Peer Review Comments and Responses for

Interagency Retail *Listeria monocytogenes* Risk Assessment Model

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By

The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup

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Introduction

Versar, Inc. conducted a peer review for the Interagency Retail *Listeria monocytogenes* (LM) Risk Assessment in accordance with Office of Management and Budget Peer Review Guidelines[1]. This peer review relates to a Sept, 2010 version of the Interagency Retail LM Risk Assessment model. Below are (i) the brief biographical sketches of the reviewers, (ii) the charge to reviewers, and (iii) the reply to reviewer comments.

Reviewers

The independent reviewers of the risk assessment included:

Dr. Leila M. Barraj is a biostatistician with experience in experimental study and survey design, data analysis, and exposure modeling. She has worked on a wide range of issues, including occupational and nutritional relative risk assessments, probabilistic exposure assessment, dietary exposure assessment and microbial risk assessments. In particular, she has designed consumer behavior surveys to collect information on water and food consumption patterns. Dr. Barraj has extensive modeling experience. She has been involved in developing the models and algorithms used in several of Exponent/Novigen's proprietary risk assessment software, including the Dietary Exposure Evaluation Model (DEEMTM), the Food Analysis and Residue Evaluation Program (FARETM), and CalendexTM, an aggregate and cumulative exposure software incorporating both temporal and spatial variability. She has developed probabilistic microbial exposure and risk assessment models and has been involved in the review of microbial risk assessment models developed by FDA and FSIS. Dr. Barraj holds a D.Sc. in Biostatistics from Harvard University and a B.S. and M.S. in Statistics from the American University of Beirut, Lebanon.

Dr. Edmund Crouch has published widely in the areas of environmental quality, risk assessment, and uncertainty analysis. He has co-authored a major text in risk assessment, *Risk-Benefit Analysis*. Dr. Crouch serves as an expert advisor to various local and national agencies concerned with public health and the environment and has served on nine National Academy of Science Committees. He has written computer programs that analyzed the results from carcinogenesis bioassays, has developed algorithms on the levels of both theory and computer implementation for the objective quantification of waste site contamination, and has designed Monte Carlo simulations to fully characterize uncertainty and variability inherent in health risk assessment. Dr. Crouch is widely regarded as an insightful peer-reviewer; he has detected and corrected numerous, critical, otherwise hidden flaws in the technical underpinnings of proposed regulations for environmental protection and related areas. Dr. Crouch holds a B.A. in Natural Sciences (Theoretical Physics) and a Ph.D. in High Energy Physics, both from Cambridge University, United Kingdom.

Dr. Renata Ivanek Miojevic is an Assistant Professor of Epidemiology at the Department of Veterinary Integrative Biosciences, Texas A&M University. Her research interests have been in

[1] Office of Management and Budget's "Final Information Quality Bulletin for Peer Review" (December 2004): http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf. This bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents.

the application and development of risk assessment, mathematical modeling, and computational methods in the epidemiology of foodborne pathogens, with particular emphasis on *Listeria monocytogenes*, *Salmonella,* and *Escherichia coli* in domestic animals, environments, and foods. Her research considers the farm-to-table food system to identify effective intervention strategies for control of these pathogens and protect human health. Dr. Ivanek has authored and co-authored 35 peer-reviewed research papers. At Texas A&M University, she teaches graduate courses on the design and conduct of epidemiological studies and mathematical modeling of infectious diseases. Dr. Ivanek holds a D.V.M from the Faculty of Veterinary Medicine, University of Zagreb (Croatia), an M.S. in Veterinary Epidemiology jointly granted by the London School of Hygiene and Tropical Medicine and the Royal Veterinary College (United Kingdom), and a Ph.D. in Comparative Biomedical Sciences from Cornell University.

Charge to Reviewers:

Peer reviewers were asked to focus on the following points when reviewing the risk assessment:

1. The approach is a discrete-event modeling framework. Is this approach and concept appropriate for the intended purpose and scope of the risk assessment to answer the risk management questions provided? If not, what problems exist and how should they be addressed? If other approaches would be more suitable, the reviewer should provide a description and an explanation.

2. The report provides an illustration of the conceptual model (see page 16, Figure 3 and page 17, Figure 4) to indicate the sources, events, and objects that may lead to transfer, growth, and removal of *L. monocytogenes* in a retail environment. Does the conceptual model adequately indicate the major relationships that may explain the transmission of this pathogen in retail? If not, explain any relationship that you believe is either unnecessary or omitted and how to consider this change in the model.

3. Review the underlying model hypotheses and assumptions. Are they reasonable and clearly identified? If not, please explain.

4. The model includes components for retail, transportation, home storage, consumption, and dose response. The basic events in the model include transfer, growth, inactivation, and partitioning of *Listeria*. Are there any additional components that should be incorporated into the model? If so, the reviewer should describe the components and explain how they will enhance the risk assessment.

5. A variety of scenarios were selected to evaluate potential interventions or mitigation controls. Are the selected scenarios adequate to evaluate effective and efficient public health benefits that may be expected to occur with these different intervention strategies? If not, how should the selected scenarios be changed, and what additional scenarios should be included?

6. Uncertainty and variability in the model are described using second-order Monte-Carlo simulations. Is this methodology appropriate for the purpose of the model and the available data? If not, explain what changes might be considered, and how they would improve the model.

7. Review the adequacy of the risk assessment model documentation. Is the report clearly written? Is it complete? Does it follow a logical structure and layout? If not, the reviewer should suggest an alternate outline and/or approach to document this risk assessment adequately and clearly.

8. Review how data are identified. Were sufficient information and explanations given to describe this process, and what criteria were used to determine the suitability of the data? Were these criteria adequate? If not, what additional criteria should be used? Overall, is the model adequately supported by the existing data? If there are other data that should be included in the model, please identify the data sources and how should it be used.

Response to Reviewer Comments

	I. RESPONSE TO GENERAL COMMENTS
Reviewer #1	*Food contamination with Listeria monocytogenes is of great concern to the safety of the U.S. food supply. The FDA/FSIS Interagency Listeria monocytogenes in Retail Risk Assessment represents a timely response that will help determine how public health is affected by current practices and potential interventions to reduce or prevent Listeria monocytogenes contamination in ready-to-eat food sliced, prepared, and/or packaged in retail facilities. Overall, the risk assessment is very thorough and comprehensive. I am impressed with the detail used to model the complex biological and technical processes occurring in the retail setting. In developing the risk assessment, the authors have conducted a thorough review of the pertinent literature and presented the information accurately in the report. The identified knowledge gaps provide an additional benefit to this effort as the scientific community, in cooperation with the food industry, will be able to focus their research efforts on the most critical research needs.* *My concerns about this risk assessment are related to its presentation, estimation of the transmission coefficients from available data, and the plan to calibrate the model to fine tune model parameters. The presentation of the model structure was a bit confusing. The main events considered in the model have not been consistently listed throughout the report (elaborated further under the response to charge question #2).* *Transmission coefficients determine cross-contamination, which is a primary process that occurs in retail. As such, transmission coefficients are critical parameters in the model. However, the available data on transmission coefficients are scarce. Furthermore, although statistical tests of the model fit favor their description using the lognormal distribution, I am concerned about the truncations*

	that were necessary for the distributions of the corresponding transmission coefficients to be bounded between 0 and 1. *With respect to the model calibration, I am worried that because of the many "moving parts" in the model, with inadequate or absent data to estimate the model parameters, calibration could result in an invalid model. Therefore, the authors should elaborate on which parameters will be calibrated and how this will be accomplished based on the only two available data sets. These and the following critiques are meant to be constructive so that the risk assessment can be improved without any intent to undermine the overall comprehensiveness of the risk assessment and report.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup recreated several of the figures to improve naming consistency. The Interagency Retail LM Risk Assessment Workgroup has evaluated the truncation of the transfer coefficients. Under the worst case scenario (log mean = -0.28, log standard deviation (sd) = 0.2), approximately 8% of values are truncated to 1. The log normal distribution naturally limits the lower value to 0. Given the over parameterization in the model, a formal calibration (e.g., minimizing some objective function) will not be possible. The risk assessment will use literature data to establish the parameters wherever possible. The authors will use expert judgment to address data gaps. The importance of these judgments will be addressed through sensitivity analysis. The Gombas et al. (2003) and Endrikat et al. (2010) data will be used to anchor the model predictions.
Reviewer #2	*My initial impression on first read-through was positive; it appeared that the overall structure and modeling approach was suitable to the risk management questions outlined at pages 11-13 of the report, or could readily be adapted to the task. However, subsequent detailed examination left me disappointed with the report as presented for the reasons to be outlined below.* *First, the raw information presented appeared generally to be accurate, in the sense that where values or distributions are reported directly from the literature, they usually correspond with what is given there, although in the small fraction of the literature that I could examine in detail there were errors (detailed below) in what was transferred to the report. The analyses that have been done on literature, particularly the evaluation of the transfer coefficients in Appendix I, are somewhat different, however.* • *They are insufficiently documented to determine exactly what was done. For example, the "Data analysis" section at page 101 simply says "(maximum likelihood method)" without specifying the likelihood function used. That likelihood function should have been different for the various papers examined depending on what and how those papers reported, and on the experiments performed. The complete analyses should be available to reviewers and ultimately the public if/when this report is published, from raw data extracted*

	from the papers to the results estimated from them (e.g. the spreadsheets or R procedures used). • *They appear to be incorrect in at least one case I examined (although this appearance may simply be due to the lack of documentation).* *Second, the clarity of the document leaves something to be desired. It is difficult to provide complete and clear documentation for a model of this nature and complexity. But the documentation is currently not complete. I had to look at the code in some cases to find out what is actually in the model; but how can I be sure that was what was intended if it is not documented (e.g. I never did find where the mass of sliced meat or cheese per customer event is documented; and only in the code did I find that all times per customer event are divided by the number of servers). The outline of the documentation appears generally to be fine (although I cannot vouch for it matching the code), but many details are lacking.* *Third, the modeling appears to have reached some conclusions without adequate analysis. I particularly find disturbing the assumption, page 18, that 'the uncertainty surrounding the existence and the "behavior" of the niches overwhelmed the other sources of uncertainty.' No basis is provided for this assumption. The preceding statement that "The model is written as a full second order Monte Carlo model that distinguishes variability from uncertainty" is thus false; only one source of uncertainty appears to have been taken into account (e.g. I could not see any inputs corresponding to the uncertainties in the transfer coefficients, or any of the other inputs to the model). This is a major deficiency, particularly as the very existence of "niches" is based on anecdotal evidence only. I see no reason to omit all the other sources of uncertainty, particularly as one of the risk management questions to be examined by the model is "What if slicer niches could be eliminated through redesign or cleaning procedures." Without the niche, the current model would predict no uncertainty, which is incorrect. I see no basic problem in including uncertainty in all the input parameters (e.g. the methodology used for the transfer coefficients is straightforward to extend to evaluate the uncertainty in the variability parameters estimated). With correct program design, this inclusion is relatively straightforward; although the current program could not support it without major changes. This is an argument for major changes in the program design!* *Fourth, it strikes me that using the R language for a model of this nature is an exercise in futility. Possibly the current code is just "proof of concept," since it is unsuitable for use in actually responding to the risk management questions, given the heroic efforts needed to get it to run enough samples. It is always necessary to get such models to run fast, and the efforts devoted to making this model parallel and get it running on a supercomputer are misdirected (as well as a waste of supercomputer time). It would be far more efficient to spend such efforts on writing the model in a fully object-oriented compiled language for running on a standard desktop machine, and using efficient algorithms.*

	Fifth, the report appears to be going out to review too soon. The authors have not finished their documentation. It needs editing to remove the non-English idioms and incorrect grammar. There need to be summary sections listing the major assumptions, the places where lack of data required analysis shortcuts, the areas where there are no data, and the places where there may be data but the literature reviews are not complete. *Finally, I was struck in several places by the apparent lack of mathematical and computer science expertise exhibited. An example of the first — the authors for some reason seemed to need to simulate a truncated logistic in order to obtain its mean and median, but obtaining the mean is a trivial exercise in integration and the median can be obtained just using arithmetic. An example of the second (beyond using R for a Monte Carlo simulation) — generating random variables by inverting the cumulative distribution is not a recommended approach for most distributions in this sort of model, because it is unnecessarily slow, yet this is the method used for at least the logistic, laplace, beta, and normal.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup agrees that certain sections of the document are incomplete and thank the reviewers for working with the version provided. Because of the novelty and complexity of the problem, the Interagency Retail LM Risk Assessment Workgroup decided to implement a peer review during the course of model development to allow for time to alter and improve the model and correct the deficiencies in documentation. Additional variables can be added to the list of uncertain variables. The current model structure is fully capable of incorporating uncertainty. The Interagency Retail LM Risk Assessment Workgroup respectfully disagrees with the comment on modeling language. The R language version is working and already being used to evaluate risk management questions. A compiled language would provide some speed benefits; however, even rapid improvements in speed (i.e., 20-times faster—the high end of our informal comparisons), parallel processing would still be needed. Once this requirement is established, speed is not a significant issue. The existing data analysis libraries and graphic packages available in R make this software an excellent choice. While R software may not be the most efficient, the random variable functions are tightly tuned and well vetted. Both approaches lead to the same final answer. For this reason, the Interagency Retail LM Risk Assessment Workgroup will continue with the current approach. The assumptions and data gaps were identified in the draft report in each section where they were relevant.
Reviewer #3	*FDA and FSIS have developed a model to track L. monocytogenes in the retail environment. The model was developed to help the Agencies in identifying potential sources and practices that may contribute to L. monocytogenes contamination in retail settings and interventions that could control, reduce, or eliminate L.*

	monocytogenes contamination of RTE foods sliced, prepared or packaged in retail facilities. *The model is clearly described in the accompanying documentation. Assumptions are clearly laid out. Major data gaps are generally identified in the report. The model is a work in progress, in that while it includes the various "pieces" and data available to date, there are still significant data gaps that need to be filled before the model can be used for an actual assessment. Hence, there is no "real conclusion" to assess. However, I do agree that the model structure is flexible enough to allow for inclusion of other events should any be identified or the incorporation of new data. Also, the model was built with the risk management questions (as laid out in Section 1.2) in mind, hence it could be used to address these questions, once the data needed become available.* *Please note, that I am not an R programmer. Hence, my review of the model focused on the review of the documentation, evaluation of how the program runs, and my experience with several test runs. I did not review the various R subroutines to make sure that they were correctly written, however, I did run test runs to confirm my understanding of some the algorithms.*
RESPONSE	Thank you for this feedback.

II. RESPONSE TO CHARGE QUESTIONS	
CHARGE QUESTION 1: The approach is a discrete-event modeling framework. Is this approach and concept appropriate for the intended purpose and scope of the risk assessment and to answer the risk management questions provided? If not, what problems exist and how should they be addressed? If other approaches would be more suitable, the reviewer should provide a description and an explanation.	
NAME	**COMMENT**
Reviewer #1	*The risk assessment is based on the discrete-even modeling framework in which the operation of a retail system is represented as a chronological sequence of events where a change of state in the system is recorded for each event. This approach seems appropriate for the intended purpose and scope of the risk assessment as well as to answer the provided risk management questions. As the authors themselves have stated, its major advantage is its flexibility and granularity. That is important because the risk assessment is likely to be revised continually as more data becomes available and as additional interventions and control measures are identified and need to be evaluated. The authors state that its only limitation is that the time sequence is not evenly spaced but controlled by the time required for each event. In addition to that, as a minor comment, I wonder if there could be simultaneous events (e.g., NFCS contamination and serving customer) and if so, how would neglecting them affect the conclusions.*
RESPONSE	A cross contamination event can contact several sites simultaneously, and the code for the model is designed to handle this situation, but testing suggests that sequential two site transfers achieve the same result.
Reviewer #2	*I believe it is an appropriate approach. However, I think the model used in the*

	report needs to be modified. Currently it attempts to model events as though they are linked to a store, but a more natural approach is to model events as linked to foodservers (since they are the generators of the events) within a store [strictly speaking, if further data become available on shoppers and they can be incorporated in the model, it is the foodserver-shopper interaction that is the event.] Linking events to the store means that the model should strictly be able to handle simultaneous events by multiple foodservers; but currently it does not do this, and is using an undocumented (I think) "hack" to handle the situation (namely, dividing the time for all operations by the number of foodservers, which may lead to errors later on).
RESPONSE	Linking events to food workers as opposed to stores is complicated, because the observational data clearly suggest that there are different types of retail stores with different operating procedures. In order to account for this variability across the industry, the model must include some level of store description. The Interagency Retail LM Risk Assessment Workgroup agrees that the description and modeling of multiple food workers was inadequate in the model supplied. The model currently only simulates a single food worker. The current model was updated to document this issue clearly.
Reviewer #3	*The model structure used allows for modeling the various events in a deli store as a chronological sequence of events. DE modeling is commonly used to model communications systems, queuing systems, and production systems. Each event "triggers" another event. The flow of events is not "scripted" or deterministic, but allows for the assignment of probabilities to the series of alternate events triggered by a given event. The advantage of this DE modeling is the fact that new events can be "inserted" between existing events, or multiple sequential events can be merged into one. A disadvantage of such a model is that it is "data thirsty".* *The modeling framework used allows for testing the impact of various mitigation strategies, if the events related to these strategies are included in the model. The model structure and series of events included in the model can be used to answer the list of "refined" risk mitigations questions provided in Section 1.2 of the report, provided the data needed to "populate" the model are available.* *The report lists in Section 1.2 a series of refined risk mitigation questions. It is not clear however, how the first initial question provided by risk managers ("What is the exposure to L. monocytogenes from consuming RTE foods prepared in retail facilities?" - Section 1.2) will be answered by the model, and how the objective of the risk assessment (as laid out in Section 1.3) relates to that initial question? Specifically, it is not clear whether the "refined" list replaces the initial questions or supplements them. If the latter, then data from a representative survey of ready to eat deli products prepared in retail facilities would answer that "initial" question. In fact, the report lists two studies (Gombas et al. 2003 and Endrikat et al. 2010) that could be used to estimate that baseline risk, assuming that these surveys are representative of current practices.*

RESPONSE	The Interagency Retail LM Risk Assessment Workgroup adjusted the risk assessment to indicate that the risk assessors considered the initial risk management questions too broad; they replaced these questions with the more refined list following stakeholder discussions.
CHARGE QUESTION 2: The report provides an illustration of the conceptual model (see page 16, Figure 3 and page 17, Figure 4) to indicate the sources, events and objects that may lead to transfer, growth and removal of Listeria monocytogenes in a retail environment. Does the conceptual model adequately indicate the major relationships that may explain the transmission of Listeria monocytogenes in retail? If not, explain any relationship that you believe is either unnecessary or omitted and how to consider this change in the model.	
NAME	**COMMENT**
Reviewer #1	*The conceptual model on page 16, Figure 3, indicates that there are four mutually exclusive major events in a retail store and shows how each of them could be further granulated into minor events. These minor events could be modeled probabilistically as shown in Figure 4 on page 17. Every minor event is associated with one or more basic processes: cross-contamination, removal, growth, inactivation, and partitioning. There seems to be some discrepancy in listing the "main events" in the report. On page 16 in Figure 3, major events are "Non Deli Time", "Serve Customer", "Wipe Down/Clean" and "NFSC Contamination". However, on page 48, paragraph 1, main events are "Sporadic Clean", "Non Deli Time", "Serve Customer", "Grow Everything", "Opening", and "Closing". Then again, during the operating hours, the four main events are considered "Non Deli Time", "Sporadic Clean", "Contamination from a Niche", "Serve Customer", and additionally, the FCSs are washed regularly. For better illustration and description of the model, these terms should be consistent throughout the report. If there are differences, they should be clearly stated and defined.* *If Figures 3 and 4 are meant to communicate the structure of the model and all possible interactions, including cross-contamination, they should be revised. With respect to transmission (cross-contamination) of Listeria monocytogenes in retail, it is not obvious from Figures 3 and 4 that cross-contamination could occur between chubs and FCSs (as shown in Figure 6). In addition, the diagrams in Figures 3 and 4 show wiping/cleaning (with the underlying removal process) as the only interaction that can occur between the worker and FCSs. However, as shown in Figure 6, cross-contamination between workers and FCSs can also occur.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup agrees with these comments. Figures 3 and 4, as well as the wording of the documentation were revised to be more consistent.
Reviewer #2	*It is not clear if this includes all such major relationships, because we don't know what they are.* *Figures 3 and 4 do not even correspond to the model described. There is no "NFCS Contamination" main event, but there is a "Contaminate from Niche" main event that is not included in those Figures [an example of incomplete/incorrect documentation]. The Wipe Down/Clean event of Figures 3 & 4 is presumably what is called "Sporadic Clean" elsewhere.*

	Some of the events shown in Figure 3 and Figure 4 are also reflected and amplified slightly in Table 6 and Table 7 (although the latter are in fact slightly different; e.g. Tables 6 & 7 only have "change gloves" where Figure 4 has "put on gloves"). It is clear that Figures 3 & 4 and Tables 6 & 7 do not fully describe the model in its current form. For example, the model has several specific NFCS within it, whereas Figure 4 simply says "a NFCS". Which one(s), and when? [This is an example of the incomplete documentation mentioned above.] I would suggest that it may be necessary to include other NFCS (and further FCS also) within the modeling, beyond even what is currently done. Specific ones that may be important and are not in the model are: foodserver face, foodserver clothing, furniture within the store (if any), multiple door handles (there is a "handle" in the NFCS sites in the input data; but the handle of what is not specified; and "refrigerator handle" is specified in Table 6, but is not explicitly in the input data). This may be an area where further research is needed first, to determine which (if any) NCFS become contaminated within such stores. *In addition, the non-"Serve customer" events may nevertheless contain actions that contribute to cross-contamination. For example, the Non-deli time may include cross-contamination events between gloves, hands, and NFCS/FCS, and even the wipe-down/clean event may result in such cross-contamination on NFCS and FCS that are not wiped down (e.g. if the foodserver has to obtain the wipe-down equipment/supplies from another room and does not remove contaminated gloves first).* *The "Contaminate from Niche" main event is currently pure speculation, as are the associated parameters, since the existence of niches must be considered speculative at the moment. I think that this lack of connection with experimental observations is one of the main problems with the model at the moment. It cannot be used to predict unless and until the concept of the niche is experimentally confirmed, and the properties of such niches are experimentally elaborated. Otherwise, it will probably be possible to select niche properties in such a way as to match any observed distributions of Listeria in consumer food servings; but such a match is unlikely to give unique information on niches or give information on other predictions of the model. Meanwhile, the model should incorporate various possibilities for recontamination from niches, such as recontamination happening during the other main events.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup has modified Figures 3 and 4 to improve the documentation and naming conventions. A number of non-food contact surfaces (NFCS) are already included in the model. The Interagency Retail LM Risk Assessment Workgroup has improved the documentation to be more consistent with their identification. The need to expand the types of NFCS simulated lacks any supporting data. A model is always a simplification of reality.

	The Interagency Retail LM Risk Assessment Workgroup agrees that the modeling of niches lacks experimental confirmation, both in the conceptual model and in the parameters used. The agencies have simplified the conceptual niche model based on discussion with other experts and the revised documentation reflects this change. The lack of experimental data is the major reason that the impact of niches and environmental contamination are evaluated through a sensitivity analysis. The Interagency Retail LM Risk Assessment Workgroup agrees that the model is over parameterized. Most process models are, which limits the ability of formal calibration to estimate parameters suitable for model prediction. Laboratory studies need to be conducted on the parameters themselves, as has been done for the transfer coefficient studies performed over the last decade.
Reviewer #3	*It is not possible to define all possible relationships that would explain how Lm would be transferred, grows, or removed in a retail environment. However, the events included in the model seem to be a reasonable list of the most important events. If future studies were to indicate that the model did not include an important event, or that some site/event is not needed, the model can be revised, given flexibility of the DE modeling framework it uses.* *The model includes a transport and a home component. While these are not necessarily part of the "retail" environment, they are needed to assess the ultimate exposure/risk for the U.S. population. However, it would be recommended to evaluate the efficacy of mitigation strategies at the intermediate output of cfu in product sold to avoid any potential effect due to home storage issues (unless it is possible to "freeze" this latter part of the model across multiple runs, but I do not think that is possible with the current model).* *The model assumes the same relative efficiency of cleaning the niche compared to its associated site (there is one DiffNiche per site). It may be useful to allow this relative efficiency to differ by* cleaning method too (wiping vs. washing vs. disinfecting).
RESPONSE	The model is capable of summarizing the *L. monocytogenes* concentrations leaving the store for each model run. While the model comparisons currently focus on the health impacts, the Interagency Retail LM Risk Assessment Workgroup agrees that comparing *L. monocytogenes* distributions would be useful and will work toward implementing these comparisons. The Interagency Retail LM Risk Assessment Workgroup has simplified our conceptual model of niches by removing differential cleaning efficiencies.
CHARGE QUESTION 3: Are the underlying model hypotheses and assumptions reasonable and clearly identified? If not, please explain.	
NAME	**COMMENT**
Reviewer #1	*For the most part, the hypotheses and assumptions underlying the risk assessment model are reasonable and clearly identified. My concerns with a few exceptions are discussed below:*

	Transfer coefficients were modeled using the lognormal distribution based on published data and the authors' assays to reflect the variability of transfer coefficients for a given source – recipient couple. However, lognormal distribution is characterized with heavy tails and requires truncation when transfer coefficients >1. Could truncation affect the model results and conclusions? If so, authors should describe the magnitude or at least the direction of the effect. Some of the figures in the appendix describing transmission coefficients show quite heavy truncation. Because of the importance of transmission coefficients in cross-contamination, which is a key process occurring in retail, I would suggest that the effect of truncation on model outputs be evaluated, and that the fit of Beta distribution be reevaluated as it is naturally bounded between 0 and 1. *One of the risk management questions on the effect of the reduction of cross-contamination is about the impact of glove use in the retail environment (the risk management question scenario 4.a.). This question is based on the hypothesis that food workers using gloves wash their hands less frequently and touch RTE products with their gloves while they would not with their hands. It is not clear how this hypothesis is being tested in the risk assessment. If the hypothesis is not testable, it would be more appropriate to list it as a model assumption.* *The modeling of cross-contamination is based on the assumption that members of the bacterial populations on two touching objects (e.g., N1 and N2) act independently, i.e., the probability of transfer for all bacteria from one object to the other is equal and constant for a given cross-contamination. This was achieved using a binomial process that assumes that the resulting number of transferred cells is the sum of N1 independent Bernoulli trials. While this assumption has been used in other models of cross-contamination, is it possible that this assumption represents an oversimplification of the cross-contamination process as bacteria may actually be transferred in groups (clusters)? It is not intuitively obvious how this simplification would affect the model outcomes. One may speculate that the simplification would underestimate the number of transfers with no bacteria transferred and overestimate the number of transfers with only a few transferred bacteria. Consequently, this would result in an overestimation of the prevalence of contaminated servings and so overestimate the human health risk associated with cross-contamination.* *Currently, the assumed levels of inactivation associated with different cleaning procedures have no obvious support from the literature. The report indicates that a literature review of washing efficiency has to be completed, which should address this concern in the future.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup tested beta distribution, but found it reduced goodness of fit statistics (see Hoelzer et al, 2012). The choice of the log-normal distribution follows the literature (Chen et al., 2001; Schaffner and Schaffner, 2007). The bacterial clumping issue is an interesting idea that hopefully will spark further

	lab research. The model as implemented aligns with the current literature both on the binomial assumption and on the transfer coefficients. If clusters of bacteria transfer simultaneously, it is likely that the literature studies on transfer coefficients reflect this already. The literature review of washing efficiency is now completed and published (Hoelzer et al, 2012)
Reviewer #2	*The underlying hypotheses and assumptions are generally reasonable, and clearly identified in general terms, but the model documentation currently lacks substantial specific detail (see elsewhere in this review for examples). However, reasonableness is not necessarily sufficient. See the previous comment on niches.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup will strive to improve the documentation to include additional details.
Reviewer #3	*The report identifies major assumptions and hypotheses, documents what data were used to assign particular values/statistical distributions, and identifies when no data or limited data are available for a particular parameter/distribution.* *Most such values can be changed by users in the excel spreadsheets. Others seem to be provided in the R-codes (e.g., growth parameters, consumption distributions, etc.) and I assume can be changed by user who is familiar with R. It may be useful to include these in the more "user-friendly" Excel workbook to allow users the ability to change them. This would be particularly useful for the parameters where FDA/FSIS has identified data gaps (e.g., growth/inactivation parameters).* *Values assigned to the distribution parameters are generally documented and appear reasonable given the available data. I had the following questions on some of the assignments:* *There seems to be an inconsistency in some of the product characteristics as listed in the worksheet "Prod" and those listed in Table 5 of the report. Based on my reading of the code in the "Store Functions.r" program, I assume that the model will use the product characteristics from the Excel spreadsheet to estimate growth. However it is not clear whether the values listed in Table 5 would have been used to derive the parameters of the Mejholm and Dagaard model?* *A $\log_{10}$ normal distribution with SD of 1 is assigned to the washing inactivation process associated with wiping, washing, sanitizing, or washing/sanitizing. The mean of that distribution is allowed to vary depending on the process. The mean values range from -1 to -3 depending on the process. For those processes where the mean is -1 that assumes that in 15% of the cases the selected value will be positive. Will that imply growth instead of inactivation for 15% of the cases? I would recommend using a smaller SD or truncating the distribution.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup agrees that the model supplied for review mixed data inputs between the spreadsheet and the R code. The current model incorporates all data inputs to the spreadsheet.

	In addition, the Interagency Retail LM Risk Assessment Workgroup has improved the documentation regarding growth parameters and the Mejlholm and Dalgaard (2007) model. The model, which truncates the washing inactivation distribution, has been revised to improve document clarity.
CHARGE QUESTION 4: The model includes components for retail, transportation and home storage, consumption, and dose response. The basic events in the model include transfer, growth, inactivation and partitioning of Listeria. Are there any additional components that should be incorporated into the model? If so, the reviewer should describe what these should be and why it is believed that these are needed.	
NAME	**COMMENT**
Reviewer #1	*The components and basic processes included in the model seem adequate. The components of the model are retail, transportation and home storage, consumption, and dose response. The basic events included in the model are cross-contamination, growth, inactivation, partitioning, and removal (note that the charge question missed removal process).*
RESPONSE	Thank you for this feedback.
Reviewer #2	*I cannot think of other such components, unless there are important modes of Listeria transport not currently examined.* *For example, are Listeria aerosolized during meat slicing (or other store operations)? A quick Google search ("meat slicing aerosol generation" in scholar.google.com) suggests they are. Moreover, the literature suggests that the inhalation route could be very efficient at infection (Bracegirdle 1994 Epidemiol Infect 112(1)69-79) of bystanders (customers) while the staff may be immunized by repeated exposure (Lefford 1979 Infect Immun 25(2)672-679). I am unaware whether any investigations of Listeria outbreaks or sporadic cases examined a potential inhalation route.* *Aerosol generation by a meat slicer could also result in contamination of "nearby" surfaces — a paper in press (Martins et al., 2010, Listeria monocytogenes in ready-to-eat, sliced, cooked ham and salami products, marketed in the city of São Paulo, Brazil: Occurrence, quantification, and serotyping. Food Control, doi:10.1016/j.foodcont.2010.07.026) suggests that aerosol contamination can occur over distances up to 2.5 m. This suggests that aerosol generation by the meat slicer should be investigated, and the model may need to incorporate contamination by this route as well as by direct contact.* *Another possibility is that major contamination occurs during events that are more sporadic than contemplated in this model. For example, during cleanout of drains (http://www.extension.org/pages/Structural_and_Public_Health_Pests:_Flies_%28Drain_Flies,_Fruit_Flies,_Fungus_Gnats%29; search for "listeria"). However, I see no need to incorporate such an obvious contamination source in this model, since the necessity of control of such sources is obvious.*

RESPONSE	To our knowledge, no cases of listeriosis from inhalation have been documented. The Interagency Retail LM Risk Assessment Workgroup agrees that the slicer may contaminate nearby areas. Studies currently underway at Virginia Tech and the University of Arkansas will provide clarity with this issue. The Interagency Retail LM Risk Assessment Workgroup agrees that rare events (e.g., events not seen during the observational study, such as drain clean out) may cause additional cross contamination. According to Endrikat et al. (2010), cross contamination should increase the prevalence of *L. monocytogenes* leaving the store by a factor of about 7. While the ratios varied, this increase was observed at all four locations studied. Given this observed prevalence increase, it is unlikely heavily dependent on very rare events.
Reviewer #3	*I agree with the components included in the model.*
RESPONSE	Thank you for this feedback.
CHARGE QUESTION 5: A variety of scenarios were selected to evaluate potential interventions or mitigation controls. Are the selected scenarios adequate to evaluate effective and efficient public health benefits that may be expected to occur with these different intervention strategies? If not, how should the selected scenarios be changed and what additional scenarios should be included?	
NAME	**COMMENT**
Reviewer #1	*The scenarios selected to evaluate the public health benefits of different intervention strategies seem adequate. As a minor comment, the scenario 4.g., "What if stores could be redesigned to refrigerate the entire deli area (i.e., no temperature abuse)?", does not seem to fit under the reduction of cross-contamination scenarios. Additionally, the scenario 5.a., "What would be the impact of providing a specific and short "sell by" and "use by" date for the products sliced to order in deli departments?", may need to be revised to indicate the level of consumer compliance with the suggested "sell by" and "use by" date (e.g., full or partial compliance).*
RESPONSE	The risk management questions reflect input from a number of stakeholders, including FDA, FSIS, industry, and consumer groups. As such, the model was designed to help the stakeholders understand the impact of an intervention (e.g., no temperature abuse); therefore, it is worthwhile to evaluate the impact of an intervention even if it does not directly address cross contamination. The Interagency Retail LM Risk Assessment Workgroup needs information on consumer compliance to evaluate the impact of date labeling fully. The current version of the model will be limited to "what-if" scenarios with regard to date the product can be hold in the deli department to evaluate the sensitivity of public health outcomes to this approach.
Reviewer #2	*This charge question is either way behind the curve or jumping the gun, depending on how it is interpreted. The model design and construction is supposed to allow responding to specific risk management questions (pages 11–13), so if those questions do not encompass changes leading to "effective and efficient public health benefits" the model scenarios may be inadequate. In this case, however, the charge question is way behind the curve, since it would require reformulating the risk*

	management questions. *On the other hand, the model scenarios designed to respond to the risk management questions are listed in Section 4.3 (pp 68–70). Those scenarios mostly respond adequately to the risk management questions as they are posed. However, this is jumping the gun, because it has yet to be shown that there are adequate data to run the model effectively so that the scenarios can provide meaningful responses to the questions posed. As a reviewer, I cannot respond to this charge question without a running model!* *However, I can comment on the scenarios response to the risk management questions (I assume that pp. 68–70 contain accurate representations of the questions):* *"Impact of 100% compliance with the FDA food code:"* *The scenarios would be adequate insofar as the specified practices do in fact match the model inputs. However, I have not examined this match.* *"Derive these results for each specific "risk factor"..."* • *Improper holding time/temperature — the use by date and temperature at each site are said to be inputs to the model. However, that is not quite true. They could be made inputs, but currently the distributions of these times and temperatures are integrated into the code of the model.* • *Poor personal hygiene — changing the probability of wearing gloves or washing hands may not capture the full range of "personal hygiene," since that also encompasses methods of handling gloves and other equipment. The model currently fails to consider "putting on gloves" or "removing gloves" as a cross-contamination event (hand-glove); I think it should. It also fails to consider non-deli operations as containing potential cross-contamination events. Again, I think it should. Both of these go to the question of "personal hygiene."* • *Contaminated equipment/protection from contamination — the Lm contamination level and probability that a site has a niche are indicated as the inputs to examine these. The first probably adequately handles contamination. However, changing the probability of a niche does not really handle the "protection from contamination" arm of this (that responds to a "better design" question). However, without a specification of what "protection from contamination," it is unclear how to respond.* *"Test the impact of the delay of the inclusion of key changes to FDA Food Code...(notably temperature)"* *The scenarios proposed — "run under conditions for the 2009, 2005 and the 2001 Food Code" — require that the inputs can be modified to match those conditions. Currently, however, the temperature distributions are hard coded into the code; they are not inputs. The model would need to be modified to include these as inputs, or to include specific input cut-offs on temperatures (for example) as inputs. There is also the problem of modeling what the inputs should be in response to these Food*

	Code changes. For example, if there is a modification to product Case holding temperatures, what will be the distribution of new temperatures under the new Food Code? Will it be the old temperatures simply modified by a cutoff, will the old temperatures just all be shifted downwards, or what? *"What would be the impact (under the modeling hypothesis) if the level/frequency ... in products ..."* *Exactly matched by an input, so this scenario is adequate.* *"What would be the impact (under the modeling hypothesis) if the level/frequency ... environmental contamination ..."* *The scenario responses are to change transfer coefficients from NFCS, reduce the probability of niches at such sites, or reduce initial concentrations at such sites. As noted, the scenario needs to relate to what this risk management question actually means, since that is not clear. The proposed scenarios appear adequate to cover most possible meanings.* *"What would be the impact ... growth inhibitors"* *Scenario proposed is adequate, since growth-inhibitor-containing products are included in the inputs.* *"What would be the impact of more frequent or more efficient cleaning of the slicers, other FCS and/or NFCS"* *Scenario proposed is adequate, since these are inputs to the model. Note that this might be affected by the undocumented "feature" that all event durations are divided by the number of foodservers.* *"What would be the impact of using separate slicers... counters..."* *The scenarios proposed for slicers is adequate (although the level of detail specified is not currently documented [I think], it does appear to be present in the model). There is no scenario proposed for counters. The model may currently be inadequate to respond to this, since it contains only FCS and NFCS, without specification as to what those surfaces represent in the store. Although it may be possible to set up contact matrices to specify that particular surfaces correspond to counters, that capability doesn't seem to be documented (either adequately, or at all).* *"What would be the impact of "pre-slicing"..."* *The scenario is said not to be yet available; the model is being modified to handle this. [Another example of this model not yet being ready for review.]* *"What is the impact of wearing gloves ..."* *The scenario is adequate, since the probability for wearing gloves is an input (however, I think the model is currently inadequate through not treating "putting on gloves" and "taking gloves off" as hand-glove cross-contamination events).* *"What if slicer niches could be eliminated ..."*

	The scenario is adequate, since the probability for a slicer niche can be set to any value. Begs the question as to existence of such niches, and the behavior of them, which are currently speculative. *"What if scale touch pads, refrigerator and deli case handles, ..."* *The scenario indicates that surfaces can be specified as either FCS or NFCS; however, it is somewhat inadequate in that the method of specification of which individual surface is which is unclear (certainly inadequately documented). The contact matrix can be used, but it is not clear how particular surfaces are selected to represent particular parts of the store and take part in particular events — they are currently associated only with particular foods.* *"What if ... no cross-contamination ..."* *The scenario is adequate, since all cross-contamination coefficients are inputs.* *"What if stores ... refrigerate deli"* *The scenario implies that the temperatures at the various parts of the store are inputs. However, as previously noted, these are currently hard-coded, so should not be considered inputs.* *"What if display cases were not touched ... (i.e. used tissues or had automatic door open/shut...)"* *The scenario for automatic doors is adequate, since the transfer coefficients are all inputs. As the response points out, use of tissues would require modification of the model, so the model currently cannot handle this risk management question.* *"What would be the impact of providing specific (short) "sell by" and "use by" ..."* *The scenario envisions that different use by dates could be simulated, and this is correct since that is an input to the model. However, I think that may be misunderstanding the question. The "use by" date of the model corresponds to the "sell by" date of the question — the question is (I think) from the point of view of the customer, not the store. So the model can handle the effect of different "sell by" dates, but it cannot handle "use by" dates (as represented to the customer), since it does not model user behavior; and user behavior is hard-wired into the code at the moment.* *"What would be the impact of a full compliance to the ≤ 40°F storage recommendation."* *Again, the scenario envisions setting the temperatures to 40° (but inadvertently, I hope, say 40°C!). However, as previously mentioned, these temperatures are hard-wired into the model.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup agrees that the reviewers received a version of the model that mixed data inputs between the Excel file and the model code. In addition, the model embedded the consumer storage time-temperature date in the code. The revised version of the model moves the data from the code to the Excel file.

	The modeling of different food workers has been clarified and the assumptions made more explicit in the documentation. The released version of the model will only track one food worker through time. The contact matrix has been expanded to include counters, so that rules for different product types only using specific counters are now possible. The Interagency Retail LM Risk Assessment Workgroup agrees that modeling pre-slicing was not completed in time for the review. It has now been finished. In addition, the agencies have improved the documentation to list what food contact and non-food contact surfaces are modeled explicitly versus those that fall into the general FCS and NFCS categories. As discussed above, the consumer data was moved from the code to the spreadsheet to make evaluation of changes in consumer behavior easier.
Reviewer #3	*I assume this relates to the scenarios listed in Section 1.2 under the "refined list of proposed mitigations". If so, the list seems reasonable.*
RESPONSE	Thank you for this feedback.
CHARGE QUESTION 6: Comment on the treatment of uncertainty and variability in the model as it is implemented in second-order Monte-Carlo simulations. Is this methodology appropriate for the purpose of the model and the available data? If not, explain what changes might be considered and how they would improve the model.	
NAME	**COMMENT**
Reviewer #1	*Uncertainty and variability are incorporated in the model through the second-order Monte Carlo simulation framework. This approach is appropriate. Basically, modeled variability is primarily from store to store – in terms of both store size and operating procedures. Two sources of uncertainty were acknowledged in the risk assessment: (i) niche existence and behavior and (ii) dose response. Due to the importance of cross-contamination in retail and the focus of this risk assessment on evaluating the relative impact of different retail practices and interventions, the uncertainty of the dose-response model was generally ignored. On the other hand, the uncertainty surrounding the niches has been modeled as it overwhelms other sources of uncertainty. In the model, for each variability run, the sites that contain niches are selected beforehand in the uncertainty loop. However, it is unclear whether the initial CFU count in a niche (which currently seems to be set to zero) and the fraction of the bacteria transferred globally to the site that are then transferred to the niche associated with the site have been considered as an uncertain or variable model parameter. This needs to be clarified in the report.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup has simplified the conceptual model for a niche based on discussions with other experts to reduce the input data requirements. The newer model is described in the current documentation.

	While the model is designed as and works as a fully 2nd order Monte Carlo, with explicit distinction between uncertainty and variability, we have found it easier to communicate to stakeholders in a different format. Each possible mitigation was evaluated for a range of different baseline store types. These baselines include, among others, stores with and without environmental and niche contamination, stores with contaminated incoming product, and stores with proper temperature control. Stakeholders and risk managers can easily see which mitigations are effective across a range of baselines.
Reviewer #2	*I have previously commented that this model is currently not a full second-order Monte-Carlo simulation (since only the niche probabilities are considered for the uncertainty loops), but should be modified to be one (by including the uncertainty of all parameters). That methodology is appropriate (when done correctly).*
RESPONSE	The model is capable of considering additional uncertainty variables. Nevertheless, the Interagency Retail LM Risk Assessment Workgroup decided to handle this issue differently for ease of communication and transparency (see previous response).
Reviewer #3	*Use of 2nd order Monte Carlo to model uncertainty is an acceptable and well established method. The report seems to imply that one major source of uncertainty was included in the model, namely the existence and behavior of niches. It is not clear from Section 2.2 of the report how this is modeled, however Section 3.3.1 ("Niches") implies that the presence/absence of a niche defines the uncertainty loop. It does not seem that the "behavior" of the niche (which I assume means potential transfer from/to niche) is modeled in the uncertainty loop. If it is, then it needs to be made clear how. Also, please note that there seems to be a typo in Figure 5 which seems to imply that the Uncertainty loop is used to select more stores?* *Also, I would recommend assessing the potential uncertainty introduced by the selection of one parametric distribution over another. For instance, what if a beta were to be used instead of a triangular distribution, etc.?*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup has rewritten the discussion of uncertainty with regard to niches to improve modeling process descriptions.
CHARGE QUESTION 7: Comment on the adequacy of the risk assessment model documentation. Is the report clearly written? Is it complete? Does it follow a logical structure and layout? If not, the reviewer should suggest an alternate outline and/or approach for adequately and clearly documenting this risk assessment.	
NAME	**COMMENT**
Reviewer #1	*The risk assessment model documentation is comprehensive. There are minor comments on the clarity of the report and its structure and layout, which are listed under the specific observations*.
RESPONSE	Our responses are addressed below.
Reviewer #2	*Currently inadequate, as previously mentioned. Reasonably clear at a high level, but omits details and appears only half-completed. The structure seems reasonable, but it may need more structure to accommodate all the details. I suggest adding sections listing the major hypotheses, assumptions, and data needs, together with*

	how missing data are (or will be) handled and how alternative hypotheses are (or will be) handled.
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup agrees. The documentation provided to the reviewers was an early draft. Assistance in identifying documentation inadequacies was one of the goals of this initial peer review. As discussed throughout, numerous changes and additions are being made to the documentation as suggested by the reviewers.
Reviewer #3	*The report is clearly written (note that the hard copy version dropped several special characters making it sometimes hard to read, but the electronic version was ok). The inclusion of the detailed information in the appendices was a great idea too.*
RESPONSE	Thank you for this feedback.
CHARGE QUESTION 8: Were sufficient information and explanations given that describe how the data were identified and what criteria were used to determine the suitability of the data? Were these criteria adequate? If not, what additional criteria should be used? Overall, is the model adequately supported by the existing data? If there are other data that should be included in the model, please identify the data sources and how should it be used.	
NAME	**COMMENT**
Reviewer #1	*Sufficient information and explanations were given to describe how the data were identified, and adequate criteria were used to determine the suitability of the data. Where data were not available, gaps were clearly indicated.*
RESPONSE	Thank you for this feedback.
Reviewer #2	*No. There is no indication of the extent or methodology for literature searches. There is no description of how data were selected for inclusion (e.g. for the transfer coefficients, it appears that any experimental data on any organism under any conditions were included, provided sufficient data were provided in the paper to derive a transfer coefficient; however, the selection criteria were not adequately specified). Since the selection criteria were not specified, I cannot comment on their adequacy, nor provide additional criteria. The model is supported only to the extent that the criteria used were in fact adequate. For example, from a superficial examination it appears that individual transfer coefficients were very different for different organisms and/or different experimenters/experimental conditions. Whether these differences truly represent variability for Lm is unclear; and whether the data selected are representative is also unclear (these need to be included in the lists of hypotheses, etc.) Clearly the model is not adequately supported as to the behavior or even existence of niches, since there are no experimental data.*
RESPONSE	The relevant peer-reviewed scientific literature was identified through searches in the National Center for Biotechnology Information (NCBI) PubMed database and cross-referenced in related published manuscripts. All abstracts were screened to identify relevant publications, obtain full-text versions of all identified manuscripts, and review the full relevant manuscripts. Manuscripts that provided no relevant quantitative data, designs or data formats, or new analyses of previously published data were excluded from the meta-analysis. The Interagency Retail LM Risk Assessment Workgroup has discussed in the literature review articles that were not included due to insufficient detail. The selection process is now detailed in Hoeltzer et al. (2012).

Reviewer #3	*There are 3 distributions assigned to the consumption amounts of Deli salad, Deli meat and deli cheese. (In the "input Functions.r" module). I would recommend checking the more recent consumption surveys (NHANES 2005-06 or 2007-08) to confirm that these gram intakes are still representative of the U.S. consumption patterns. Also would recommend confirming that all deli meats do indeed have the same gram distribution. It may be worth it to refine that distribution by breaking into two (or more?) distributions based on type of deli meat. The same recommendation applies to deli salads.* *The report states that there are no sales data to define the distribution of serving size per sale. I would suggest checking the Nielsen Scantrack database or other similar databases like, for instance, the databases associated with store rewards/membership cards that track supermarket product sales.*
RESPONSE	The Interagency Retail LM Risk Assessment Workgroup thanks the reviewer for these comments. The agencies had previously reviewed Nielsen Scantrack data but did not find the data applicable. In addition, the agencies investigated the NHANES 1999–2006 data for the new version of the model (see Appendix 2 of the report). The Interagency Retail LM Risk Assessment Workgroup has requested data from Food Marketing Institute and have incorporated the supplied data.

SPECIFIC OBSERVATIONS			
NAME	**COMMENT**		
Reviewer #1	**Page**	**Line**	**Comment**
	21	Line 3	*Delete "Figure/" in "…Figure/Table 2".* **RESPONSE:** Corrected.
	28	1st paragraph	*It would be useful to start the section "Cross-contamination when one object includes a niche" with a definition of niche.* **RESPONSE:** Definition added.
	29	Line 6	*In "where **A** is the (n×n) matrix of transfer coefficients Ti,j, with ai,i…." consider adding "with entry of A ai,I" after Ti,j.* **RESPONSE:** Done.
	29	Line 13	*Correct typo in "Slicing is a complex process in terms of bacterial transfer"* **RESPONSE:** Corrected.
	29	Line 20	*Explain "rpm"* **RESPONSE:** Done.
	31		*The first square bracket in "normal (-2.122, .848) truncated on]-∞]" should, I assume, be (-∞, 0]".* **RESPONSE:** Corrected.
	32	Line 14	*Correct typo in "… remaining number following this loss of bacteria".* **RESPONSE:** Corrected.
	3	Line 17	*Consider adding ", denoted C_0," after "bacteria" in "…a part of these C_0 bacteria are transferred to the slicer following…"* **RESPONSE:** The original wording is correct.
	33	Line 2	*Figure 9. Consider rephrasing the text "The formula refers to expected values. In the model, stochastic model are used." to something along the lines of "The formula refers to expected values. In the model, parameters m, e, and a are sampled from the corresponding probability distributions."* **RESPONSE:** Rephrased the text.
	34		*Consider elaborating with an example at the end of "A lag time in the growth is observed in case of rapid change in the bacterial environment."* **RESPONSE:** The level of environmental change necessary to induce a lag time is not well documented or understood in the literature. The Interagency Retail LM Risk Assessment Workgroup =revised the documentation to reflect this.
	38	Last line	*Correct typo "over- or under- estimates the response"* **RESPONSE:** Corrected.
	41	Lag time	*What is the rationale for assuming that bacteria do not*

				undergo lag phase when changing environment in retail. It is reasonable to assume that there will be no lag time if transfer happens from one FCS to another. However, will there be lag time if the transfer happens from a manufacture contaminated chub to a FCS? Is there any report in the literature that indicates the absence of lag phase in environmental contamination? If this data is available, the report should reference it to support the modeling assumptions. Alternatively, the report should indicate data gaps and clearly state assumptions made. **RESPONSE:** The available data on lag phases is somewhat lacking, particularly on environmental surfaces. The Interagency Retail LM Risk Assessment feels that assuming no lag phase is conservative with respect to protecting public health.
		43	3.2.4. Partitioning	*The authors state the assumption of a homogeneous contamination of the chub and the salad. The binomial distribution is then used to determine the number of bacteria in a slice (or serving of salad) rather than estimating N1=N0*m/M. Consequently, it is not clear if the implicit assumption is that bacteria are distributed homogeneously or inhomogeneously in the chub.* **RESPONSE:** The use of a binomial distribution as used here assumes a homogeneous contamination.
		44	Top	*Repeated "m the scale of the site (e.g. mass of a food in g.),"* **RESPONSE:** Corrected.
		44	Transfer, inactivation, partitioning	*Based on the title of the subparagraph, readers would expect to read about how separation of cells into integer cells and a unique growing cell is dealt with in modeling of inactivation and partitioning. However, this is not mentioned at all.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup modified the way stochastic growth is handled, using a Yule process (Yule, 1925).
		45	Figure 11	*Missing "s" in "occurs"* **RESPONSE:** Corrected.
		47	Top	*Correct typos in: "More than one site of each category may be present in the store"* **RESPONSE:** Corrected.
		47	25-26	*Correct typos: "This matrix of contacts allows specifying which…."* **RESPONSE:** Corrected.
		48	4th paragraph	*What data support is available for the chosen Normal*

				(3,0.3) for the duration of the non-deli time? **RESPONSE:** No data has been identified, and this continues to be a data gap.
		48	5th paragraph	*What data support is available for the chosen Normal (10,1) for the duration of the sporadic cleaning?* **RESPONSE:** None at this time. Existing data gap.
		49	1st paragraph	*What data support is available for setting the probability of main event "Contamination from a niche" to 1%?* **RESPONSE:** The conceptual model of niche contamination has been significantly modified. While the input data are still a data gap, their importance has been evaluated through a sensitivity analysis.
		49	1st paragraph	*What does it mean that the niche event does not have a duration?* **RESPONSE:** Sporadic movement of cells from the niche to the associated site occurs instantaneously.
		49	4th paragraph	*Correct typos and verb usage in "Additionally, <u>At</u> the end of all major <u>event</u>, the bacterial growth that occurred during that period of time <u>is</u> evaluated and all bacterial population <u>number</u> <u>are</u> updated, according to the models presented in section 3.2.2."* **RESPONSE:** Corrected.
		50	1st paragraph	*Correct typos in "<u>touché</u> the scale" and in "these alternatives were evaluated <u>form</u> the observational study"* **RESPONSE:** Corrected.
		50-51	Tables 6 and 7	*Is there a better column heading than "Frequency/condition"? Possibly, revise to say "Frequency/total observations".* **RESPONSE:** Changed to "Number of times observed/total observations".
		51	Below Table 7	*Correct typo in: "It is currently assumed that it takes a time following a normal (4, 0.4) minutes per pound to serve deli meat, <u>deli</u> cheese or deli salad."* **RESPONSE:** Corrected.
		55	1st paragraph	*Missing "in" after "proposed" in "storage will be modeled using the distributions proposed Table 9"* **RESPONSE:** Corrected.
		59	Figure 14	*Consider adding numbers to the scale of colors on the top of the graph to indicate contamination level (or at least range 0-10^8)* **RESPONSE:** Scale description added to figure title.
		60	Figure 15	*Consider adding "up to" after "stands for" in "the height of the rectangle stands for 1E6 bacteria."* **RESPONSE:** Done.

		61	Figure 16	*What is the time period, a day, or the duration of simulation? Should figure capture read "An example of the time of contamination for each site over the simulated period of time"?* **RESPONSE:** Corrected.
		61	1st paragraph	*Indicate that the text refers to Figure 16. The text does not correlate with legends in Figure 16. Upper panel shows the fraction of time a site was contaminated not "the mean length of time". Middle panel shows the mean number of events in which a site was contaminated. The lower panel should be explained.* **RESPONSE:** Done.
		62	3rd paragraph	*When creating output for the summary of serving, it would be useful to add medians into the output in addition to means.* **RESPONSE:** Agree and done.
		64	Figure 17	*Was the very high level of contamination on sale #10 or #7?* **RESPONSE:** Corrected.
		67	Figure 20	*The sink was contaminated in 265 cases, not 256 cases.* **RESPONSE:** Corrected.
		68	1st paragraph	*With so many data gaps, calibration of unknown parameters may be problematic. Will there be any control measures/restrictions in calibration?* **RESPONSE:** The model is highly over parameterized for calibration, particularly given the lack of available retail monitoring. Currently, the *Listeria* concentration in retail sliced product is available, and studies are underway to monitor *the Lm* concentration through time at different locations within the deli. Given the data paucity, it is unlikely that a formal calibration process will be used. Judgment and expert opinion will still be necessary.
		71	Last paragraph	*Correct typos in "it builds a "virtual deli", <u>make</u> it <u>works</u>, and"* **RESPONSE:** Corrected.
		73	Middle of the page	*Correct typo in "probInStore: probability that the product is in the store. If probInStore ≥ 1, this number of product will be present in all <u>store</u>."* **RESPONSE:** Corrected.
			Last paragraph	*It is stated "Symmetry between transfer coefficients is not assumed, although common" However, for cross-contamination involving the slicer, it is assumed that a=b. Please clarify.* **RESPONSE:** The mean transfer coefficients are given

				in Table 3. When treated as a matrix, this table is typically symmetric. For example, the transfer coefficient from cheese to sink and the transfer coefficient from sink to cheese are currently the same number. But since the entire matrix is a data input, different values can be entered for transfer between the two sites depending on which site is the source. The slicer is indeed an exception with a always equal b. The reason (identifiability) is given on page 134.
		99	1st paragraph	*Correct typo in "A lettuce outbreak strain of E. coli O157:H7 was used to quantitate the pathogen's survival in…"* **RESPONSE:** Corrected.
		106	Line 2	*Consider adding "points" after "data" in "Note: only one publication and 5 data."* **RESPONSE:** Done.
		120	Table 21	*Column headings, correct typo in "nb experiment"* **RESPONSE:** Corrected.
		122	3rd paragraph	*Correct typos in "Various pattern implying the preparation of a recipe. 10^8 bacteria were placed on the chicken, and the final number of bacteria on the salad was estimated ((de Jong et al. 2008)). From these results, (van Asselt et al. 2008) derived some transfer coefficients and compare them to literature data. Most of the transfer are global (e.g.: from chicken to salad via hand). We can only use as input estimated performance of washing. Overall transfer rate may be used as a control."* **RESPONSE:** Corrected.
		123	Line 1	*Confusing sentence: "The interesting result is that a single failure in washing leads to similar final contamination than multiple failures." Should "similar" be "smaller"? Alternatively, should "than multiple failures" be "to multiple failures"?* **RESPONSE:** Corrected.
		127	Figure 24	*Label axes.* **RESPONSE:** Done.
		133	Last paragraph	*Paragraph starting with "64: …." is not clear.* **RESPONSE:** Corrected.

Reviewer #2	*Some of these are included also in the comments above:* *I suggest using standard notational conventions — symbols should refer to physical quantities, so encode both value and unit. Follow the conventions of ISO 80000-1:2009, including (b) use the MKS system. I recommend that all values in code be in MKS; all conversions should occur on input and output. Similarly all logarithms should be natural within the code (and also in the mathematical development); again, any conversions occur on input and output.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup agrees with these comments and has modified the documentation and files to be more consistent and better annotated. The one exception is with logarithms, where the use of log10 is more natural. Note that the base for log scale, if properly implemented, does not impact any results. *Are those distributions for transfer functions variability distributions or uncertainty distributions?* **RESPONSE:** They are variability distributions. *What assumptions are made about transfer functions in doing the analyses of the literature data? Are transfer functions assumed to be species/strain dependent? Surface-dependent? Experimenter-dependent?* **RESPONSE:** The transfer functions were not assumed to be strain/surface/experimenter dependent. See Hoelzer et al., 2012. *What were the likelihood functions used for analysis of the experimental literature?* **RESPONSE:** Log likelihood for parametric fitting *Use of R is fine for setting up an initial "try it out" model, but is inadequate for running this model and obtaining useful information in a reasonable amount of time. The open nature of R is pointless if it is to be coupled to Excel using ODBC (Open Database Connectivity).* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup disagrees. R appears quite suitable for this work. The model, with runs times of approximately 2 hours, are adequate using a suitable high performance parallel computer. Several open source or freely available office packages are capable of creating and reading Excel files. See OpenOffice and LibreOffice for example. *Evaluation of some of the literature seems dicey --- interpretation of the papers/analysis applied. Much of this is not clear because not documented.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup are not aware of any literature that was not considered, but will continue to conduct literature review as the risk assessment continues. *It is poor practice to encode experimental/observational results into the code (e.g. fractions of time various employees did various things, temperature distributions). Design the program to accept these as data inputs.*

	RESPONSE: The Interagency Retail LM Risk Assessment Workgroup agrees, and the current version of the model moves these data from the code to the spreadsheet. *Many of the random number generators cannot be recommended. While they work, the method used (inversion of the cumulative density) is not recommended for use in Monte Carlo algorithms or elsewhere where speed of generation is important. Please consult a standard text, the recommended one being Non-Uniform Random Number Generation by Luc Devroye, freely available at http://cg.scs.carleton.ca/~luc/rnbookindex.html.* **RESPONSE:** The benefits of using the built-in R functions outweighs the time and effort required to recode and validate slightly faster versions that produce the same results. *Page 8. Citing to (Draughon, 2006) is an inadequate citation since this reference apparently does not exist. It apparently was a talk at a symposium, with no write-up; but that is of no use to the reader and does not provide a reference for the data. [Something should be available at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, according to 74FR3617-3619. However, even the docket entry for this reference at www.regulations.gov (Docket FDA-2008-N-0658) has only header material.] The FSIS (2009) reference is somewhat better, since scattered throughout it are some of the data. The analysis of Appendix A of FSIS (2009) suggests the data are available somewhere. Give a citation to a location that allows complete retrieval of the data. The cumulative densities of Figure 2 are apparently from FSIS (2009). However, that reference deliberately modified the raw data before fitting (e.g. it assumed that 29 of the retail samples were detects at 0.3 MPN/g, contrary to the observations). A correct analysis should be performed using the actual observations, taking account of the methodology of the MPN methodology, or whatever methodology was actually used, to determine the likelihood function).* **RESPONSE:** These are the best references available. A full summary of the data, including all quantified positive concentrations, is given in FSIS (2009). A full analysis of the data is provided in Appendix A of the comparative risk analysis (FSIS 2009). *Pages 28-29. What happens if the sum of the $T_{i,j}$ at fixed j exceeds unity?* **RESPONSE:** The whole paragraph was removed because the model currently does not include any cross contamination between more than two objects. The only exception is during the slicing process, but this specific model is fully described in the report. *Page 29. $T_{i,j}$ is used for both the transfer coefficient and the number of organisms, potentially leading to confusion.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup will change this notation in a future version of the report. *Page 31. Why is it considered necessary to perform a simulation to obtain the mean*

	and median of the distribution for a in Table 4 (and Table 23)? All that is needed for the analytic calculation of the mean is the indefinite integral $$\int \frac{xe^{-x}}{\left(1+e^{-x}\right)^2}dx = \frac{x}{1+e^{-x}} - \ln\left(1+e^{x}\right) + \text{constant}$$ *while the analytic calculation of the median is trivial (the exact values are 8.08406061…% and 7.69305622…%; the 1E7 iterations give accuracies of about 1 in the fourth significant digit for the mean, and 2 in the fourth significant digit the median).* **RESPONSE:** Because this portion of the work has already been completed and yields the same answer, the Interagency Retail LM Risk Assessment Workgroup are not sure the comment is relevant. *Page 38. These equations for the φ presumably apply only for the same ranges of values given in the equations for the corresponding γ on page 36 to 37 (and are zero outside that range). This should be made explicit.* **RESPONSE:** Because the growth model is multiplicative, once any of the γ coefficients become 0, the entire growth rate reduces to 0. *Page 41. Growth model on sites. There presumably are limiting "densities" on sites also. (This is stated on page 46 under "Sites", but it should be stated here). These could be CFU/unit surface area, or total CFU (in niches?). Whether it is "safe" depends on the value of EGR, which could be chosen negative!* **RESPONSE:** The model allows for growth at sites, but the EGR is currently set to 0 (i.e., no growth). For baseline runs, the Interagency Retail LM Risk Assessment Workgroup assumes that growth at each location does not occur. Maximum possible densities for food are treated as a constant for all food categories. Maximum possible densities for sites are not considered. Page 46 has been modified to reflect this. *Page 41. The growth model should be stochastic, especially if it is extended to a death model (negative EGR). See comment below at page 43.* **RESPONSE:** The current growth model is a growth-only model. The lowest egr value is 0 (no growth). Negative values are not returned. The new negative binomial growth model is actually stochastic, and the specification of the egr now does include a stochastic component. *Page 42. The data gap is more extensive than indicated. The existence of niche sites, and the washing efficiency within the niche site (if it exists) has to be determined. Currently it is assumed that cleaning efficiency of the niche is correlated with cleaning efficiency of the site, but this may not be true. Other possibilities should be allowed.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has revised our conceptual model of a niche so that washing/sanitizing no longer affects the niche. See the revised report. *Page 43. Section 3.2.5. I asked about this during the presentation, and was told that*

	this approach was adopted because using stochastic processes resulted in wider variations, and this approach appears to average over those variations. This description is from memory; and I may not have got the idea correct originally. However, the approach is unnecessary and misguided. There is no reason not to use stochastic growth and death models (they are straightforward with the pure growth/death model used). This entirely removes any problem with real numbers in the growth model, since only integers are needed. Moreover, any additional variance should not be considered a nuisance --- that is exactly why the stochastic model is being used; it is an error to attempt to smooth out such variation artificially. Further, the programming becomes much more straightforward – there is no need to keep track of the non-integer pieces. In practice, it still may be sensible to use real numbers in the implementation; for small enough values these represent integers exactly, and can hold large numbers where necessary. This approach requires some care in implementing integer distributions (like binomial, multinomial, etc.), but that is not difficult. **RESPONSE:** After consideration, the Interagency Retail LM Risk Assessment Workgroup generally agrees with this comment and has converted the growth model to the discrete negative binomial of Yule (Yule, 1925) as described by Vose (2008). This change is further described in the revised documentation. *Page 46. Is it adequate to use generic FCS and NFCS? Should the foodworkers face/mouth area and/or clothing be considered separately, considering the frequency of contact with such areas is likely much higher than with other NFCS.* **RESPONSE:** The observational study did not note significant contact with clothing or with face/mouth. At this point, the Interagency Retail LM Risk Assessment Workgroup has decided not to include these as possible sites. *Page 47. Niches. It is not stated explicitly that the "value sampled from a triangular distribution" is a variability, not an uncertainty (or is it?).* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has revised our conceptual model of a niche so that capture from the site and a corresponding triangular distribution is not used. See the revised report. *Page 48. Main Events. The model appears to not really correspond with reality. It has all actions within a deli tied into a linear sequence. This might be fine with a single foodworker, but in a multi-person deli several operations may occur simultaneously. A better approach would probably be to track the individual foodworkers.* **RESPONSE:** The model is only designed to track a single food worker through time. The documentation has been revised to make this assumption more explicit. *Page 48. Main Events. Operating the Deli. What is the basis for the durations given (i.e. what data?).* **RESPONSE:** New data on durations has been collected since the peer review. These data and analysis are included in the revised report.

	Pages 48-49. Main Events. Operating the deli. In Section 3.4.1, we are given the duration for the "Non Deli Time" event, the "Sporadic Clean" event, and the "Contamination from Niche" event, but not the duration of the "Serve a customer" event. The duration is not described in Section 3.4.2 either. It would help to point out where in the text the duration(s) may be found. But on what data are they based? **RESPONSE:** No data at this time. Existing data gap. *Page 48. Main Events. Operating the deli. The code (event.getduration) indicates that the duration of every event is divided by the number of store workers. This means that the statements about duration on page 48 are incorrect. It also looks like a workaround to ensure that the total store activity scales with the number of workers; but this approach will fail if any modeled process actually (now or in a future modification of the methodology) depends on the duration of the event, since clearly the duration of events is not inversely proportional to the number of foodworkers in a store. A better approach would be to model the events of each individual foodworker.* **RESPONSE:** The model is only designed to track a single food worker through time. The documentation has been revised to make this assumption more explicit. The code that divided time by the number of food workers has been removed. *Page 49, 3.4.2. What is the basis for the 0.25 or 0.5 pound mass selection and their associated probabilities?* **RESPONSE:** As described in Section 3.4.2, this is an existing data gap. *Pages 49-50, 3.4.2. Table 6 and Table 7 appear to assume that the foodworker is wearing gloves at the start. That may be true of the stores that were observed, but is it always true? There probably should be an option for ungloved operation as well (with or without hand washing). And subsequent probabilities (e.g. change gloves) would probably be different for the different initial conditions (e.g. "change gloves" vs. "put on gloves").* **RESPONSE:** The food worker does not always wear gloves at the start. *Page 52, Table 8. "Change glove" should surely be a hand-glove contamination event. Are there any measured data on this action?* **RESPONSE:** Software code that implements a hand-glove contamination event has been added to the model. *Page 52, Table 8. This appears to be inadequate, since there is no basic event by which the glove status of a foodworker can change. You need both a "remove glove" and a "put on glove" basic event, both of which are (potentially) hand-glove cross-contamination events (unless the foodworker has been very carefully trained, and uses that training consistently).* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has added a "put on glove event" to Table 8. *Page 52, Table 8. "Wash hands" is treated as a single event of inactivation. But it*

	is two events, one of inactivation (wash hands), one potentially of cross-contamination (dry hands), depending on the method used to dry hands. **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup agrees, but at this time the agencies have decided not to include a "dry hand" cross-contamination. *Page 52, Section 3.4.4. "Within one store, the temperature is considered" what? There is a missing section here. Presumably that meant to say "constant" at the end.* **RESPONSE:** Corrected. *Pages 52-53. "... one temperature is drawn from the respective distribution for deli meat, deli cheese and deli salad at the beginning of the simulation and these values are used for the whole simulation within this store." This implies that different products (meat, cheese, salad) are kept in different produce Cases within the store (or at least in places with different temperatures within the same produce Case). Table 6 on page 50 implies that the same produce Case ("the case") is used for both meat and cheese (whereas salad might be a separate produce Case, Table 7). Make clear in the text that there can be distinct produce Cases within a store for meat, cheese and salad. The code setup associates the temperature with the product, as described in the text, not with the produce Case. However, the contact matrix in the spreadsheet effectively associates the product with the produce Case. Thus, there is the potential (which occurs in the example we were supplied with, since the contact matrix implies the same produce Case for cheese and salad for Case.2 and Case.3) for the product temperatures to be (assumed to be) different within the same produce Case. While that is possible if the products are stored in different parts of the same produce Case, it is unlikely that the spread of temperatures for that situation would be so wide as the full distribution of retail temperatures. I suggest that the temperatures be assigned to the produce Cases, and obtained for the product based on which produce Case contains that product.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has revised the model to include a case temperature distribution, which is then taken as the food temperature. The temperature is updated/reselected on a daily basis. *Page 53. Figure 12 is misleading. The empirical distributions have about 891 points for bologna and 919 for potato salad, not the 100 or so shown here. The code apparently gets this correct (although I did not check every entry!).* **RESPONSE:** Ties exist and account for the different heights of the jumps in the cdf plots. *Page 54. Is there a distinction between the two specifications for Δt in the "Time, temperature, and model" section at the top of the page?* **RESPONSE:** Yes, Δt is for time. It is different for deli meat and deli salad. ΔT is for temperature, which also differs for these two categories. The Interagency Retail LM Risk Assessment Workgroup has added text to better note the distinction. *Page 54. Growth during transport.* *The multiplier in the equation should be Δt not t.*

	RESPONSE: Changed. *Page 54. Growth during transport.* *That equation is only correct if $T_0 > T_{min}$; otherwise growth does not start until T reaches T_{min}. The code gets this wrong, predicting growth only if the mean temperature during transport exceeds T_{min}. But some growth will occur if $T_f > T_{min}$. It is not difficult to get it correct (modify Δt to be the time increment after T* reaches $T_{\min}$, etc.). And this correct algorithm should be correctly documented. (Note: T_0 can indeed be lower than *T_{min} in the EcoSure data).* **RESPONSE:** Corrected. *Page 68. "What if slicer niches could be eliminated through redesign or cleaning procedures". The idea would be to set the probability for a slicer niche to zero. However, that might require some further thought about analysis of the slicer literature, and the slicer computer model. Currently, the literature is examined as though there is no slicer niche, with a large loss of organisms (with no indication of where those organisms are supposed to go). The computer model, on the other hand, assumes that these "lost" organisms all go into the slicer niche, and that the niche has no effect during slicing. If this is how the slicer operates, then the procedure described might be appropriate. But what if the niche does exist, and does have an effect during slicing. Would that be identifiable in evaluating the literature data? I suspect not for most experiments. And what would be the effect on the parameter values in the computer model (which would also have to be modified to incorporate the effect of the niche during slicing)? In particular, assuming that the niche does have an effect during slicing could perhaps explain the curve obtained by Sheen & Hwang (2008).* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has revised the conceptual model of a niche so that transfer from the slicer to the niche does not occur. See the revised report. *Page 93. I looked at Chai et al. 2008 as an example. The initial contaminations reported there are between 1E2 and 1E5 MPN, not MPN/gram. Also Table 2 reports the effect of washing, not heat treatment.* **RESPONSE:** This misunderstanding is due to typos in the report. The values should have been reported as MPN, not MPN/g. The wording was revised to "washing" rather than heat treatment. The data were included correctly in the meta analysis. *Page 99. I looked at Zhao et al. 1998 as another example. The lack of documentation as to how the analysis was performed makes it impossible to say whether this paper was correctly interpreted. It does not report measurements in sufficient detail to obtain 59 independent estimates for board-vegetable transfer coefficients — there are 59 measurements of CFU on vegetables, but no corresponding measurements for the board. Instead, there are multiple distinct measurements on the board. It is possible to write a likelihood function to correctly encode the literature data, but I cannot tell if this was done correctly to evaluate this experiment.*

	RESPONSE: Given the variability and not always complete explanation of the experiment and results, the Interagency Retail LM Risk Assessment Workgroup has aggregated the different papers' data to fit one parametric likelihood function. *Page 100. Footnote 3. The method described for extracting data from graphs is incompletely described. It clearly loses much useful information from many electronic publications. In many such cases the .pdf file obtained from the publisher contains digital information for the graphics that can be readily extracted by printing out the postscript describing the page and extracting the coordinates directly. For cases where the .pdf file obtained from the publisher contains only bitmap information, it is very often necessary to de-skew the data after digitizing the axes and point locations. I recommend using an arbitrary 4 x 4 matrix for this, obtained by minimizing the variance of points from the axes with known coordinates. I can give more information on these methods if desired.* **RESPONSE:** Thank you for this offer. The Interagency Retail LM Risk Assessment Workgroup believes the data were adequately extracted from the graphs but will consider de-skewing if greater accuracy is needed. *Page 101. Footnote 6. Why use mean and SD, why not transform to median and GSD, at least approximately (assume lognormal distribution)? That would remove at least some of the bias.* **RESPONSE:** The footnote meant: this approach does not lead to a bias for the estimated mean if the geometric mean is provided in the reference. Actually, the mean, and not the median, is usually not provided in the references
Reviewer #3	*I attempted to run several simple scenarios to determine how the model would behave. I had the following observations:* *The report (p. 76) states that the stores ID (A, B, C, etc.) are used to interpret output. However, I do not think that I saw the store ID in any of the summary outputs?* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup has added the store ID to the summary output. *In an attempt to see what happens at the "extremes," I set the probability for all niches to zero. The program crashed.* **RESPONSE:** This was a bug in the program that has been corrected. *Also, I added a 4 store (store D) in the store worksheet and assigned it a given probability. After I ran that scenario, I deleted the additional row and resaved the "LmRetailData.xls" workbook and tried to run the model, but it crashed.* **RESPONSE:** The Interagency Retail LM Risk Assessment Workgroup is still investigating what might have caused this error but have not been able to replicate it to date.

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