated literature search to obtain additional data to use in this risk assessment.*

Response: FSIS appreciates this comment but it should be noted that a full literature review was conducted to develop the LM Comparative Risk Assessment. FSIS agrees that much of the data used to develop the risk assessment was based on government reports and this is because these data are publicly available, and also additional data were obtained from the docket and literature. However, this is not necessarily a weakness of the analyses. The references have been updated in the LM Comparative Risk Assessment. In addition, a peer-reviewed paper based on the LM Comparative Risk Assessment was published in the *Journal of Food Protection* in April 2010 (Endrikat *et al*., 2010). The Draughon (2006) study that provided integral data to this risk assessment used trends that were similar to those published by Gombas *et al.* (2003) and the manuscript is undergoing revision prior to submission for peer-review publication.

Comment C-3: *The enumeration data from the NAFSS study appear to be based on counts obtained on MOX agar (p.25). It is not clear whether Lm confirmation was conducted for colonies on MOX agar and whether the data in Table 1 (p.7) reflect levels for confirmed Lm or levels on MOX agar (which would be Listeria spp.) Assuming all colonies on MOX are Lm would overestimate the Lm levels because not all Listeria colonies on MOX will be confirmed as Lm, as data obtained from the NFPA 2000-2001 study show. The NAFSS study should be published in a peer-reviewed scientific journal so that the methods used in the survey study can be fully examined to ensure the Lm prevalence and enumeration data are accurate and reliably consistent with data quality requirements.*

Response: Typical colonies appearing on MOX plates were spot inoculated onto RAPID' *L. mono* (BioRad, Hercules, CA) for species identification. Additionally, MOX plates characterized by esculin hydrolysis were screened for genetic confirmation using Gene-Trak assay (Neogen Corporation, Lansing, MI). The LM Comparative Risk Assessment report has been updated to include this information (Appendix, section A-1).

Comment C-4: *The dose-response models from the 2003 risk assessment were used in the 2009 study. Even though the previous approach in anchoring the scales of the dose-response curves to FoodNet illness data remains plausible, the shapes of the dose-response curves should be re-examined to determine whether they are still adequate. The re-examination should take into consideration the most recent dose-response relationship developed from data collected in guinea pigs (Williams et al., 2007), which is a biologically more plausible animal model (Lecuit et al., 2001; Nightingale et al., 2008) than the model derived from mouse data used in the 2003 risk assessment.*

Response: FSIS appreciates these comments and has reviewed these papers. Several of these studies focus on strain virulence and genetics of *Listeria monocytogenes.* The

current data available from retail and processing plant are not yet adequate to consider modeling different *Listeria monocytogenes* strains through the food chain. As new data becomes available, this may change. The dose-response model for *Listeria monocytogenes* is one of the most uncertain aspects of any *Listeria monocytogenes* risk assessment. However, the dose-response model affects all 23 or 26 food categories equally, so it is unlikely to have a significant impact on the relative proportion of the deaths across these food groups. As the goal of this project is to compare different deli meat categories, FSIS deemed that the existing 2003 FDA-FSIS dose-response model approach was acceptable given that the LM Comparative Risk Assessment was used to inform specific risk management questions. FDA and FSIS are aware of additional dose-response data that have been made available. FDA and FSIS are reviewing data to consider additional dose-response relationships.

Comment C-5: *To ensure the validity of data collection, the scientific community has used the premise of peer-review to critically analyze and critique an experiment's objectives, methodology, results and conclusions. This transparency of experimental design and sharing of data allows peers with high level of knowledge and expertise to evaluate the research to determine its strength and validity. The draft references a public presentation of the research of Draughon (2006). Currently, the results of this research are not published or have not been made available by the agency for review. We encourage the agency to be more transparent on data being included in the policy decision-making process.*

Response: FSIS appreciates this comment and has taken adequate steps to address this concern. A peer-reviewed paper based on the LM Comparative Risk Assessment was published in the *Journal of Food Protection* in April 2010 (Endrikat *et al*., 2010). The Draughon (2006) study that provided integral data to this risk assessment used trends that were similar to those published by Gombas *et al.* (2003) and the manuscript is undergoing revision prior to submission for peer-review publication.

Comment C-6: *It would be nice to see improvement in the explanation and data surrounding the variety of factors that cause increased pathogen growth on retail-sliced deli products.*

Response: The Interagency Retail Risk Assessment will address this concern by determining the effect on public health of current practices and potential interventions that reduce or prevent *Listeria monocytogenes* contamination in RTE deli foods. The goal of the LM Comparative Risk Assessment was not to formally investigate the factors that lead to increased concentrations on retail-sliced products, but rather to determine if the increase significantly impacted public health.

Comment C-7: *The sampling techniques employed produced at .17% L. monocytogenes rate of prevalence for pre-packaged meats compared to the 1.39% L. monocytogenes rate of prevalence for retail-sliced product. The data used provided an accurate depiction of the current situation. Similar results were provided from the 2003 and 2006 study.*

Response: FSIS appreciates this comment.

Comment C-8: *FSIS is urged to use the data from this risk assessment to maintain robust Listeria controls over FSIS-regulated products, including refuting FDA's call for weaker tolerances on FDA-regulated products entering the retail environment.*

Response: The aim of the Interagency Retail Risk Assessment is to evaluate *Listeria monocytogenes* cross-contamination of retail and to ascertain the effect on public health of current practices and potential interventions that reduce or prevent *Listeria monocytogenes* contamination in RTE foods. This information will further guide risk management strategies to reduce, control or limit the risk of listeriosis associated with RTE products.

(D) Risk assessment Clarity

Comment D-1: *In the executive summary "RESULTS" section on p.2, results based on the 2006 RTI time/temperature data were shown. On the other hand, in the "Results" section of the document (not Appendices), results based on time/temperature data in the 2003 risk assessment were shown (p.18). The results on p.2 and p.18 are not consistent, while the results on p.2 are consistent with those from Appendix II (p.44). It would be clearer if the results from Appendix II are placed in the main document.*

Response: FSIS appreciates this comment and has updated the LM Comparative Risk Assessment.

Comment D-2: *The draft risk assessment report indicated that consumer behavior data from the RTI study were used to determine time/temperature distributions for pre-packaged and retail-sliced products (p.40-41). It is not clear, however, whether only data for deli meats from the RTI study were used to derive the distributions shown in Tables 19 and 20. Since the RTI study generated data for products other than deli meats (e.g. bagged salad, smoked seafood), it would be helpful to clarify if a data subset from the RTI study was used in this risk assessment.*

Response: Only data from deli meats were used to generate the consumer behavior time–temperature distributions. A statement to that effect has been included in the LM Comparative Risk Assessment.

Comment D-3: *With regard to data needs (p.23), it appears that more data on handling practices at retail would also be useful to help determine risk factors, since analysis showed that retail-sliced samples collected in the afternoon were more than twice likely to test positive for Lm (p.27).*

Response: The Interagency Retail Risk Assessment will assess the effect of current practices and potential interventions in reducing or preventing *Listeria monocytogenes* contamination in RTE foods. Ongoing studies observing retail workers and monitoring *Listeria monocytogenes* concentrations over time at retail stores will provide helpful data for this work.

Comment D-4: *Clarification of the Executive Summary to include more discussion of the results and conclusions made in the draft report is recommended, as it does not highlight many significant results. An example of this is "…RTE meat and poultry products sliced at retail are approximately 9 times more risky on an annual basis than prepackaged product." This text has been used in many public FSIS presentations as an important conclusion of this risk assessment and the absence of the text in the Executive Summary is conspicuous. Clarification of this issue will reduce reader confusion of the Executive Summary and accurately summarize the conclusions of the risk assessment.*

Response: FSIS has revised the Executive Summary of the LM Comparative Risk Assessment to better reflect the integration of Appendix II and also to incorporate the updated risk assessment model runs suggested by these comments.

Comment D-5: *It is recommended that FSIS correct the mislabeling of Alternative 3 in Table 5. The current text reads "(2) Neither post processing lethality nor antimicrobial growth inhibitor" but should read "(3) Neither post processing lethality nor antimicrobial growth inhibitor".*

Response: FSIS agrees with this comment and the correction has been made in the LM Comparative Risk Assessment.

Comment D-6: *A refinement of the antimicrobial growth inhibitors used within the draft, specifically in Appendix I is recommended. A majority of meat scientists would not consider sodium erythorbate, ascorbic acid and citric acid as antimicrobial growth*

inhibitors. The recommendation is that FSIS remove said ingredients as antimicrobial agents from the draft and their use to classify products.

Response: FSIS agrees with this comment, and sodium erythorbate, ascorbic acid and citric acid have been removed from the list.

Comment D-7: *The Draft Risk Assessment does provide a sufficient amount of clarity. The testing data was placed in charts with descriptions of results that were easy to interpret. The data clearly supports the final results of the Draft Risk Assessment.*

Response: FSIS appreciates this comment.

Comment D-8: *This risk assessment, using current retail contamination data and consumer behavior data, confirms that the retail environment represents a very real risk of increased Listeria contamination. Approximately 83% of all Listeria cases attributed to deli meats are associated with deli meats sliced at retail. The result clearly indicates that controls in the retail environment must be strengthened - not just on FSIS-regulated products, but also on those FDA-regulated products that may enhance the risk at retail, such as deli-prepared salads, cheeses and smoked seafood. Because Listeria can continue to live on food contact surfaces and then migrate to foods, it is vitally important that the entire retail environment is kept from contamination. This risk assessment shows why: FSIS-products entering the retail environment can easily be contaminated by Listeria already existing in deli cases and on food contact surfaces.*

Response: FSIS and FDA initiated the Interagency Retail Risk Assessment to assist both agencies in understanding the dynamics of *Listeria monocytogenes* in a retail setting.

Comment D-9: *FDA's 2008 proposal to allow certain FDA-regulated products to carry Listeria at rates of 100 cfu/g necessarily increases the likelihood of contamination of products at retail. This risk assessment provides even more evidence that this proposal is fatally flawed. Data that has been generated under a zero tolerance policy will reflect less risk, and will skew the resulting data toward underestimating the resulting levels of Listeria in the retail environment. Specifically, data should be requested on the prevalence and levels of Listeria entering the retail environment in countries where a level of 100 cfu/g is tolerated.*

Response: The potential for cross-contamination from non-growth supporting FDA regulated products to growth supporting RTE deli meats will be considered as part of the Interagency Retail Risk Assessment. FSIS will continue to monitor reports of listeriosis

rates and outbreaks from countries that allow a 100 cfu/g level in RTE foods that do not support the growth of *Listeria monocytogenes*.

(E) Other comments

Comment E-1: *The Draft Risk Assessment scientifically provided data that clearly demonstrates a much higher likelihood of Listeria monocytogenes positive product being produced at retail slicing operations than similar FSIS inspected establishments. This is likely due, in large part, to the great disparity between regulatory oversight and expectation at FSIS inspected establishments versus retail operations. The appropriate regulatory bodies should provide necessary oversight in the retail operations, adequate to assist and provide guidance in the identification of sanitation, equipment and employee handling inadequacies to ensure the further processing of these ready-to-eat products under sanitary conditions. In the absence of such oversight and guidance, the wholesomeness and safety of the product may continue to be compromised.*

Response: FSIS and FDA have initiated an Interagency Retail Risk Assessment to further guide risk management strategies to reduce, control or limit the risk of listeriosis associated with RTE foods.

Comment E-2: *Given the success of 9 CFR 430, and the significant body of existing validation studies, FSIS should consider products produced under Alternatives 1 and 2 as separate and distinct from products produced under Alternative 3, the former have proven Listeria monocytogenes reduction and/or growth inhibitors. As such, on a risk-adjusted basis, these products are much less likely to be a vector bringing Listeria monocytogenes to the deli counter.*

Response: Currently, products that are manufactured under Alternative 3 (use of sanitation only, or, neither post processing lethality nor antimicrobial growth inhibitor) are subject to more sampling by FSIS compared to products made under Alternatives 1 (combined use of post processing lethality and antimicrobial growth inhibitor) and 2 (use of either post processing lethality or antimicrobial growth inhibitor) (9 CFR 430, 68FR 3422; June 6, 2003). However, because product from all alternatives are opened and handled at retail and since the deli meat itself is not the only source of *Listeria monocytogenes* in retail environments (Corby 2009), deli meat from any of the alternatives can become contaminated at retail. Growth inhibitors continue to provide some protection, but post-processing lethality does not.

Comment E-3: *FSIS should strongly consider requiring the segregation of products in Alternative 1 and 2 from Alternative 3 in terms of storage, handling, and slicing in the*

retail environment, in order to reduce the risk of cross-contamination among the products. At minimum, this proposed regime must be studied and evaluated as a possible element in the reduction of risk at the deli counter.

Response: FSIS believes that while segregation of products is one potential option, it is likely not the only solution to reducing the risk of listeriosis from contamination of products with *Listeria monocytogenes* in the retail setting. This is one of the issues that will be examined by the Interagency Retail Risk Assessment.

Comment E-4: *The fundamental working issues of deli counter hygiene, worker hygiene, and adequate safety steps beyond the products themselves must be considered in the overall risk environment. Given the ubiquitous nature of Listeria monocytogenes, we must work to limit exposure to deli counter products from multiple fronts. Deli counters should operate under a regime clearly analogous to the standards for food factories.*
The cleanest, lowest-risk deli counters, operating under a best practices model, should rank something like Alternative 1 for meat production. Further, the deli counter should be required to publicly display its proven hygiene standard and ranking for public information and awareness. Customers could then choose accordingly. This would drive deli counters to operate at the best standards or wither.

Response: As part of data gathering efforts for the Interagency Retail Risk Assessment, studies are planned to examine the behaviors of deli workers while handling, slicing, and packaging retail deli products, and to conduct and validate risk maps[8] of *Listeria monocytogenes* in retail deli environments.

Comment E-5: *FSIS must also adopt a wider view of the food production system and the environment created after the adoption of 9 CFR 430. Why not take the opportunity to massively reduce Listeria monocytogenes exposure throughout the supply chain by meaningfully and convincingly reducing the possibility of Listeria monocytogenes contamination prior to shipment from the food plant. Further, why not seriously reevaluate the risks embedded under Alternatives 1, 2 and 3?*

Response: Evidence has shown that there is reduction in *Listeria monocytogenes* contamination after the implementation of 9 CFR 430 in federally inspected establishments (Figure 2) while evidence showed that retail deli products still posed some risk. This risk will be examined in the Interagency Retail Risk Assessment.

[8] Risk maps are effective tools to evaluate, compare risk factors, and to identify high-risk areas in the retail deli. Prevalence data and expert opinion will be combined to develop a risk map of *Listeria monocytogenes* contamination in retail deli environments.

FSIS Regulatory Testing for Lm in RTE Products, 1990-2009 (All Years, All Random/Risk-based Samples)

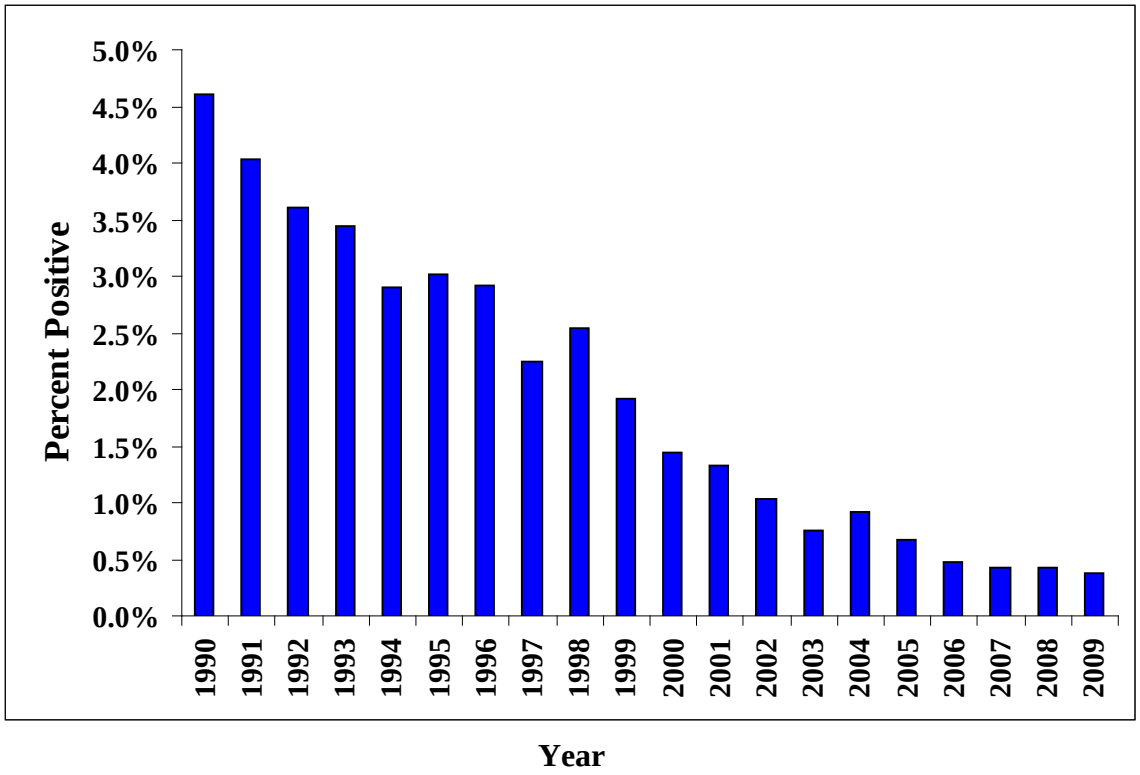

Figure 2 - Prevalence of *Listeria monocytogenes* in federally inspected facilities from the all RTE monitoring programs[9]

Comment E-6: *The expectation is that meat products produced under Alternatives 1 and 2, properly processed and handled, represent the least risk within the chain. Isn't it time to reassess the viability of continuing to allow the production of Alternative 3 products within the present heightened environment of food safety concerns and the demonstrated knowledge of proven, successful methods for Listeria monocytogenes and other pathogen control?*

Response: See the response to Comment A-2. FSIS will continue to use sound science in its risk assessments as required by law to issue, influence and update its risk management decisions.

Comment E-7: *Given the state of the art in product handling, the repeatedly demonstrated effectiveness of thermal pasteurization methods in prepackage and post package lethality steps, as well as the serious merits of high pressure processing,*

[9] http://www.fsis.usda.gov/Science/Micro_Testing_RTE/

particularly for sliced products, FSIS should also consider reevaluating the current definitions for the Alternative 1 and 2 standards.

Response: FSIS continues to evaluate new technologies and its regulatory policies. This comment, however, is not directly related to the LM Comparative Risk Assessment.

Comment E-8: *FSIS should tighten the standards for lethality. At present, simply requiring a greater than 1 log reduction does not meet the state of the art, as defined by many validation studies. Reductions of 2.5 to 4 log are commonplace, whether using infrared pasteurizing, hot water submersion, both in tandem, or though high pressure processing. Why not grade the entry into Alternatives 1 and 2 on the proven degree of Listeria monocytogenes lethality. This would gear the system to a more complete, more effective "sterilization", not merely reduction in pathogens. Further, why not allow or require multiple thermal and/or mechanical pasteurizing steps as a path to Alternative 1 or 2? Given that FSIS has established a precedent by granting Alternative 1 status to some processors using only thermal steps with proper validation, such protocols should regularly be allowed as normal for the standard. The overall goal should be demonstrated measured lethality to Listeria monocytogenes and other pathogens, with minimal adulteration of the actual product. Such measures would ensure that both prepackaged deli products as well as those sold over the deli counter would represent significantly less risk as a vector within the overall food supply chain.*

Response: FSIS continues to evaluate new technologies and its regulatory policies. This comment, however, is not directly related to the LM Comparative Risk Assessment.

Comment E-9: *FSIS should consider studying the limits of focusing so closely on pasteurization and chemicals for risk reduction. Steps must be taken and study conducted to consider the mechanical handling environment as a part of the risk factors. Highly automated, state of the art food plants are simply cleaner and safer.*

Response: FSIS continues to evaluate new technologies and its regulatory policies. This comment, however, is not directly related to the LM Comparative Risk Assessment.

Comment E-10: *Why not consider the audit of the production environment and handling process as a key element in the path to Alternative 1 or 2 designations? Such an effort would transcend mere sanitation regimes to evaluate the whole range of risk reduction elements embedded within the equipment in use, such as cook bag sanitation prior to slicing operations, or antimicrobial evaporator coils in freezers and chillers, as two limited examples. Such an approach would further improve the overall safety of the food supply chain.*

Response: FSIS appreciates this comment; however, it is not directly related to the LM Comparative Risk Assessment.

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