Interagency Risk Assessment:

Listeria monocytogenes in Retail Delicatessens

Response to Public Comments

The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup

September 2013

This document summarizes interagency response to public comments on a quantitative, scientific assessment of (1) the risk of listeriosis posed by consumption of ready-to-eat (RTE) foods commonly prepared and sold in delicatessens in retail food stores and (2) how that risk may be impacted by changes in practice. This quantitative risk assessment (QRA) [described in the Interagency Risk Assessment: *Listeria monocytogenes* in Retail Delicatessens – Technical Report, hereafter called the "Technical Report"] was conducted collaboratively by the Department of Health and Human Services (DHHS) Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN) and the United States Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS), in consultation with the DHHS Centers for Disease Control and Prevention (CDC). Members of the food industry, academic institutions, and consumer-advocacy groups provided input, and many activities were included to ensure transparency and stakeholder engagement in the development of the risk assessment.

As part of these efforts, USDA/FSIS and FDA/CFSAN held a public meeting, on May 22, 2013, to present the risk assessment, including the modeling approach and studies conducted to fill specific data needs of this assessment. Prior to the public meeting, USDA/FSIS and FDA/CFSAN requested public input on the draft risk assessment (92 *Federal Register* 27939). Specifically, input was requested on:

- the overall risk-assessment approach used;
- the assumptions made;
- the modeling techniques;
- the data used; and
- the clarity and transparency of the documentation in this draft QRA.

The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup received 12 separate sets of comments from the public and stakeholders through FSIS Docket No. FSIS-2013-0019 and FDA Docket No. FDA-2013-N-0494. The Workgroup has carefully considered them and re-evaluated the draft technical report and model in light of these comments. Based on this re-evaluation, the Workgroup has updated and finalized the technical report. Following is a discussion of the comments related to the technical report and/or risk assessment model.

1. Editorial comments

Comment: A number of comments were received on the clarity of the report.

Response: The final version of the report has undergone a review by a technical-writing editor, to correct grammar and spelling issues and improve readability.

2. Dose-response model

Comment: Further explanation of the dose-response model was requested.

Response: As fully described in Section 6.4.4 of the Technical Report, the dose-response model was taken from the Food and Agriculture Organization – World Health Organization (FAO/WHO) risk assessment (FAO/WHO, 2004). The dose-response model used was

$$\text{Prob}(\text{inf} \mid D) = 1 - \exp(-r\,D)$$

where D was the simulated dose (the product of the *L. monocytogenes* concentration at the time of consumption and the serving size) and r was the probability that one cell causes illness in the consumer. The point estimates for r used in this model were 1.06×10^{-12} for the susceptible population and 2.37×10^{-14} for the non-susceptible population (FAO/WHO, 2004). The resulting dose-response models for each population are shown below, in Figure A1.

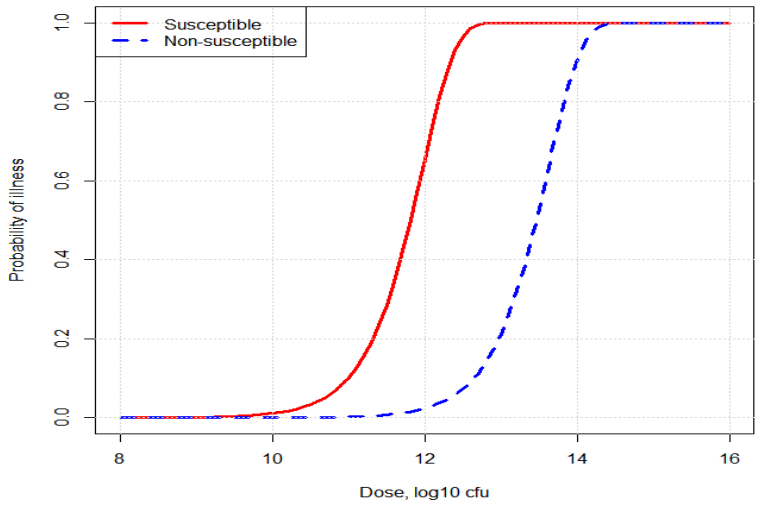

Figure A1. Dose-response models used in the risk assessment (from FAO/WHO, 2004)

Note that the significant uncertainty about each of the dose-response models was not included in the analysis, because the risk assessment focused on changes in risk per serving, compared with a baseline.

3. Hard-cheese modeling

Comment: A further explanation of the growth characteristics and storage times for hard cheese, as used in the model, was requested, as the risk assessment appears to overestimate the risk of listeriosis per serving for hard cheese.

Response: Section 6.4.2 of the Technical Report describes the storage time and temperature patterns in consumers' homes. For the times and temperatures, soft-cheese data were used in lieu of hard-cheese data. Home-storage times and temperatures for sliced-to-order hard cheeses are not available. However, the growth rates for hard cheese used in the model were appropriate for hard cheese; i.e., the growth rates for soft cheeses were not used to model the growth rates of hard cheeses. See section 6.1.2 of the Technical Report for a discussion of the growth-rate model, as well as Table 2 of the Technical Report. Examples of hard cheese in the model include Monterey Jack, American, and provolone, all of which had growth rates of 0/hour at both 4°C and at 10°C (Table 2 of the Technical Report). Thus, we do not believe that the risk assessment overestimates the risk of listeriosis per serving for hard cheese, as suggested by the commenter.

4. Sources of* L. monocytogenes, *with reference to pre-slicing

Comment: Further explanation of the sources of *L. monocytogenes*, especially with regard to the pre-slicing results, was requested.

Response: The sources of *L. monocytogenes* entering the deli area for each of the six baselines are shown in Table A1, below.

Table A1. Source of *L. monocytogenes* entering deli, for each baseline

Baseline	Incoming concentrations on chubs (observed through in-plant testing by FSIS)	Environmental / niche contamination	One additional product more highly contaminated than others. Hypothetical situation.
1. Multiple niches	√	√	
2. No niche	√		
3. Incoming growth chub	√		√
4. Incoming non-growth chub	√		√
5. Temperature control	√		
6. Niche and temperature control	√	√	

All of the baselines used the concentration estimated from the FSIS *L. monocytogenes* verification sampling program data (FSIS 2009, 2012) for incoming chubs, with a mean of $\log_{10}$

concentration estimated to -9.2 $\log_{10}$ cfu/g (See Technical Report). Thus, most of the incoming chubs contained no *L. monocytogenes* bacteria. On occasion, however, and as desired for this model input, this distribution did include a contaminated chub. Two baselines (#3 and #4) evaluated situations in which one incoming product was contaminated at a level higher than that of other products (a mean of $\log_{10}$ concentration of -5 $\log_{10}$ cfu/g for these specific incoming products, compared with -9.2 $\log_{10}$ cfu/g for the other incoming products).

Pre-slicing products in the morning in the retail deli department was found to increase the risk for all baselines, compared with slicing the products when ordered, except in baseline #4, with an incoming highly contaminated non-growth chub. Thus, pre-slicing increased the risk of listeriosis from deli products prepared in a typical deli with or without environmental/niche contamination (baselines #1 and #2). *L. monocytogenes* bacteria originating from occasional contaminated chubs, as observed within FSIS' verification sampling program, was sufficient to increase the risk from pre-sliced deli products, compared with those that were not pre-sliced.

5. Impact of consumer storage practices

Comment: An evaluation of consumers' storage practices (time, temperature) was requested.

Response: The Workgroup ran additional scenarios. In a first scenario (S1 below), products were kept at home during a time similar to that in the baseline (see section 6.4 of the Technical Report), but all home refrigerators had a temperature lower than, or equal to, 40°F. (The distribution of home-refrigerator temperature, as specified in section 6.4 of the Technical Report, was truncated to 40°F.) In a second scenario (S2 below), the home refrigerator temperatures were set back to the one used in the baseline, but all meat products and salads were consumed within 3 days post purchase, and all cheese products were consumed within 4 days post purchase. (The distribution of home-storage time before consumption, as specified in section 6.4 of the Technical Report, was truncated to 3 or 4 days.) All other parameters were set as in the baseline conditions described in the report.

These scenarios were run for two baseline retail conditions: "Multiple Niche 100W" [i.e., a retail deli with multiple niches that releases *L. monocytogenes* to food-contact surfaces at a rate of 100 colony-forming units (cfu) on an average weekly frequency] and "No Niche" (i.e., a retail deli with no niches or environmental *L. monocytogenes* transfer). The results are provided in Table A2.

Table A2. Predicted absolute risk of invasive listeriosis for the susceptible population per serving of ready-to-eat food sliced or prepared and sold at retail delis according to the baseline conditions and the scenario. In parentheses: relative change to the respective baseline condition.

Scenario		Baseline Retail Deli Conditions	
		Multiple Niche 100W	No Niche
	Predicted risk per serving, baseline conditions (taken from Table 19 of the Technical Report)	1.7×10^{-7} (Reference)	1.4×10^{-7} (Reference)
S1	Products are kept in home as in the baseline, but all home refrigerators have a temperature lower than, or equal to, 40°F	0.0042×10^{-7} (-100%)	0.0027×10^{-7} (-100%)
S2	Home-refrigerator temperature distribution as in the baseline, but all meat products and salads are used within 3 days post purchase, and all cheese products are used within 4 days post purchase	0.021×10^{-7} (-99%)	0.014×10^{-7} (-99%)

The predicted risk of listeriosis was almost eliminated if the products were stored at home less than 3 to 4 days or if home-refrigerator temperatures were lower than, or equal to, 40°F. Note that these scenarios assumed a complete implementation of the recommendations by the consumers (home-refrigerator temperature in the first scenario and use-by days in the second scenario). The reductions in the risk were then overestimated, compared with what would happen if the interventions were implemented with less-than-perfect compliance.

These scenarios confirm the dramatic impact of home-storage duration and temperature on the risk of listeriosis. It was observed in this study, as well as in other national and international risk assessments on listeriosis (FDA/FSIS, 2003; FAO/WHO, 2003), that the risk of listeriosis was driven by storage, for a longer period of time and at higher-than-recommended temperatures, of contaminated ready-to-eat products that supported growth. This risk assessment shows, additionally, that the risk was reduced by avoiding contamination and cross contamination of these products beforehand.

6. Transfer coefficients & growth on surfaces and niches

Comment: Further clarification was requested on the source of the transfer coefficients, especially as related to the abiotic surrogate (e.g., Glo-Germ™) experiments.

Response: At no point did the cross-contamination model use transfer coefficients based on abiotic surrogates. The transfer coefficients were derived solely from experiments using bacterial transfer, including *L. monocytogenes*, as described in Hoelzer et al. (2012). The fluorescence-based research of Maitland et al. (2013) was used to validate which sites were included in the model, not to provide transfer coefficients.

7. Growth on surfaces and niches

Comment: Questions arose about growth of *L. monocytogenes* on equipment surfaces and within niches.

Response: We agree that the model did not evaluate *L. monocytogenes* growth on surfaces. The model actually includes growth terms for equipment and other surfaces, but, in all scenarios that were run, these growth rates were set to zero per hour. We were unable to find sufficient data to include this term. Thus, the risks presented by the report are conservative; i.e., the risks are likely to be higher if growth on equipment surfaces is included.

Note that a growth model was not extended to niches. Niches were assumed to always have a sufficient number of bacterial cells present for any simulated transfer. Therefore, growth on equipment surfaces is likely to increase the importance of cross contamination, but not niche/environmental contamination, as formulated in the current model version.

8. Extending the model

Comment: A comment was made regarding whether the model could be extended to include retail testing and additional areas in the retail deli.

Response: Retail testing as a risk mitigation strategy may be evaluated in a future version of the model. Note that a large number of servings had to be simulated for model convergence, because most of the servings were not contaminated. This may suggest that the impact of food-contact-surface testing may be limited. Researchers at Cornell University and Purdue University have found persistent *L. monocytogenes* at several sites in typical delis, which they attribute, in part, to the open nature of the retail environment.

Incorporating retail storage areas and coolers may be considered in a future version of the model. Currently, however, data are lacking for these areas.

9. Higher levels of* L. monocytogenes *on incoming product

Comment: A request was made to evaluate incoming product with higher *L. monocytogenes* levels, taking into consideration different growth categories.

Response: All incoming products have a $\log_{10}$ normal distribution of concentration (in $\log_{10}$ cfu/g), as specified in section 6.5 of the Technical Report, with a mean of -9.2 and standard deviation of 2.9. (See the Technical Report for details.) In the additional scenarios shown below, the concentration of some incoming products is set to exactly 100 cfu per gram. The "non-growth" products were selected as the products with a growth rate of 0.00 per hour at a temperature of 10°C (see Table 2 in the Technical Report). All the scenarios were run in a "No Niche" baseline (i.e., a retail deli with no niches or environmental *L. monocytogenes* transfer). The results are provided in Table A3, below.

Table A3: Predicted absolute risk of invasive listeriosis for the susceptible population per serving of ready-to-eat food sliced or prepared and sold at retail delis according to various scenarios.

	Scenario	With cross contamination	Without cross contamination
	Predicted risk per serving, "No Niche baseline (taken from Table 19 of the Technical Report)	1.4×10^{-7}	1.1×10^{-7}
B1	All incoming products have a concentration of 100 cfu/g	300×10^{-7}	300×10^{-7}
B2	All incoming products that support growth have a concentration of 100 cfu/g	300×10^{-7}	300×10^{-7}
B3	All incoming products that do not support growth have a concentration of 100 cfu/g	66×10^{-7}	1.2×10^{-7}

These additional scenarios confirm the major results from the report, notably the findings from the baseline conditions considering a highly contaminated incoming product. These additional scenarios are also consistent with the sensitivity analysis (Figure 15 of the Technical Report), which found that increasing *L. monocytogenes* concentration on incoming product always increased the risk of listeriosis, especially if the product supported growth. Briefly, an increased contamination of a product that supported growth directly increased the average predicted risk (see Scenario B2, with and without cross contamination). Increased contamination of a product that did not support *L. monocytogenes* growth increased the average predicted risk indirectly, through cross contamination of products that did support growth (see Scenario B3). Concurrently, without retail cross-contamination, there was no increased risk from ready-to-eat products that did not support growth of *L. monocytogenes;* the risk was essentially equal to the baseline (1.2×10^{-7}). When there was cross-contamination at retail, the risk of listeriosis increased to 66×10^{-7} when incoming product did not support growth of *L. monocytogenes* and to 300×10^{-7} when incoming products did support growth of *L. monocytogenes.*

Note that these additional scenarios assumed that the proportion of incoming ready-to-eat products with ≥100 *L. monocytogenes*/g would shift from 0.01% (see Table 13 of the Technical Report) to 100%. This scenario might be considered somewhat extreme. While the trend observed from these additional scenarios confirm the findings of the quantitative risk assessment – that increasing the level of *L. monocytogenes* on ready-to-eat products (both those that supported growth and those that did not) increased the predicted risk of listeriosis – the actual predicted risk estimates should be considered theoretical.

REFERENCES

FAO/WHO, Risk assessment of *Listeria monocytogenes* in ready-to-eat foods - Technical report, in *Microbiological Risk Assessment Series, No. 5*2004, Food and Agriculture Organization of the United Nations and World Health Organization: Rome. p. 269. Available from: http://www.fao.org/docrep/010/y5394e/y5394e00.htm.

FDA/FSIS, Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. 2003, Food and Drug Administration, United States Department of Agriculture, Centers for Disease Control and Prevention. p. 541. Available from: http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm183966.htm.

FSIS, *Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry and Egg Products, and Environmental Samples*, 2009: Washington, DC. p. 21. Available from: http://www.fsis.usda.gov/PDF/MLG-8.pdf.

FSIS. *The FSIS Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products, 1990–2011*. 2012 [cited 2013 March, 26]. Available from: http://www.fsis.usda.gov/Science/Micro_Testing_RTE/.

Hoelzer, K., Pouillot, R., Gallagher, D., Silverman, M.B., Kause, J., and Dennis, S. Estimation of *Listeria monocytogenes* transfer coefficients and efficacy of bacterial removal through cleaning and sanitation. *International Journal of Food Microbiology*, 2012. **157**(2): p. 267-277.

Maitland, J., Boyer, R., Gallagher, D., Duncan, S., Bauer, N., Kause, J., and Eifert, J. Tracking Cross Contamination Transfer Dynamics at a Mock Retail Deli Market using GloGerm™. *Journal of Food Protection*, 2013. **76**(2): p. 272-282.