Appendices-FSIS Risk Assessment for Risk-Based Verification Sampling

The 2005 risk ranking algorithm described in these appendices is derived from the 2003 Listeria monocytogenes risk assessment model and the 2006 risk ranking algorithm is modified according to updated information from modification to the risk assessment model in 2006. Further modifications to the risk ranking algorithm made after 2007 are described in the companion document in this series.

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APPENDIX I. Executive Summary 2003 FSIS *Listeria monocytogenes* Risk Assessment

The 2003 FSIS *Listeria monocytogenes* (Lm) Risk Assessment is the one of several human health risk assessment, used to inform a highly significant regulation, to be formally reviewed and approved by the US Office of Management and Budget in compliance with Executive Order 12866. The entire text of the report can be accessed at www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf.

The 2003 FDA-FSIS *Listeria monocytogenes* risk assessment (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm) serves as the basis for the baseline *L. monocytogenes* risk ranking algorithm. The median number of illnesses per serving is used in estimating the equivalent deli meat volume (EDMV) for RTE products other than deli meat. The algorithm uses the EDMV of each RTE product multiplied by the expected number of *L. monocytogenes* in each gram of product for each risk alternative in order to estimate individual establishment risk at retail. The summation of these risks over all RTE product categories manufactured in an establishment is standardized to that of deli meat in order to obtain the risk ranking of each establishment in the sampling frame. The risk ranking is the basis for risk-based sampling since higher risk establishments are sampled in preference to lower risk establishments.

SCOPE AND MANDATE

This risk assessment was initiated in February 2002 in response to public comments on the Food Safety and Inspection Service (FSIS) proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* [66 FR 12589, February 27, 2001]. Several comments indicated a need for a stronger scientific basis for the proposal to require testing and sanitation of food contact surfaces for *Listeria* species. This risk assessment was developed to: 1) provide insight into the relationship between *Listeria* species on food contact surface(s) and *Listeria monocytogenes* in RTE meat and poultry products; and 2) evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, growth inhibitors, and combinations of these interventions to mitigate contamination of RTE meat and poultry products and reduce the subsequent risk of illness or death from *Listeria monocytogenes*.

PUBLIC HEALTH REGULATORY CONTEXT

Listeria monocytogenes is a foodborne pathogen that results in about 2,500 cases of listeriosis annually in the United States. Of these cases, approximately 90% require hospitalization, and 20% progress to death. Those at greatest risk of listeriosis are the elderly, those with suppressed or compromised immune systems (e.g., those who have received a bone marrow transplant, cancer treatment, etc.), and fetuses and newborns.

Listeria monocytogenes occurs widely in both agricultural (e.g., soil, water and plants) and food processing environments (e.g., air, drains, floors, machinery). This pathogen grows at low oxygen conditions and refrigeration temperatures, and therefore survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although

frequently present in raw foods (dairy, meat, poultry, fruits, and vegetables), *Listeria monocytogenes* can also be present in ready-to-eat (RTE) foods due to post-processing contamination (i.e., after lethality treatment and before packaging). Of the RTE foods contaminated with *Listeria monocytogenes,* deli meat was identified in a 2001 Food and Drug Administration and FSIS risk ranking evaluation of RTE foods as posing the highest annual risk of listeriosis.

FSIS has taken several steps to reduce contamination, and the subsequent risk of illness or death, from *L. monocytogenes* in RTE meat and poultry products. These include the following:

1) establishment of a "zero tolerance" (e.g., no detectable level of viable pathogens permitted) for *L. monocytogenes* in RTE meat and poultry products; 2) requirement that establishments consider *Listeria monocytogenes* in their HACCP plans and adopt and follow written Sanitation Standard Operating Procedures (Sanitation SOPs) to reduce the likelihood that harmful bacteria will contaminate finished products (e.g., RTE meat and poultry products); 3) development of a proposed regulation [66 FR 12589, February 27, 2001] for establishments that do not have *Listeria monocytogenes* as part of their HACCP plan, to verify, through microbiological testing of food contact surfaces, that the establishment's Sanitation SOPs are controlling *Listeria* species and the establishment take corrective action when a food contact surface tests positive for *Listeria* species; and 4) initiation of this risk assessment to provide a scientific basis to guide regulations for in-plant interventions (e.g., testing and sanitation of food contact surfaces) to mitigate the risk of listeriosis from RTE meat and poultry products.

RISK MANAGEMENT QUESTIONS

In the Fall of 2002, FSIS risk managers requested that the risk assessment be designed in order to evaluate the following specific questions:

- How effective are various food contact surface testing and sanitation (corrective action) regimes (e.g., vary the frequency of testing by plant size – large, small, and very small plants) on mitigating *Listeria monocytogenes* in finished RTE product, and reducing the subsequent risk of illness or death?; and

- How effective are other interventions (e.g., post-processing interventions or growth inhibiting packaging) in mitigating *Listeria monocytogenes* in finished RTE product, and reducing the subsequent risk of illness or death?; and

3) What guidance can be provided on testing and sanitation of food contact surfaces for *Listeria* species (e.g., the confidence of detecting a positive lot of RTE product given a positive food contact surface test result)?

LISTERIA RISK ASSESSMENT MODEL

To address these risk management questions, a dynamic in-plant Monte Carlo model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and *L. monocytogenes* in a production lot of RTE product at retail was developed using currently available data. The outputs of the in-plant model (e.g., concentration

of *Listeria monocytogenes* on deli meats at retail) were used as inputs into specific components of an updated version of the 2001 FDA/FSIS risk ranking model. The draft 2001 FDA/FSIS risk ranking model (see http://www.foodsafety.gov/~dms/lmrisk.html), developed to identify which RTE foods pose the greatest risk of listeriosis, was updated with data and information provided during the public comment period after the release of this draft model. The outputs of the in-plant model were calibrated to the concentration of *Listeria monocytogenes* in deli meats at retail in the updated version of the 2001 FDA/FSIS risk ranking model. The updated FDA/FSIS risk ranking model then tracks the level of *Listeria monocytogenes* in deli meat from retail to table and provides estimates of the subsequent risk of illness or death from consuming these products. These two connected models – the in-plant model and the updated 2001 FDA/FSIS risk ranking model – comprise the overall FSIS *Listeria* risk assessment model.

By changing in-plant practices, such as the frequency of testing and sanitation of food contact surfaces, the FSIS risk assessment model can evaluate the impact of these practices in reducing the annual risk of illness or death from *L. monocytogenes* in RTE meat and poultry products.

RISK ASSESSMENT OUTPUTS

Findings from the risk assessment model outputs include the following:

1. Food contact surface found to be positive for *Listeria* species greatly increased the likelihood of finding RTE product lots positive for *Listeria monocytogenes*
2. Frequency of contamination of food contact surfaces with *Listeria* species appears to encompass a wide timeframe, and the duration of a contamination event lasts approximately a week.
3. The proposed minimal frequency of testing and sanitation of food contact surfaces (66 FR 12589, February 27, 2001), results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail.
4. Increased frequency of food contact surface testing and sanitation leads to a proportionally lower risk of listeriosis.
5. Combinations of interventions (e.g., testing/sanitation of food contact surfaces, pre- and post-packaging interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of RTE products with *Listeria monocytogenes* and reducing the subsequent risk of illness or death.
6. Specific model outputs relating to *Listeria monocytogenes* concentrations at retail and the resulting public health impacts of various interventions will be developed and presented at the public meeting on February 26, 2003.

Appendix II. Excerpts from the 2003 FSIS *Listeria monocytogenes* Risk Assessment: Modeling Methodology

Model Overview

This appendix reviews the theoretical considerations upon which the 2003 FSIS *Listeria monocytogenes* (*L. monocytogenes*) risk assessment was based. The model estimates the concentration of *L. monocytogenes* at retail and used a mass balance approach to track both the food contact surfaces and product over time in order to determine the number and distribution of organisms. This mass balance approach ensures that the number of microorganisms at both the beginning along the continuum to the end of the processing system remains the same. In other words, living, dead and growth cells are tracked. This helps to ensure that none of the pathogenic organisms is lost as they migrate from food and non-food contact surfaces to product from plant to retail when the risk per serving size is considered per lot. The initial development and implementation of the *L. monocytogenes* risk ranking algorithm depended on the assumptions and results of the 2003 FSIS *L. monocytogenes* risk assessment at retail prevalence model.

2003 FSIS Listeria monocytogenes Risk Assessment Excerpts

The 2003 FSIS *Listeria* risk assessment model includes a dynamic in-plant Monte Carlo model that predicts *L. monocytogenes* concentrations at retail. Dynamic means that the bacterial concentrations are predicted in each lot of RTE product over time. Monte Carlo means that many of the parameters for the model are stochastic random variables, and that different values are selected for each lot produced. For example, the fraction of *Listeria* that transfer from the food contact surface to the lot varied from lot to lot, but fell within a limited range and matched the probability distribution of the available data.

Monte Carlo sampling is used throughout the 2003 FSIS *Listeria* risk assessment, in both the in-plant dynamic model and the 2003 FDA/FSIS retail-to-table exposure assessment for deli meats. The inputs for the in-plant dynamic model of the 2003 FSIS *Listeria* risk assessment are modeled as variability distributions without the inclusion of parameter uncertainty. Inclusion of parameter uncertainty would have required substantial computational time requirements. This was a reasonable simplifying assumption in the model given that it is a generally accepted practice to exclude uncertainty in a model input if variability is thought to dominate (e.g., Small, 2000). In cases, as seen in this risk assessment, where parameter uncertainty is swamped by model uncertainty, it is not useful or pragmatic to invest a substantial amount of time required to draw fine distinctions between uncertainty and variability that may not be credible or useful. Instead, use of simpler modeling strategies may be more meaningful and pragmatic (Casman, 1999). Therefore, FSIS finds it reasonable, pragmatic and sufficient to use a simple, broad distribution to characterize in-plant model parameters

In the 2003 FSIS *Listeria* risk assessment, model inputs are assumed to be independent of one another. Without empirical information, specifying dependencies of inputs would be purely hypothetical. It seems

reasonable to assume that variable model inputs (e.g., frequency, duration, and level of contamination) are independently distributed.

The primary output of the in-plant model is the concentration of *L. monocytogenes* in RTE meat and poultry products at retail. This output was then coupled with the 2003 FDA/FSIS retail-to-table exposure assessment for deli meats and the 2003 FDA/FSIS dose-response model to predict human health impacts.

A mass balance approach was used as the basis of the in-plant model. The number and disposition of *Listeria* organisms are tracked for both food contact surface area and the product over time. For example, as *Listeria* organisms move from the food contact surface area to the product, the concentration on the food contact surface area decreases and the product lot concentration increases so that the same total number of *Listeria* organisms is present. The total number of organisms can change due to growth of new organisms, die-off from sanitation, or transfer from external sources such as harborage sites.

The in-plant model incorporates food contact surface testing, product testing, sanitation, pre- and post-packaging interventions, and the effect of growth inhibitors (or product reformulation). The output of the in-plant model is combined with the updated version of the 2001 FDA/FSIS exposure retail-to-table pathway for deli meats and *Listeria* dose-response relationship to estimate the risk of illness or death on a per serving and per annum basis from *L. monocytogenes* in RTE product. Risk estimates are provided as a function of: testing (*Listeria* species) and sanitation frequency (based on plant size) of food contact surfaces (FCSs), testing (*L. monocytogenes*) and disposition of RTE product, pre- and post-packaging interventions, and growth inhibitors. The conditional likelihood of detecting *L. monocytogenes* in products, given that the FCS tests positive for *Listeria* species, was also evaluated.

To date, the model has been run for deli meats. Deli meats were selected because the 2001 FDA/FSIS risk ranking analysis determined that this food category posed the greatest risk of illness and death among consumers.

Model Parameters

The data available within the published literature dealing with *Listeria* in the processing plant environment is rather sparse. Data limitations, the limited time available for model development, and the intended use of the model, dictated the following:

1) The model only considers food contact surface as source of *Listeria* species/*L. monocytogenes* in product. In practice, *Listeria* could also arise from inadequate lethality treatment or from direct deposition from non-food contact surfaces.

2) Only a generic food contact surface is modeled. A lot, for purposes of this analysis, consists of product produced in a shift or 8-hour period. There is no spatial component within the plant (e.g., slicer, convey belt, etc.).

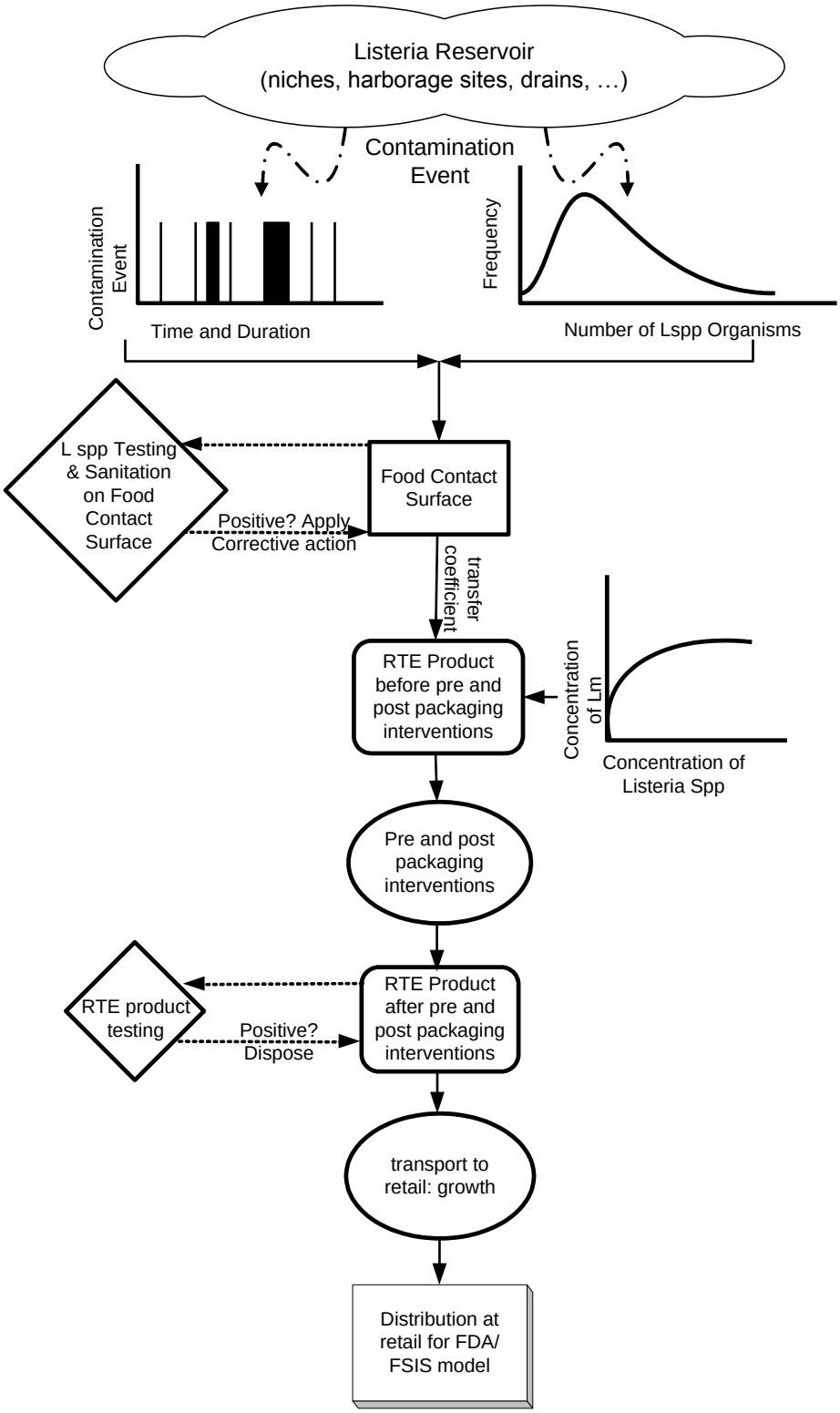
3) The model assumes *Listeria* species are evenly distributed across food contact surfaces, and *L. monocytogenes* are evenly distributed within a lot of product. In other words, the variability across a food contact surface or within a lot is not accounted for in this model.

4) The model operates on a RTE product lot basis. This is the smallest unit of RTE product for which model results are available.

5) Interventions, such as sanitation and testing, would affect the distribution of *Listeria* at retail, but did not change the timing, duration, or concentrations transferred during a contamination event.

Conceptual In-plant Dynamic Model

A schematic overview of the conceptual model is provided in Appendix II Figure 1 below. The model assumes that a *Listeria* reservoir exists in the plant and is capable of contaminating the food contact surface. This reservoir can be harborage sites such as floor drains or air conditioning ducts, or other surfaces/equipment in the plant. Lunden *et al.* (2002) provides an example of a long term harborage site. The authors described sequential *L. monocytogenes* contamination at three plants as a dicing machine was moved from plant to plant, even while typical sanitation measures were being taken.



Appendix II. Figure 1. Conceptual Model for the "In-plant" Component of the FSIS Listeria Risk Assessment.

The FSIS *Listeria* risk assessment model supposes that *Listeria* species move from this reservoir onto the food contact surface during what is termed a contamination event. The key parameters defining a contamination event are:

- the time between initialization of events (i.e., how often is a food contact surface contaminated?);
- the duration of the event (i.e., how long does it last?); and
- the amount of *Listeria* species transferred from the in-plant reservoir to the food contact surface.

Time series *Listeria* species prevalence on various pieces of equipment were available from an FSIS in-depth verification conducted in a plant that was associated with an *L. monocytogenes* outbreak in humans (Hynes 2000). The data were analyzed using survival analysis and distribution fitting using NCSS statistical software (Hintz 2001). Several distributions were compared, and the $\log_{10}$ normal distribution had the greatest likelihood. On a $\log_{10}$ scale, the mean time between contamination events was 1.08 with a standard deviation of 0.46. This is approximately 20 days ± 29 days.

Tompkin (2002) provided a table of sequential weekly *Listeria* species testing results and the number of weeks that *Listeria* species positives persisted. These data were analyzed using survival analysis and distribution fitting with NCSS (Hintz 2001). A $\log_{10}$ normal distribution was selected based on the quality of the fit and the ease of interpretation. On a $\log_{10}$ scale, the mean contamination event duration was 0.60 with a standard deviation of 0.57. This is approximately 9 days ± 20 days.

There was no reported literature available to estimate the loading parameter. The mean and standard deviation of the loading were calibrated so that the predicted retail *L. monocytogenes* distribution matched the FDA model distribution. The process is described below.

Once on the food contact surface, *Listeria* species can be transferred to the lot of RTE product being processed, be removed from the food contact surface through sanitation at the end of each lot processing, or stay on the surface. Published studies support the concept that RTE product is primarily contaminated by food contact surface. In a study of *L. monocytogenes* in French delicatessen plants, Salvat *et al.* (1995) found that contact of cooked product with contaminated surfaces was a major route of product contamination, as was cross contamination between raw and cooked product. Some fraction of the *Listeria* species on the food contact surface is transferred to the lot. This fraction is the transfer coefficient, which can range from 0 to 1. A transfer coefficient of 0 indicates that none of the *Listeria* species are transferred. A transfer coefficient of 1 indicates that all the *Listeria* species are transferred to the product lot being processed.

If the contamination event is continuing, the new *Listeria* species transferred from the reservoir will be added to the *Listeria* species already on the food contact surface.

The model starts by stochastically generating the start time and duration for each contamination event that will be needed for the simulation. These parameters are simply random variates drawn from distributions described above.

The model also stochastically generates the timing for the requested testing of lots and FCS. These too are simply random variates.

For each RTE lot produced during a contamination event, the concentration of *Listeria* species on the food contact surface is increased by a stochastic amount to account for the transfer of organisms from the harborage site to the food contact surface. The *Listeria* species concentration on the food contact surface at the end of the time period LS_j is calculated as:

$$LS_j = \left(LS_{j-1} + \delta(j)\right) \left(1 - TC_j\right) \left(1 - s_j\right)$$

where
LSj *Listeria* spp. concentration on food contact surface at end of lot j (cfu/cm^2)
TCj transfer coefficient for lot j (dimensionless)
δ(j) added *Listeria* spp. concentration added to the food contact surface if a contamination event is ongoing (cfu/cm^2)
s_j Sanitation effectiveness for lot j (dimensionless)

Montville *et al.* (2001) and Chen et al. (2001) found that transfer coefficients of bacteria were log normally distributed based on testing a variety of foods and surfaces such as hands, lettuce, and spigots. The range of transfer coefficients varied from 0.01% to 10%, with a standard deviation of about 1 log.

Midelet and Carpentier (2002) prepared *L. monocytogenes* biofilms by contacting meat exudates with 5x10^7 cfu/ml to stainless steel slides for 3 hours. The planktonic bacteria were then removed by washing and the results used to estimate the fraction of *Listeria* transferred. Transfer coefficient values ranged from 0.45 to 1 depending on the surface material. The risk assessment model used a log normal distribution with a standard deviation of 1 and with Midelet and Carpentier's mean transfer coefficient. Values generated above 100% transfer were simply truncated at 100%. The resulting empirical distribution was no longer log-normal.

Sanitation is considered at the end of each lot production. The sanitation effectiveness s_j for each time period (or lot produced) is:

$$s_j = \begin{cases} s_1 & \text{if 1st lot of day} \\ s_2 & \text{if 2nd lot of day} \\ s_e & \text{if } LS_{\text{j-slag}} \text{ tested, positive, and enhanced sanitation option selected} \end{cases}$$

Values of 0.5, 0.75, and 0.95 were used for s_1, s_2, and s_e respectively. This results in a standard daily sanitation effectiveness of 87.5%, or just less than a one log10 reduction in the amount of contamination remaining on food contact surfaces. A similar level of effectiveness was estimated for cleaning of stainless steel surfaces experimentally inoculated with a biofilm of *Pseudomonas aeruginosa* and *Staphylococcus aureus* by Gibson *et al.* (1999).

For each lot processed, the food contact surface can also be tested for *Listeria* species and various mitigation steps taken if the surface tests positive. A positive food contact surface test

can also trigger a required lot of RTE product to be tested for *L. monocytogenes*. It can also trigger a more intensive sanitation (i.e., enhanced sanitation) of the food contact surface at the end of lot processing. This effectiveness was set at 95% for the base model. The enhanced cleaning was always lagged in time to allow for the time between the testing and when the results would be available.

The *L. monocytogenes* concentration in the RTE lot is then calculated as:

$$LM_j = \left(LS_{j-1} + \delta(j)\right) * TC_j * \frac{A_{j*}}{M_j} * R_j$$

where

LM_j *L. monocytogenes* concentration in RTE product lot j (cfu/g)
A_j food contact surface area at lot j, stochastic (* only varies for new contamination event) (cm)
M_j mass of lot j (g)
R_j *L. monocytogenes* / *Listeria* spp. ratio for lot j (dimensionless)

The area of the food contact surface was needed to convert between concentration of *Listeria* species on the surface and total number of organisms present on the food contact surface. Limited data was available for this parameter. Base runs assumed that the area varied as a uniform random number from 100,000 cm^2 to 1,000,000 cm^2. While treated as a random variable, the value was held constant while a contamination event was occurring.

Once the number of *Listeria* species present in the product lot was calculated, the concentration of *Listeria* species per gram was then calculated. This was then converted to a concentration of *L. monocytogenes*. A ratio of *L. monocytogenes* to *Listeria* species is used for each lot to estimate this concentration.

No data were available on the ratio of concentrations of *L. monocytogenes* to *Listeria* species. Data, however, were available on the prevalence of *L. monocytogenes* to *Listeria* species (i.e., data on when a food contact surface was found positive for *Listeria* species, whether or not the surface was also positive for *L. monocytogenes*). These prevalence data were available from the published literature (Tompkin 2002) and some unpublished industry data provided to FSIS (Cornell University, November 2002). These data fit a normal distribution with a mean of 52% and a standard deviation of 26%. Values generated outside 0 -100% were rounded to 0% or 100% appropriately.

Either immediately before packaging or after being sealed in the final package, the lot can undergo additional post-lethality treatment, which is intended to further reduce the level of potential pathogens, such as *L. monocytogenes*, in RTE products.

$$LMPP_j = \begin{cases} LM_j & \text{if } RN_j \geq FPP_k \\ LM_j * (1 - PP_k) & \text{if } RN_j < FPP_k \end{cases}$$

where

$LMPP_j$ *L. monocytogenes* concentration in RTE lot j after post processing interventions (cfu/g)
PP_k Post processing intervention effectiveness for plant size k (dimensionless)
FPP_k Fraction of lots for plant size k that undergo post processing interventions (dimensionless)
RN_j Uniform random number used to test if lot j should undergo post processing

Only a percentage of the lots produced by each different plant size were assumed to undergo post processing interventions. The decision on which lots undergo post processing was a simple binomial test based on the fraction of lots appropriate for the given plant size.

After these interventions, the lot can then be tested for *L. monocytogenes*, either because of routine lot testing or because a food contact surface tested positive for *Listeria* species. If a test-and-hold procedure is in place, the lot tested for *L. monocytogenes*, based on a food contact surface positive for *Listeria* species, is the lot produced at the time the food contact surface sample was collected. If a test-and-hold procedure is not in place, the lot testing response is lagged by the time it takes to analyze a food contact surface sample for *Listeria* species and obtain results of this test, i.e., lot testing is applied to a lot lagging behind the tested food contact surface. The model used a lag time of 3 days. RTE product lots that test positive for *L. monocytogenes* are removed from the food supply.

After pre- and post-packaging interventions and possible additional RTE product testing, the lot proceeds to retail. During the transport from the processing plant to retail, bacterial growth could occur which increased the concentration of *L. monocytogenes*. A constant logarithmic growth factor is applied in the model. The product or packaging could be formulated to reduce the growth.

$$LMGI_j = \begin{cases} LMPP_j * 10^{GF} & \text{if } RN_j \geq FGI_k \\ LMPP_j * 10^{GF + \log 10(1 - GI)} & \text{if } RN_j < FGI_k \end{cases}$$

where

$LMGI_j$ *L. monocytogenes* concentration in lot j after growth and growth inhibition during transport to retail (cfu/g)
GF Growth factor applied to all lots
GI Growth inhibition factor
FGI_k Fraction of lots for plant size k that undergo growth inhibition (dimensionless)
RN_j Uniform random number used to test if lot j should undergo growth inhibition

The model used a log growth factor of 1. The growth inhibition varied during scenario analysis.

The testing procedure for *L. monocytogenes* in a lot was calculated by first generating a Poisson random number using a population mean as mean cfu's within the sample (sample mass * concentration):

$$n_{sample\,j} = Poisson\left(SM_j * LM_j\right)$$

The RTE lot sample is judged positive by

$$LMR_{sample\,j} = \begin{cases} positive \text{ if } \mathrm{LM}_{\mathrm{sample,j}} > 0 \text{ and } (1-\mathrm{p})^{\mathrm{n_{sample}}} < \mathrm{U}(0,1)_j \\ negative \qquad \text{otherwise} \end{cases}$$

where

$LM_{sample\ j}$	total *L. monocytogenes* cfu in test sample j (cfu)
p	probability of detecting 1 *L. monocytogenes* cfu in test if present (dimensionless)
$U(0,1)_j$	uniform random number between 0 and 1 (dimensionless)
$LMR_{sample\ j}$	*L. monocytogenes* test result for lot j (positive or negative)

The testing procedure for food contact surfaces was similar, with the relevant substitutions of area tested for sample mass.

Once the number of organisms in the sample was known, the probability that a test to detect the presence of the pathogen would yield a positive or negative result could be determined by using a binomial distribution:

$$1-(1-p)^n$$

where p is the probability of detecting 1 cfu in the sample, and n is the number of cfu's in the sample from the Poisson calculation. The p probability is based on the detection limit and microbiological test sensitivity, and is the input parameter to the risk assessment model. A baseline value of 75% probability was used for both FCS sampling and RTE lot sampling. This is consistent with reported limit of detection (FSIS Microbiological Laboratory Guidebook) and tests sensitivity (Hayes *et al.,* 1992).

FSIS (2003) reported a survey among RTE processors of deli meats (and hot dogs) to evaluate the fraction of the deli meat food supply produced by large, small and very small plants. Additionally, the pounds per shift per line for each plant size were also estimated. The survey found that for deli meats, about 48% of the food supply is produced by large plants, 48% by small plants, and the remaining 4% by very small plants. The estimated average production volume in pounds of deli meats per line per shift were provided in the report.

Lot weights (i.e., pounds of deli meat per line per shift) were varied stochastically from lot to lot. Simulated lot weights less than 1000 pounds were rounded up to 1000 pounds.

While the survey found that the average mass of a lot of RTE product varied by plant size. However, there is no evidence of a difference in the occurrence of *L. monocytogenes* in RTE product by plant size. To reconcile differences in lot mass with equivalency in *L. monocytogenes* occurrence by plant size, the model was adjusted for food contact surface sizes. This adjustment eliminated the unintended bias that would have resulted from assuming the same food contact surface size regardless of plant size.

Appendix III. Modifications to the 2003 FSIS *Listeria monocytogenes* Risk Assessment model

In order to evaluate the proposed risk-based sampling for *L. monocytogenes* in RTE meat and poultry products, FSIS modified the 2003 FSIS *L. monocytogenes* (Lm) risk assessment model in 2006. The small business administration (SBA) size categories of very small, small and large plants are replaced by estimates of high, medium, and low production volume.

1. Introduction

The goal of this research was to evaluate formally the proposed risk based sampling for *L. monocytogenes* in RTE meat and poultry in accordance with 9 CFR 430. A second version of the computer model used for the 2003 *L. monocytogenes* Risk Assessment was developed that was designed to incorporate the various Alternatives currently used. The alternatives are: product that receives both a growth inhibitor and a post processing lethality step (Alternative 1), product that receives either a growth inhibitor or a post processing lethality step (Alternative 2), and finally product that receives neither (Alternative 3).

2. Model Description

FSIS wrote the original and updated versions of the 2003 FSIS *Listeria* risk assessment model in R©, an open source statistics and programming language. Appendix II includes the baseline input data set. The software and documentation are available at http://www.r-project.org/. The results presented here were produced in R© version 2.1.

The updated version of the model uses the same mass balance approach as in the 2003 FSIS *L. monocytogenes* Risk Assessment and as previously been described in the final report of that document available at http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf.

Differences between the 2003 and 2006 versions of the model include:

1. Conducted a more formal calibration of the bacterial loadings parameters {i.e., mean and standard deviation of bacterial cells added to the food contact surface (cfu/cm^2)}. The food contact surface sampling and corresponding interventions to match the current FSIS guidelines (9 CFR 430 Interim Final Rule).
2. The model uses a time period of one year for number of tests per line, but is designed so that any consistent time period can be used without changing the model code. For example, number of tests per quarter can be used as long as all values are input with these same units.
3. Converted data that are now treated as single values, such as the log kill for post-processing lethality to Alterative-specific values with only minimal code changes. For example, if FSIS wishes to distinguish plants using post-processing lethality between

those that achieve 1 log kill and those that achieve 2 log kill, only two lines of code need to be modified.

4. Eliminated the graphical user interface, which was no longer necessary.

3. Results

3.1 Lot volume

The model design used one of two classifications to simulate the volume of each lot produced. The first classification is based on HACCP category (large, small, very small). The second classification is based on volume of production, with plants in the upper 25% of production considered large, plants in the next 25% of production considered small, and plants in the lower half of production considered very small. These categories correspond to those used in the previous risk assessment, the 2003 FSIS *L. monocytogenes* Risk Assessment.

The FSIS economic analysis provides a breakdown of different food processing plants into the various categories, Appendix III Table 1 and 2. This data was available for HAACP categories (large, small, and very small) but was not available for volume classification. The base run assumes the same fractional production among the different Alternatives for the HACCP and volume-based categories. Note that this assumption does not affect the results used for the Plant Risk Ranking model because each Alternative was modeled separately to obtain the respective Q80.

Appendix III. Table 1: Summary of HACCP plant size distribution among FSIS Alternatives

HAACP Establishment	**Size**	**Size**	**Size**	
Alternative	**Large**	**Small**	**Very Small**	**Total**
1	9	24	16	49
2	108	675	1,514	2,297
3	13	308	445	766
Total RTE MPP establishments	130	1,007	1,975	3,112

Appendix III. Table 2: Fraction of Total Mass Production by Alternative and HACCP size.

HAACP Establishment Characteristic	**Size**	**Size**	**Size**	
Fraction total grams	0.48	0.48	0.04	
Alternative	**Large**	**Small**	**Very Small**	**Total**
1	0.0332	0.0114	0.0003	0.04
2	0.3988	0.3217	0.0307	0.75
3	0.0480	0.1468	0.0090	0.2

HACCP lot distributions use a normal (Gaussian) distribution to generate lot sizes. Volume based categories use a log-normal distribution. The base data set, shown in Appendix III Table 3, assumes a 50%–50% split in Alternative 2 between plants using a post-processing lethality step and plants using growth inhibitors.

The current published regulations (9 CFR part 430 in Federal Register Volume 68 No. 109 [Docket No. 97-013F] June 6, 2003) were used to develop a set of actions to be undertaken in response to a positive finding for a food contact surface of product lot, as well as food contact and lot testing efforts that vary by Alternative. These data are provided in Appendix III Table 4.

Appendix III. Table 3. Summary of Annual Pounds Production Volume by Alternative and HACCP Size

Parameter	Alternative 1			Alternative 2						Alternative 3		
	L-PP&GIP	S-PP&GIP	VS-PP&GIP	L-PP	S-PP	VS-PP	L-GIP	S-GIP	VS-GIP	L-none	S-none	VS-none
	1L	1S	1VS	2LPP	2SPP	2VSPP	2LGI	2SGI	2VSGI	3L	3S	3VS
Fraction PP	1	1	1	1	1	1	0	0	0	0	0	0
Fraction GIP	1	1	1	0	0	0	1	1	1	0	0	0
lot mass mean - HAACP	19,371	7,100	2,800	19,371	7,100	2,800	19,371	7,100	2,800	19,371	7,100	2,800
lot mass std dev - HAACP	14,000	10,600	9,500	14,000	10,600	9,500	14,000	10,600	9,500	14,000	10,600	9,500
production fraction – HAACP	0.0332	0.0114	0.0003	0.1994	0.1609	0.0153	0.1994	0.1609	0.0153	0.0480	0.1468	0.0090
lot mass mean - volume	18,420	1,488	573	18,420	1,488	573	18,420	1,488	573	18,420	1,488	573
lot mass std dev - volume	45,155	2,115	251	45,155	2,115	251	45,155	2,115	251	45,155	2,115	251
production fraction – volume	0.0332	0.0114	0.0003	0.1994	0.1609	0.0153	0.1994	0.1609	0.0153	0.0480	0.1468	0.0090

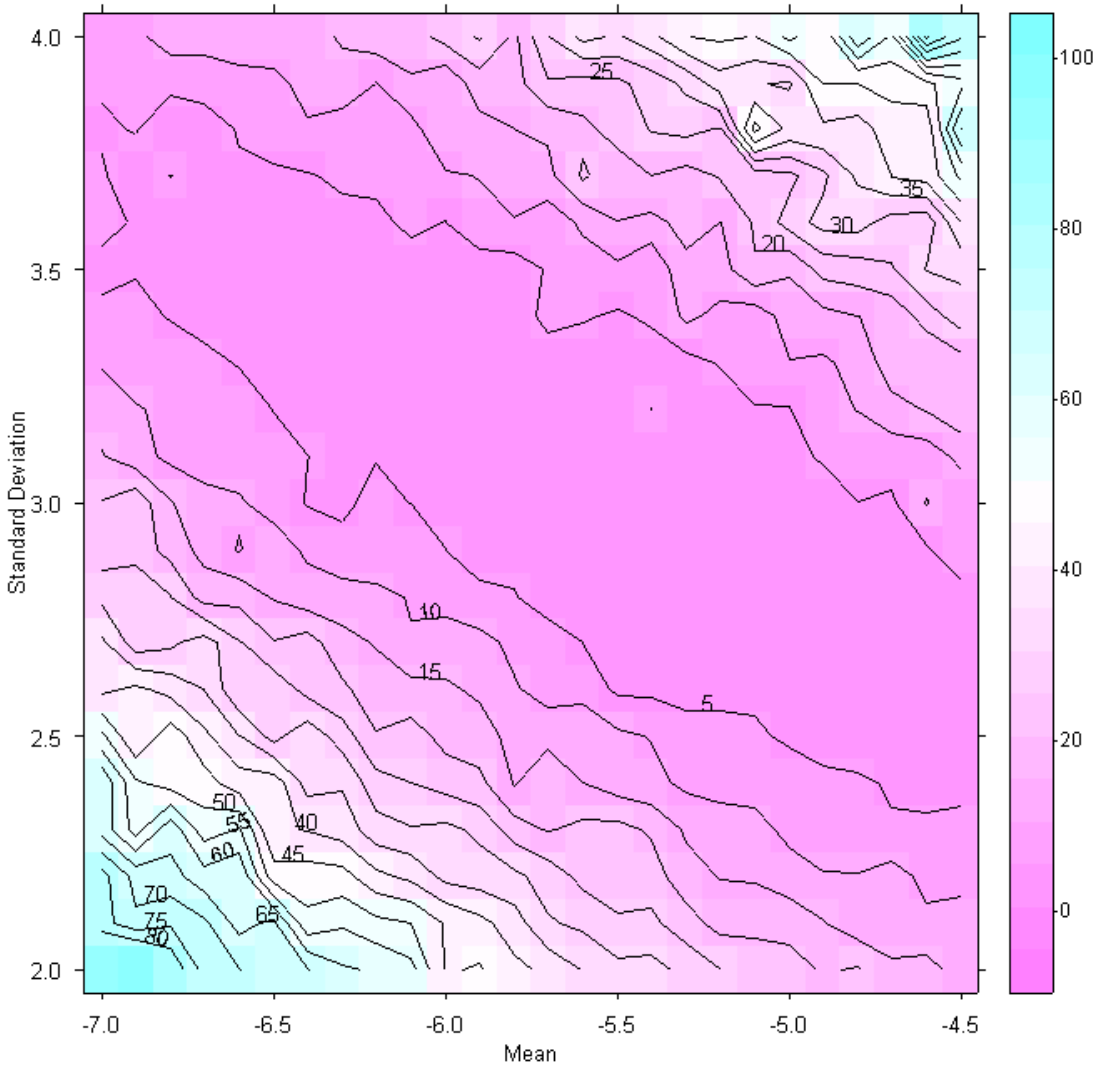
Appendix III. Table 4. Interpretation of 9 CFR 430 Rules for Interventions and Sampling Requirements

Parameter	Alternative 1			Alternative 2						Alternative 3		
	L-PP&GIP	S-PP&GIP	VS-PP&GIP	L-PP	S-PP	VS-PP	L-GIP	S-GIP	VS-GIP	L-none	S-none	VS-none
	1L	1S	1VS	2LPP	2SPP	2VSPP	2LGI	2SGI	2VSGI	3L	3S	3VS
FCS tests per line per year	2	2	2	4	4	4	4	4	4	48	24	12
Lot tests per line per year	0	0	0	0	0	0	0	0	0	0	0	0
FCS positive triggers Enhanced Clean	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
FCS positive triggers test of next FCS	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
FCS sequential trigger	Inf	Inf	Inf	Inf	Inf	Inf	3	3	3	2	2	2
FCS positives above sequential positives trigger hold lots	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
FCS positives above sequential positives trigger forced lot test lots	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Lot positive requires lot to be disposed	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Lot positive requires test next lot	N	N	N	N	N	N	N	N	N	N	N	N

A Food Contact Surface sequential trigger of Inf (infinity) implies that a sequential positive trigger is not used and no number of positives will ever force the corrective action for the Alternative plants.

3.2 Calibration

A formal calibration was conducted for the mean and standard distribution of the *L. monocytogenes* loading levels while a contamination event is ongoing. Appendix III, Figure 1 contains the results. The results, presented in a contour plot, illustrate the sum of squared log residuals between the observed retail *L. monocytogenes* distribution as provided by the FDA/FSIS (2003) report and the model output, assuming no sampling, no post processing, and no growth inhibition. Because the FSIS data represent the distribution over the past few years, this was deemed appropriate.



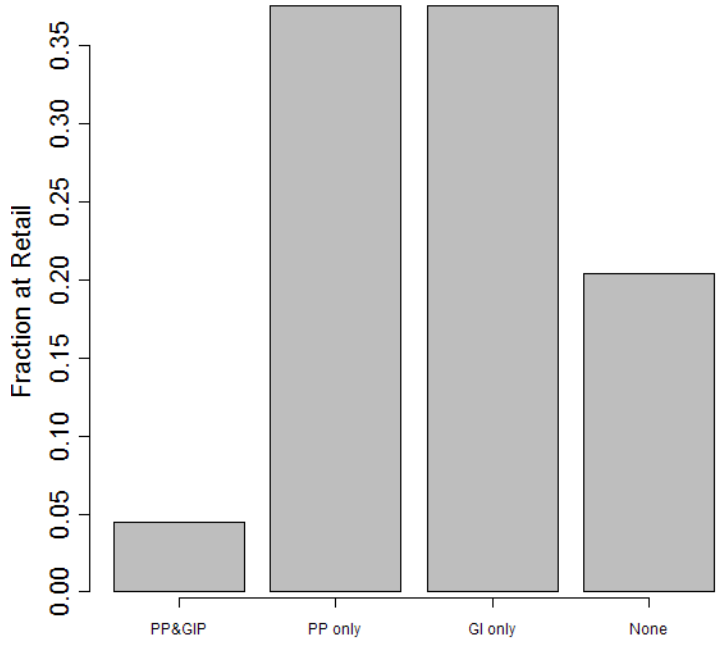
Appendix III. Figure 1. Contour plot of the sum of squared log residuals.

The final best estimates for loading patterns were a log mean loading of -5.35 cfu/cm^2 and a standard deviation of 3.06. For comparison, the values used in the 2003 FSIS *L. monocytogenes* Risk Assessment were -6 and 3.5 respectively.

3.3 Model Output

The model produced a variety of tables and figures from the model output. Each is shown below. Table 5 simply repeats the data inputs for the various Alternatives, which is used for checking and data archival purposes.

Appendix III Figure 2 illustrates the distribution of RTE product among the various Alternatives. Recall that, until better data become available[1], the baseline dataset assumes an equal split in Alternative 2 between post-processing lethality (2a) and growth inhibitor use (2b).



Appendix III. Figure 2. Distribution of RTE product among Alternatives

[1] This work was completed prior to receipt and verification of all completed 10,240-1 Forms but FSIS has since updated it with the submissions of the updated form in 2006.

Appendix III. Table 5. Model Output for Checking Alternative Specific Inputs

Plant	Fraction	Lot Mass Mean (log10 lb)	Lot Mass SD	No. FCS Samples per Period (year)	No. Lot Samples per Period (year)	Fraction Post Processing Lethality	Fraction Growth Inhibitor	FCS Sequential Trigger	FCS Enhanced Clean	Test Next FCS After FCS Positive	Lot Dispose If Positive	Test Next Lot if Lot Positive	FCS Positive Forces Lot Test
1-L	0.033231	3.842	0.606	2	0	1	1	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
1-S	0.01144	2.933	0.457	2	0	1	1	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
1-VS	0.000324	2.72	0.182	2	0	1	1	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
2-L-PP	0.199385	3.842	0.606	4	0	1	0	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
2-S-PP	0.160874	2.933	0.457	4	0	1	0	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
2-VS-PP	0.015332	2.72	0.182	4	0	1	0	Inf	TRUE	TRUE	TRUE	FALSE	FALSE
2-L-GI	0.199385	3.842	0.606	4	0	0	1	3	TRUE	TRUE	TRUE	FALSE	TRUE
2-S-GI	0.160874	2.933	0.457	4	0	0	1	3	TRUE	TRUE	TRUE	FALSE	TRUE
2-VS-GI	0.015332	2.72	0.182	4	0	0	1	3	TRUE	TRUE	TRUE	FALSE	TRUE
3-L	0.048	3.842	0.606	48	0	0	0	2	TRUE	TRUE	TRUE	FALSE	TRUE
3-S	0.146812	2.933	0.457	24	0	0	0	2	TRUE	TRUE	TRUE	FALSE	TRUE
3-VS	0.009013	2.72	0.182	12	0	0	0	2	TRUE	TRUE	TRUE	FALSE	TRUE

Appendix III Table 6 provides the same data, along with a sum of the fractions that equals to 1. It also includes the total fractions of deli meat product with and without growth inhibitor. Note that the product with growth inhibitor includes all of Alternative 1 and some portion from Alternative 2. The product without growth inhibitor includes the remaining portion of Alternative 2 and all of Alternative 3. This distinction is important for modeling growth from retail to consumption.

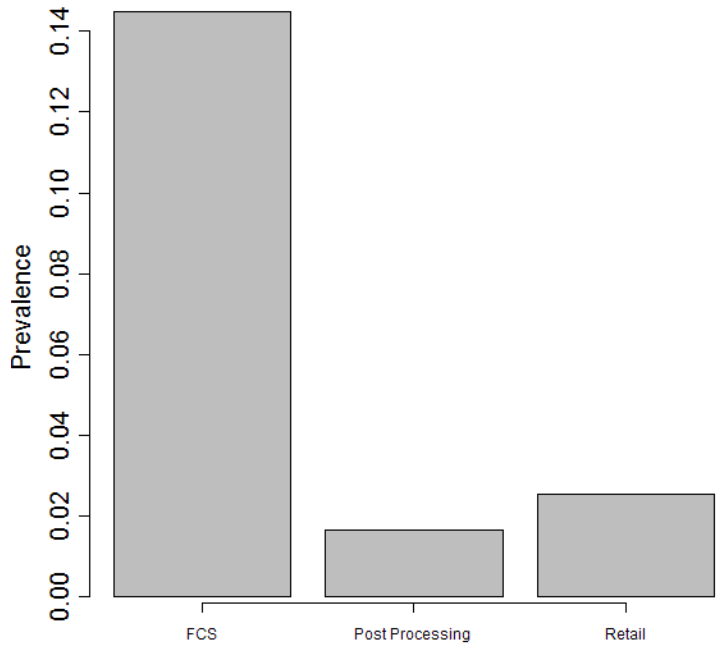
Appendix III. Table 6. Distribution of RTE product among Alternatives

Type of Fraction	Fraction
Fraction of lots with both Post Processing Lethality & Growth Inhibitor :	0.04500
Fraction of lots with only Post Processing Lethality:	0.37562
Fraction of lots with only Growth Inhibitor:	0.37561
Fraction of lots with neither Post Processing Lethality nor Growth Inhibitor:	0.20377
Check - sum of fractions:	1.00000
Fraction without Growth Inhibitor :	0.57939
Fraction with Growth Inhibitor :	0.42061

Appendix III Table 7 and Appendix III Figure 3 provide prevalence data at various stages within the plant and at retail for all product categories combined. As expected, the food contact surface has the highest prevalence. The product after any post-processing has the lowest prevalence. The prevalence at retail is slightly higher because of growth during storage and shipment from the plant to retail.

Appendix III. Table 7. *L. monocytogenes* prevalence at various stages of production

Prevalence Category	Prevalence
FCS Prevalence:	0.145
Post Processing Prevalence:	0.017
Actual Retail Prevalence:	0.025



Appendix III. Figure 3. *L. monocytogenes* prevalence at various stages of production

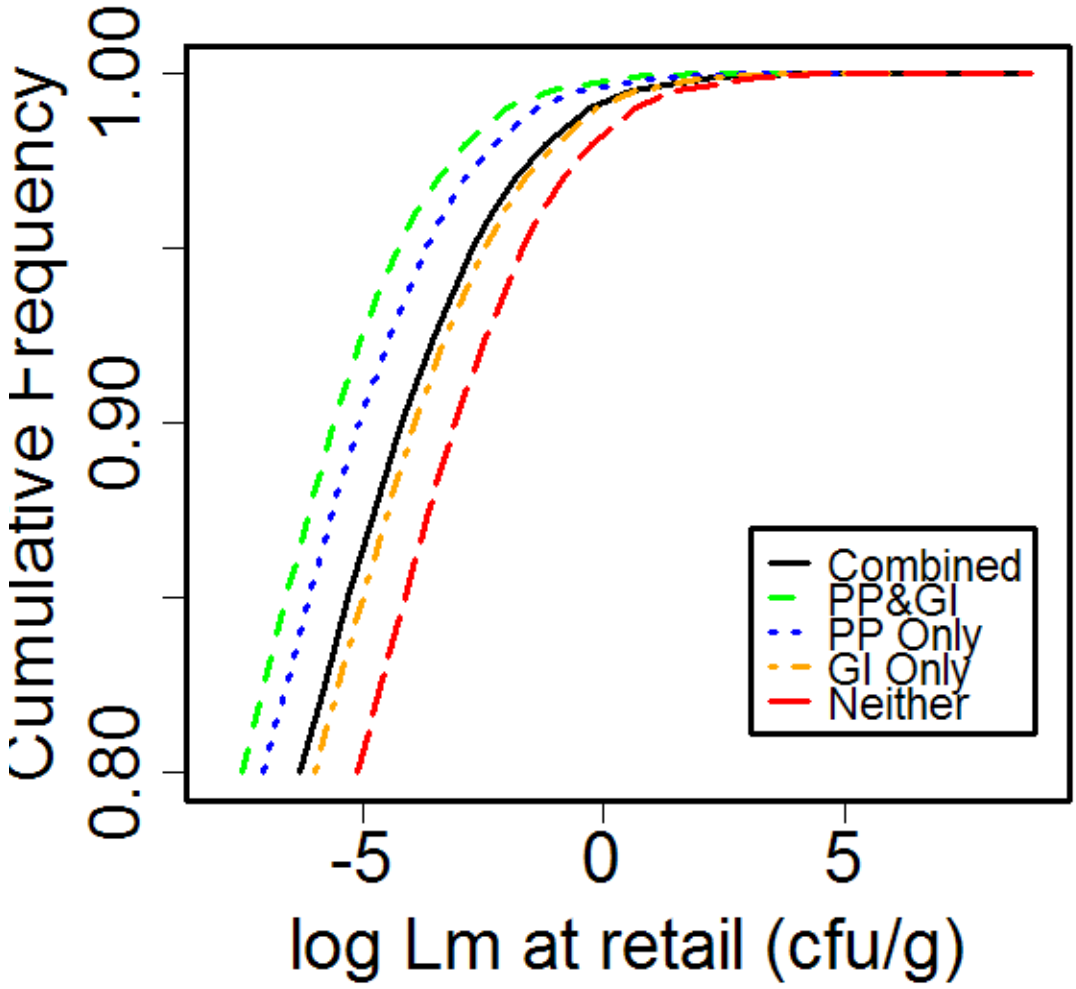
Appendix III Table 8 and Appendix III Figure 4 provide actual *L. monocytogenes* concentration distributions at retail among the various Alternatives. Product with post-processing lethality is shifted to the right because the concentrations are lower. Product with only growth inhibitor is shifted to the right of product with the additional lethality step but to the left of product that receives neither option. The post-processing concentration is the same as for the product that receives no post-processing lethality treatment, but less growth from plant to retail occurs.

Appendix III. Table 8. *L. monocytogenes* quantiles (cfu/g) at retail and for each alternative

Percentile	Combined	Both Post Processing Lethality & Growth Inhibitor	Post Processing Lethality Only	Growth Inhibitor Only	Neither Post Processing Lethality nor Growth Inhibitor	Without Growth Inhibitor	With Growth Inhibitor
0.8	4.69E-07	3.07E-08	8.13E-08	9.73E-07	7.75E-06	3.73E-07	6.44E-07
0.825	1.53E-06	8.64E-08	2.47E-07	3.15E-06	2.37E-05	1.21E-06	2.13E-06
0.85	4.97E-06	2.55E-07	7.46E-07	1.03E-05	7.41E-05	3.94E-06	6.91E-06
0.875	1.71E-05	7.41E-07	2.38E-06	3.37E-05	0.000236	1.34E-05	2.31E-05
0.9	6.46E-05	2.52E-06	8.31E-06	0.000124	0.000838	5.14E-05	8.66E-05
0.925	0.000293	9.31E-06	3.45E-05	0.000536	0.003459	0.00024	0.00038
0.95	0.001832	5.06E-05	0.000204	0.003197	0.020413	0.001528	0.00233
0.96	0.004578	0.00012	0.000476	0.007856	0.047831	0.00387	0.005686
0.97	0.01388	0.000347	0.00133	0.023016	0.13516	0.011873	0.017092
0.98	0.05831	0.001312	0.005226	0.092356	0.536918	0.050171	0.070012
0.99	0.520622	0.009489	0.042782	0.746792	4.499101	0.46424	0.585635
0.995	3.848921	0.077615	0.281543	5.186146	30.48733	3.619316	4.113228
0.999	192.9363	2.779988	15.24276	181.3635	1,560.497	230.9541	147.6188
0.9995	900.9061	9.911883	76.86857	888.6455	7,026.353	1,062.049	714.9968
0.9999	20,513.98	262.7162	1,260.883	2,1659.01	1,88435.1	2,5614.67	16,650.5
1	7.6E+08	8,385.005	194,285.2	9,823,139	7.6E+08	7.6E+08	9,823,139

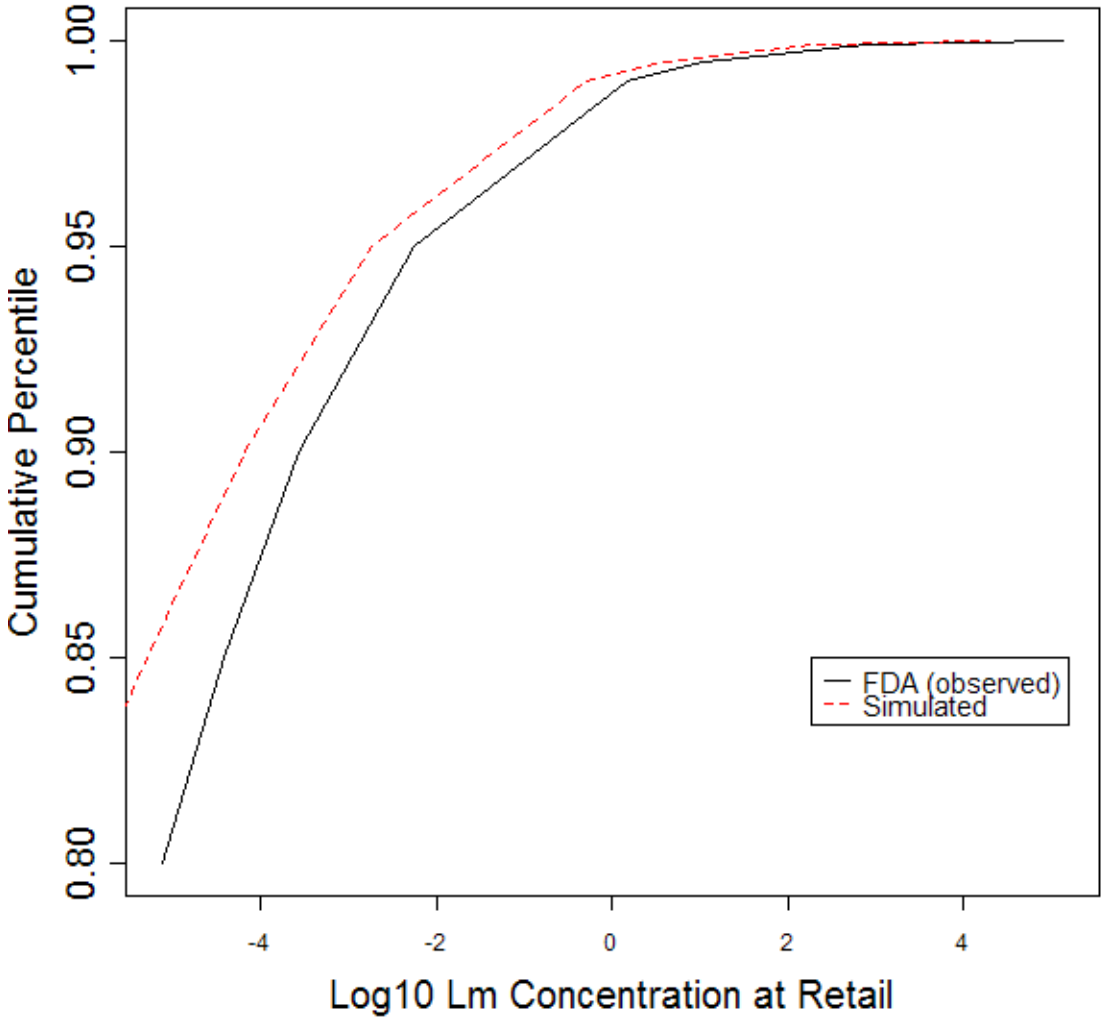
The final two columns represent the product with and without growth inhibitors. These represent the two distributions that should be passed to the 2003 FDA/FSIS model to predict changes from retail to consumption. Because of the antimicrobial additions, the product with growth inhibitors will have less growth, and therefore reduced health impacts and less risk of listeriosis, than product without growth inhibitors.

Recall that these concentrations are at retail, and thus the full benefit of growth inhibitors is not included in the retail results shown.



Appendix III. Figure 4. Quantiles of *L. Monocytogenes* at Retail

Appendix III Figure 5 displays the cumulative distributions at retail from the 2003 FDA/FSIS model and the results of the simulation. Because the FSIS data represents actual observed concentrations at the time the report was prepared, the lower simulation results indicate the improvement obtained from the 3 Alternatives. As mentioned above, the health impacts are even better than indicated because some portion of the RTE product includes growth inhibitor.



Appendix III. Figure 5. Comparison of observed retail *L. monocytogenes* concentrations using FSIS data, and simulated results for the different Alternatives.

3.4 Testing Efficacy

Current rules require a variety of food contact surface and lot testing frequencies depending on the Alternative. Appendix III Table 9 and Appendix III Figure 6 depict the efficacy of the food contact surface and lot testing.

As discussed in the original risk assessment, the requirement for a certain number of sequential food contact surface positives before a lot can be tested limits the usefulness of food contact testing. The model simulates a stochastic duration of a contamination event. Thus, *L. monocytogenes* contamination is clustered in time. The time lag required by finding a fixed number of sequential positives before a lot test greatly reduces the chance of finding a positive lot. The contamination event is usually over before the lot testing takes place. This situation is worsened because certain Alternatives are never forced to test a lot despite the food contact results. This regulatory scenario is quite different from the original risk assessment, which found that food contact surface testing can be quite beneficial if a positive finding requires immediate lot testing.

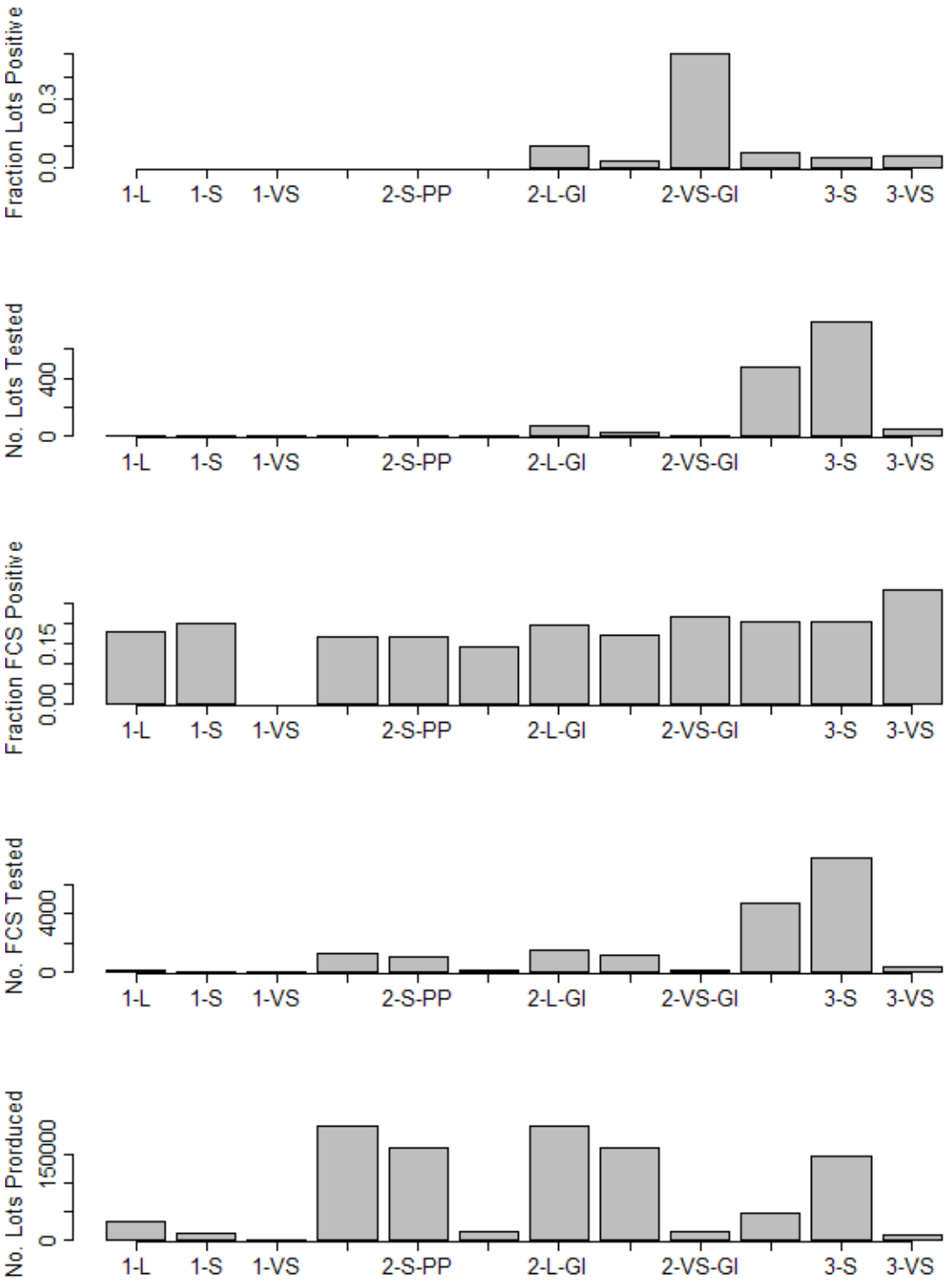
For the 1,000,000 lots simulated only 1,422 lots were actually tested, and only 81 of these were found positive. While the 5.6% prevalence is much higher than the overall prevalence of 1.7%, the removal of 81 lots out of 1,000,000 is not expected to have a significant health impact. The health impact from the various Alternatives will arise from the lower starting concentrations (after post-processing lethality) and lower growth (when growth inhibitors are used), not from product and food contact surface testing as defined here.

Appendix III. Table 9. Food Contact Testing Results Based on 1,000,000 Total Lots Simulated

Plant	Lots Modeled	Lots Used At Retail	Both Post Processing Lethality & Growth Inhibitor	Post Processing Lethality Only	Growth Inhibitor Only	Neither Post Processing Lethality nor Growth Inhibitor	FCS Tests	FCS Positives	FCS Theoretical Positives	Fraction FCS Positives
1-L	33,231	33,231	33,231	0	0	0	111	20	5,528	0.180
1-S	11,440	11,440	11,440	0	0	0	40	8	1,631	0.200
1-VS	324	324	324	0	0	0	0	0	50	NaN
2-L-PP	199,385	199,385	0	199,385	0	0	1,311	219	28,739	0.167
2-S-PP	160,874	160,874	0	160,874	0	0	1,061	180	24,319	0.170
2-VS-PP	15,332	15,332	0	15,332	0	0	98	14	2,477	0.143
2-L-GI	199,385	199,378	0	0	199,378	0	1,475	293	26,592	0.199
2-S-GI	160,874	160,873	0	0	160,873	0	1,131	193	23,084	0.171
2-VS-GI	15,332	15,331	0	0	15,331	0	114	25	2,509	0.219
3-L	48,000	47,967	0	0	0	47,967	4,693	959	7,340	0.204
3-S	146,812	146,776	0	0	0	146,776	7,805	1,617	21,011	0.207
3-VS	9,011	9,008	0	0	0	9,008	345	98	1,551	0.284

Appendix III. Table 9 (continued). Lot Testing Results Based on 1,000,000 Total Lots Simulated

Plant	Lots Modeled	Lots Used At Retail	Lot Tests	Lot Test (Systematic)	Lot Test (because previous FCS Positives)	Lot Test (because previous Lot Positive)	Lot Test Positive After Post Processing	Lot Theoretical Positives After Post Processing	Lot Theoretical Retail Used Positives	Fraction Lot Positives
1-L	33,231	33,231	0	0	0	0	0	221	285	NaN
1-S	11,440	11,440	0	0	0	0	0	52	66	NaN
1-VS	324	324	0	0	0	0	0	1	1	NaN
2-L-PP	199,385	199,385	0	0	0	0	0	1,088	2,400	NaN
2-S-PP	160,874	160,874	0	0	0	0	0	944	2,001	NaN
2-VS-PP	15,332	15,332	0	0	0	0	0	69	166	NaN
2-L-GI	199,385	199,378	73	0	73	0	7	4,707	5,694	0.096
2-S-GI	160,874	160,873	29	0	29	0	1	3,975	4,803	0.034
2-VS-GI	15,332	15,331	2	0	2	0	1	392	493	0.500
3-L	48,000	47,967	476	0	476	0	33	1,294	2,356	0.069
3-S	146,812	146,776	787	0	787	0	36	3,690	6,768	0.046
3-VS	9,011	9,008	55	0	55	0	3	254	469	0.054



Appendix III. Figure 6. Results of Food Contact Surface Testing

4. Conclusions

A second version of the 2003 FSIS *L. monocytogenes* Deli Meat Risk Assessment model has been developed to allow greater flexibility in analyzing management questions and to represent more appropriately the current policy framework. Preliminary analysis indicates that the strategy of the various Alternatives reduce prevalence and concentration at retail and would result in an improvement to public health.

5. Future Work

The integration of the model output with the FSIS retail to consumption model still needs to be completed. With the release of new data available for this model in the future, several components of the model will need to be modified and updated. Recalibration of the model using more recent and extensive sampling data in plants is needed because of improvements within food processing establishments. Investigation of the effectiveness of hold-and-test scenarios needs to be conducted by comparing different hold-and-test strategies with varied lots being hold and tested. Instead of using constant growth of *L. monocytogenes* from plant to retail, new approaches and data will be available to account of the influence of lag time of *L. monocytogenes*, the variability of storage temperature and storage time, as well as the variable growth rates of *L. monocytogenes* in RTE food. The additional modifications include allowing for separate *L. monocytogenes* distributions at retail with different growth patterns to account for the product with and without growth inhibitors, and extending these different growth rates during consumer handling. This will update the 2003 *L. monocytogenes* deli meat risk assessment to include the prediction of actual health impacts rather than just concentrations of *L. monocytogenes* at retail. Moreover, the values of some variables in the model need to be updated according to forthcoming relevant publications.

Appendix IV. Excerpt from the Interim Final Rule to Control *L. monocytogenes* in RTE meat and Poultry Products 9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products)

The interim final rule (http://www.fsis.usda.gov/oppde/rdad/frpubs/97-013f.htm) published in the Federal Register is the regulation by which FSIS samples post-lethality exposed RTE products in order to verify control of *L. monocytogenes*. This requires each establishment to provide information on the types and volumes of product manufactured on FSIS Form 10,240-1. Also, establishments are asked to report how often they test their post-lethality exposed food contact surfaces per line each month or year depending on the alternative used to control *L. monocytogenes*. This Form data provided production volume information used in the risk-based sampling algorithm in 2005.

Interim Final Rule Excerpts

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface, which is contaminated with *L. monocytogenes*.
(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment, which may be an antimicrobial agent that reduces or eliminates microorganisms on the product, and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:
(i) The post-lethality treatment must be included in the establishment's HACCP plan,. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP, or other prerequisite program.
(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with 9 CFR Part 417 Sec. 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process used was shown to be effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment, which may be an antimicrobial agent that reduces or eliminates microorganisms on the product or an antimicrobial

agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process used was shown to be effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;
(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;
(C) State the frequency with which testing will be done;
(D) Identify the size and location of the sites that will be sampled; and
(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.
(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment is effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and additional tests in the surrounding food contact surface area.

(B) as are necessary to ensure the effectiveness of the corrective actions.(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce, the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products. (c) For all three alternatives in paragraph (b): (1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment. (2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur. (3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416. (4) If *L. monocytogenes* control measures are included in the HACCP

plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4. (5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14. (6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. (7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan, or its Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel. (d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section. (e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates, or reduces, or suppresses, or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

For Additional Information: http://www.fsis.usda.gov/oppde/rdad/frpubs/97-013f/lm_rule_compliance_guidelines_may_2006.pdf

Appendix V. Excerpts from FSIS Directives, Notices and Forms Pertaining to RTE Risk-Based Sampling Programs

This Appendix lists the issuances released by FSIS since it started the *L. monocytogenes* risk-based sampling program initiative. Current directives and notices can be found at: http://www.fsis.usda.gov/regulations/regulations_directives_&_notices/index.asp.

A summary of each Notice and Directive is provided to describe the purpose for which it was issued. These directives and notices were necessary to enumerate policy changes and to pass down instructions to FSIS personnel as the risk-based sampling program evolved over the years. This Appendix also includes the latest version of FSIS Form 10,240-1 and shows an example of the data entries generated to inform risk based sampling program in the earliest version of the form. Notice 41-11 states the terms for discontinuation of the form and anticipates the use of inspector collected data as replacement for industry collected form data.

Appendix V. FSIS Directive 10,240.4 issued 10/02/03

Verification Procedures for the *L. monocytogenes* Regulation and Microbial Sampling of RTE Products for the FSIS Verification Testing Program

PURPOSE
This directive provided Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) with instructions for verifying whether establishments are complying with the regulations in 9 CFR part 430, *Requirements for Specific Classes of Product* (Attachment 5). In addition, this directive included verification procedures for RTE products other than those applicable to 9 CFR part 430 and clarified current sampling instructions.

Key (RTE Regulations, 9 CFR 430.1) Definitions from Attachment 5 of FSIS Directive 10,240.4

Antimicrobial agent A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment A process, including the application of an antimicrobial agent, which eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.
Post-lethality exposed product Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

Appendix V. FSIS Notice 61-04 issued 12/23/04

Listeria monocytogenes Risk-Based **Verification Testing Program – Phase 1: Introduction of a New Sampling Project – RTE001**

PURPOSE
This notice introduced the addition of a new *L. monocytogenes* risk-based verification testing program, RTE001, for the sampling of only post-lethality exposed RTE meat and poultry products. The scheduling of this sampling project was implemented in January 2005.

This new program was added to the following programs currently in use by inspection program personnel to collect RTE sample: **ALLRTE:** Under this project, inspection program personnel randomly collect any post-lethality exposed and non-post-lethality exposed RTE product produced at official establishments, and **RTERISK1:** Under this project, inspection program personnel follow the product priority list in FSIS Directive 10,240.4, Chapter 3, *CSIs Responsibilities for Collecting Samples of RTE,* to determine how to select a RTE product for FSIS verification sampling. In this project inspection program personnel collect both post-lethality exposed and non-post-lethality exposed RTE product produced at official establishments.

Appendix V. FSIS Directive 10,240.5 issued 3/15/06

Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance with the *Listeria monocytogenes* Regulation and Introduction of Phase 2 of the Lm Risk-Based Verification Testing Program

PURPOSE

This directive was issued to provide direction to Enforcement, Investigations, and Analysis Officers (EIAOs) and Public Health Veterinarians (PHVs) trained in the EIAO methodology for collecting samples under a newly created Routine Risk-Based sampling program. The new program abbreviated, RLm, addressed the testing of food contact, environmental (non-food contact), and intact product samples. The directive also provided personnel trained in the EIAO methodology with instructions for (1) assessing an establishment's food safety system for compliance with 9 CFR Part 430 and (2) verifying the validation data associated with the alternatives selected by the establishment.

Key Points Covered:

1. EIAO/PHV assessment of compliance with 9 CFR Part 430
2. Sample collection responsibilities of the EIAO/PHV for the new RLm sampling program
3. Enforcement

New Testing Programs:

1. The RLm testing program consist of the following sampling projects:
    a. RLMCONT: the routine risk-based testing of surfaces that have direct contact with RTE product in the RTE production area, e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops.
    b. RLMENVR: the routine risk-based testing of environmental (non-food contact) surfaces in the RTE production areas, e.g., floors, drains, walls, air-vents, overhead structures; and
    c. RLMPROD: the routine risk-based testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift.

FSIS uses a risk-based methodology that ensures that establishments with the greatest probability of producing RTE meat and poultry products contaminated by *L. monocytogenes* are scheduled for testing under this program.

NOTE: EIAO is the working title for the CSO position referenced in FSIS Directive 10,240.4 of 10/02/03.

Appendix V. FSIS Directive 10,240.4, Revision 1 issued 3/15/06

Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* Regulation and Introduction of Phase 2 of the Lm Risk-Based Verification Testing Program

PURPOSE

This directive was reissued to provide Consumer Safety Inspectors (CSIs) with direction for implementation of the newly created Routine *L. monocytogenes* Risk-Based (RLm) sampling program in FSIS Directive 10,240.5. This testing program referred to as the Food Contact, Environmental (Non-Food Contact), and Intact Product Verification Testing Program, which is abbreviated as "RLm." This directive also provided verification instructions for RTE products when establishment product disposition occurs off-site. In addition, this directive provided CSIs with instructions for verifying whether establishments are complying with the regulatory requirements in 9 CFR Part 430, *Requirements for Specific Classes of Product*. Finally, this directive included sample collection responsibilities for the CSI under the ALLRTE and RTE001 sampling projects

Key Points Covered:

1. CSI verification of 9 CFR Part 430
2. Sample collection responsibilities of the CSI for the ALLRTE and RTE001 sample projects
3. Enforcement
4. Verification of corrective actions
5. Disposition of RTE product occurring off-site

APPENDIX V. Example FSIS FORM 10, 240-1

To date, FSIS has issued three versions of the form with the latest dated 08/19/2009. Each iteration improved ease of use, electronic availability, and address the need for additional information. Although the data on the form are self-reported by the industry, it does serve as a very important tool to determine the relative risk of products processed/manufactured in an establishment, to obtain information on the volume of products produced on an annual basis, and to determine under which of the three alternatives RTE product is produced.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS (Alternative 1)** *(See Instructions on Page 4)*	1a. ESTABLISHMENT NAME		1b. EST. NO.
	1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
	1d. CITY	1e. STATE	1f. ZIP CODE

ALTERNATIVE 1: Both a post-lethality treatment and an antimicrobial agent or process are used.

2. Annual Production Volume (enter actual lbs.)

DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIBUTION FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED PRODUCTS [3]	FERMENTED PRODUCTS (with or without cooking) [4]	DRIED PRODUCTS [5]	SALT-CURED PRODUCTS [6]

ALTERNATIVE 1 **3. (check applicable boxes below):**		DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
		SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED [3] PRODUCTS	FERMENTED PRODUCTS (With or without cooking) [4]	DRIED [5] PRODUCTS	SALT-CURED PRODUCT [6]
A. Validated log reduction of *Listeria monocytogenes* by your post-lethality treatment:	▪ more than 2 logs							
	▪ 2 logs							
	▪ 1 log							
	▪ less than 1 log . .							
B. Validated or highest increase in *Listeria monocytogenes* allowed by your antimicrobial agent or process:	▪ less than 1 log . .							
	▪ 1 log							
	▪ 2 logs							
	▪ more than 2 logs							
C. How often do you test food contact surfaces per line each year?	▪ more than 4 times							
	▪ 3 or 4 times . . .							
	▪ 2 times							
	▪ less than 2 times							

Footnotes:

1 Deli product: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official est., & typically is assembled in a sandwich for consumption (9 CFR 430.1). Examples include ham, bologna, chicken roll, turkey breast, olive loaf

2 Hot dog product: A ready-to-eat meat or poultry frank, frankfurter, or weiner such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1). Examples include hot dogs, wieners, frankfurters

3 Examples include chicken nuggets, chili, fully cooked bacon, frozen dinners/entrees

4 Examples include dry salami, Lebanon bologna, cervelat, thuringer, summer sausage, pepperoni

5 Examples include jerky, dried beef, dried duck breast, basturma, carne seca

6 Examples include country cured ham, prosciutto, dry cured duck, coppa, cappicola

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL	5. SIGNATURE OF AUTHORIZED EST. OFFICIAL	6. DATE

FSIS FORM 10,240-1 (03/30/2004) PAGE 1 of 4

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS (Alternative 2)

(See Instructions on Page 4)

1a. ESTABLISHMENT NAME		1b. EST. NO.
1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
1d. CITY	1e. STATE	1f. ZIP CODE

ALTERNATIVE 2: Only a post-lethality treatment OR only an antimicrobial agent or process is used.

2. Annual Production Volume (enter actual lbs.)

DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIBUTION FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED PRODUCTS [3]	FERMENTED PRODUCTS (with or without cooking) [4]	DRIED PRODUCTS [5]	SALT-CURED PRODUCTS [6]

ALTERNATIVE 2

3. (check applicable boxes below):

		DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
		SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED [3] PRODUCTS	FERMENTED PRODUCTS (With or without cooking) [4]	DRIED PRODUCTS [5]	SALT-CURED PRODUCT [6]
A. Validated log reduction of *Listeria monocytogenes* by your post-lethality treatment:	▪ more than 2 logs							
	▪ 2 logs							
	▪ 1 log							
	▪ less than 1 log							
	▪ not applicable							
B. If using post-lethality agent, how often do you test food contact surfaces per line each year?	▪ more than 8 times							
	▪ 5,6,7, or 8 times							
	▪ 4 times							
	▪ less than 4 times							
OR								
C. Validated or highest increase in *Listeria monocytogenes* allowed by your antimicrobial agent or process:	▪ less than 1 log							
	▪ 1 log							
	▪ 2 logs							
	▪ more than 2 logs							
	▪ not applicable							
D. If using antimicrobial agent or process, how often do you test food contact surfaces per line each year?	▪ more than 8 times							
	▪ 5,6,7,or 8 times							
	▪ 4 times							
	▪ less than 4 times							

Footnotes:

1 Deli product: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official est., & typically is assembled in a sandwich for consumption (9 CFR 430.1). Examples include ham, bologna, chicken roll, turkey breast, olive loaf

2 Hot dog product: A ready-to-eat meat or poultry frank, frankfurter, or weiner such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1). Examples include hot dogs, wieners, frankfurters

3 Examples include chicken nuggets, chili, fully cooked bacon, frozen dinners/entrees

4 Examples include dry salami, Lebanon bologna, cervelat, thuringer, summer sausage, pepperoni

5 Examples include jerky, dried beef, dried duck breast, basturma, carne seca

6 Examples include country cured ham, prosciutto, dry cured duck, coppa, cappicola

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL	5. SIGNATURE OF AUTHORIZED EST. OFFICIAL	6. DATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS (Alternative 3)** *(See Instructions on Page 4)*	1a. ESTABLISHMENT NAME		1b. EST. NO.
	1c. STREET ADDRESS *(P.O. Box alone not acceptable)*		
	1d. CITY	1e. STATE	1f. ZIP CODE

ALTERNATIVE 3: Only a sanitation program with testing is used.

2. Annual Production Volume (enter actual lbs.)

DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DISTRIBUTION FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED PRODUCTS [3]	FERMENTED PRODUCTS (with or without cooking) [4]	DRIED PRODUCTS [5]	SALT-CURED PRODUCTS [6]

ALTERNATIVE 3

3. (check applicable boxes below):

		DELI PRODUCTS [1]		OTHER THAN DELI PRODUCTS				
		SLICED AND PACKAGED AT OFFICIAL EST.	TO BE SLICED AFTER DIST. FROM OFFICIAL EST.	HOT DOG PRODUCTS [2]	FULLY COOKED [3] PRODUCTS	FERMENTED PRODUCTS (With or without cooking) [4]	DRIED PRODUCTS [5]	SALT-CURED PRODUCT [6]
A. How often do you test food contact surfaces per line each month?	▪ more than 4 times							
	▪ 4 times							
	▪ 3 times							
	▪ 2 times							
	▪ 1 time							
	▪ less than 1 time							
B. Since implementation of the rule, what combined percentage of food contact surface and environmental samples are positive for any *Listeria* spp. or *Listeria*-like organisms:	▪ less than 1 %							
	▪ 1-2 %							
	▪ 3-5 %							
	▪ 6 - 10 %							
	▪ more than 10 %							
C. What category best describes your establishment?	☐▪ very small							
	☐▪ small							
	☐▪ large							

Footnotes:

1 Deli product: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official est., & typically is assembled in a sandwich for consumption (9 CFR 430.1). Examples include ham, bologna, chicken roll, turkey breast, olive loaf

2 Hot dog product: A ready-to-eat meat or poultry frank, frankfurter, or weiner such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1). Examples include hot dogs, wieners, frankfurters

3 Examples include chicken nuggets, chili, fully cooked bacon, frozen dinners/entrees

4 Examples include dry salami, Lebanon bologna, cervelat, thuringer, summer sausage, pepperoni

5 Examples include jerky, dried beef, dried duck breast, basturma, carne seca

6 Examples include country cured ham, prosciutto, dry cured duck, coppa, cappicola

4. PRINT NAME/TITLE OF AUTHORIZED ESTABLISHMENT OFFICIAL	5. SIGNATURE OF AUTHORIZED EST. OFFICIAL	6. DATE

ESTIMATES OF ANNUAL PRODUCTION VOLUME

FSIS collects estimates of the annual production volume and related information on post-lethality exposed ready-to-eat (RTE) meat and poultry products. Establishments that produce these products are required by 9 CFR 430.4(d) to make this information available to FSIS at least annually. FSIS uses the information as a basis for directing its verification activities, including microbiological sampling, at affected establishments.

The regulations classify the products by the Listeria control alternative used:

ALTERNATIVE 1:	Establishment uses a post-lethality treatment and an antimicrobial agent/process
ALTERNATIVE 2:	Establishment uses either a post-lethality treatment or an antimicrobial agent/process
ALTERNATIVE 3:	Establishment uses sanitation and a testing program and uses neither a post-lethality treatment nor an antimicrobial agent or process

Note: An antimicrobial agent/process can be considered a post lethality treatment if it reduces the level of *L. monocytogenes* in the post-lethality exposed product (e.g. growth inhibitor packaging). The establishment must validate, document and verify the reduction.

- Examples of post-lethality treatments are steam pasteurization, hot water pasteurization, high pressure process.
- Examples of antimicrobial agents are sodium diacetate, potassium lactate, and growth inhibitor packaging.
- Examples of antimicrobial processes are freezing or drying.

INSTRUCTIONS FOR COMPLETING THE FORM:

ITEMS 1a - f

- Enter establishment's name, number and address.

ITEM 2 ANNUAL PRODUCTION VOLUME

- Enter your establishment's annual production volume in hundreds, thousands, or millions of pounds, as appplicable, of post-lethality exposed RTE meat and poultry products for each Alternative in each product category column.

ITEM 3 ALTERNATIVE 1 - ALTERNATIVE 3

- For Alternative 1 and Alternative 2, in each product category column, as applicable, check the box that most nearly corresponds to your establishment's control of *L. monocytogenes (Lm),* the log reduction or growth limitation achieved, and the frequency of food-contact surface verification testing. Please make sure that you check the box corresponding to the least log reduction achieved by the post-lethality treatment or the highest growth limitation allowed by the antimicrobial agent or process for each product category.
- For products in Alternative 3, check the box that most nearly corresponds to the establishment's frequency of food-contact surface testing; the combined percentage of positive food contact surface and other environmental samples since the implementation of the rule; and the size category that best describes the establishment. The percentage of combined positive food contact surface and other environmental samples is obtained by: adding the number of positive food contact surface and the number of other positive environmental samples, dividing the sum by the total number of combined food contact surface and other environmental samples tested and multiplying the result by 100.

ITEMS 4-6

- Print Name and Title of Authorized Official
- Signature and Date of Authorized Official and Date Signed

SUBMIT THE COMPLETED FORM TO THE FOLLOWING ADDRESS:

- FSIS-USDA-Data Analysis and Statistical Support Staff
  202 Cotton Annex
  300 12th Street, SW
  Washington, DC 20250

  Telephone #: (202) 720-3219
  Fax #: (202) 690-0824

Please send a revised form anytime there is a significant change in the Alternative category or volume of production.

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Appendix V. Sample Data

from FSIS Form 10,240-1 (03/30/04 version)
Available at: **http://www.aamp.com/documents/ListeriaForm10240-1.pdf**

The submission of Form 10,240-1 (03/30/2004 version) by establishments producing RTE product under the regulation of 9CFR 430 generated a database containing entries such as those below. These data inform the risk based sampling program. Establishment numbers have been removed to protect confidentiality. Volume is provided in pounds of production per year. The latest version of FSIS FORM 10,240-1 is included here. Three versions of the form, which are dated as follows: 03/30/2004, 01/30/2006 and 08/19/2009 have been released since the inception of the interim final rule. The 2006 version incorporated questions such as plant size category, columns for frozen and pate products to add to the list of "other than deli products". Establishments were able to complete and submit the 2006 version online. The only difference between the 2006 and 2009 versions is the change in the mailing address and the fax number to send the completed forms if not submitted online.

However, the use of this form has been discontinued as of September 30, 2011 through the issuance of FSIS Notice 41-11 on 8/10/2011. FSIS plans to continue to use the information from the form to determine FSIS verification sampling frequencies pending the full implementation of the Public Health Information System (PHIS).

Sample Data

Record Number	Deli SlicedVol	DeliNot SlicedVo	Hot Dog Vol	Fully Cooked	Ferment-ed Vol	Dried Volume	SaltCu redVol	Alternative 1,2[2] or 3
20040003	**0**	**0**	**0**	**100000**	**0**	**0**	**0**	**3**
20040004	**0**	**7859000**	**0**	**0**	**0**	**0**	**0**	**3**
20040005	**0**	**6573266**	**0**	**0**	**0**	**0**	**0**	**3**
20040006	**0**	**0**	**0**	**0**	**0**	**323426**	**0**	**3**
20040007	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**
20040008	**0**	**0**	**0**	**580382**	**0**	**0**	**0**	**3**
20040009	**10000**	**6000**	**0**	**300000**	**0**	**0**	**0**	**3**
20040010	**0**	**0**	**0**	**1404000**	**0**	**0**	**0**	**2**
20040011	**0**	**0**	**0**	**154100**	**0**	**5200**	**0**	**2**
20040012	**0**	**0**	**10000**	**690000**	**0**	**0**	**0**	**3**
20040014	**0**	**0**	**0**	**77603**	**0**	**0**	**0**	**3**
20040015	**29160**	**0**	**0**	**0**	**0**	**0**	**0**	**3**
20040016	**0**	**8762000**	**0**	**0**	**0**	**0**	**0**	**2**
20040017	**0**	**0**	**0**	**2000**	**0**	**0**	**0**	**3**
20040018	**21000**	**0**	**0**	**362430**	**0**	**0**	**0**	**3**
20040019	**0**	**0**	**0**	**1506240**	**0**	**0**	**0**	**3**
20040020	**0**	**0**	**0**	**308000**	**0**	**0**	**0**	**3**
20040021	**1800000**	**1000000**	**0**	**0**	**0**	**0**	**0**	**1**
20040022	**0**	**0**	**0**	**1047126**	**0**	**0**	**0**	**2**
20040023	**1150**	**76221**	**230766**	**0**	**0**	**0**	**0**	**3**
20040024	**16700**	**0**	**0**	**0**	**0**	**0**	**0**	**3**
20040025	**0**	**0**	**0**	**26000**	**0**	**0**	**0**	**3**
20040026	**0**	**0**	**0**	**999100**	**0**	**0**	**0**	**3**
20040027	**0**	**780**	**0**	**0**	**0**	**0**	**0**	**3**

[2] As explained in detail elsewhere, Alternative 2 is split between choice one(2A) and choice two(2B). For simplicity of presentation this particular table does not reflect this division although the actual database does.

Appendix VI. Excerpts from the "Compliance Guidelines to Control *Listeria monocytogenes* in Post-lethality exposed ready-to-eat meat and poultry products"

[The most current version of the entire document can be viewed at http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf]

Verifying the Effectiveness of the Sanitation Program

This Appendix provides excerpts from the compliance guidelines issued by FSIS to the industry in controlling *L. monocytogenes* in their post-lethality exposed environment. Important components of the process of verifying the effectiveness of sanitation program are provided. The five components are described below. This document identifies environmental testing in addition to food contact surface testing as integral components of an establishment *L. monocytogenes* control system and further justifies the use of *L. monocytogenes* food contact surface and environmental sampling data in the risk-ranking algorithm. Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes a) recommended testing of food contact surfaces to verify the effectiveness of the sanitation program for each alternative from 9 CFR 430, b) a guide to testing for *Listeria* spp. or *Listeria*-like organisms, c) an example of a hold-and-test scenario, and d) an example of a sentinel site program.

1. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. Sampling is required for Alternatives 2 (using antimicrobial agents or processes only) and 3, and recommended for Alternative 1. The sampling frequencies increase from Alternative 1 to Alternative 3 because the control program for *L. monocytogenes* decreases in intensity and effectiveness from Alternative 1 to 3. These frequencies should be increased if there is construction, change in the HACCP plan, roof leaks, or other events that could change or increase the probability of product contamination. Samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur. Establishments can also develop their own sampling plan based on their operations, or have a processing authority develop a sampling plan.

Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like or similar surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination. The establishment is encouraged to hold all products being tested

until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

a. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.

i. Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent and process are expected to reduce and inhibit the growth of *L. monocytogenes* in the product.

ii. Sample at least 1 square foot area for each surface, if possible.

iii. Record the test results.

iv. If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like or organisms:

(1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.

(2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan.

(3) Record the corrective actions taken.

(4) Retest the food contact surface.

(5) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.

(6) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

b. Alternative 2–Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of *L. monocytogenes*.

i. If a post-lethality treatment is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.

(1) Sample at least 1 square foot area for each surface, if possible.

(2) Record the test results.

(3) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:

(a) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing.

(b) If the FCS test is positive for *L. monocytogenes*, the product that came in direct contact with a food contact surface would not summarily be considered

adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan.

(c) Record the corrective actions taken.

(d) Retest the food contact surface.

(e) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.

(f) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

ii. If an antimicrobial agent is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. (Sampling is required in this case).

(1) Sample at least 1 square foot area for each surface, if possible

(2) Record the test results.

(3) Each time a FCS test positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.

(4) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.

(5) If 3 consecutive tests of food contact surfaces are positive for *Listeria* spp. or *Listeria*-like organisms:

(a) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing.

(b) Record the corrective actions taken.

(c) Hold the product.

(d) Test product for *L. monocytogenes*.

(e) Retest the food contact surface.

(f) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.

(g) If the test results for the product are positive for *L. monocytogenes*,

(i) Recall the product, if already shipped, and

(ii) Destroy the product, or

(iii) Re-work the product with a process that is destructive of *L. monocytogenes*.

c. Alternative 3–Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*. (Sampling is required in this case)

i. For establishments that produce non-deli or non-hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted once a month for large, small, or very small volume establishments.
ii. For establishments producing deli and hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments.

FSIS regards production volume as a more important risk factor than establishment's size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break point between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey**.**
iii. Sample at least 1 square foot area for each surface, if possible.
iv. Record the test results.
v. If the first test result of a food contact surface is positive for *L. monocytogenes, Listeria* spp., or *Listeria*-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP, or prerequisite program) and record.
vi. If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
vii. Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
viii. For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., *Listeria*-like organisms:

(1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
(2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
(3) Record the corrective actions taken.
(4) Hold the product (see hold-and-test scenario below and in Attachment 6).
(5) Test product for *L. monocytogenes* at a rate that provides a level of statistical confidence that the product is not adulterated.
(6) Conduct follow-up test of the food contact surface each day until the test result is negative for *Listeria* spp., *Listeria-like* organisms.
(7) At the same time, continue to hold each day's production lot until the test results for the food contact surfaces are negative.
(8) If the test results for the product are positive for *L. monocytogenes*,

(a) Destroy the product, or
(b) Re-work the product with a process that is destructive to *L. monocytogenes*.

ix. For establishments producing products other than hotdogs or deli meats, if the third consecutive test of food contact surfaces is positive for *Listeria* spp., or *Listeria-like* organism (sampling is required in this case):

(a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
(b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
(c) Record the corrective actions taken.
(d) Hold the product.
(e) Test product for *L. monocytogenes*.
(f) Retest the food contact surface.
(g) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
(h) If the test results for the product are positive for *L. monocytogenes*,
    (i) Destroy the product, or
    (ii) Re-work the product with a process that is destructive of *L. monocytogenes*.

For repeated FCS positives, the establishment should also conduct a comprehensive investigation to determine the cause and source of the contamination. This establishment should:

a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.
b. Review traffic control patterns, equipment layout, and adherence to employee hygiene procedures.
c. Locate niches
    i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for *L. monocytogenes*
    ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination
d. Thoroughly clean and sanitize the individual parts.
    i. Intense scrubbing is necessary to breakup or dislodge a biofilm.
    ii. A change of cleaning or sanitizing solutions may be indicated.
    iii. Fogging of the equipment or room with a sanitizer such as quaternary ammonium compounds, could be used if problems persist.
e. Reassemble and test again during operation until the FCS test negative on consecutive tests.

At the same time as the comprehensive investigation, the establishment should examine and review its HACCP plan, Sanitation SOP, or its prerequisite program where the sanitation and testing programs are included, evaluate and determine if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of verifying that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

2. Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3

The chart below shows the frequencies of testing food contact surfaces that establishments in Alternatives 1, 2 and 3 should conduct for verification of the effectiveness of their sanitation program. Establishments should consider these frequencies when determining the level of *Listeria* control they believe is prudent in their establishments based on their operation and historical data. Those establishments assuming these levels of verification testing likely would be subject to more intense verification activity by FSIS, and their vulnerability regarding the scope of a recall likely is increased in situations where product in commerce is linked to their establishment. The scope of a recall is dependent, in part, upon the level and type of documentation that establishment maintains on the on-going effectiveness of their operation.

Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2, and 3.

	Food Contact Surface Testing	
	Higher Frequency	Lower Frequency
Alternative 1	>2/year/line	2/year/line
Alternative 2	>4/year/line	4/year/line
Alternative 3		
Non-deli, non-hotdogs	> 1/month/line	1/month/line
Deli, hotdogs:		
Very Small volume plant	>1/month/line	1/month/line
Small volume plant	>2/month/line	2/month/line
Large volume plant	>4/month/line	4/month/line

3. Testing Food Contact Surfaces and Other Environmental Surfaces for Listeria spp. and Listeria-like Organisms

RTE meat and poultry establishments perform many different microbiological testing programs, including:

• **Testing for the presence of *Listeria* spp. or *Listeria*-like organisms.** These organisms are appropriate for use as indicators of *L. monocytogenes* because their presence indicates the possible presence of the pathogen. If tests for these organisms are negative, it is unlikely that *L. monocytogenes* is present. Tests for *Listeria* spp. or *Listeria*-like indicator bacteria are

typically abbreviated versions of *L. monocytogenes* methods, terminated after enrichment and screening steps, but before *Listeria monocytogenes* is confirmed, specifically:

o Tests for *Listeria* spp**.** organisms are rapid screening procedures involving genus *Listeria*-specific immunoassays, genetically-based or other rapid assays, in which a positive result is obtained but not confirmed as *Listeria monocytogenes*

o Tests for *Listeria***-**like organisms are typical cultural procedures in which potential positives are indicated by biochemical reactions in differential broth or plating media, but are not confirmed as *Listeria monocytogenes*

• **Testing methods to enumerate *Listeria* spp. or *Listeria*-like organisms.** Such methods are appropriate for enumerating the number, but are not sensitive enough for determining the presence or absence of these microorganisms, if present at low levels. Enumeration methods do not include an enrichment period, and therefore are not sufficiently sensitive for the requirements of a testing program designed to detect low numbers of organisms present. In addition, the surface area tested must be factored into the results in order to make a best estimate of the number of organisms present in that specified area. FSIS realizes that there may be circumstances when the establishment chooses to use such enumeration methods for their own purposes. Such techniques are important when trying to ascertain the likely level of contamination that comes into contact with RTE product. However, the establishment must provide scientific justification for any testing methods used for environmental testing, and a rationale for the conclusions derived from such testing.

• **Testing for aerobic plate counts (APC), total plate counts (TPC), coliforms, ATP etc.** Such tests are not appropriate indicators for *L. monocytogenes* as they cannot establish the presence or absence of this organism. Testing for these organisms is appropriate for monitoring the effectiveness of the sanitation procedures or the level of contamination during processing.

To ensure that any potential *Listeria* spp. or *Listeria*-like organisms are detected, it is necessary for the method used to provide the lowest possible limit of detection (*i.e.*, maximum sensitivity for detection) for these organisms. Testing methods meeting the following criteria are most likely to be suitable for this purpose:

• The method is used by a regulatory body or has been validated by a recognized independent body (*e.g.*, AOAC, AFNOR, ISO), using the FSIS *Listeria monocytogenes* qualitative method as a reference method. A validated method from a scientifically robust study using the FSIS *Listeria monocytogenes* qualitative method as a reference method is also acceptable but may be subject to FSIS review. The validation procedure should be consistent with the goal of providing sensitive qualitative detection of environmental *Listeria*,
AND

• The method includes an enrichment period that allows for the recovery and resuscitation of any sub-lethally injured cells also allows for the outgrowth (multiplication) of very low numbers of *Listeria* to levels that can be detected by the test method. In general, direct-plating

enumeration methods, which do not include a period for outgrowth of cells and cannot detect microorganisms at very low levels, are inappropriate for ensuring that *Listeria* contamination is not present on food contact or other environmental surfaces,
AND

• The method must accommodate analysis of the entire sample sponge (or other sampling device), and all associated diluent, to maximize the possibility of detecting any cells that are present. By only analyzing a portion of the diluent or by not testing the sponge or swab, any *Listeria* remaining in the untested sample portion would not be represented, thereby decreasing the potential for detecting *Listeria* contamination. Quantitative methods, including direct-plating and most-probable-number methods, typically test only a portion of the diluent and so are inappropriate for ensuring *Listeria* are not present on food contact or other environmental surfaces.

The establishment is responsible for the choice of methods. It is the establishment's responsibility to share this guidance document with microbiological consultants and testing laboratories so that all parties understand what methods and sample test portions are appropriate for the intended purpose. Also, any methods used should be validated to ensure that they can reliably detect the presence of *Listeria* spp. or *Listeria*-like organisms on food contact and other environmental surfaces. In addition, the establishment should maintain documentation related to the selected testing procedure.

If an establishment chooses not to use a proven methodology for food-contact and other environmental-surface testing, it may be assuming a greater risk of allowing adulterated product into the marketplace, and therefore being confronted with recall requests and regulatory actions. Should FSIS question the suitability of the method employed by an establishment, it may choose to review the scientific basis for the sampling and testing procedures used. In such a circumstance, the establishment could be subject to focused verification checks, including review of recordkeeping, observation of production, and collection of product and environmental sampling for testing.

FSIS method for analysis and confirmation of *L. monocytogenes* and other FSIS microbiology laboratory methods are available and can be downloaded at
http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook

4. Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3

Assuming it takes to 3 days to obtain a test result for *Listeria* spp., or *Listeria*-like organisms:
Day 1 – Take food contact surface (FCS) samples

Day 4 –FCS sample (from Day 1) negative for *Listeria* spp. or *Listeria*-like organisms.
- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

If FCS sample positive (from Day 1) for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Continue production.

Day 7 – Follow-up FCS sample (from Day 4) is negative for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

If follow-up FCS sample (from Day 4) is positive for *Listeria* spp., or *Listeria*-like organisms.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold and test Day 7 product lot (for *L. monocytogenes* or *Listeria* spp. or *Listeria*-like organisms).
- ✓ Continue production, hold product from the day's production

Day 8 –

- ✓ Test FCS-- target most likely source of contamination and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 9 –

- ✓ Test FCS-- target most likely source of contamination and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 10 –

If FCS sample (day 7 sample) is negative for *Listeria* spp., or *Listeria*-like organisms.

- ✓ Continue production and hold product from days 7, 8, 9, and 10 until the results from Day 7 product testing and Days 8, 9, 10 FCS testing are available and found negative, unless there is compelling justification that affected products are not adulterated.
- ✓ Resume FCS testing according to frequency stated in sanitation program

If FCS sample (day 7 sample) is positive for *Listeria* spp., or *Listeria*-like organisms:

- ✓ Hold and test product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms
- ✓ Take corrective action
- ✓ Intensive cleaning and sanitizing
- ✓ Take FCS sample-- target most likely source of contamination and additional tests in surrounding FCS area

Day 14 – If Day 7 product is positive for *L. monocytogenes*, destroy product, or rework product with a process that is destructive of *L. monocytogenes*. Recall product if already in commerce.
If product is positive for *Listeria* spp., verify that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions, are not adulterated by testing to provide compelling justification.

If the establishment tests FCS samples for *L. monocytogenes,* and the FCS test positive for the pathogen, the sampled lot is considered adulterated.

Every time there is a second or more (consecutive) follow-up FCS positive, product is held and tested for *L. monocytogenes*. Only product lots implicated with a second or more (consecutive) follow-up FCS positive are held and tested. Every time there is a product positive for *L. monocytogenes*, product is held, and destroyed, or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued.

Repeated FCS positives would imply a critical sanitation problem and the establishment needs to conduct intensive testing and intensive cleaning and sanitizing. At the same time, the establishment should investigate the cause and source of the contamination and review the documents where the sanitation and testing programs are included to determine if there are design or execution flaws. The establishment should have provisions in their sanitation and testing program for these kinds of situations.

A joint industry group has completed guidelines titled "Industry Best Practices for Holding Tested Products." This document was designed to encourage all establishments to hold products that are tested for adulterants until the results are received and to assist companies in developing best practices to ensure that they in fact do so. To obtain a copy of this document, visit the International HACCP Alliance website at the following address:
http://haccpalliance.org/alliance/bestpractices.html

5. Sentinel Site Program Example

Some establishments have adopted a sentinel site program for the control of *L. monocytogenes* in RTE meat and poultry products. A sentinel site program is similar to traditional *Listeria* control programs – separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate *Listeria* when it is detected. The distinctive characteristic of this control program is that in the case of a positive *Listeria* test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur.

The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a food contact surface or non-food contact surface tests positive for *Listeria* spp. or *Listeria*-like organisms, testing is intensified in the identified area.

If a non-food contact surface sampling site is found to be positive for *Listeria* spp. or *Listeria*-like organisms during routine monitoring, intensified sampling is initiated as soon as possible. Under intensified sampling, three samples per day (one each at pre-op, 1st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for *Listeria* spp. or *Listeria*-like organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for *Listeria* spp. or *Listeria*-like organisms. Once nine consecutive samples are found negative, that site will be returned to routine sampling.

Similarly, the food contact surface site that initially tests positive for *Listeria* spp. or *Listeria*-like organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for *Listeria*, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP, since *Listeria* would, at that point be considered a hazard not reasonably likely to occur. The site testing positive for *Listeria* would be considered a suspect harborage for *L. monocytogenes* and corrective actions taken. Testing becomes the verification step.

Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, 1st shift, 2nd shift) be taken until nine consecutive samples are negative for both *Listeria* spp. and *L. monocytogenes*. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both *Listeria* spp. and *L. monocytogenes*. All products that have contact with that particular site must be placed on hold pending test results.

If nine consecutive samples are negative for *Listeria* spp. and *L. monocytogenes*, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for *L. monocytogenes*. Any sites testing positive for *L. monocytogenes* would require testing of the product.

<u>Sentinel Site Program Example Flowchart</u>

1. Routine Environmental Sampling
    a. 5 samples/line/week
        i. 3 – food contact surface samples
        ii. 2 – non-food contact surface samples
        iii. *Listeria* spp.
2. Non-food Contact Surface Testing
    a. If negative for *Listeria* spp., continue Routine Environmental Testing
    b. If positive for *Listeria* spp., intensify sampling

        i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling

iii. If any sample is positive, continue sampling 3 samples/site/day until 9 consecutive samples are negative

3. Food Contact Surface (FCS) Testing
   a. If negative for *Listeria* spp., continue Routine Environmental Testing
   b. If positive for *Listeria* spp., intensify sampling
      i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
      ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
      iii. If any sample is positive, make sanitation for that site a CCP
4. CCP Testing
   a. Collect 3 samples samples/site/day for 3 consecutive days for *Listeria* spp. **and** *L. monocytogenes* (9 consecutive samples)
   b. If 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, return to Routine Environmental Sampling and eliminate the CCP
   c. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*
      i. Place product on hold
      ii. Release product if site and production date have negative results for *L. monocytogenes*
      iii. Continue testing until 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, then return to Routine Environmental Sampling and eliminate the CCP
   d. If any sample is positive for *L. monocytogenes*, test the product for *L. monocytogenes*
      i. Reprocess or destroy product testing positive for *L. monocytogenes*

6. Risk-based verification testing program

Risk-Based Sampling. Before the implementation of risk-based verification sampling, samples were collected under sampling project codes ALLRTE (all RTE products – both post-lethality exposed and non-post-lethality exposed), RTERISK1 (product priority list based on FSIS Directive 10,240.4), and RTE001 (establishments are identified for sampling based on risk ranking). For ALLRTE, all establishments, regardless of plant size, production volume, or process design had an equal chance of being sampled each fiscal year. Results from this project were unbiased to the extent that production practices were not addressed as they are in the other RTE verification sampling projects. Overall prevalence of the pathogens, for which FSIS tests, in all types of operations can be ascertained. FSIS randomly collected one sample of product at a time from an individual establishment and tested for pathogens of public health concern, namely, *Listeria monocytogenes, Salmonella,* and *E. coli* O157:H7. Inspection program personnel carried out HACCP, Sanitation SOPs, and prerequisite program verification activities, including the review of records and laboratory results, to verify that establishments are properly addressing the control of pathogens.

The implementation of the risk-based verification program consists of two phases. Phase 1 of the risk-based verification testing program was implemented in January 2005 with the issuance of FSIS Notice 61-04 announcing the RTE001 project for testing of post-lethality

exposed ready-to-eat (RTE) meat and poultry products for *L monocytogenes*. Project RTE001 was designed to consider the Alternative (i.e., 1, 2. or 3 of 9 CFR 430.4) that the establishment selected for the production of post-lethality exposed products. That is, sampling was based on the risk of *Listeria* contamination of products produced under the three Alternatives. In Phase 2, this concept was expanded to include testing of food contact surfaces, environmental (non-food contact surfaces), and finished product. As more samples are taken for the RTE001 sampling project, sample project RTERISK1 will be discontinued. The ALLRTE project will still be continued in Phase 2.

In Phase 1, a checklist (Procedures for the Evaluation of Establishment Control Programs for *Listeria monocytogenes*) was developed to evaluate the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by the establishment to control *L. monocytogenes* in their post-lethality exposed RTE meat and poultry products. The checklist will be completed by Enforcement, Investigation and Analysis Officers (EIAOs) whenever a Food Safety Assessment (FSA) is conducted.

Follow-up Sampling. When a sample taken under the sampling projects outlined above is found to be positive for a pathogen, FSIS will conduct follow-up verification testing after the establishment has taken its corrective and preventive actions. The follow-up sampling will be conducted under the Intensified Verification projects, as described below.

Intensified Verification Testing. These projects are designed for testing in any operation involving any RTE meat or poultry product, regardless of the establishment's control procedures, the production volume, etc., due to the production of adulterated product (i.e., the pre-shipment review has been completed), investigative purposes (e.g., as a result of an outbreak of foodborne disease), or concern that the establishment may not be properly controlling for pathogens. The projects may include instructions to Inspection program personnel to collect multiple samples. Intensified verification testing will include:

1. Increased frequency and number of samples taken for product testing (as compared to targeted verification testing), and the collection of environmental samples.
2. Increased FSIS record verification checks regarding the design and implementation of the food safety system. These sampling projects will be scheduled by OFO through OPHS on a case-by-case basis.

Appendix VII. Establishment *L. monocytogenes* Risk Ranking Algorithm and Modifications

This appendix provides additional information for the establishment *L. monocytogenes* (Lm) risk ranking algorithm modifications (2005 and 2006 versions). The 2006 version makes minor changes in the Risk3 variable constants compared to the baseline 2005 version.

In the 2005 algorithm baseline dataset, there are 1,820 total establishments, of these 1,409 are in Alternative 3; this is 71% of all establishments in the RTE001 program. About 23% of all establishments, or 454 establishments, claim Alternative 2. Of these establishments, 397 of those, or 20%, are in Alternative 2b, using a growth inhibitor or process. Fifty-seven, or 3% of establishments, apply a post-processing lethality and so are in Alternative 2a. Exactly 118 establishments claim Alternative 1; this is about 6% of all establishments. There are 1,675 establishments (92%) that claim only one alternative and 161 (8%) that claim multiple alternatives.

2005 Dataset

	Alternatives		One Alternative	
Variable	Number	Percent	Number	Percent
Establishments	1,820	91.9	1675	100.0
Alternative1	118	6.0	82	4.9
Alternative2a	57	2.9	34	2.0
Alternative2b	397	20.0	293	17.5
Alternative3	1,409	71.1	1,266	75.6
Total Alternatives	1,981	100.0	1,675	100.0
Multiple Alternatives	161	8.1	145	8.7

The 2006 dataset includes 2,067 establishments in RTE001, of which 1,401 are in Alternative 3; this is about 56% of the total. About 39% of all establishments, or 967 establishments, claim Alternative 2. Of this number, 654, or 26%, are in Alternative 2b, using a growth inhibitor or process. And 313, or 13% of establishments, apply a post-processing lethality step and so are in Alternative 2a. Alternative 1 includes 125 establishments; this is about 5% of all establishments with post-lethality exposed RTE products.

2006 Dataset

	Alternatives		One Alternative	
Variable	Number	Percent	Number	Percent
Establishments	2,067	82.9	1,724	100.0
Alternative1	125	5.0	78	4.5
Alternative2a	313	12.6	57	3.3
Alternative2b	654	26.2	343	19.9
Alternative3	1,401	56.2	1,246	72.3
Total Alternatives	2,493	100.0	1,724	100.0
Multiple Alternatives	426	17.1	343	19.9

Data Sources

Self-reported Compliance with the Interim Final Rule to Control L. monocytogenes and Type of Product Processed and Volume of Production

The 2005 algorithm uses 7 RTE product classes from FSIS form 10,240-1 (2004) that report the annual production volume for each class in pounds. The product classes are deli meat sliced, deli meat unsliced, hot dogs, cooked products, fermented products, dried products, and salt-cured products.

The 2006 algorithm uses 7 RTE product classes from FSIS form 10,240-1 (2006) that report the annual production volume for each class in pounds. The product classes are deli meat sliced, deli meat unsliced, hot dogs, cooked products, fermented products, dried products, and salt-cured products.

Past History of Laboratory Results for L. monocytogenes Testing

The 2005 and 2006 algorithms use the product testing results reported for the RTE001 risk-based sampling program taken from the FSIS Pathogen Reduction Enforcement Program (PREP) database. Results are reported by product type based on whether results are positive or negative by establishment number with collection and analysis dates.

Establishment L. monocytogenes Risk Ranking Algorithm Equations

The basic form of the equations is in a two-part analysis. The first part estimates the establishment baseline risk score obtained from form data describing each establishment's alternative(s) and annual production volume for RTE product categories. There are seven categories for the 2005 and 2006 algorithm versions. The establishment baseline risk scores (Risk2) are ranked (Rank Risk2). Part 2 analysis adjusts the establishment baseline risk rank with historical laboratory results. Risk3 increases the risk ranking with past positive *Lm* results while Risk1 increases establishment risk to the very top risk ranks. Risk4 decreases establishment risk rank when there are no positive *Lm* results. Establishment risk rank is not changed if there are no reported laboratory results. The general form of the risk ranking equation is:

Risk Rank = Risk1 + Rank Risk2 + Risk3 – Risk4

Raw Baseline Risk Score Calculation

The 2005 and 2006 algorithms uses a three mass component equation to calculate the equivalent deli meat volume (EDMV) component of the baseline risk score for each alternative. The final sum is taken over all establishment alternatives. The baseline risk score is equal to the product of the EDMV and the establishment alternative Q80 (the 80th quantile of the expected *Lm* contamination distribution). This means there are four equations with three possible mass components for every establishment alternative and level of production. The values are taken as high, medium, or low based on the EDMV distribution over all establishments. The basic equation for each alternative yielding the EDMV is:

$$\sum[(mass_{deli} + \frac{\text{frankpergramrisk}}{\text{delipergramrisk}} * mass_{frank} + \frac{\text{otherpergramrisk}}{\text{delipergramrisk}} * mass_{other}) * \text{delipergramrisk}]_{alt}$$

The risk ratios relative to deli meat in this equation are calculated using values taken from the FSIS/FDA quantitative risk assessment shown in Appendix VII Table 1.

Appendix VII. Table 1. Product risk factors used for the 2005 and 2006 Algorithms from the 2003 FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of RTE Foods.

Product Category	Median number of illnesses per serving	Median Serving Size (grams)	Number of illnesses per gram	Risk ratio relative to deli (dimensionless)
Deli	7.70×10^{-8}	56	1.38×10^{-9}	1
Frankfurter	4.56×10^{-9} (7% @ 6.5×10^{-8} and 93% @ 6.3×10^{-11})	57	8.00×10^{-11}	5.82×10^{-2}
Other	1.70×10^{-11} (value for fermented RTE product)	57	2.98×10^{-13}	2.17×10^{-4}

The establishment EDMV (pounds/year obtained from form data, converted to grams) is multiplied by the respective alternative expected component *Lm* contamination Q80 (cfu/g) for high, medium, and low volume production shown in Table 2. The division between each production volume is at the 50th and 75th percentiles of the EDMV distribution. The baseline score for the 2005 algorithm is calculated from the equations below with the specific masses substituted for each establishment alternative. The risk scores represent total annual *Lm* colony forming unit (cfu) production by individual establishments available at retail.

The establishment risk scores are the baseline risks that are adjusted by the other component risk factors after converting to ranks in order to obtain the adjusted baseline risk rank for each establishment. The establishments with the largest adjusted baseline risk ranks are chosen for sampling.

Appendix VII. Table 2. Quantiles (Q80) of the L. monocytogenes distribution at retail by **alternative.**

Alternative	Q80	Retail Prevalence	Relative Risk
1-H	1.40E-08	0.00711	1.097591
1-M	1.25E-08	0.00684	1.056208
1-L	1.10E-08	0.00648	1.000000
2-PP-H	8.20E-08	0.01232	1.902718
2-PP-M	6.74E-08	0.01219	1.881717
2-PP-L	6.10E-08	0.01172	1.808987
2-GI-H	1.53E-06	0.03105	4.794365
2-GI-M	1.29E-06	0.02973	4.590511
2-GI-L	1.16E-06	0.02824	4.361056
3-H	7.24E-06	0.04488	7.011566
3-M	7.08E-06	0.04541	6.929975
3-L	5.65E-06	0.04401	6.795457

For high volume establishments, the baseline risk score is calculated as:

Plant risk score =

$$\left[\left(mass_{deli,1-H} + 5.82x10^{-2} * mass_{frank,1-H} + 2.17x10^{-4} * mass_{other.1\text{-}H}\right) * 1.40x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP-H} + 5.82x10^{-2} * mass_{frank,2-PP-H} + 2.17x10^{-4} * mass_{other.2PP\text{-}H}\right) * 8.20x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-H} + 5.82x10^{-2} * mass_{frank,2-GI-H} + 2.17x10^{-4} * mass_{other\ 2GI\text{-}H}\right) * 1.53x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-H} + 5.82x10^{-2} * mass_{frank,3-H} + 2.17x10^{-4} * mass_{other.3H}\right) * 7.24x10^{-6}\right]$$

For medium volume establishments, the baseline risk score is calculated as:
Plant risk score =

$$\left[\left(mass_{deli,1-M} + 5.82x10^{-2} * mass_{frank,1-M} + 2.17x10^{-4} * mass_{other.1\text{-}M}\right) * 1.25x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP\text{-}M} + 5.82x10^{-2} * mass_{frank,2-PP-M} + 2.17x10^{-4} * mass_{other.2PP\text{-}M}\right) * 6.74x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-M} + 5.82x10^{-2} * mass_{frank,2-GI\text{-}M} + 2.17x10^{-4} * mass_{other\ 2GI\text{-}M}\right) * 1.29x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-M} + 5.82x10^{-2} * mass_{frank,3-M} + 2.17x10^{-4} * mass_{other3\text{-}M}\right) * 7.08x10^{-6}\right]$$

Finally, for low volume establishments, the baseline risk score is calculated as:
Plant risk score =

$$\left[\left(mass_{deli,1-L} + 5.82x10^{-2} * mass_{frank,1-L} + 2.17x10^{-4} * mass_{other.1\text{-}L}\right) * 1.25x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-PP\text{-}L} + 5.82x10^{-2} * mass_{frank,2-PP-L} + 2.17x10^{-4} * mass_{other.2PP\text{-}L}\right) * 6.74x10^{-8}\right] +$$
$$\left[\left(mass_{deli,2-GI-L} + 5.82x10^{-2} * mass_{frank,2-GI\text{-}L} + 2.17x10^{-4} * mass_{other\ 2GI\text{-}L}\right) * 1.29x10^{-6}\right] +$$
$$\left[\left(mass_{deli,3-L} + 5.82x10^{-2} * mass_{frank,3-L} + 2.17x10^{-4} * mass_{other3\text{-}L}\right) * 7.08x10^{-6}\right]$$

Adjustment for Historical Laboratory Results

The baseline risk score for each establishment is converted to a risk rank and then adjusted by one of three risk factors. The procedure is the same that adjusts the baseline risk rank with historical laboratory results at retail. The 2005 and 2006 algorithm versions base their rankings on contamination at retail. The general equation used for adjusting the baseline risk score is as follows:

$$\text{Adjusted Baseline Risk} = w_1\,\text{Risk1} + w_2\,\text{Baseline Risk2 Score}_{\text{rank}} + w_3\,\text{Risk3} - w_4\,\text{Risk4}$$

The three risks are: Risk1- the risk of a current positive result; Risk2 is the baseline risk of a positive result; Risk3- the risk of a positive result within the past six months; and Risk4- the (negative) risk of having a negative result within the past six months. Each of the risks carries its own weight. Most of the risk is associated with the baseline Risk2 where w_2 equals 1.0, but the weight of Risk1, w_1, equal to the number of ranks, is more important since any input requires an immediate sample while Risk3 and Risk4 have much smaller contributions due to comparatively smaller weights than Risk1 similarly having an affect only when the risks are not equal to zero.

To determine appropriate weighting factors for the historical microbiological results of *L. monocytogenes* testing in establishments, FSIS used the 2003 FSIS *L. monocytogenes* Risk Assessment model, *LM*RA v2.0. One million sequential lots of RTE product were produced for an establishment operating under Alternative 3 (no growth inhibitor or additional post processing). Within the model each lot was tested before it left for retail distribution, and the results recorded. After the model was run, FSIS evaluated the time series of lot test results. Whenever a positive lot was found, a window of 1 year's data (720 lots) was combined with the same window for any other positive. The window stores the number of positives found for a given time period from the initial positive finding. FSIS converted this value to a fraction of all positives in the simulation, and the results are shown in the illustrative example below.

Illustrative example:

Using a simulation of 4 lots and a window of 4 lots (Recall that for the graphs shown later, 1,000,000 lots were simulated and the window was 720 lots or 1 year.)

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Lot 1 is negative. Skip

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Lot 2 is positive. Store the next 4 results.

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Running window total: [0,0,1,1] (i.e. the blue cells)

Lots 3 and 4 are negative. Skip.

Lot 5 is positive. Add the next 4 lot results to the running window total

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Running window total: [0,0,1,1] + [1,0,1,1] = [1,0,2,2]

Lot 6 is positive. Add the next 4 lot results to the running window total

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Running window total: [1,0,2,2] + [0,1,1,1] = [1,1,3,3]

Lot 7 is negative. Skip.

Lot 8 is positive. Add the next 4 lot results to the running window total.

Lot	1	2	3	4	5	6	7	8	9	10	11	12
Result	0	1	0	0	1	1	0	1	1	1	0	0

Running window total: [1,1,3,3] + [1,1,0,0] = [2,2,3,3]

Skip the remaining lots (9 through 12) because there is not a full length window available for them.

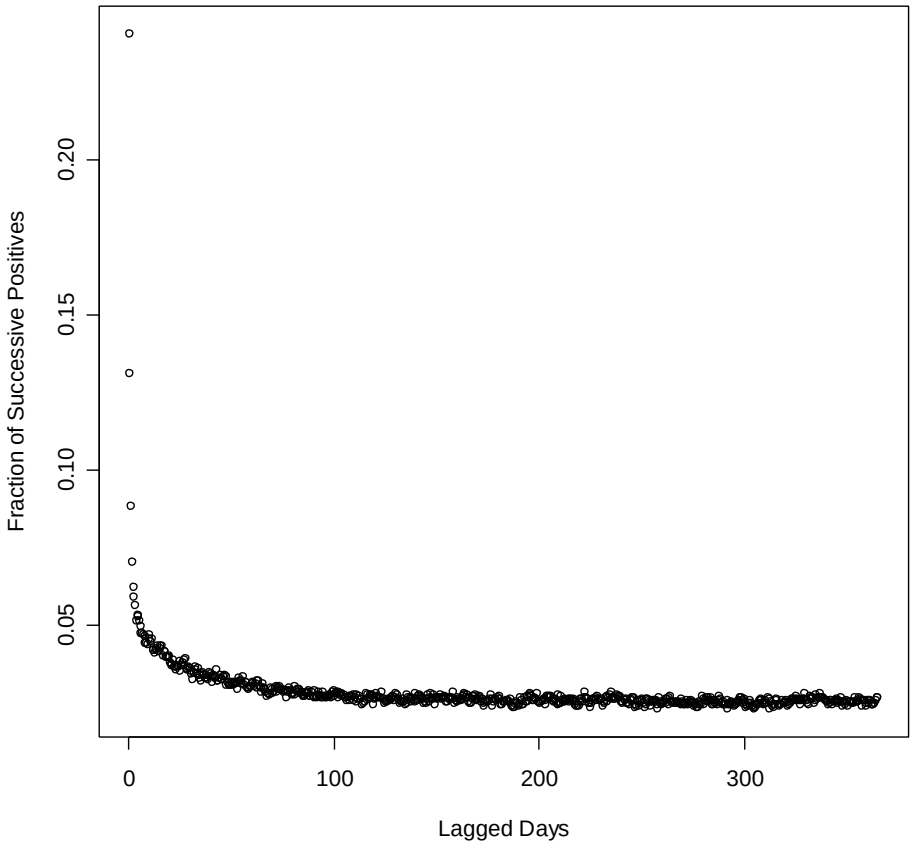
There were 4 *L. monocytogenes* positives in the 8 lots analyzed. Convert the running window total to fraction by dividing by the number of positives.

Fraction of successive *L. monocytogenes* positives: [2,2,3,3] / 4 = [0.5, 0.5, 0.75, 0.75]

Therefore, 50% of the time, a *L. monocytogenes* positive is followed by a positive. 50% of the time, a positive is followed by a positive 2 lots later. Seventy-five percent of the time, a *L. monocytogenes* positive is followed by a positive 3 lots later, and so on.

For more realistic data sets, the fraction of successive *L. monocytogenes* positives is initially high then decreases as the lag spacing or time separation increases.

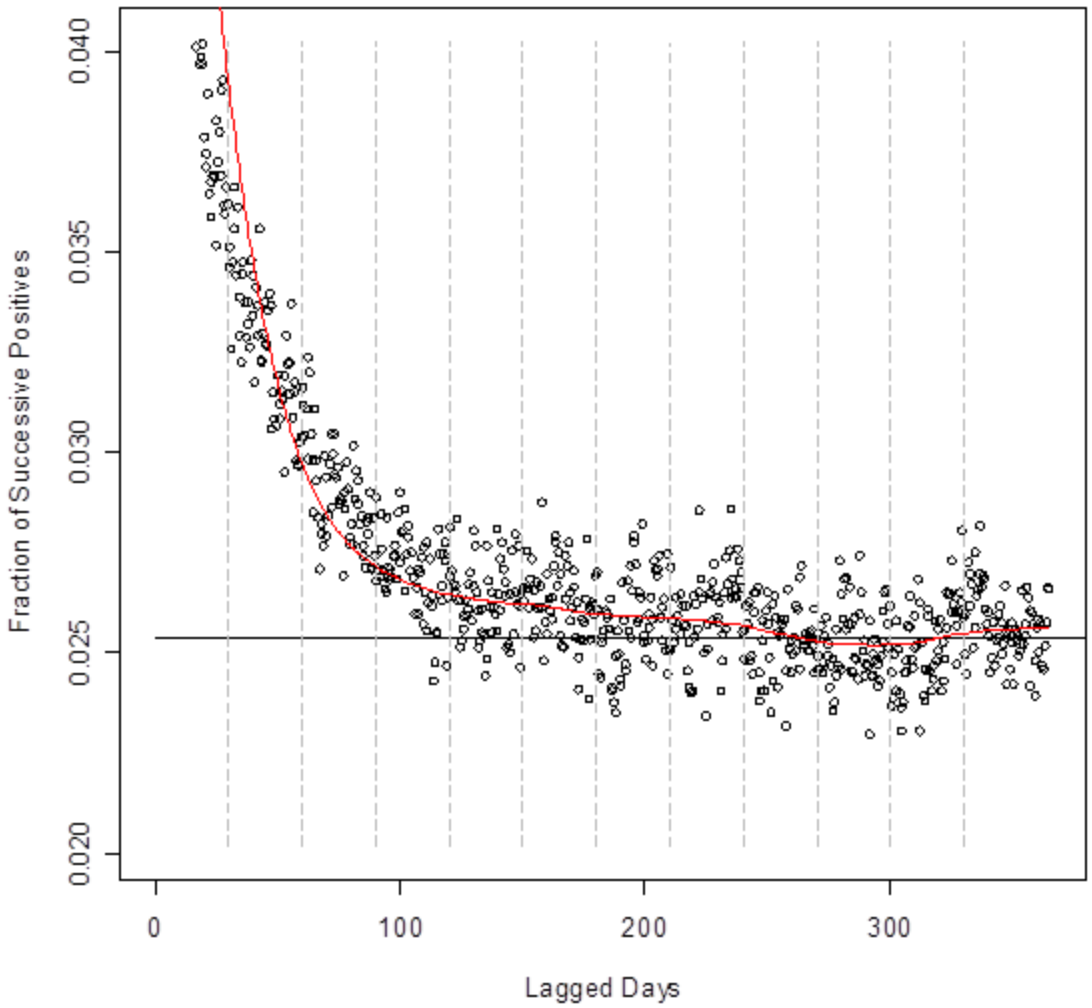
The results for the actual model simulation are shown graphically in Appendix VII Figure 1. The y-axis is the fraction of successive *L. monocytogenes* positives and the x-axis is the time lag spacing or time separation from the positive finding.



Appendix VII. Figure 1. Fraction of successive *L. monocytogenes* positives for post-processing lot testing versus separation in time.

As expected, the influence decreases over the first several days and months and then reaches a relatively constant baseline value.

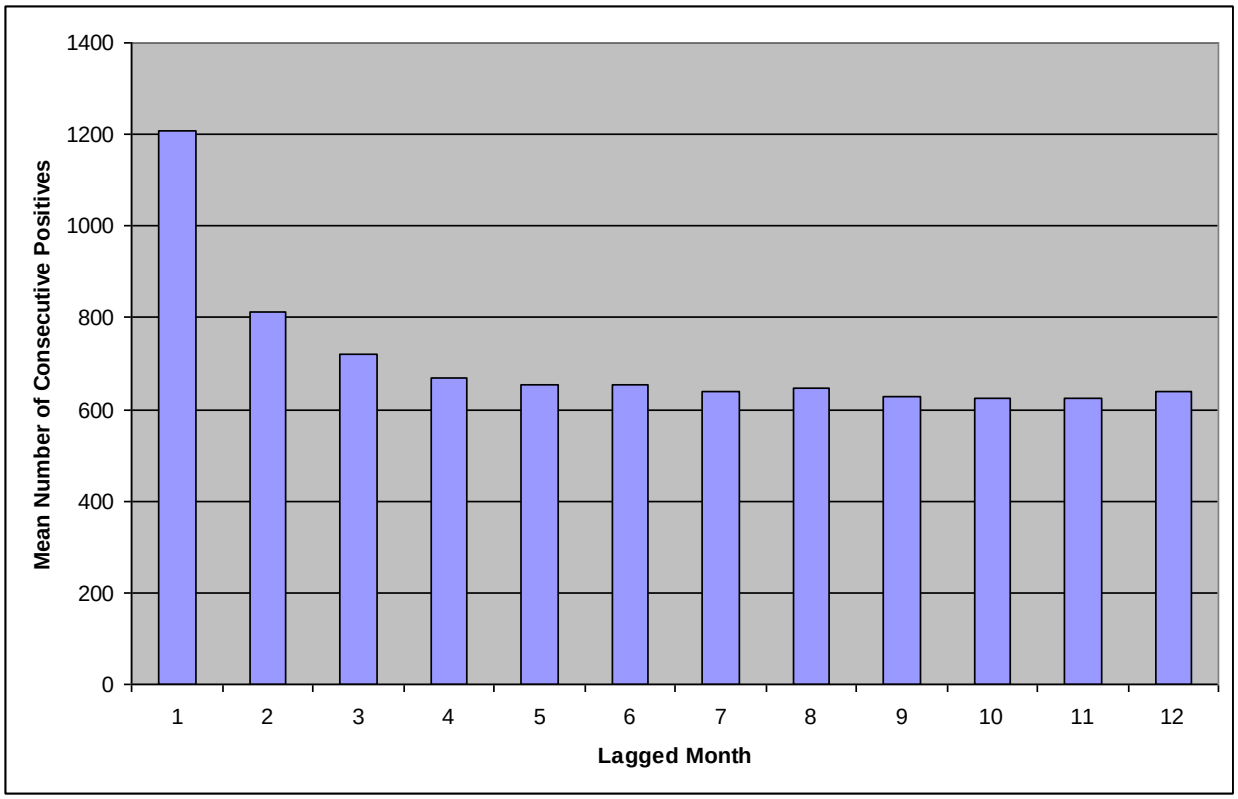
The same data are shown in Appendix VII Figure 2 below, but it focuses only on the lower portion of the graph. The horizontal line is the average fraction of successive *L. monocytogenes* positives for the last 100 lag days and represents a baseline value. When the sampling is done this far apart in time, the results are effectively random. The red curve represents a smoothed fit to the data points. The gray dashed vertical lines are spaced 1 month apart.



Appendix VII. Figure 2. Zoomed scale to better evaluate difference from baseline.

Some judgment must be used to decide when the smoothed red curve is "close enough" to the baseline value. At 3 months, there appears to be a small but real difference between the smoothed and baseline values. The range for the individual fractions around 3 months does not include the baseline. The range begins to include the baseline at 4 months. At 6 months, the difference is almost imperceptible. These results would suggest an influence time between 4 and 6 months.

Monthly weights for the first 6 lagged months were calculated by compositing the number of consecutive *L. monocytogenes* positives on a monthly basis. These results are shown in Appendix VII Figure 3. The values for lagged month 2–6 were then rescaled to sum to 1 and are provided in Appendix VII Table 3.



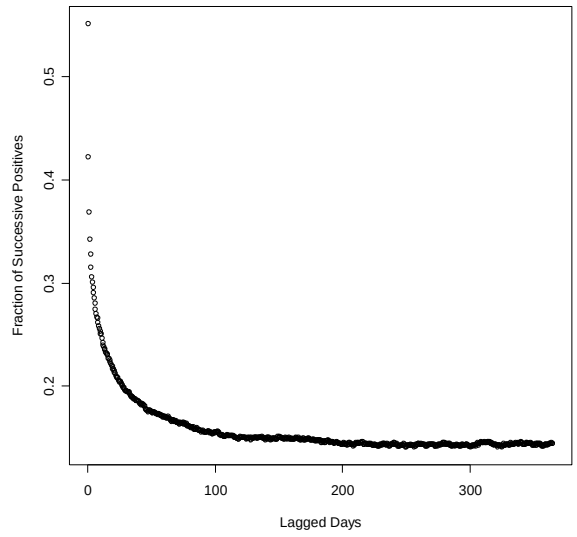
Appendix VII. Figure 3. Mean number of consecutive *L. monocytogenes* positives per month

Appendix VII. Table 3. Weights for Positive *L. monocytogenes* Results in Previous Six Months

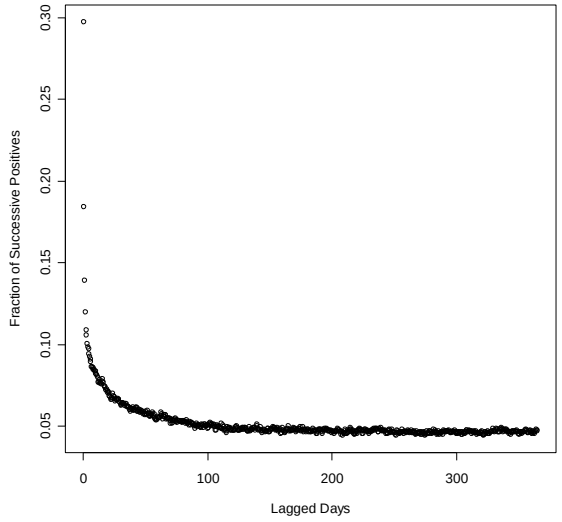
Lagged Month	Weight
1	--
2	0.231
3	0.205
4	0.191
5	0.186
6	0.186

Successive sampling for *L. monocytogenes* in product at the establishment is more likely to have a shorter duration for positive findings compared to either food contact surface testing or retail product testing. *L. monocytogenes* must move from the food contact surface to the product. The time for transport from plant to retail allows for *L. monocytogenes* growth. Lots with very low levels of contamination escape detection, but the concentration may subsequently increase to detectable and infectious levels.

The plots for testing food contact surfaces and product at retail (prior to any distribution) are given in Appendix VII Figure 4 and Figure 5.



Appendix VII. Figure 4. Fraction of successive positives for food contact surface testing versus separation in time.



Appendix VII. Figure 5. Fraction of successive positives for lots of product tested at retail versus separation in time.

Both food contact surface testing and retail product testing show higher degrees of correlation than product testing at the establishment, especially at shorter time differences. This is especially true of food contact surfaces.

2006 Version Update for Adjusting Historical Risk

Risk 3 is the risk associated with past positive cultures in individual establishments with a six-month inclusion window. Additional theoretical research on the Risk 3 weights was done using an intensive simulation of the alternative 3 establishment contamination scenarios that updated the values of these weights used in the 2005 algorithm.

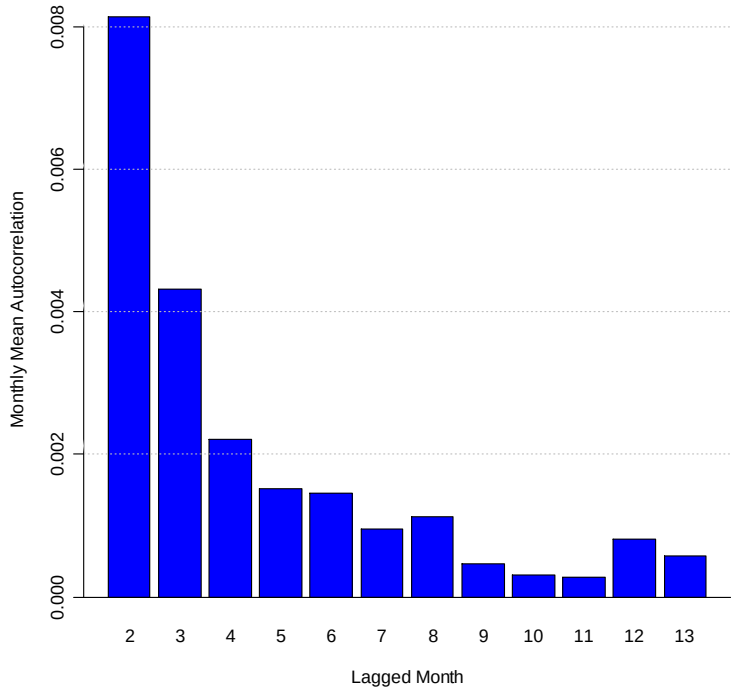
2006 Algorithm Risk3 Weights

Appendix VII Table 4 shows the 2005 version and 2006 version weights side by side. The difference is that more weight is given to months 2 and 3 than to 4, 5, and 6 and additionally giving less weight than for establishments having positive culture results in months 4, 5, and 6 than the 2005 algorithm. Appendix VII Figure 6 shows the basis for the new weights in terms of a contamination simulation using the updated in-plant dynamic process model from the 2003 deli meat risk assessment (*LM*RA ver.2) for one million sequential lots over one year for a two shift plant under alternative 3 so that 60 shifts equal one month. The decline in contamination after the initial contamination event is shown to be significant after three months in distinction from the 2005 algorithm where the decline was less pronounced.

This time series of positive and negative results was then analyzed using the standard autocorrelation function (acf) in R with a maximum lag of 1 year. Autocorrelation is a measure of how a variable changes over time relative to its past performance. The variable of interest is a positive *L. monocytogenes* finding in a RTE product lot. The influence drops of over the first several days and months, and then reaches a relatively constant baseline value with the 95% confidence band centered at 0.002 that just includes months 5 and 6 (Appendix VII Figure 6). This analysis of Risk3 weights is considered an improvement because an estimate of statistical accuracy is made for the entire set of weights.

Appendix VII. Table 4. Weights used to increase establishment baseline risk score rank based on previous positives

Lagged Month	Weight 2005	Weight 2006
2	0.231	0.4614
3	0.205	0.2446
4	0.191	0.1252
5	0.187	0.0861
6	0.186	0.0826
Sum	1	1



Appendix VII. Figure 6. Monthly Mean Autocorrelations for *Lm* Recontamination of FCS Obtained from *LM*RA v2.0

Risk Ranking Model Development

The basic model used to assess model fit to the data, sensitivity analysis, and uncertainty analysis is uniformly the same. The model uses a linear system of equations corresponding to the input variable matrix, X, and the output variable column vector, Y. Equation (1) is the linear model and equation (2) is the solution column vector, B, for the linear system.

(1) $Y = X B$
(2) $B = (X' X)^{-1} X' Y$

In order to compare input and output variables on the same unit standard deviation scale, all variables are transformed by subtracting the mean and dividing by the standard deviation (Z transformation). This transformation removes the intercept from the linear system of equations. To control the error distribution on the linear model, rank regression also is used. Because the error distribution becomes an error distribution on ranks, bootstrapping is used to estimate the non-normal error distribution and approximate t-tests for significance are used. The exact

implementation of the linear model is explained in the appendices on sensitivity analysis and uncertainty analysis.

In order to describe the progression of development of the establishment *Lm* risk ranking algorithm, the plan used is to focus first on the 2005 and 2006 datasets and their analysis. The two initial version datasets correspond to the first two phases of the algorithm development. The initial algorithm is described by the 2005 algorithm dataset that is not bootstrapped and provides a baseline model for the risk ranking algorithm. A minor modification with bootstrapped estimates is described by the 2006 algorithm dataset. The datasets were chosen because they bracket the expected extremes of the output establishment risk rank distribution. The 2005 dataset represents the minimum number of alternatives and establishments and the 2006 dataset represents the maximum number of alternatives and establishments observed in the RTE001 program over the initial two-year period.

Because the risk ranking model is based on the analysis of ranks, the model used for the algorithm is analyzed in two parts. The first part estimates the baseline risk ranking for each establishment and the second part estimates the adjusted baseline risk ranking for each establishment based on historical performance. The model is broken down into baseline establishment risk ranking, adjusted baseline establishment risk ranking, and the evaluation of the combined algorithm parts for the final establishment risk ranking.

Baseline L. monocytogenes Establishment Risk Ranking

A model for baseline *L. monocytogenes risk* was developed from the FSIS risk assessment for deli meat risk at retail (FSIS, 2003). The two initial datasets are based on annual FSIS data estimates for 2005 and 2006 are used to show the development of the *L. monocytogenes* baseline risk ranking algorithm from the deli meat risk assessment model. The input data varies by dataset to show the stepwise development of the baseline risk ranking as part of the adjusted *L. monocytogenes* risk ranking algorithm. This form of analysis will be carried to completion in additional algorithm version updates.

2005 Dataset Baseline Risk Ranking

The risk model used for the risk ranking algorithm is a linear and assumes independent risk factors that enter the model as single non-interacting factors. The 2005 baseline risk model has three product volume risk factors: individual establishment deli meat annual production; individual establishment hot dog annual production; and individual establishment other RTE product annual production. Each risk factor is multiplied by the constants (risk ratios) in Appendix VII Table 1 thereby converting the RTE volumes to equivalent deli meat volumes (EDMV); and then each EDMV is multiplied by the Q80, the *Lm* contamination distribution constant for alternative and RTE product subdivided into high, medium, and low production volume for the EDMV of each establishment. The summary statistics for these input distributions are shown in Appendix VII Table 5. The equation used for the baseline risk (Risk2) is:

Risk 2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

The establishment *Lm* risk rank is found by ranking all establishments in ascending order according to their calculated baseline risk. Baseline risk is characterized as Risk2 because Risk1 is the more important regulatory risk defined as a current positive *Lm* result or a regulatory policy decision to sample a particular establishment. Notice that Risk2 is the product of EDMV and Q80 summed for each of an establishment's alternative and production volume.

Appendix VII. Table 5. Summary Statistics for 2005 Dataset Input Variables

Statistic	Deli Meat	HotDog	Other	Q80	EDMV
average	1,667,227	996,984	22,414,534	5.19E-06	1,730,115
stdev	9,515,906	7,900,256	837,248,882	2.75E-06	9,625,318
min	0	0	0	1.10E-08	0
max	267,930,569	175,000,000	37,264,000,000	7.24E-06	268,488,756
median	0	0	78,095	7.08E-06	801
CV%	570.8	792.4	3735.3	52.9	5,56.3
skewness	14.5	12.5	44.5	-0.9	14.2
kurtosis	330.4	198	1,980.1	-1	3,19.5
N	1,981	1,981	1,981	1,981	1,981

Statistic	Deli Meat*	HotDog*	Other*	Risk 2
average	4.69	0.12	0.01	4.82E+00
stdev	26.99	0.79	0.28	2.71E+01
min	0	0	0	2.72E-10
max	440.41	15.56	12.35	4.40E+02
median	0	0	0	2.73E-03
CV%	575.3	656	3363	563.1
skewness	9.8	10.5	44.5	9.7
kurtosis	114.7	139.5	1,978.3	112.9
N	1,981	1,981	1,981	1,981

*Distribution has been transformed by multiplying by deli meat risk ratio constants and the Q80 constants.

The transformed distributions for deli meat, hot dogs, and other RTE products are represented in units of annual *Lm* cfu contamination per establishment shown in Appendix VII Table 6. These values are used in a standardized rank regression in order to determine the sensitivity and uncertainty of the risk factors on the *Lm* risk ranking outcome. The rank distributions were used because the input variables deviated significantly from normal distributions as indicated by the skewness and kurtosis statistics shown in Appendix VII Table 6. This is mainly due to many establishments having zero volumes for certain RTE products giving the input distributions a pronounced positive skew and positive kurtosis (skewed to the right and peaked).

The relationship of the output baseline risk rank variable to the three input variables is shown in Appendix VII Table 7. The regression coefficients (b) shown in this table are standardized in order to make comparisons in the same standard deviation units (Sb). The overall regression and the individual regression components are each highly significant. The order of relationship to the output ranked variable is Deli Meat > Other > Hot Dogs. R-squared represents the proportion of the variance in the output rank variable that is accounted for by the linear regression on ranks. In this case this means that 76% of the variance was accounted for by the regression model and 24% was not. Since the variance of the risk ranks is fixed by the bounds set by the number of ranked alternatives the focus of uncertainty is on the 24% of the variance not accounted for by the model.

Appendix VII. Table 6. Input Variable Statistics

Statistic	Deli Meat*	HotDog*	Other*	Risk 2
average	4.69	0.12	0.01	4.82E+00
stdev	26.99	0.79	0.28	2.71E+01
min	0.00	0.00	0.00	2.72E-10
max	440.41	15.56	12.35	4.40E+02
median	0.00	0.00	0.00	2.73E-03
CV%	575.3	656.0	3363.0	563.1
skewness	9.8	10.5	44.5	9.7
kurtosis	114.7	139.5	1,978.3	112.9
N	1,981	1,981	1,981	1,981

*Transformed variable

Appendix VII. Table 7. Standardized Regression Coefficients for Full 2005 Algorithm Dataset

Variable	b	Sb
Deli Meat	0.8542*	0.0122
HotDog	0.1473*	0.0117
Other	0.3087*	0.0116
R-Squared	0.7604*	0.2396

*Statistic significant at $p<0.05$

2006 Dataset Baseline Risk Ranking

This dataset was the foundation for developing sensitivity and uncertainty analysis for the risk ranking algorithm. The input variables are all the same except that the dataset is larger (N=2,493) and allows bootstrap estimates based on a sample size of 1,981 the sample size of the 2005 dataset. Appendix VII Table 8 include the statistics for 2,493 lines of data. Bootstrapped estimates appear in the sections on sensitivity and uncertainty analysis. The estimates are based on the same formula for calculating Risk2 as in the baseline 2005 dataset. Notice that the Q80 and Rank Risk2 distributions are approximately normal based on the skewness and kurtosis statistics. This means

that the model error distribution is applicable to t-test significance tests based on ranked data that will have negligible bias. The baseline risk equation used is:

Risk 2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Appendix VII. Table 8. 2006 Dataset with Raw Data and Transformed Baseline Input Variables

Raw Data Statistics

statistic	Deli Meat	Hot Dog	Other	Q80
average	2,083,956	53,150	4,218	3.62E-06
stdev	13,051,080	429,068	161,967	2.69E-06
min	0	0	0	1.10E-08
max	301,520,000	10,185,000	8,086,288	7.24E-06
median	0	0	20.2244	4.65E-06
CV%	626.3	807.3	3840.1	74.3
skewness	14.87	13.15	49.9	0.03
kurtosis	298.38	219.23	2490.89	-1.52
N	2,493	2,493	2,493	2,493

Transformed Data Statistics

statistic	Deli Meat*	Hot Dog*	Other*	Risk2	Rank Risk2
average	4.81	6.23E-03	1.50E-06	4.82	1,247
stdev	31.01	4.43E-02	5.38E-05	31.01	720
min	0	0.00E+00	0.00E+00	0	1
max	564.08	9.07E-01	2.68E-03	564.08	2493
median	0	0.00E+00	7.76E-09	0	1247
CV%	644	710.3	3591.3	643.4	57.7
skewness	11.18	11.38	49.85	11.18	0
kurtosis	148.38	161.11	2487.95	148.27	-1.2
N	2,493	2,493	2,493	2,493	2,493

*Distribution has been transformed by multiplying by deli meat risk ratio constants and the Q80 constants

Appendix VII Table 9 shows the same order of relationship as in the 2005 dataset: Deli Meat > Other > Hot Dog. Each input variable is significant, and the overall regression model is significant. Also, about 20% of the rank variance is not explained by the model.

Appendix VII. Table 9. Standardized Baseline Regression Coefficients for 2006 Algorithm Dataset

Variable	b	sb
Deli Meat	0.8526*	0.0098
Hot Dog	0.1825*	0.0094
Other	0.2502*	0.0093
R-Squared	0.8011*	0.1989

*Statistic significant at $p<0.05$

Adjusted L. monocytogenes Establishment Risk Ranking

The adjusted baseline *L. monocytogenes* risk ranking algorithm development is shown through the progression of the same two datasets used for the baseline risk ranking algorithm development. The adjustment is based on historical establishment process control using FSIS regulatory *L. monocytogenes* sampling data. The adjustment increases the establishment risk ranking for poor performance and decreases the risk ranking for good performance. FSIS defines poor performance as any positive *L. monocytogenes* result within the last six months. The agency defines good performance as no positives and negative *L. monocytogenes* results within the last six months.

2005 Dataset Adjusted Baseline Risk Ranking

The equations used for determining the adjusted baseline risk ranking with all the constants are shown below.

Adjusted Risk Rank = 1981x Risk1 + Rank Risk2 + 495.25 x RR x Risk3 / 7.0116 + 495.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.2310 x month2 + 0.2050 x month3 + 0.1910 x month4 + 0.1870 x month5 + 0.1860 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6) / 28

The maximum rank with this dataset is 1,981 so this is set as the limit for Risk1. The maximum change in risk rank is set at 25% of the total number of ranks (495.25). Appendix VII Table 2 lists the variable for prevalence relative risk at retail (RR) with the maximum as 7.011566. The constant coefficients for Risk3 sum to one. The monthly variables contain the total number of positive *Lm* laboratory results for Risk3 by month and the total number of negative *Lm* laboratory results for Risk4 by month. The maximum number of negative laboratory results is set at 28 over six months. Appendix VII Table 10 shows the distribution statistics for adjusted baseline risk as risk transformed variables. Only the rank transformed variables at this stage have near normal distributions. Appendix VII Table 11 shows the standardized rank regression coefficients, which are significant and account for more than 99% of the total output rank variability. The order of the

risk rank coefficients for adjusted baseline risk rank is: Rank Risk2 > Risk1 > Risk3 > Risk4. The combined effects of Risk1 and Risk3 are greater than the effect of Risk4.

Appendix VII. Table 10. Risk Transformed Adjusted Baseline Input Variables for the 2005 Algorithm Dataset

Statistic	RankRisk2	Risk1	Risk3	Risk4	AdjRankRisk2
average	991	12	3	-21	986
stdev	572	154	23	24	592
min	1	0	0	-311	-248
max	1,981	1,981	246	0	3,673
median	991	0	0	-16	987
CV%	57.7	1281.3	708.1	-114.2	60.1
skewness	0.0	12.7	7.2	-3.3	0.2
kurtosis	-1.2	160.5	50.6	21.1	-0.3
N	1,981	1,981	1,981	1,981	1,981

Appendix VII. Table 11. Standardized Adjusted Baseline Regression Coefficient Results for the 2005 Algorithm Dataset

Variable	b	S_b
Rank Risk2	0.9950*	0.0016
Risk1	0.1229*	0.0015
Risk3	0.0462*	0.0015
Risk4	-0.0298*	0.0016
R-Squared	0.9954*	

*Statistic significant at p<0.05

2006 Dataset Adjusted Baseline Risk Ranking

The equations used for the 2006 algorithm are shown below. The maximum rank is 2,493, and it is set as the limit on Risk1. The maximum shift in risk ranking for any establishment is set at 25% of the maximum rank (623.25). As with the 2005 baseline algorithm, the maximum retail prevalence relative risk is set at 7.0116. The major change in this algorithm is the redefinition of the constant coefficients for Risk3 due to new data. The maximum number of negative laboratory results is again set at 28 over six months. Appendix VII Table 12 shows the risk transformed input and output variables for the adjusted baseline risk ranking. Appendix VII Table 13 shows that all the standardized rank regression coefficients and the regression model are significant. The regression coefficient for Risk4 has more of an effect than in the 2005 algorithm because the order of

coefficients is now: Rank Risk2 > Risk4 > Risk1 > Risk3. Risk1 and Risk3 compensate for the effect of Risk4.

Adjusted Risk Rank = 2493x Risk1 + Rank Risk2 + 623.25 x RR x Risk3 / 7.0116 + 623.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

Appendix VII. Table 12. Risk Transformed Adjusted Baseline Input Variables for the 2006 Algorithm Dataset

Statistic	RankR2	R1	R3	R4	AdjRankR2	RiskRank
average	1,247	14	2	-440	832	1,247
stdev	720	221	29	570	807	720
min	1	0	0	-3729.3	-2265	1
max	2493	3498	652.7	0	5873	2493
median	1247	0	0	-241.7	866	1247
CV%	57.7	1576.1	1205.7	-129.5	97	58
skewness	0	15.7	16.6	-2.23	0.19	0
kurtosis	-1.2	244.8	311.2	5.5	3.8	-1.2
N	2,493	2,493	2,493	2,493	2,493	2,493

Appendix VII. Table 13. Standardized Adjusted Baseline Regression Coefficient Results for the 2006 Algorithm Dataset

Variable	b	sb
rankRisk2	1.0207*	0.0030
Risk1	0.0850*	0.0028
Risk3	0.0355*	0.0028
Risk4	0.1453*	0.0030
R-Squared	0.9803*	0.0197

*Statistic significant at $p<0.05$

Listeria monocytogenes Establishment Risk Ranking Algorithms

The development of two risk ranking algorithms is shown using the same two datasets used in baseline and adjusted baseline establishment risk ranking based on the progression of two initial *L. monocytogenes* risk ranking models.

2005 Dataset Risk Ranking Algorithm

Appendix VII Table 14 shows the raw data statistics for the 2005 dataset. Appendix VII Table 15 shows the number of establishments and total number of alternatives in each category. The data indicate that 8.1% of the establishments have more than one alternative. Because the baseline and baseline adjustment input data are not normally distributed, the robust rank regression is justified. This dataset serves as the lower limit for the number of alternatives and the number of establishments to be used for comparison with the following datasets with more establishments and alternatives represented.

Appendix VII. Table 14. Summary of Input and Output Variables for 2005 Dataset

Raw Data Statistics

Statistic	Deli Meat	Hot Dogs	Other	Q80	Risk2	RankRisk2
average	1,667,227	996,984	22,414,534	5.19E-06	4.82E+00	991
stdev	9,515,906	7,900,256	837,248,882	2.75E-06	2.71E+01	572
min	0	0	0	1.10E-08	2.72E-10	1
max	267,930,569	175,000,000	37,264,000,000	7.24E-06	4.40E+02	1,981
median	0	0	78,095	7.08E-06	2.73E-03	991
CV%	570.8	792.4	3735.3	52.9	563.1	57.7
skewness	14.5	12.5	44.5	-0.9	9.7	0
kurtosis	330.4	198	1980.1	-1	112.9	-1.2
N	1,981	1,981	1,981	1,981	1,981	1,981

Transformed Data Statistics

Statistic	Risk1	Risk3	Risk4	AdjRankRisk2	RiskRank
average	12	3	-21	986	991
stdev	154	23	24	592	572
min	0	0	-311	-248	1
max	1,981	246	0	3,673	1,981
median	0	0	-16	987	991
CV%	1281.3	708.1	-114.2	60.1	57.7
skewness	12.7	7.2	-3.3	0.2	0
kurtosis	160.5	50.6	21.1	-0.3	-1.2
N	1,981	1,981	1,981	1,981	1,981

Appendix VII. Table 15. 2005 Dataset Alternatives

Variable	Number
Establishments	1,820
Alternative1	118
Alternative2a	57
Alternative2b	397
Alternative3	1,409
Total Alternatives	1,981
Multiple Alternatives	8.1%

The full risk ranking model used for this version of the establishment *Lm* risk ranking algorithm is as follows. The ranks of the baseline risk2 variable described in the Risk2 equation are taken and then adjusted with Risk1, Risk3, and Risk4. The coefficients making up the weights for each of these risk factors are taken from Appendix VII Tables 1–3. The weight for Risk1 is equal to the number of alternatives. The weight for Risk3 is the product of the RR coefficient for the establishment alternative product volume relative risk divided by the maximum RR and 495.25 which is 25% of the total ranks of 1,981. The weight for Risk4 is 495.25 times the adjusted establishment alternative product volume RR divided by the maximum RR. The adjusted RR is the negative of the maximum RR minus 1. The month1-6 variables are the number of positive *Lm* results in the respective months for Risk3 and the number of negative *Lm* results in the respective months for Risk4.

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 1981x Risk1 + Rank Risk2 + 495.25 x RR x Risk3 / 7.0116 + 495.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.2310 x month2 + 0.2050 x month3 + 0.1910 x month4 + 0.1870 x month5 + 0.1860 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

Appendix VII Table 16 shows the standardized regression coefficients for one-stage and two-stage model for the equations described. The one-stage regression model of seven input variables does not take into account the stepwise nature of the calculation. Additionally, the deli meat, hot dog, and other RTE products variables have insignificant p-values and therefore do not seem important to the final rank output because the correlated nature of the data has not been taken into account. The two-stage model corrects these deficiencies. Appendix VII Table 16 illustrates why the two-part regression is preferred to a single regression model because of the reasons stated.

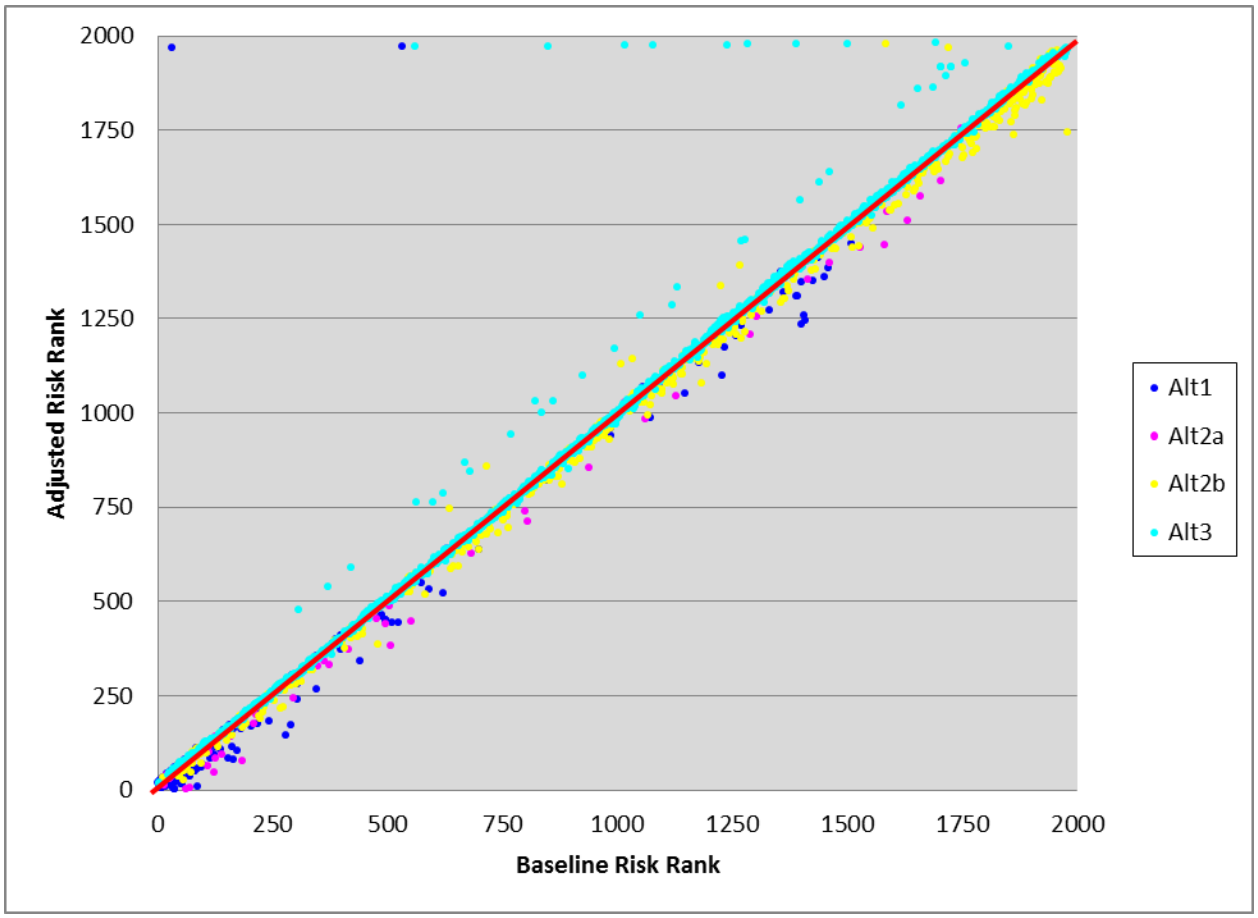
Appendix VII. Table 16. Standardized Regression Coefficients for One-Stage and Two-Stage Models with Significance in the 2005 Algorithm

One-Stage Model			Two-Stage Model		
Variable	b	S_b	Variable	b	S_b
Deli Meat	0.0038	0.0032	Deli Meat	0.8542*	0.0122
HotDog	0.0015	0.0017	HotDog	0.1473*	0.0117
Other	0.0023	0.0019	Other	0.3087*	0.0116
-	-	-	R-Squared	0.7604*	
Rank Risk2	0.9912*	0.0032	Rank Risk2	0.9950*	0.0016
Risk1	0.1228*	0.0015	Risk1	0.1229*	0.0015
Risk3	0.0462*	0.0015	Risk3	0.0462*	0.0015
Risk4	0.0298*	0.0016	Risk4	-0.0298*	0.0016
R-Squared	0.9954*	0.0046	R-Squared	0.9954*	

*Statistic significant at $p<0.05$

Appendix VII Figure 7 plots baseline risk ranks versus adjusted baseline risk ranks. This graph shows the 1,981 establishment baseline risk ranks on the diagonal red line bisecting the figure while the adjusted risk ranks appear off the diagonal line.

Appendix VII. Figure 7. 2005 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks



2006 Dataset Risk Ranking Algorithm

Appendix VII Table 17 shows the raw data statistics for the 2006 dataset. Appendix VII Table 18 shows the number of establishments and total number of alternatives in each category. More than 17% of the establishments have more than one alternative. Compared with the baseline 2005 algorithm dataset there are more establishments in each alternative and more total establishments. Because the baseline and baseline adjustment input data are not normally distributed, the robust rank regression is again justified. This dataset serves as the bootstrapped lower limit for the number of alternatives and the number of establishments to be used for comparison with the following datasets with more establishments and alternatives represented.

Appendix VII Figure 8 shows some difference from that shown in Appendix VII Figure 7 for the baseline dataset. This figure shows more dispersion on both sides of the diagonal representing the baseline establishment ranking. Establishments showing deviation from the diagonal have their risk ranking increased when above the line and their risk ranking decreased when below the line. Recall that adjustments increasing risk ranking are due to positive *Lm* sampling results. A decreased risk ranking is due to negative *Lm* sampling results.

Appendix VII. Table 17. Summary of Input and Output Variables for 2006 Dataset

Raw Data Statistics

Statistic	Deli Meat	Hot Dogs	Other	Q80	Risk2	RankRisk2
average	2,083,956	53,150	4,218	3.62E-06	4.93E+00	1,247
stdev	13,051,080	429,068	161,967	2.69E-06	3.12E+01	720
min	0	0	0	1.10E-08	2.03E-10	1
max	301,520,000	10,185,000	8,086,288	7.24E-06	5.64E+02	2493
median	0	0	20	4.65E-06	1.21E-03	1247
CV%	626.3	807.3	3,840.1	74.3	632.2	57.7
skewness	14.87	13.15	49.9	0.03	11.1	0
kurtosis	298.38	219.23	2,490.89	-1.52	146.33	-1.2
N	2,493	2,493	2,493	2,493	2,493	2,493

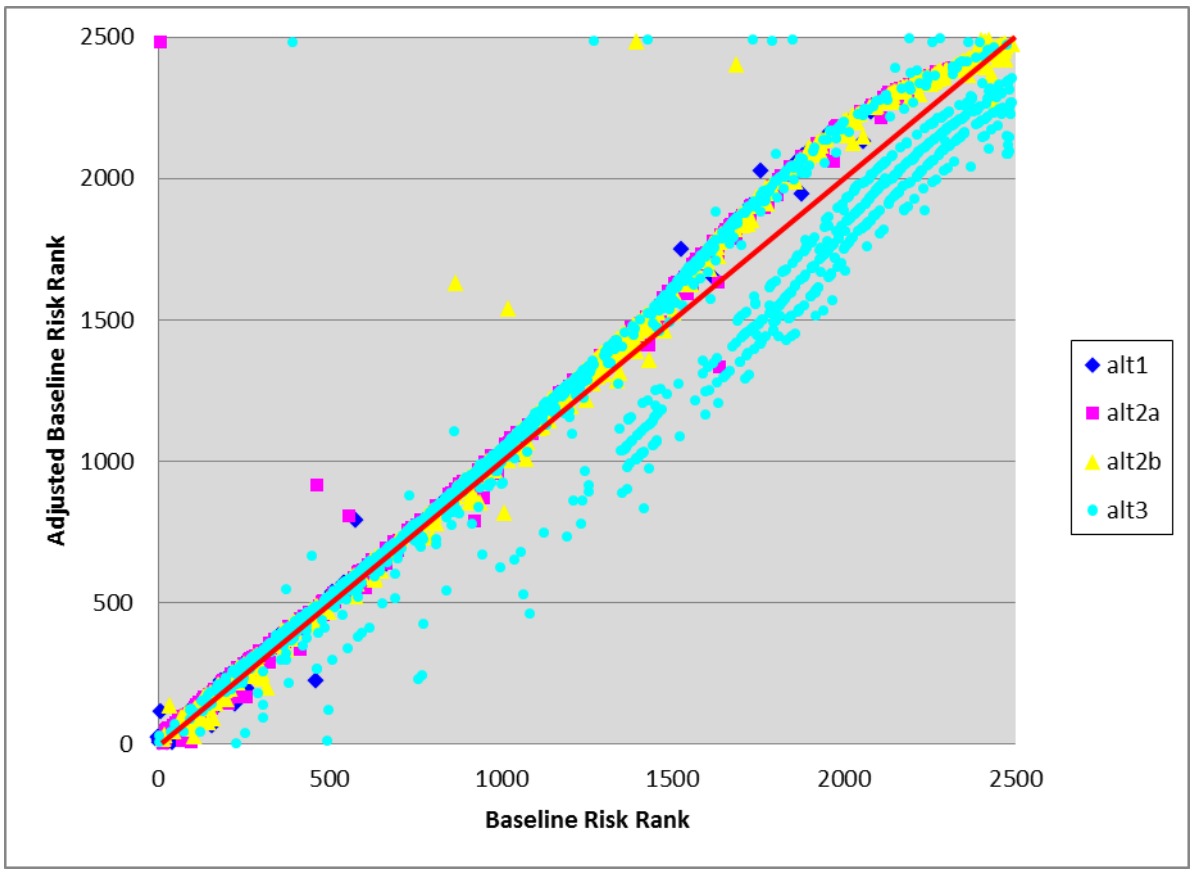
Transformed Data Statistics

Statistic	Risk1	Risk3	Risk4	AdjRankR2	RiskRank
average	14	2	-440	832	1,247
stdev	221	29	570	807	720
min	0	0	-3,729.3	-2,265	1
max	3,498	652.7	0	5,873	2,493
median	0	0	-241.7	866	1,247
CV%	1,576.1	1,205.7	-129.5	97	58
skewness	15.7	16.62	-2.23	0.19	0
kurtosis	244.8	311.15	5.45	3.78	-1.2
N	2,493	2,493	2,493	2,493	2,493

Appendix VII. Table 18. 2006 Dataset Establishment Alternative Numbers

Variable	Number
Establishments	2,067
Alternative1	125
Alternative2a	313
Alternative2b	654
Alternative3	1,401
Total Alternatives	2,493
Multiple Alternatives	17.1%

Appendix VII. Figure 8. 2006 Algorithm Baseline versus Adjusted Baseline Establishment Risk Ranks



The risk ranking equations used are shown below. In this instance, Appendix VII Table 19 shows that the two-stage model and all input variables are significant. The model accounts for more than 97% of the rank variance, but the regression coefficients feeding into Rank2 are of the same or less magnitude than the baseline risk adjustment factors. Because the signs are negative and not positive for Deli Meat and Other RTE products they do not make sense as negative contributors to the final risk ranking. This is another reason supporting the use of a two-part rank regression model.

The equations used for the 2006 algorithm are:

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 2,493x Risk1 + Rank Risk2 + 623.25 x RR x Risk3 / 7.0116 + 623.25 x Risk4 x (RR- 7.0116 – 1) / 7.01156

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/28

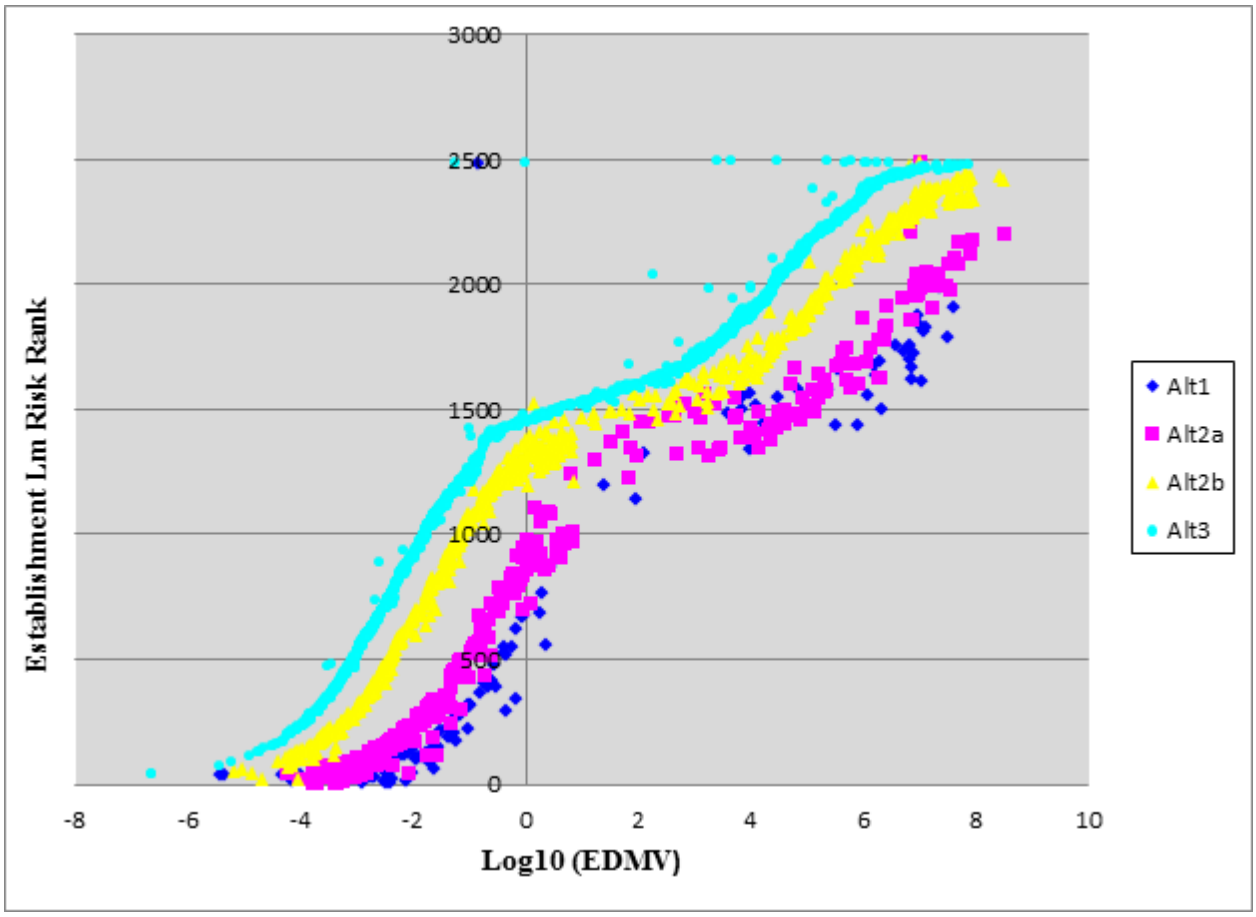
Appendix VII. Table 19. Standardized Rank Regression Coefficients for the One-Stage and Two-Stage 2006 Algorithm

One-Stage Model			Two-Stage Model		
Variable	b	sb	Variable	b	sb
Deli Meat	-0.0198*	0.0095	Deli Meat	0.8528*	0.0134
Hot Dog	0.0109*	0.0046	Hot Dog	0.1828*	0.0176
Other	-0.0239*	0.0051	Other	0.2504*	0.0164
-	-	-	R-Squared	0.8014*	
rankRisk2	1.0349*	0.0098	Rank Risk2	1.0079*	0.0036
Risk1	0.0852*	0.0274	Risk1	0.0643*	0.0228
Risk3	0.0443*	0.0101	Risk3	0.0224*	0.0049
Risk4	0.1842*	0.0059	Risk4	0.0384*	0.0030
R-Squared	0.9721*		R-Squared	0.9955*	

*Statistic significant at $p<0.05$

Appendix VII Figure 9 shows some similarity between the same plots for the 2005 and 2006 datasets. Alternative 1 has the lowest risk ranks and alternative 3 has the highest risk ranks with alternative 2a and 2b being intermediate for both datasets. There is an obvious change in trend for alternatives with EDMV less than one. This is because the majority of establishments added to the 2005 dataset were in the low RTE product risk category that caused the trend to change in the lower EDMV range.

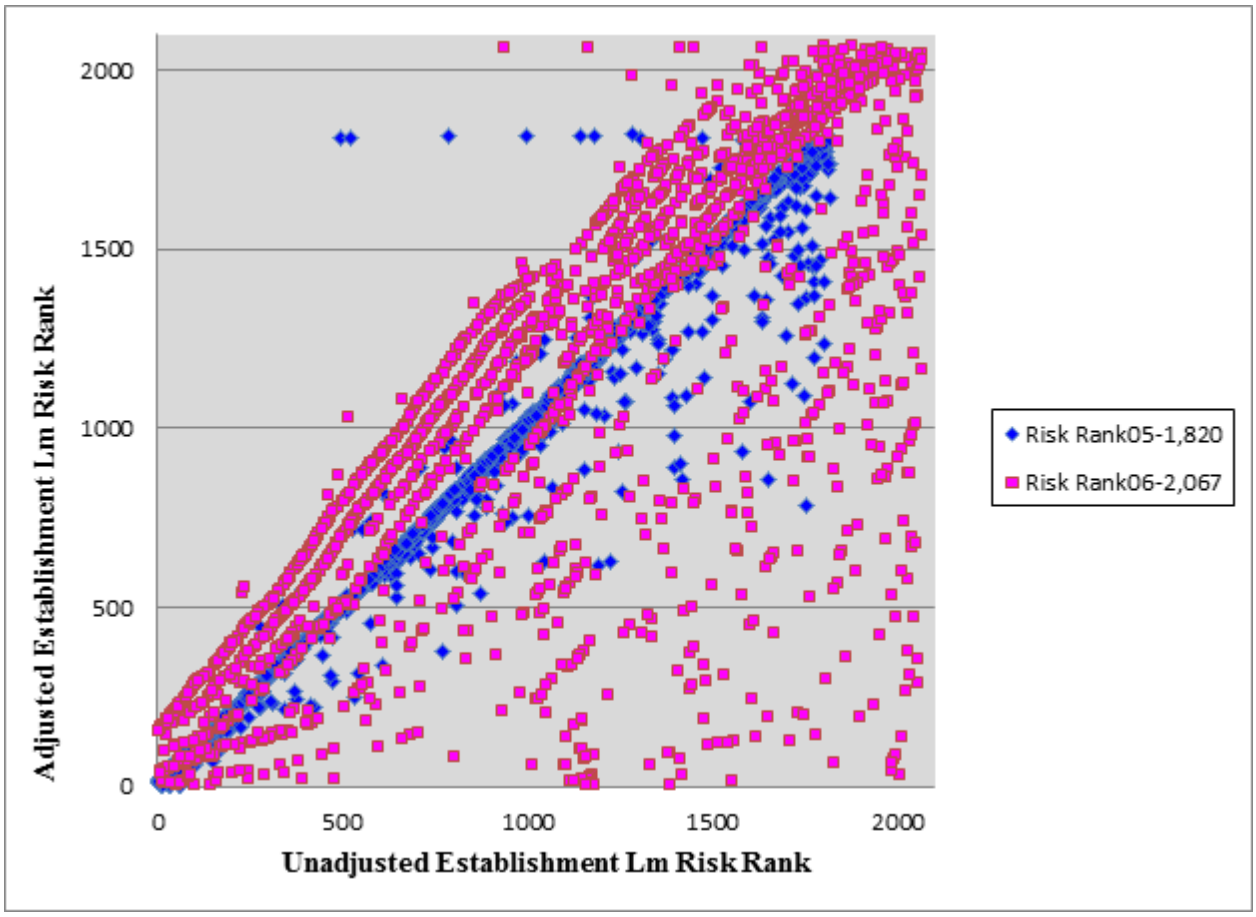
Appendix VII. Figure 9. 2006 Algorithm Adjusted Baseline Establishment Risk Ranks versus Log10 of EDMV (n=2,493)



Establishment Lm Risk Rank

The *L. monocytogenes* establishment risk rank is determined by ranking the establishment adjusted Risk2 ranks that are calculated for each establishment's baseline alternative product volume subset. The adjusted ranks have to be ranked again because they are no longer ordinal integers. This is accomplished by summing the ranks over establishment alternatives before the final establishment ranking and then ranking the summed establishment ranks. By performing the establishment ranking in this way, establishment laboratory results can be collected to perform the Risk2 adjustment by alternative. This achieves the same final establishment risk ranking as when the establishment sum is done on Risk2 or on the sum of Risk2 ranks. The final adjustment can be done either by establishment or by establishment alternative with the same result. Appendix VII Figure 10 shows the 2005 and 2006 Lm risk ranking algorithm dataset results for adjusted baseline ranks versus baseline ranks by individual establishments. The 2006 data shows that the magnitude of adjustment for historical results is larger than for 2005 data. This mainly due to the fact that the 2006 dataset added substantially more low risk establishments than were in the 2005 dataset.

Appendix VII Figure 10. Baseline versus Adjusted Baseline for 2005 and 2006 Establishment *Lm* Risk Ranking Algorithm Datasets – Ranks Correspond to Individual Establishments



Appendix VIII. Sensitivity Analysis

L. monocytogenes Risk Ranking Model Sensitivity Analysis

Sensitivity analysis is a kind of uncertainty analysis used to identify the variables in the risk ranking model that are most important to the outcome variable estimate. The outcome variable is the establishment *L. monocytogenes* (Lm) risk rank and the input variables are those described in appendix VII for the two *L. monocytogenes* risk ranking algorithm models characterized on two datasets. This appendix identifies the input variables that are most important to determining the risk outcome for each risk model. Even though a given input variable may show a large effect on the output risk ranking it still may not be significant in the rank regression model analysis (it may not have a significant p-value) due to extreme variability. A test is considered significant with a p-value of less than 0.05. This appendix only addresses sensitivity of the output risk ranking to individual input variables. The significance of the individual input variable variability in relation to uncertainty is addressed in Appendix IX. The models are analyzed by selecting components or subcomponents of baseline risk factors and adjusted baseline risk factors. The sensitivity analysis model used in each case is the standardized linear regression model on the transformed input and output variables as ascending ranks.

The method used for finding the standardized regression coefficients (b) and their standard errors (S_b) is as follows. Each one of the input and output variables are transformed into an ascending rank distribution of ordinal risk ranks. The highest risk establishment has the highest rank. The matrix of input and output variables is transformed into a Spearman rank correlation matrix. As shown in equation (1), the inverse of the correlation matrix of the input variables $(R_{xx})^{-1}$ is multiplied by the column vector of the output correlations with the input variables (R_{xy}). This product equals the column vector of standardized regression coefficients (b).

The standardized regression coefficient variability for b (S_b) is found from taking the square root of the error mean square (EMS) of the standardized regression multiplied by the associated square root of the diagonal element of the inverse input variable correlation matrix $(R_{xx})^{-1}$ (equation 2). In matrix terms the formulas are given below, where the x subscript refers to input variables and the y subscript refers to the output variable and R is the Spearman rank correlation matrix:

(1) $b = (R_{xx})^{-1}R_{yx}$
(2) $S_b = \sqrt{\{EMS\ (R_{xx})^{-1}\}}$

The standardized Spearman regression coefficients are adjusted with the inverse standardized Spearman correlation matrix. These adjusted coefficients provide a more accurate description of the effect of individual input risk variables on the output risk ranking than the independently derived rank correlations. The standardized regression coefficients are proportional measures of

input risk impact on output risk ranking. The sensitivity of the risk ranking to standard unit change in input risk variable is defined in standardized regression coefficient units.

The sensitivity associated with each input variable is shown graphically in three types of charts. The first chart is a horizontal bar chart. Input variables with greatest sensitivity are at the top of the figures. The second type of graphic is a spider chart showing the unit change in the output rank variable when changing each input variable one at a time in standardized units from the base value of each input variable. In the spider chart, the greater the slope of an input risk variable the greater the sensitivity. The third type of graphic is given as a tornado plot of the magnitude of the effect of each input risk variable on the standardized risk rank output. This graphic shows how wide a range of unit output ranks is affected with a standard unit change in input risk variable. Input risk variables with greatest sensitivity are at the top of the tornado plot.

All the statistics in this appendix and plots are derived from the standardized rank regression analysis that are based on bootstrap estimates. The bootstrap estimates are minimum variance unbiased estimators (MVUE) derived as particular U-statistics specific for this analysis (Hoeffding W, 1948). This is a consequence of the resampling done on each dataset. The base dataset has 1,981 rows of data. This is taken as the standard bootstrap sample size that is applied to the 2006 dataset. The bootstrap resampling only coincides with a standard bootstrap sample equal to the size of the alternative population in the 2005 dataset where resampling can be done with a sample size of 1,981. The resampling rate is 100% for the 2006 dataset.

2005 Dataset Algorithm

Baseline Risk Ranking

The 2005 dataset is the standard of comparison for the 2006 dataset. This algorithm has three baseline input variable components described by equation (3).

(3) Risk 2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

The three components are additive and sum to Risk 2, the baseline risk. The Q80 quantiles in equation (1) eliminate the product and size indexes for simplicity. The sensitivity analysis uses rank regression on the ranks of the input and output variables. The magnitude of the standardized regression coefficients and their associated errors indicate the variable sensitivity ranking and the variability of the input and output variables shown in Appendix VIII Figures 1 through 3.

Appendix VIII Figure 1 shows the order of sensitivity in terms of a horizontal bar plot as Deli Meat > Other RTE products > Hot Dogs. The variability of each component is significant in the regression due to the small error component (S_b). Related significance tests for uncertainty also are shown in Appendix IX. Appendix VIII Figure 2 shows the sensitivity of the input variables in terms of a spider plot. Sensitivity was assessed by independently changing each input variable from

its base value and evaluating the slope of each input variable as a function of percentage change from base on the output risk rank variable in standardized units. This spider plot reaffirms that the order of sensitivity as Deli Meat > Other RTE products > Hot Dogs based on slope magnitude.

Appendix VIII Figure 3 shows the sensitivity of each input variable on the output risk rank variable in terms of a tornado plot where the bootstrap variability limits of each input distribution represented as the length of the tornado's horizontal bars are equal to the magnitude of change in the output risk rank distribution. The same sensitivity order is again shown to be: Deli Meat > Other RTE products > Hot Dogs.

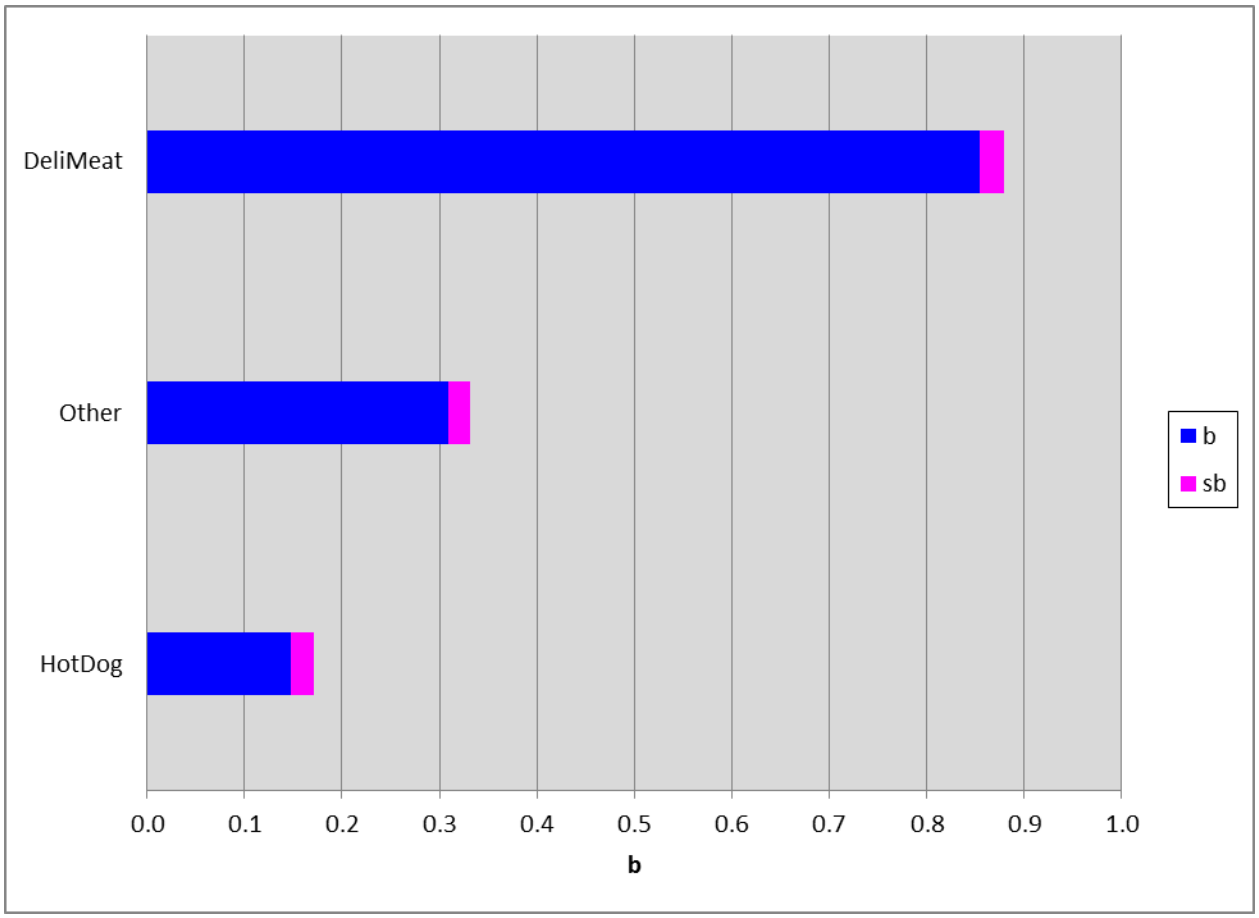
Appendix VIII Table 1 shows that there is no statistical difference between the bootstrapped and not-bootstrapped regression coefficients, but there is a difference between the error estimates. The R-squared statistic that represents the proportion of the total variance explained by the regression model is larger for the bootstrapped estimates and the error estimates of the input risk factors are also larger for the bootstrapped estimates. The appendix on uncertainty analysis will address the issue of these apparent differences in error estimation.

Appendix VIII. Table 1. Not-Bootstrapped and Bootstrapped Baseline Rank Regression Coefficients for 2005 Dataset

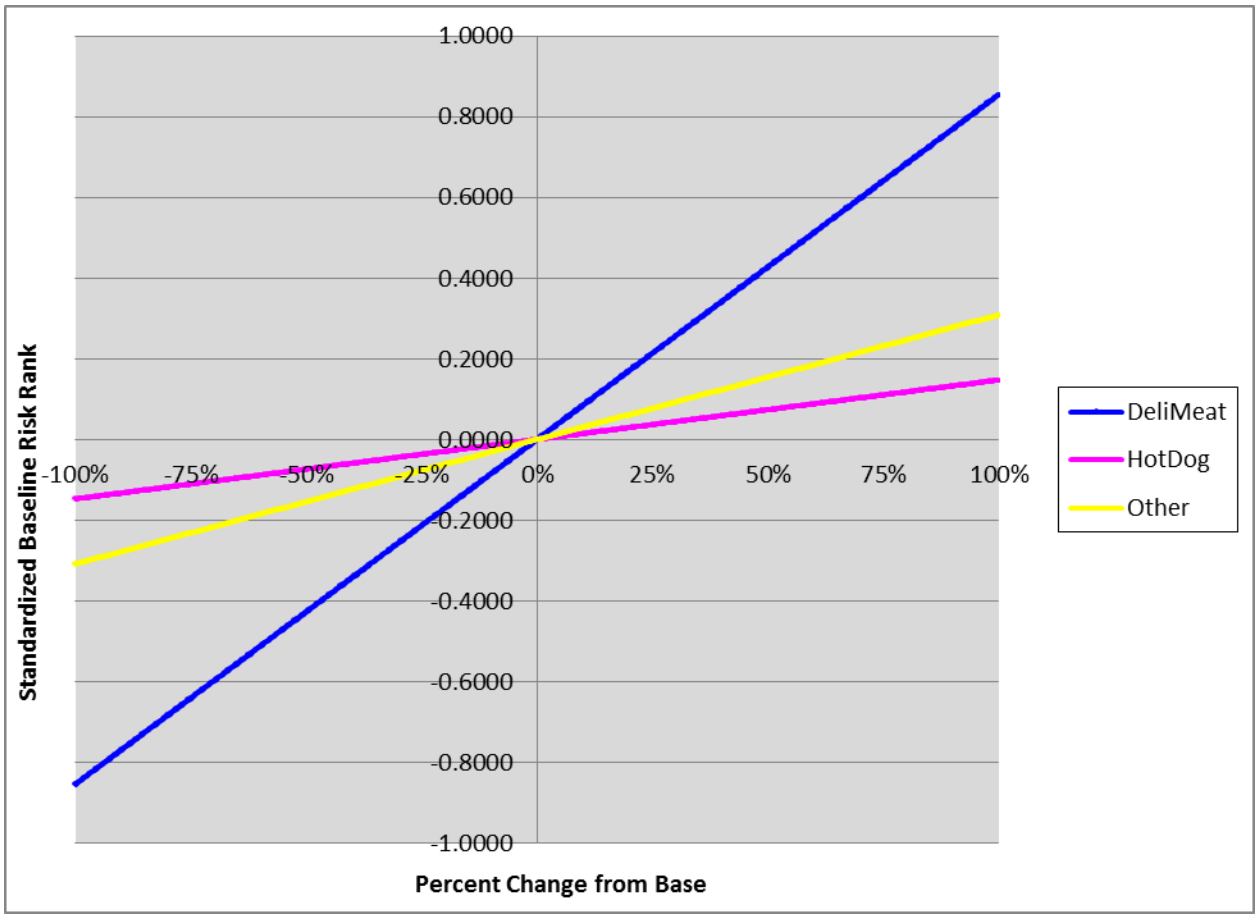
	Not-Bootstrapped		Bootstrapped	
Variable	b	sb	b	sb
Deli Meat	0.8542*	0.0122	0.8542*	0.0156
HotDog	0.1473*	0.0117	0.1474*	0.0187
Other	0.3087*	0.0116	0.3102*	0.0177
R-Squared	0.7604*	0.2389	0.7611*	0.2389

*Significant regression coefficient component

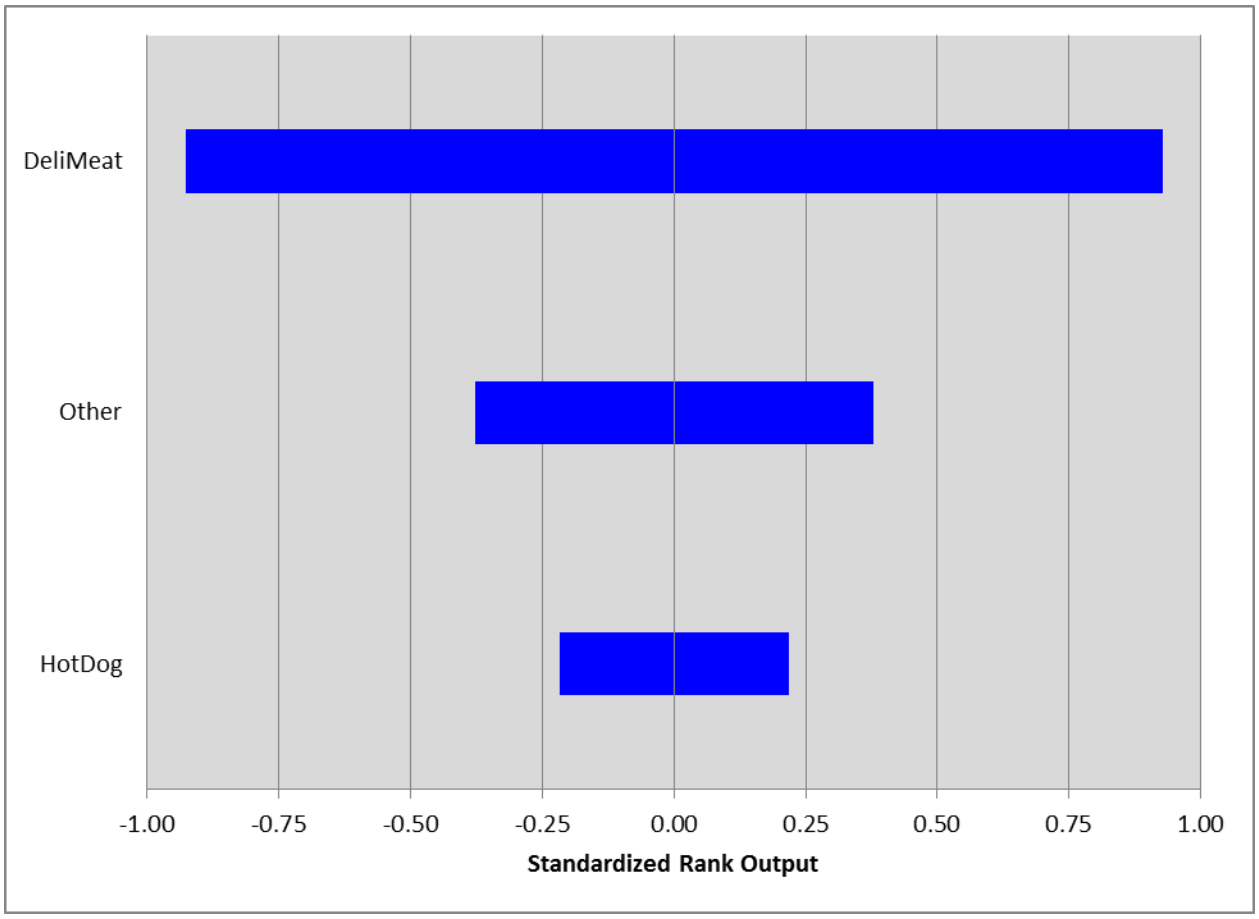
Appendix VIII. Figure 1. Sensitivity of Baseline Input Variables—Horizontal Error Bar Plot, 2005 dataset



Appendix VIII. Figure 2. Sensitivity of Baseline Input Variables—Spider Plot, 2005 dataset



Appendix VIII. Figure 3. Sensitivity of Baseline Risk Rank Output Variable—Tornado Plot, 2005 dataset



Adjusted Listeria monocytogenes Establishment Risk Ranking

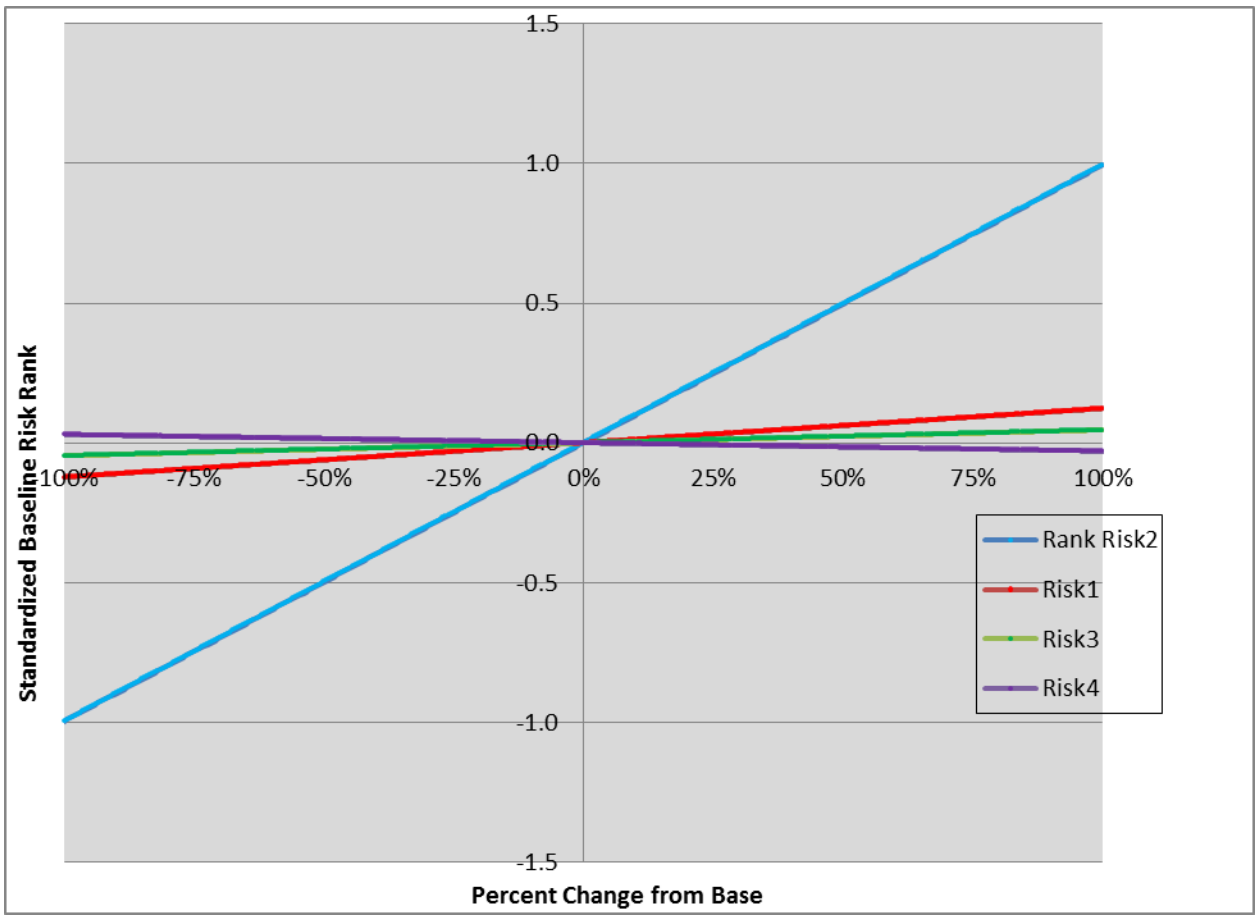
Appendix VIII Table 2 shows the significance of rank regression for adjusted baseline input variables. All input variables also are significant. The plot of the variable sensitivities is shown in Appendix VIII Figure 4. The order of sensitivity is: Rank of Risk2 > Risk1 > Risk3 > Risk4.

Appendix VIII. Table 2. Not-Bootstrapped and Bootstrapped Adjusted Baseline Rank Regression Coefficients for 2005 Dataset

	Not-Bootstrapped			Bootstrapped	
Variable	b	S_b	Variable	b	S_b
Rank Risk2	0.9950*	0.0016	RankRisk2	0.9957*	0.0036
Risk1	0.1229*	0.0015	R1	0.1227*	0.0259
Risk3	0.0462*	0.0015	R3	0.0460*	0.0041
Risk4	-0.0298*	0.0016	R4	0.0297*	0.0019
R-Squared	0.9954*	0.0046	R-Squared	0.9960*	0.0040

*Significant regression coefficient component

Appendix VIII. Figure 4. Sensitivity of Adjusted Baseline Input Variables—Spider Plot, 2005 Dataset



L. monocytogenes Establishment Risk Ranking Algorithm

2006 Dataset Algorithm

This dataset examines the risk factor component, subcomponent variability, and uncertainty. The *L. monocytogenes* risk ranking model includes 37 subcomponents for the 2006 algorithm version. This section examines the feasibility of using an aggregated subcomponent risk factor model rather than the full component model.

One-Stage Risk Component Analysis

Initial model development required a complete analysis of all the input components. Because there are 12 combinations of alternative and volume production for each establishment applied across four risk variables equaling 48 possible categories, some assessment of the usefulness in doing a completely portioned analysis was necessary. The 2006 dataset provided a way to simplify the fully partitioned model based on the limited data for the Risk1 variable. This reduced the number of

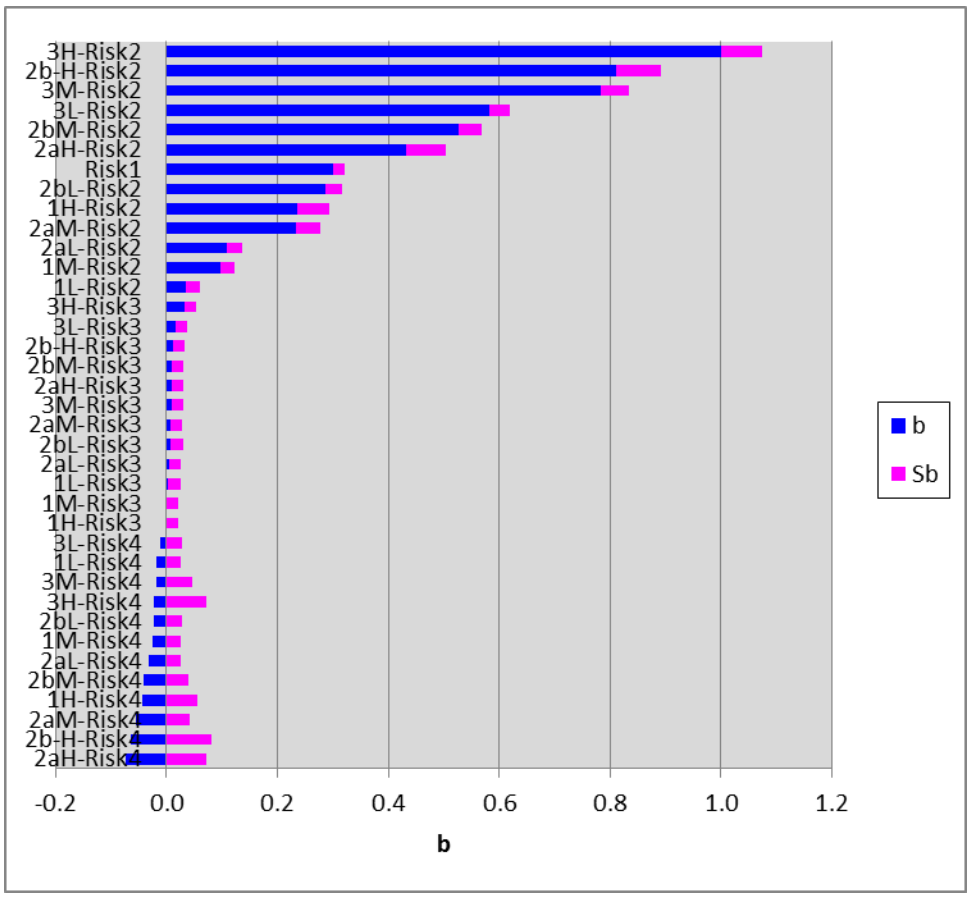
partition components to 37. Appendix VIII Table 3 shows the variable names and non-bootstrapped standardized regression coefficients. The first element of the risk subcomponent names is for alternative (1, 2a, 2b, and 3), the second element is for volume size (H-high, M-medium, L-low), and the last element is for risk component (Risk1, Risk2, Risk3, and Ris4). Risk1 has no subcomponents. Only twelve of the risk subcomponent coefficients are significant. Appendix VIII Figure 5 shows the horizontal bar plot for this data. The component variables for Risk1 and Risk2 proved the most sensitive. Due to the large number of input variables, most of the input variables became insignificant even though the R-square statistic was 0.999749 explaining nearly 100% of the total risk rank variance. This can occur when an excessive number of explanatory variables are entered in a multiple regression model, which over parameterizes it. Appendix VIII Figure 6 tornado plot illustrates the risk rank output extremes due to each input variable. Only twelve of these variables are significant and the rest have negligible effect even though in a simpler model with fewer input variables some of these risk factors would have a significant effect. The spider plot of the data in Appendix VIII Table 3 appears in the main body of this report.

Appendix VIII. Table 3. Component Baseline and Adjusted Baseline Rank Regression Coefficients for 2006 Algorithm Dataset

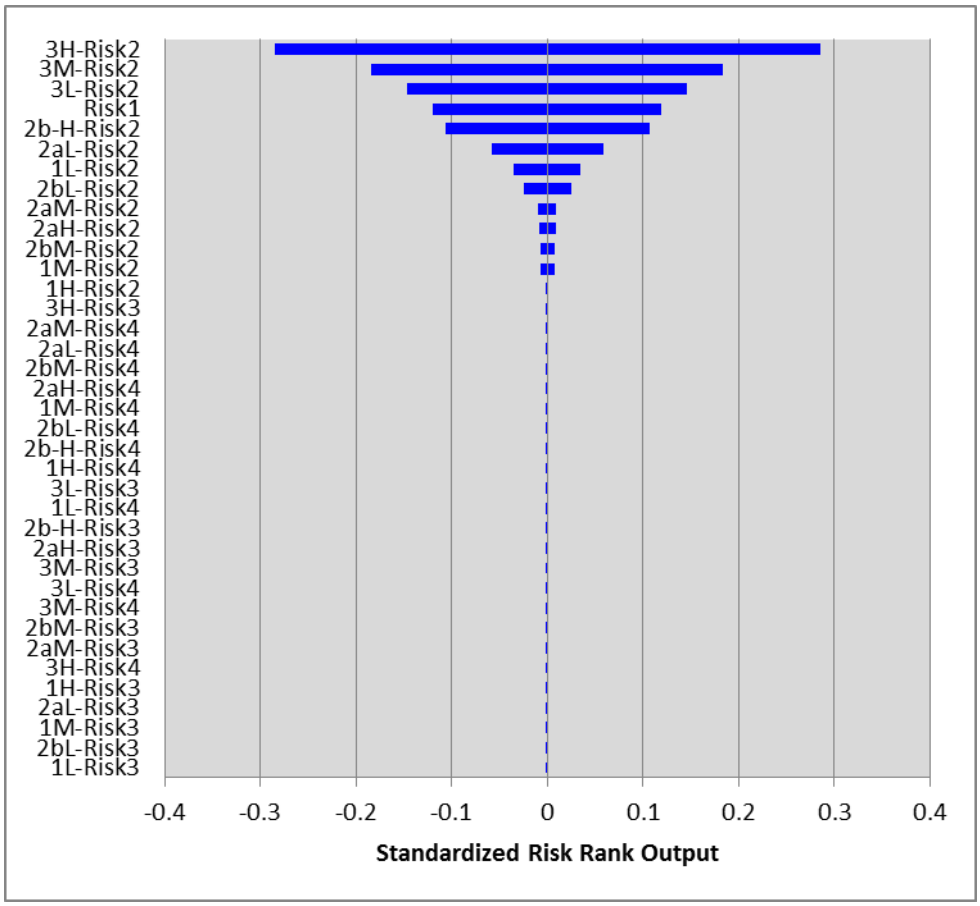
Input	b	Sb	Input	b	Sb	Input	b	Sb
Risk1	0.3005*	0.0211	1H-Risk3	0.0000	0.0219	1M-Risk4	-0.024	0.0258
1H-Risk2	0.2350*	0.0574	1M-Risk3	0.0000	0.0214	1L-Risk4	-0.019	0.0251
1M-Risk2	0.0964*	0.0266	1L-Risk3	0.0035	0.0214	2aH-Risk4	-0.075	0.0709
1L-Risk2	0.0343	0.0257	2aH-Risk3	0.0095	0.0210	2aM-Risk4	-0.055	0.0419
2aH-Risk2	0.4326*	0.0716	2aMRisk3	0.0081	0.0209	2aL-Risk4	-0.032	0.0258
2aM-Risk2	0.2331*	0.0435	2aL-Risk3	0.0048	0.0210	2b-H-Risk4	-0.064	0.0806
2aL-Risk2	0.1090*	0.0273	2bH-Risk3	0.0108	0.0209	2bM-Risk4	-0.042	0.0389
2bH-Risk2	0.8102*	0.0822	2bMRisk3	0.0096	0.021	2bL-Risk4	-0.024	0.0271
2bM-Risk2	0.5268*	0.0427	2bL-Risk3	0.0077	0.0215	3H-Risk4	-0.022	0.0711
2bL-Risk2	0.2875*	0.0293	3H-Risk3	0.0329	0.0213	3M-Risk4	-0.019	0.0457
3H-Risk2	1.0010*	0.0743	3M-Risk3	0.0094	0.0210	3L-Risk4	-0.012	0.0271
3M-Risk2	0.7832*	0.0505	3L-Risk3	0.0155	0.0209			
3L-Risk2	0.5826*	0.0364	1H-Risk4	-0.0434	0.0561			

*Significant regression coefficient component

Appendix VIII. Figure 5. Sensitivity of Component Baseline and Adjusted Baseline Input Variables—Horizontal Bar Plot, 2006 Dataset



Appendix VIII. Figure 6. Sensitivity of Component Baseline and Adjusted Baseline Input Variables—Tornado Plot, 2006 Dataset



Appendix VIII Table 4 where Risk1, Risk3, and Risk4 are entered in the regression model as single components, but baseline Risk2 is entered as four additional components. Although the regression is significant, individual risk components that should be significant do not test significantly. The problem is that the model itself is partitioned into two parts and does not lend itself to rank regression for the full one-stage model. This is because the first part of the model is for baseline establishment risk ranking determined by the ranks of deli meat, hot dogs, and other RTE products. The second part of the model is for the adjustment of the baseline establishment risk ranking by Risk1, 3, and 4 as ranks while the baseline (Risk2) is defined independently of the adjustment ranks. The independence of the two model parts is lost when the model is collapsed into one part.

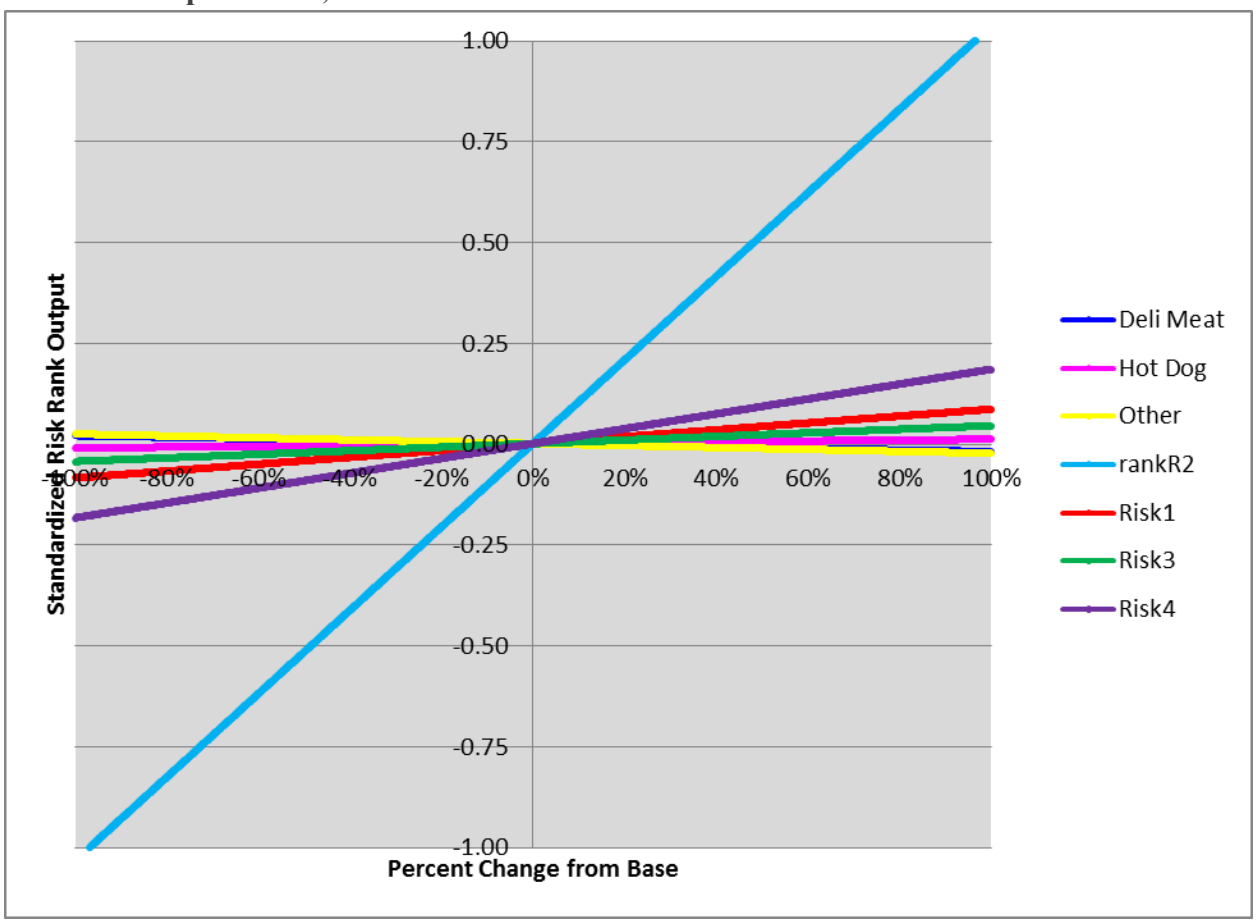
Appendix VIII Figures 7 and 8 illustrates the problem. The adjustment factors for the ranks of Risk2 have secondary impact while the components of baseline Risk2 (deli meat, hot dogs, and other) have negligible impact even though they are essential to the calculation of Risk2. Additionally Appendix VIII Table 4 shows deli meat and other variables to have negative signs indicating they decrease risk rather than increase it in the one-stage model. This is contrary to reason and evidence that the two-stage model is to be preferred.

Appendix VIII. Table 4. One-Stage Baseline and Adjusted Baseline Rank Regression Bootstrapped Coefficients for 2006 Algorithm Dataset

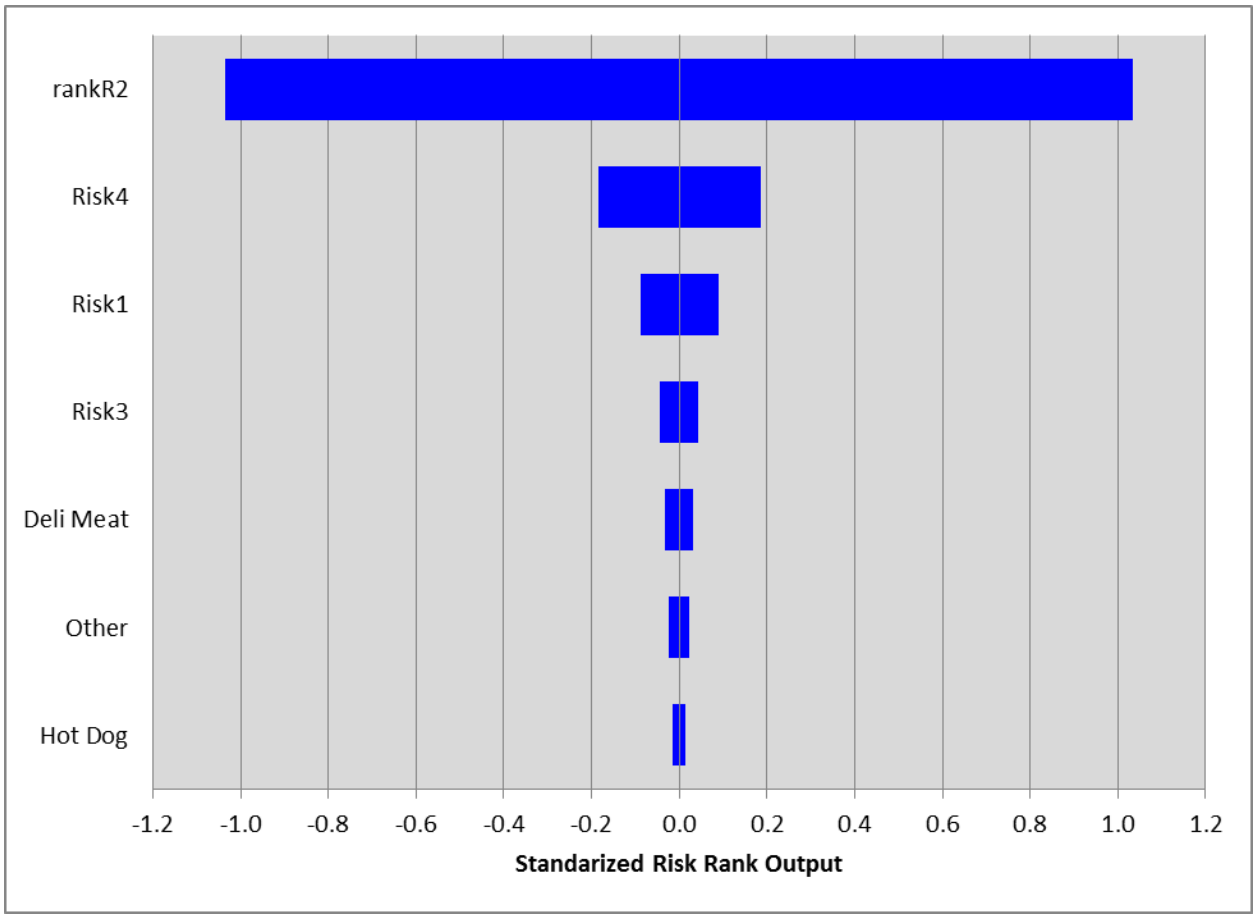
Variable	b	sb
Deli Meat	-0.0198	0.0190
Hot Dog	0.0109	0.0091
Other	-0.0239	0.0102
rankR2	1.0349*	0.0196
Risk1	0.0852*	0.0548
Risk3	0.0443*	0.0202
Risk4	0.1842*	0.0118
R-Squared	0.9721*	

*Significant regression coefficient component

Appendix VIII. Figure 7. Sensitivity of One-Stage Baseline and Adjusted Baseline Input Variables—Spider Plot, 2006 Dataset



Appendix VIII. Figure 8. Sensitivity of One-Stage Baseline and Adjusted Baseline Input Variables—Tornado Plot, 2006 Dataset



Two-Stage Risk Component Analysis

This section replicates the two-stage analysis used for the 2005 dataset. Stage-one estimates the establishment *L. monocytogenes* baseline risk ranks and stage-two estimates the adjusted establishment *L. monocytogenes* risk ranks. The two-stage analysis is followed throughout Appendix VIII and IX as the model of choice.

Baseline Risk Ranking

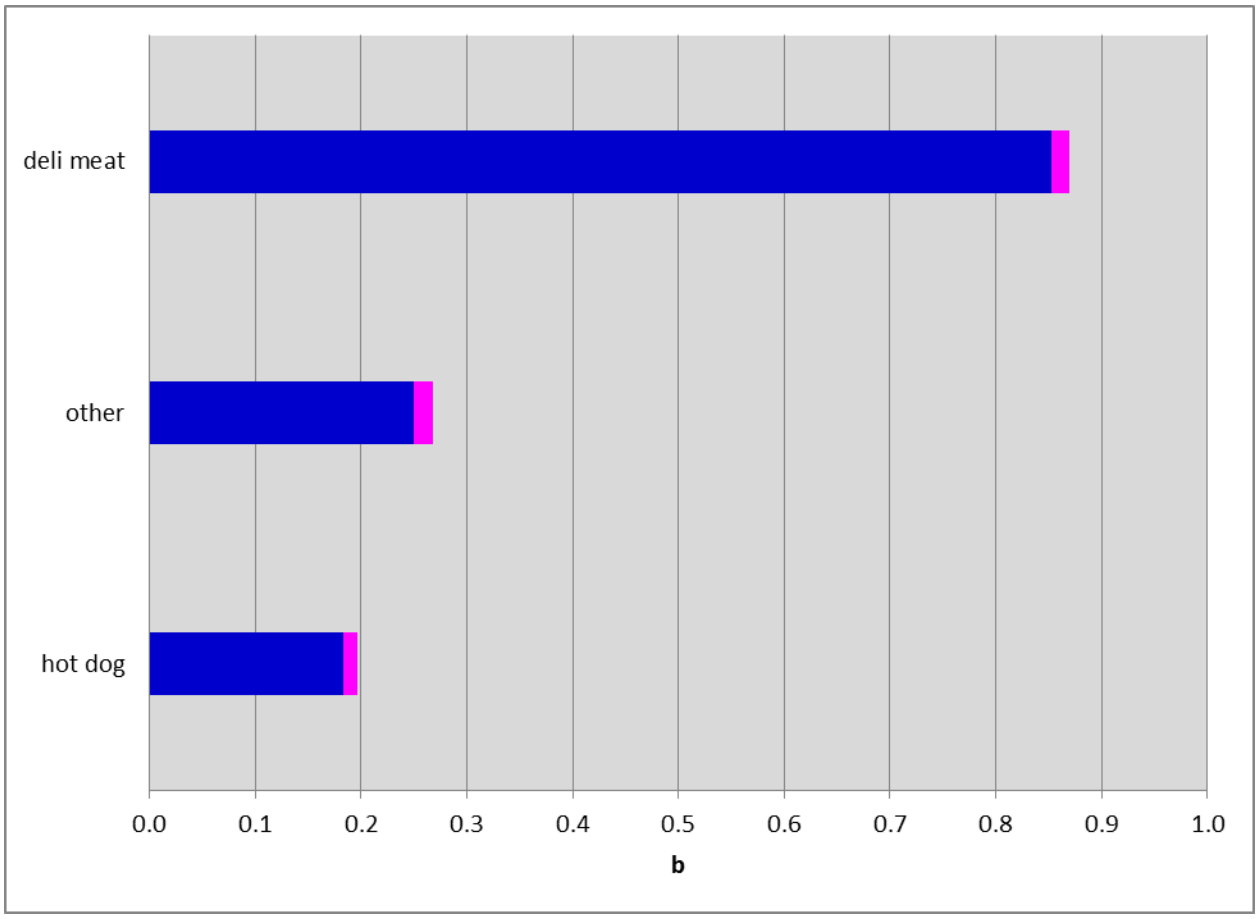
The baseline rank regression is significant and the three risk factors in the regression are also significant. The order of sensitivity is: Deli Meat > Other RTE products > Hot Dogs as shown in Appendix VIII Table 5. Other RTE products are apparently more sensitive than the higher risk hot dog products because of the greater mass of other RTE products relative to the mass of hot dogs. The horizontal bar plot in Appendix VIII Figure 9 shows the same relative ordering of risk components in terms of relative magnitude for the rank regression coefficients. The spider plot in Appendix VIII Figure 10 shows the same relative ordering of slope factors (unit rate of change in baseline ranks per unit change in input risk factor) therefore illustrating the relative greatest impacts on baseline risk rank output. The tornado plot in Appendix VIII Figure 11 shows the same ordering of risk component absolute effect on the magnitude of the baseline risk rank output.

Appendix VIII. Table 5. Bootstrapped Baseline Rank Regression Coefficients for 2006 Dataset

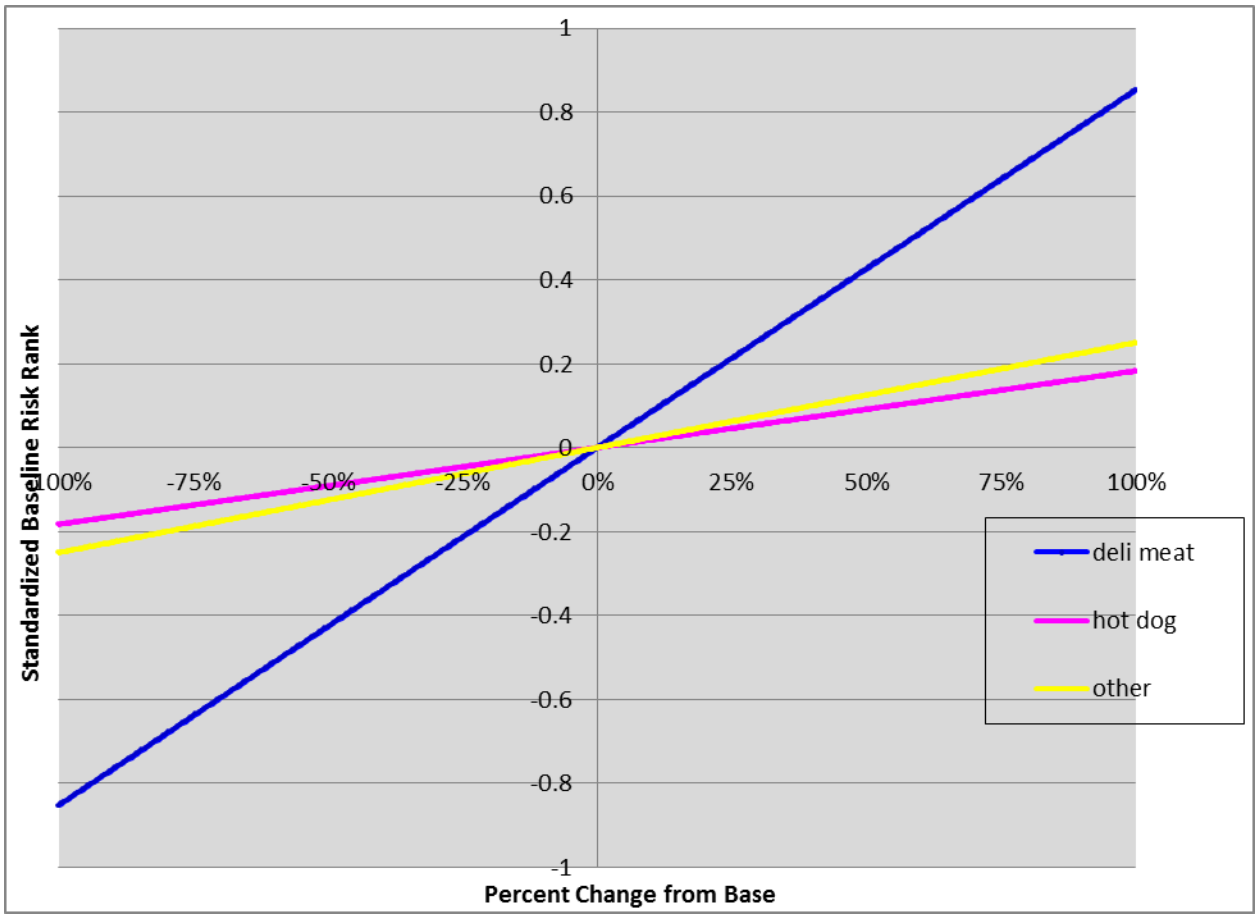
Variable	b	sb
Deli Meat	0.8542*	0.0122
HotDog	0.1473*	0.0117
Other	0.3087*	0.0116
R-Squared	0.7604*	

*Significant regression coefficient component

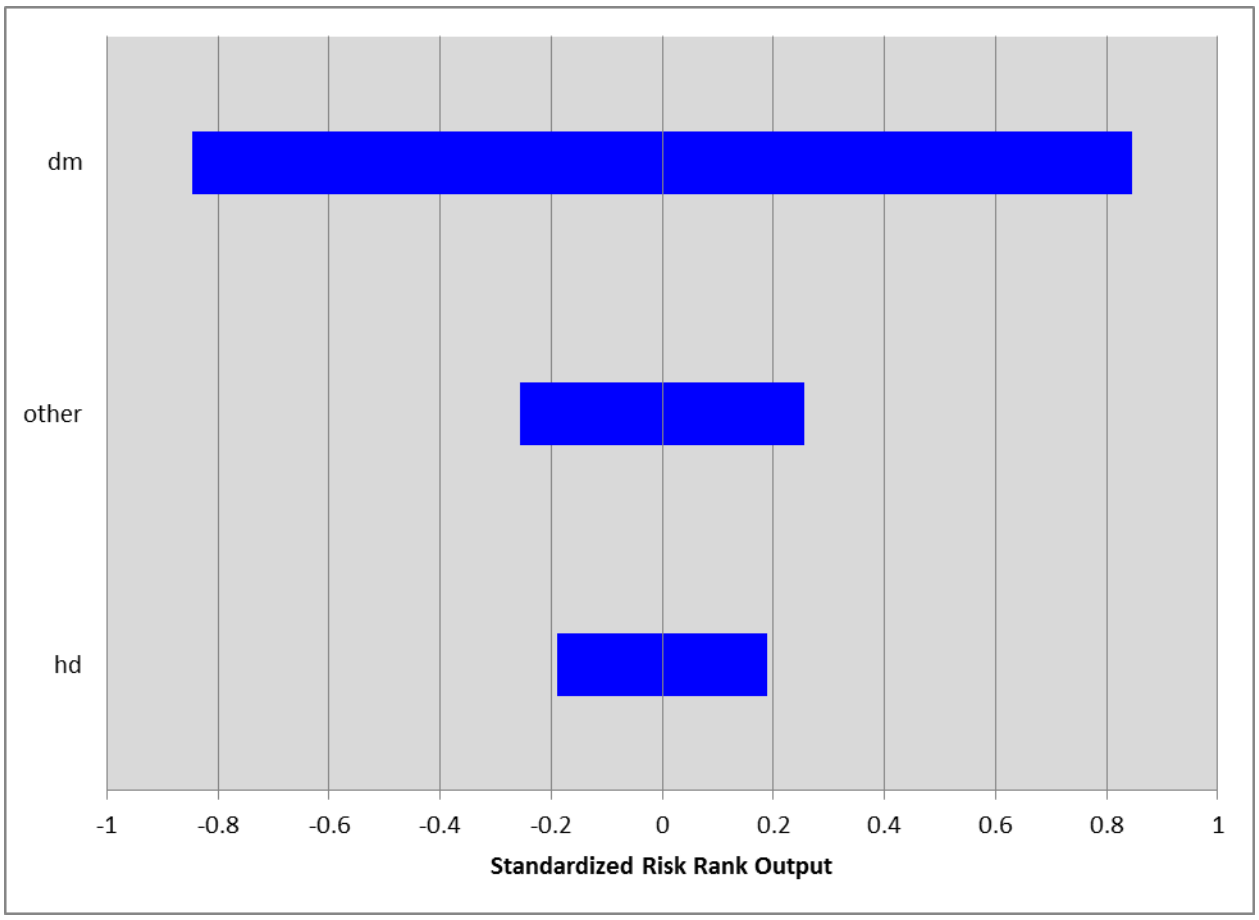
Appendix VIII. Figure 9. Sensitivity of Baseline Input Variables—Horizontal Bar Plot, 2006 Dataset



Appendix VIII. Figure 10. Sensitivity of Baseline Input Variables—Spider Plot, 2006 Dataset



Appendix VIII. Figure 11. Sensitivity of Baseline Input Variables—Tornado Plot, 2006 Dataset



Adjusted L. monocytogenes Establishment Risk Ranking

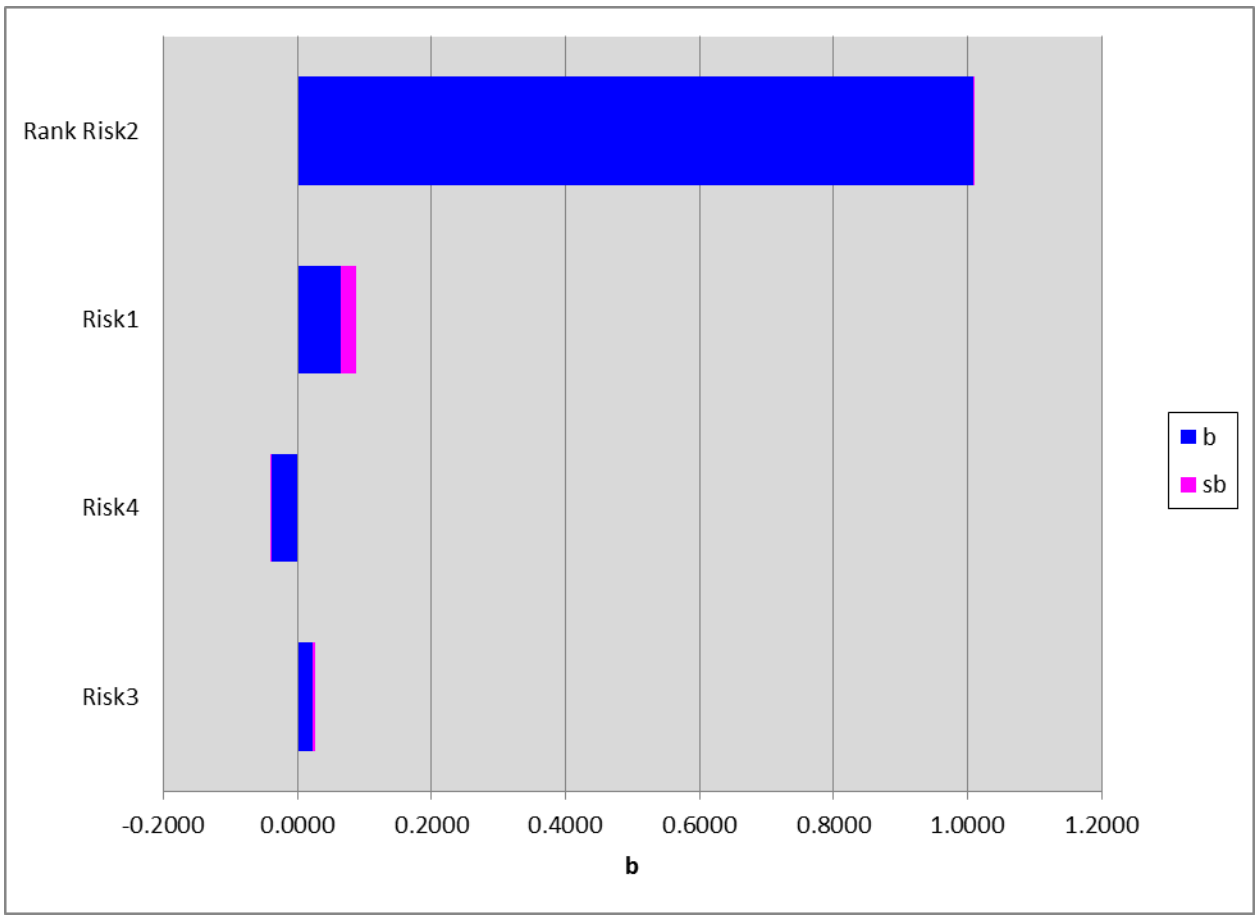
The adjusted baseline rank regression is significant and the four risk factors in the regression also are significant. The order of the absolute value of sensitivity (b) is: Rank Risk2 > Risk1 > Risk4 > Risk3 as shown in Appendix VIII Table 6. There is nearly an equivalence of the Risk3 with Risk4 effects. This occurs because Risk3 increases the establishment risk ranking for poor historical performance and Risk4 decreases the establishment risk ranking for good performance. The horizontal bar plot in Appendix VIII Figure 12 shows the same ordering of risk component magnitude for the rank regression coefficients. The spider plot in Appendix VIII Figure 13 shows the same ordering of slope factors (unit rate of change in baseline ranks per unit change in input risk factor) showing the individual component rates of impact on the baseline risk rank output. The tornado plot in Appendix VIII Figure 14 shows the same relative ordering of absolute effects on the magnitude of the baseline risk rank output.

Appendix VIII. Table 6. Bootstrapped Adjusted Baseline Rank Regression Coefficients for 2006 Dataset

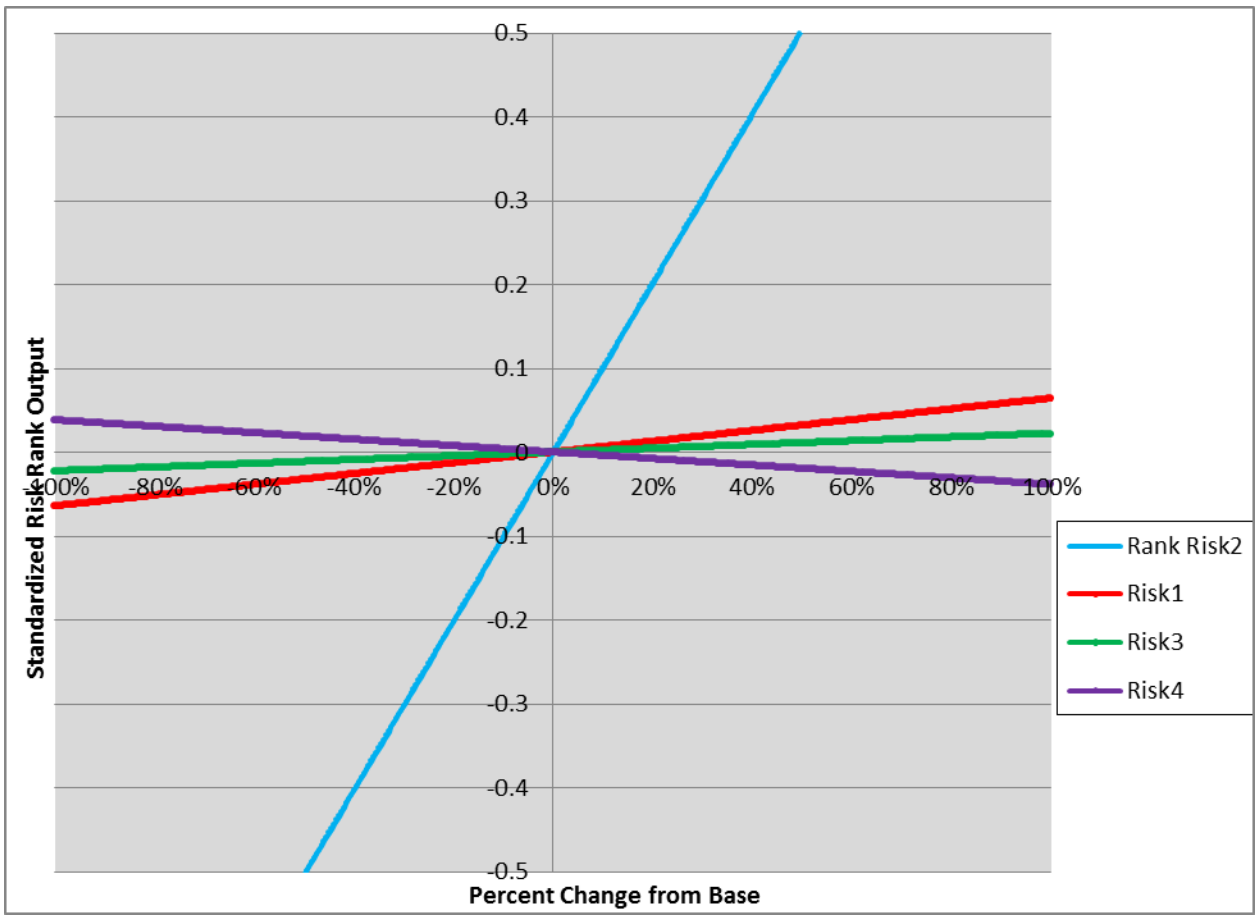
Variable	b	sb
Rank Risk2	1.0079*	0.0036
Risk1	0.0643*	0.0228
Risk3	0.0224*	0.0049
Risk4	-0.0384*	0.0030
R-Squared	0.9955*	

*Significant regression coefficient component

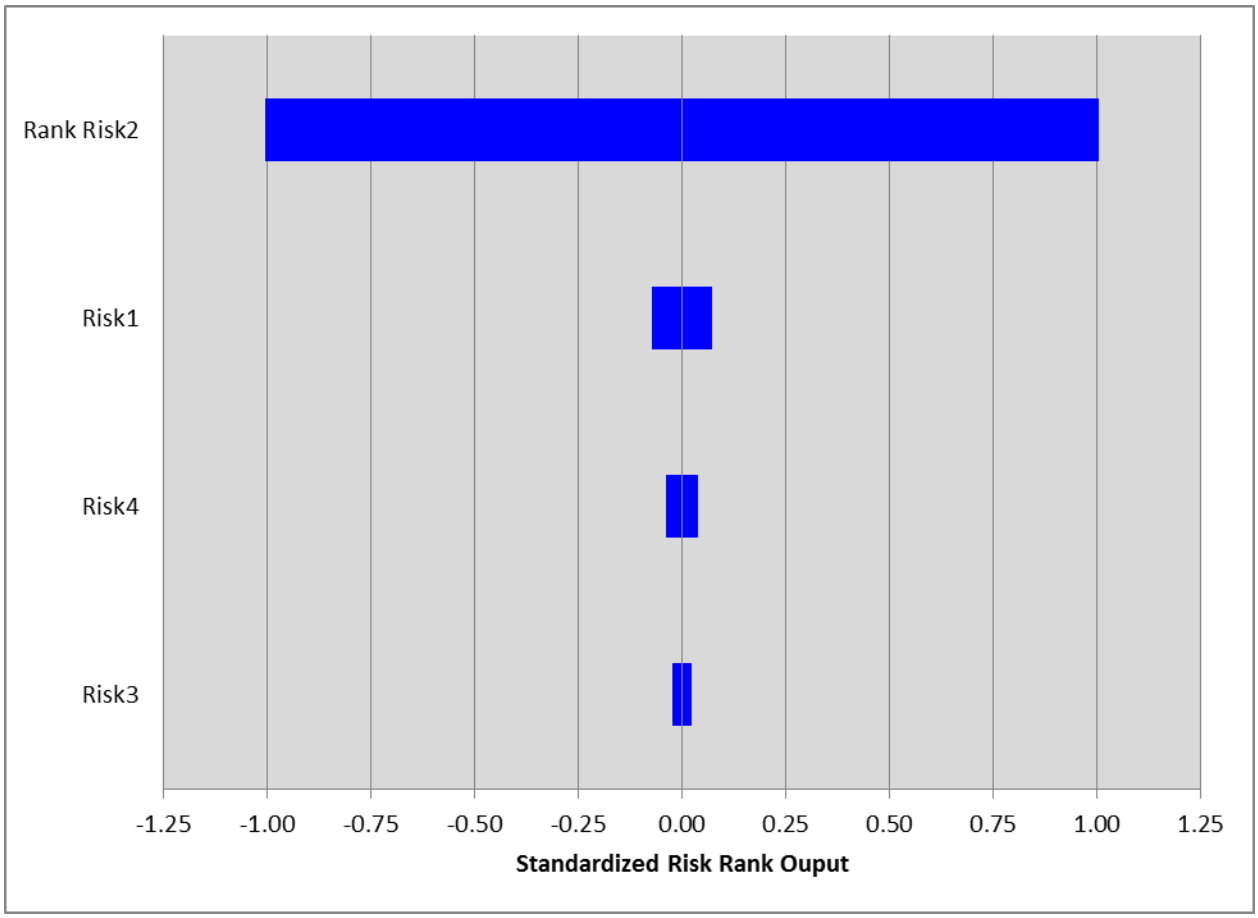
Appendix VIII. Figure 12. Sensitivity of Adjusted Baseline Input Variables—Horizontal Bar Plot, 2006 Dataset



Appendix VIII. Figure 13. Sensitivity of Adjusted Baseline Input Variables—Spider Plot, 2006 Dataset



Appendix VIII. Figure 14. Sensitivity of Adjusted Baseline Input Variables—Tornado Plot, 2006 Dataset



Listeria monocytogenes Establishment Risk Ranking Algorithm

Summary of Results

Appendix VIII Table 7 summarizes the algorithm's stage 1 input variable effect on the baseline Risk2 rank output variable for the 2005 and 2006 algorithms. The algorithm's stage 2 adjusted baseline input variable effect on the establishment *L. monocytogenes* risk ranking variable is also shown. The baseline input variables for the 2005 and 2006 versions can be directly compared. The table shows that the order of sensitivity is the same for these versions: Deli Meat > Other RTE products > Hot Dogs. Because there are more data points in the 2006 version, the R-squared statistic increases. The stage 2 analysis shows Risk2 > Risk1 > Risk3 or Risk4. The negative sensitivity effect of Risk4 is consistent for both algorithms.

Appendix VIII. Table 7. Bootstrapped Rank Regression Coefficients Representing Stage 1 Baseline Output Rank Variable Sensitivity and Stage 2 Adjusted Baseline Input Variables Sensitivity by Algorithm

Variable	2005	2006
Deli Meat	0.8542	0.8528
HotDog	0.1473	0.1828
Other	0.3087	0.2504
R-Squared Stage 1	0.7604	0.8014
Rank Risk2	0.9950	1.0079
Risk1	0.1229	0.0643
Risk3	0.0462	0.0224
Risk4	-0.0298	-0.0384
R-Squared Stage 2	0.9954	0.9955

Appendix IX. Uncertainty Analysis

Uncertainty in the *L. monocytogenes* risk ranking algorithm is characterized by an orthonormal set of input variables that partition the total uncertainty variability. The uncertainty distribution is determined by the bounded variability of the establishment *L. monocytogenes* risk rank output variable. The 2005 dataset provides a baseline variability of 1,981 alternatives for 1,820 establishments. The baseline rank distribution is for 1,981 ranks. The larger dataset of 2,493 alternatives from the 2006 dataset is used for a provisional upper bound on the uncertainty estimate that will be improved upon with additional data. The bootstrap risk ranking model parameter estimates for 1,981 randomly selected alternatives bounded at the upper and lower limits of 1,981 and 2,493 alternatives and 1,820 and 2,067 establishments provide an estimate of the feasible uncertainty distribution for the *L. monocytogenes* risk rank variable. Provisional uncertainty bounds for the output rank variable of 1,981 and 2,493 alternatives are obtained for the 2006 dataset. This is because 1,981 is the smallest number of alternatives observed and 2,493 is the maximum number of alternatives observed over a two-year period. The uncertainty distribution modeled captures the maximum feasible uncertainty in the number of establishments and the similar uncertainty in the percentage of alternatives. The uncertainty in the total percentage of alternatives is captured by uncertainty iterations over the feasible range of alternative percentages.

The formulas used to partition the uncertainty distribution of establishment *L. monocytogenes* risk ranks are as follows. The linear equations for rank regression are given in matrix form (Hettmansperger and McKean, 1998). The matrix X corresponds to the matrix of ranked input variables and the column vector Y corresponds to the establishment risk rank output variable. The column vector B corresponds to the regression coefficients for the ranked variables in equation (1) and the column vector b corresponds to the standardized regression coefficients (b) for the Z transformed X and Y variables in equation (2). The column vector b* (equation 4) is the solution set of regression coefficients for the orthogonal matrix Ux (equations 3 and 4) of input variables that partitions both the Z transformed output variable Zy (equations 2 and 3) and the untransformed rank output variable Y (equation 4). The matrix Ux is obtained using the modified Gram-Schmidt orthonormalization procedure. Because Ux and its inverse are identical, multiplying Ux and Y in equation (4) provides the coefficients (b*) that when squared sum to R-squared, the proportion of the variability in Y that is accounted for by the regression of X on Y. The column vector Var of variance components of Y in equation (5) represents the solution for each input risk component.

(1) $Y = X\,B$
(2) $Zy = Zx\,b$
(3) $Zy = Ux\,b^*$
(4) $b^* = (Ux)^{-1}\,Zy$
(5) $R^2 = \Sigma\,(b^*)^2 = Var$

The uncertainty distribution is obtained by bootstrapping 1,981 to 2,493 alternatives over the solution space of the rank regressions for 1,000 iterations at each alternative using the 2,493 input vectors for the 2006 dataset.

Similar to Appendix VIII, all the statistics in this appendix and plots are derived from the standardized rank regression analysis that is based on bootstrap estimates. The bootstrap estimates are minimum variance unbiased estimators (MVUE) derived as particular U-statistics specific for this analysis (Hoeffding, 1948). The main assumption is that the sampling is done independently and randomly on identically distributed variables. This criterion is satisfied because the population distributions are bootstrapped rank distributions. The U-statistics are the bootstrapped means, and the N-weighted variances of the bootstrapped rank regressions resampled at the standard size of 1,981. Because the 2005 and 2006 datasets have different sampling frequencies due to different total populations there exists an uncorrected bias. The bootstrap resampling only coincides with a standard bootstrap sample equal to the size of the alternative population in the 2005 dataset where resampling can be done with a sample size of 1,981. The resampling rates is 100% for the 2006 dataset therefore the bias is minimized. The most efficient number of bootstrap iterations was found to be greater than 2,000 because the extreme values of the statistics rapidly converged with iterations less than 1,000. The standard number of bootstrap iterations was held at 10,000. Significance tests on parameters use a modified t-test under the assumption that the bootstrapped variances asymptotically approach normal distributions. The standard t-test formula for a two-sided test for a critical value at $p<0.05$ is used with the bootstrapped mean and variance substituted at the regression degrees of freedom.

It is important to realize that the vector Var is the solution vector being bootstrapped (equation 5). Var represents the component variances that sum to R-squared in proportion to the amount of variance explained by the rank regression model. Equations (6) and (7) show that R^2 and Var equivalently partition the uncertainty in the Var(Y). The independent regression coefficient components of Var each represent the uncertainty explained by the model in standardized units. The variance of these components is the square of the component regression coefficients. The variances of the model component variances are found from squares of the bootstrapped component regression coefficients that sum to the bootstrap coefficient uncertainty in equation (8). The proportional uncertainty not explained by the bootstrapped statistics (1-Var-SVar) equation (9) is equal to 1 minus R-squared (the model uncertainty not explained) minus the sum of the uncertainty component variances of the bootstrapped statistics (the bootstrap uncertainty explained, SV). The total proportional uncertainty explained (Var+SVar) is the sum of the model and bootstrapped coefficient uncertainties. The proportioned total uncertainty for V(Y) is the sum of the model and bootstrapped uncertainties explained and the uncertainties not explained by these estimates in standardized units (V+SVar+UVar) equation (10). The assumption is made that the component uncertainties not explained by the bootstrapped estimates (UVar) are proportional to the

uncertainties explained by the bootstrapped estimates (SVar).

(6) $Var(Y) = [R^2 + (1-R^2)] Var(Y)$
(7) $Var(Y) = [Var + (1-Var)] Var(Y)$
(8) $SVar = \Sigma (Sb)^2$
(9) $UVar = 1- Var- SVar$
(10) $Var(Y) = [Var + SVar + UVar] Var(Y)$

2005 Dataset Algorithm

The 2005 dataset estimates uncertainty by bootstrapping the population at the size of the population. It fixes the uncertainty analysis at 1,981 data points per input variable rank distribution.

Baseline Risk Ranking

The baseline risk rank uncertainty with this dataset involves characterizing the input variable variability with respect to percentage attribution of the total output error variability. The uncertainty for each input variable component is determined by the model estimated regression coefficients and the attendant coefficient uncertainty associated with the bootstrap statistics. Appendix IX Table 1 shows that without bootstrapping, 24% of the error variance is not explained by the rank regression model because the R^2 statistic indicates that 76% of the output variability is accounted for by the model. Appendix IX Figure 1 shows that the percentage error components of the input variables in order of explained variability are: Deli Meat > Other RTE products > Hot Dogs. Deli Meat is the most important and significant explanatory variable contributor. The table shows that the division of 76% of the error explained by the model is allocated exactly among the three input variable components. The model uncertainty is indicated by the output error not explained by the model. The bootstrap statistics partition the unexplained model error. The U-statistics estimate that 5% of the previously unexplained model error is due to rank coefficient estimation variability (SVar%) and the remaining 19% of the unexplained model error is portioned into uncertainty for each component (UVar%). The order of uncertainty in this case is: Other RTE products > hot dogs > deli meat.

Appendix IX Figure 1 represents the percent accountability of total variability and uncertainty in the baseline regression. The total variability sums up to 100%. The horizontal bar representing R-squared shows that 76% of the variability is accounted for by the model. The component variabilities (Var%) for deli meat, hot dogs, and other RTE products sum up to 76% while the component variances (SVar%) sum up to 5%. The component uncertainties (UVar%) sum up to 19%. So, the total variability and uncertainty in the output risk ranks is partitioned among the input variable components.

Appendix IX Table 1 shows how the partitioning occurs. The non-bootstrapped components

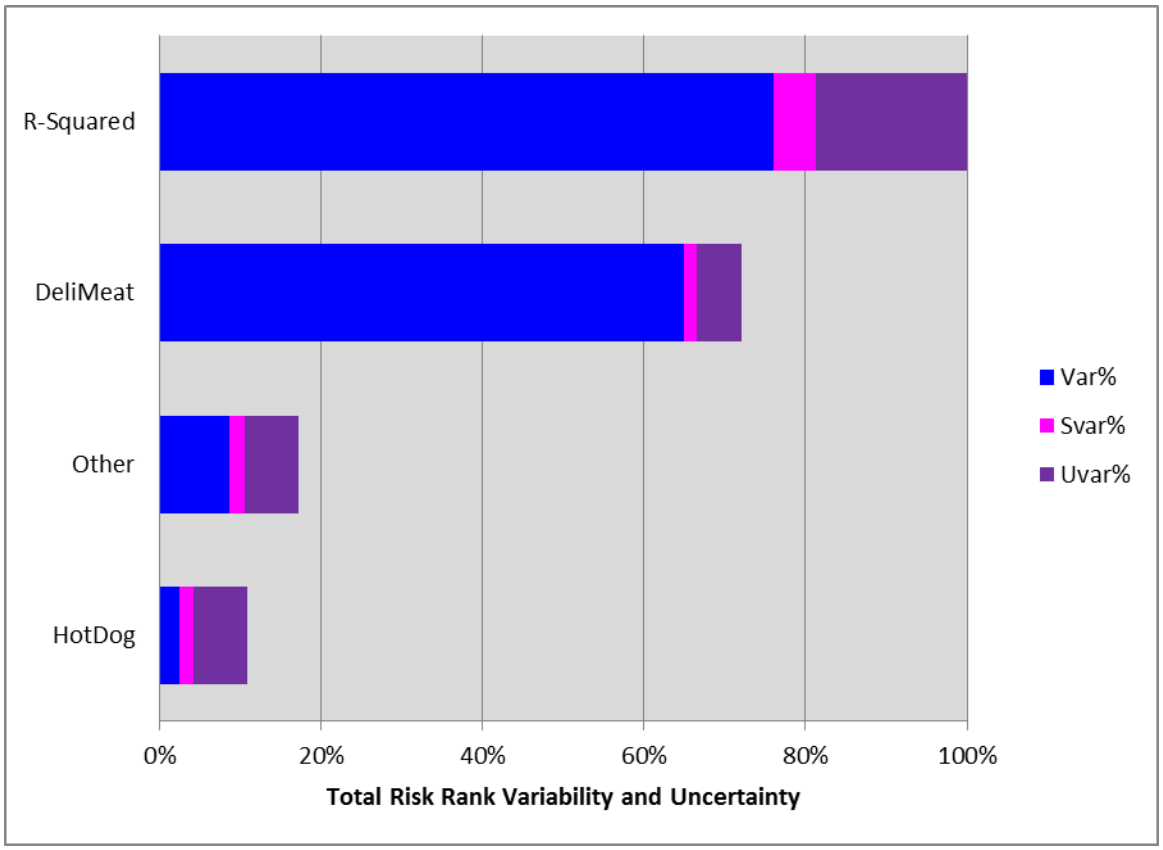
partition the total variance explained by the risk ranking model to equal the value of R-squared (Var % column) and similarly the bootstrapped dataset closely provided the same partition (Var% in the bootstrapped column). The partition is exact and the error variance calculated from the residuals of each component is equal to the other components (SVar% columns). The component uncertainty estimates for the not-bootstrapped model are all equal to the percent of 1 minus R-squared because no component distinction is possible. The significance test for the component variances is calculated from the ratio of the component Var% divided by the standard error of Var%. The standard error of Var% is equal to the square root of 1 minus R-squared divided by the degrees of freedom (1,981-3) which is the same for each component. The bootstrap uncertainty estimates come from portioning the remainder of the variance not explained by the regression, which is 24%. The sum of the not-bootstrapped uncertainty Svar% is 24%. The bootstrapped data provides another estimate of the component error variance Svar% that is smaller in this particular resampling problem (5.15% versus 24%). Uncertainty not explained by bootstrapping (Uvar% equal to 18.79%) is estimated as the difference between the total bootstrapped S%var and the total unexplained variance (24%-5.15%). This uncertainty is then partitioned among the input risk components in proportion to the component bootstrapped uncertainty estimate. This analysis determines the significance of the variance component (Var%) due to each orthogonal regression coefficient and partitions the variance remaining after determining these component variances and their bootstrapped error variances. The significance of the partitioned component uncertainty is inferred by magnitude of the component uncertainty partition accompanied by the non-significance of the variance component. If the variance component is significant then the associated uncertainty can be considered negligible.

Appendix IX. Table 1. 2005 Dataset Input Component Percent Variability

	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%**	Variable	Var%	SVar%	UVar%
Deli Meat	65.10%	5.90%	Deli Meat	65.02%*	1.51%	5.50%
HotDog	2.40%	5.90%	HotDog	2.39%*	1.81%	6.61%
Other	8.60%	5.90%	Other	8.65%*	1.83%	6.68%
R-squared	76.0%*	24.00%	R-Squared	76.06%*	5.15%	18.79%

*Significant percent variability component
**Variance from Appendix VIII model coefficient formula equation (2)

Appendix IX. Figure 1. Percent Accountability of Total Error in Baseline Regression



Adjusted Listeria monocytogenes Establishment Risk Ranking

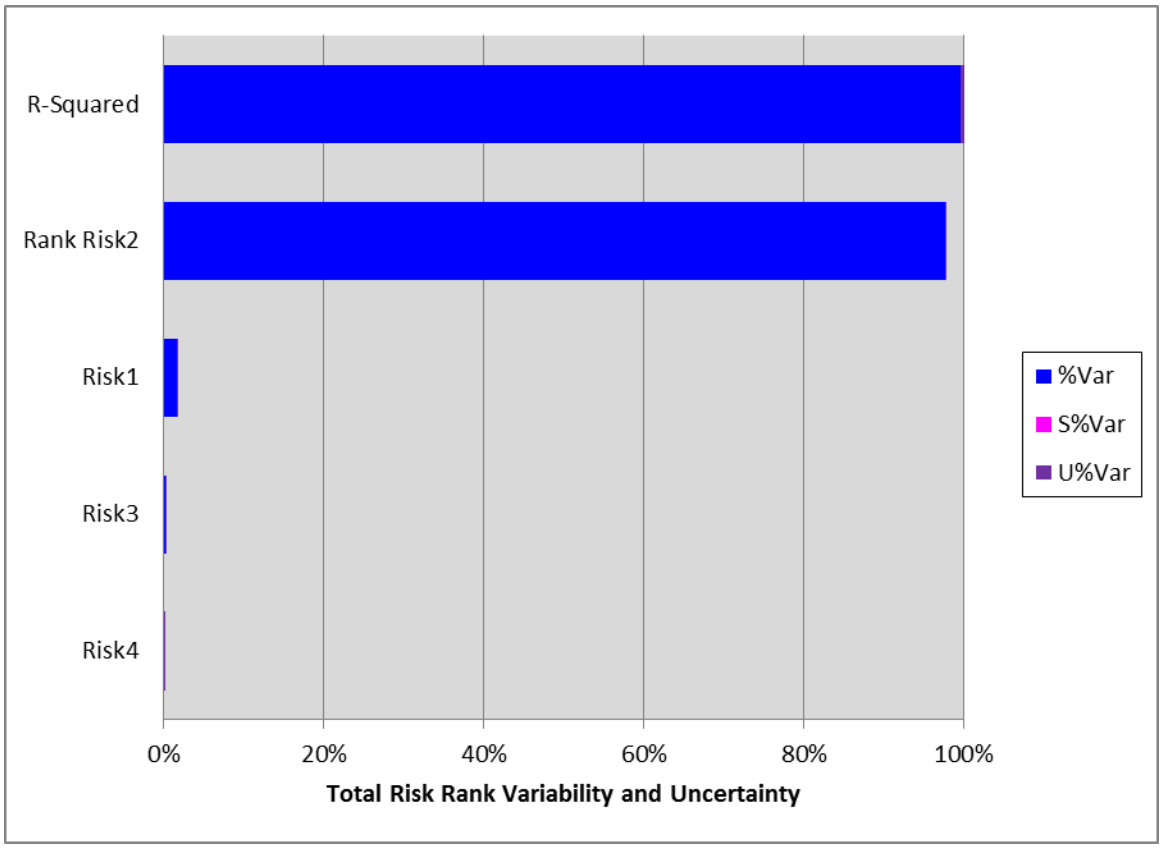
The adjusted baseline risk rank component variability is shown in Appendix IX Table 2. The regression model is significant. The four input risk factors contribute significantly in explaining the total variability; therefore the component uncertainty is not important. Appendix IX Figure 2 shows the total variance partition that is primarily influenced by the Risk2 ranks. With this model, only 95.5% of the total variability in the establishment *L.monocytogenes* risk ranks is accounted for and 0.5% of the variability is not accounted for by the model. The variability not explained by the model is partitioned into 0.03% risk rank parameter variability and 0.37% parameter uncertainty.

Appendix IX. Table 2. 2005 Dataset Adjusted Baseline Input Component Variability and Uncertainty

	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Rank Risk2	97.70%*	0.01%	Rank Risk2	97.69%*	0.01%	0.20%
Risk1	1.55%*	0.01%	Risk1	1.62%*	0.01%	0.17%
Risk3	0.21%*	0.01%	Risk3	0.21%*	0.00%	0.01%
Risk4	0.08%*	0.01%	Risk4	0.08%*	0.00%	0.00%
R-Squared	99.54%*	0.46%	R-Squared	99.60%*	0.03%	0.37%

*Significant percent variability component

Appendix IX. Figure 2. Percent Accountability of Total Error in Adjusted Baseline Regression for 2005 Dataset



Establishment Alternative and RTE Product Production Volume Bootstrap Uncertainty Estimates, 2005 Dataset

Bootstrap estimates for U-estimators were done in parallel with rank regression coefficient estimates, as well as establishment alternative and RTE product production volumes. These estimates provide uncertainty estimates for the variables that show the range of values for each particular distribution that cannot be observed for the static dataset. Appendix IX Table 3 shows the variability in alternatives for the establishment population. Similarly, Appendix IX Table 4 shows the bootstrapped uncertainty for the percent of establishments producing each of the three RTE product categories. Notice that the total percentage is greater than 100% because establishments can produce more than one category of RTE product. Table 4 also shows the percentage uncertainty in the annual volume of production. In this year, there was substantial variability in the 'other' RTE products category. Each of the factors listed in these two tables impact the *Lm* risk ranking algorithm output rank variable according to their range of variability. The percent standard errors correspond to uncertainty estimates for these variables.

Appendix IX. Table 3. Bootstrap Estimates for Percent of 1,981 Establishments in *Lm* Risk Alternatives, 2005 Dataset

	2005			
Alternative	Average%	Stderr%	Min%	Max%
1	5.93	0.52	4.09	7.98
2a	2.88	0.37	1.41	4.34
2b	20.06	0.91	16.56	23.67
3	71.13	1.02	67.14	74.91

Appendix IX. Table 4. Bootstrap Estimates for Percent of 1,981 Alternatives from 1,820 Establishments Producing Three Categories of RTE products and Percent of the Total Annual Volume Production, 2005 Dataset

	2005			
%Establishments	Deli Meat	Hot Dog	Other	Total
Average	38.73	20.61	83.5	142.84
Stderr	1.1	0.91	0.84	
%Volume	Deli Meat	Hot Dog	Other	Total
Average	6.66	3.99	89.35	100
Stderr	0.86	0.71	75.54	

2006 Dataset Algorithm

This dataset provides the first opportunity to examine risk factor component and subcomponent variability and uncertainty. As explained in Appendix VII, there are 37 subcomponents to the establishment *Lm* risk ranking model for the 2006 algorithm version. This section examines the feasibility of using an aggregated subcomponent risk factor model rather than the full component model.

Baseline and Adjusted Baseline Risk Subcomponent Model

Appendix IX Table 5 shows the result of uncertainty analysis for the 37 risk factor subcomponent model. The four major factors: Risk1; Risk2; Risk3; and Risk4 are described with subcomponents. In Table 5 the subcomponents are coded with the alternative (1, 2a, 2b, and 3), the production volume size (H-high, M-medium, and L-low), and the major risk factor. 3- high volume-Risk2 (3H-Risk2) has the greatest uncertainty. The Risk1 input variable and the high- and medium-volume Risk2 variables in alternative 2b and alternative 3 were the most significant uncertainty subcomponents. The figure for Table 3 appears in the main body of the report as an uncertainty plot in standard units. It was decided to aggregate all subcomponents in the following one-stage model for the 2006 algorithm following the same 7 risk component structure as the 2005 algorithm: *Lm* Risk Rank = rank Risk1 + rank Deli Meat + rank Hot Dogs +rank Other RTE products + rank Risk3 + rank Risk4

Appendix IX Table 6 shows the uncertainty analysis for this model. Appendix IX Figure 3 shows the uncertainty components as a horizontal bar graph. The rank regression was significant as were all the variance components. Therefore the uncertainty was not significant. The uncertainty estimates for this model show no apparent problem with analysis. However, examination of the sensitivity analysis in Appendix XIII shows the model to overestimate the sensitivity of the risk factors adjusting the rank of Risk2 and to underestimate the importance of the components of Risk2 due to the one-stage model structure. Therefore, the two-stage model structure is preferred and used for the remainder of the uncertainty analysis.

Appendix IX. Table 5. Percent Variability and Uncertainty in 37 Subcomponent Risk Model Baseline Risk Ranking and Adjusted Baseline for 2006 Dataset

Input	SVar %	Uvar %	Input	SVar %	Uvar %	Input	SVar %	Uvar %
3H-Risk2*	1.03	13.91	2aL-Risk2	1.13	1.74	2bM-Risk3	0.99	0.75
2bH-Risk2*	1.14	11.25	1M-Risk2	2.05	1.52	2bH-Risk3	1.74	0.73
3M-Risk2*	0.7	10.84	1H-Risk4	2.94	1.52	2aL-Risk4	2.33	0.72
3L-Risk2*	0.5	7.93	3M-Risk4	2.71	1.24	2aL-Risk3	0.83	0.72
2bM-Risk2*	0.59	7.29	2bM-Risk4	2.54	1.15	3L-Risk4	0.76	0.72
2aH-Risk2*	0.98	5.9	1L-Risk2	2.35	1.05	1L-Risk3	0.57	0.7
Risk1*	0.29	4.13	3H-Risk3	2.22	0.86	3M-Risk3	0.65	0.69
2bL-Risk2*	0.41	4.03	2aH-Risk3	2.29	0.82	1H-Risk3	0.87	0.67
1H-Risk2*	0.86	3.52	2bL-Risk3	3.46	0.79	1M-Risk3	0.5	0.66
2aM-Risk2*	0.63	3.39	2aM-Risk3	4.71	0.77	1L-Risk4	0.8	0.63
2bH-Risk4*	0.58	2.32	2bL-Risk4	1.2	0.76	1M-Risk4	0.6	0.63
2aH-Risk4*	0.61	2.21	2aM-Risk4	1.1	0.76			
3H-Risk4	1.45	1.93	3L-Risk3	1.69	0.76			

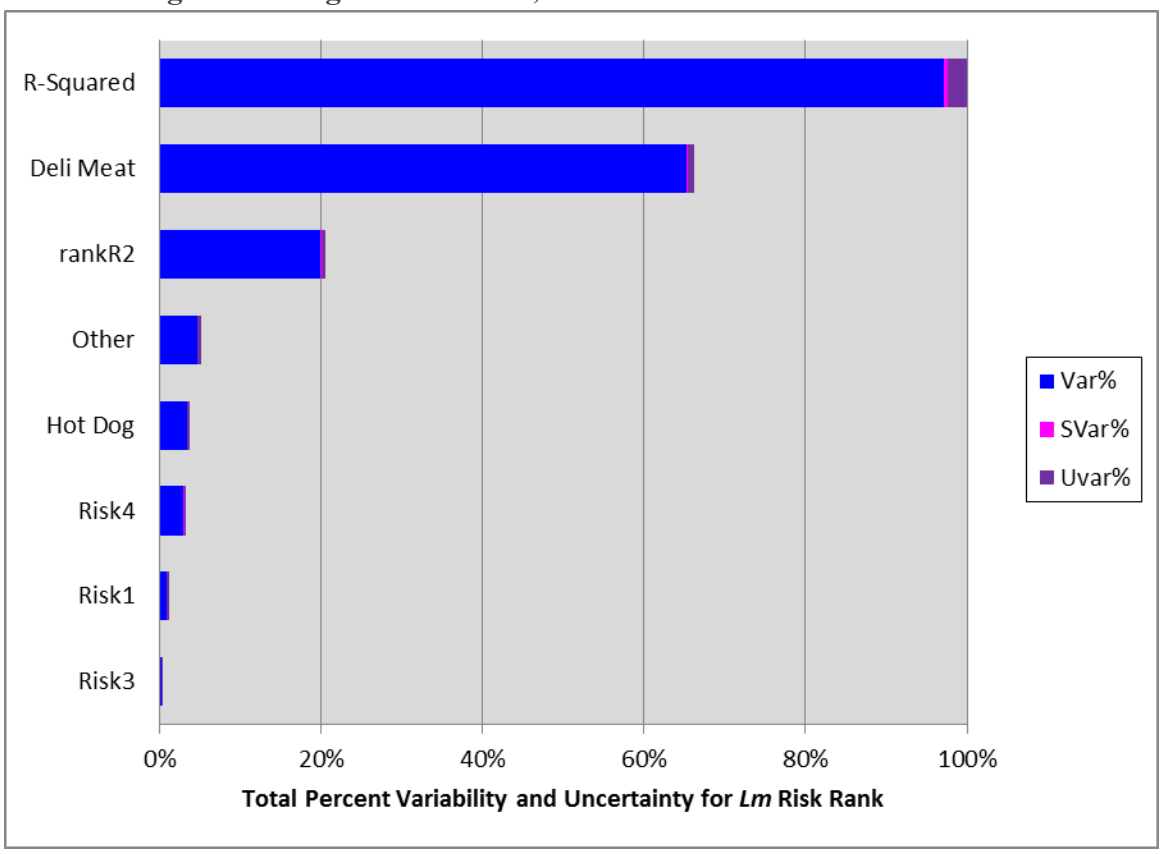
*Significant percent variance component (component not shown)

Appendix IX. Table 6. Percent Variability and Uncertainty in 7 Subcomponent Risk Model Baseline Risk Ranking and Adjusted Baseline for 2006 Dataset

Variable	Var%	SVar%	Uvar%
Deli Meat	0.6524*	0.0014	0.0076
Hot Dog	0.0339*	0.0006	0.0031
Other	0.0463*	0.0007	0.0039
rankR2	0.1997*	0.0009	0.005
Risk1	0.0083*	0.0005	0.0026
Risk3	0.0016*	0.0001	0.0004
Risk4	0.0299*	0.0002	0.001
R-Squared	0.9721*	0.0043	0.0236

*Significant percent variability component

Appendix IX. Figure 3. Percent of Total Variability and Uncertainty of Risk Components in the One-Stage Rank Regression Model, 2006 Dataset



The following two-stage *Lm* risk model was used for the final analysis of the 2006 dataset.
rank Risk2 = rank Deli Meat + rank Hot Dogs + rank Other RTE products
Lm Risk Rank = rank Risk1 + rank Risk2 + rank Risk3 + rank Risk4

Baseline Risk Ranking – Two-Stage Algorithm

The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. Appendix IX Table 7 shows the rank variance partitioning. The bootstrapped rank regression explains 80% of the total variance with 20% unexplained by the model. The variance components are all significant, Therefore, the uncertainty is not significant. The uncertainty is proportional to the component variability. Appendix IX Figure 4 shows this relationship clearly because the horizontal bar plot shows the exact variance partitions that total 100% of the Risk2 rank variance.

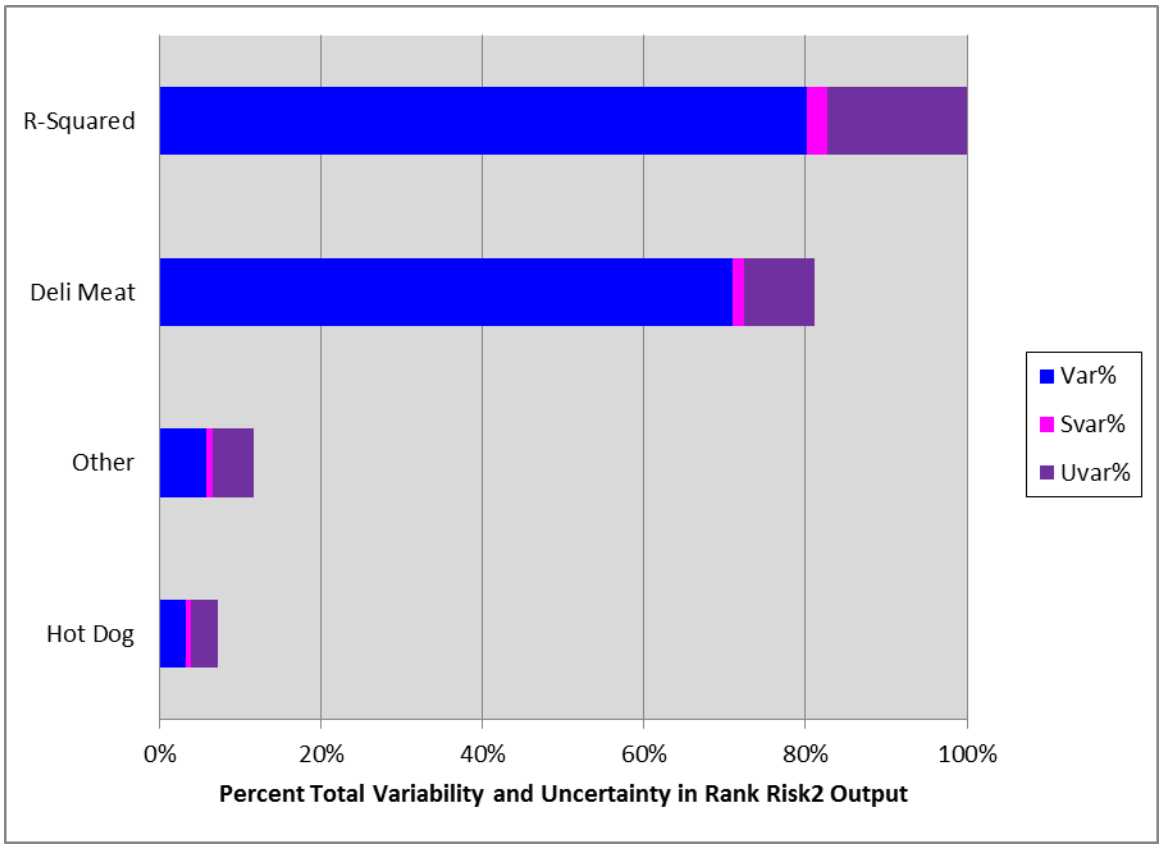
Because each of these risk components also had significant sensitivity in this model, the associated uncertainty of each risk component can be ignored and improvement in the model is not necessary. The establishment *L. monocytogenes* risk ranking is reasonable.

Appendix IX. Table 7. Percent Variability and Uncertainty in Baseline Risk Ranking for 2006 Dataset

Variable	Var%	Svar%	Uvar%
Deli Meat	71.03%*	1.33%	8.82%
Hot Dog	3.30%*	0.52%	3.41%
Other	5.81%*	0.76%	5.02%
R-Squared	80.14%*	2.61%	17.25%

*Significant percent variability component

Appendix IX. Figure 4. Percent Variability and Uncertainty in Baseline Risk Ranking Input Components, 2006 Dataset



Adjusted L. monocytogenes Establishment Risk Ranking – Two Stage algorithm

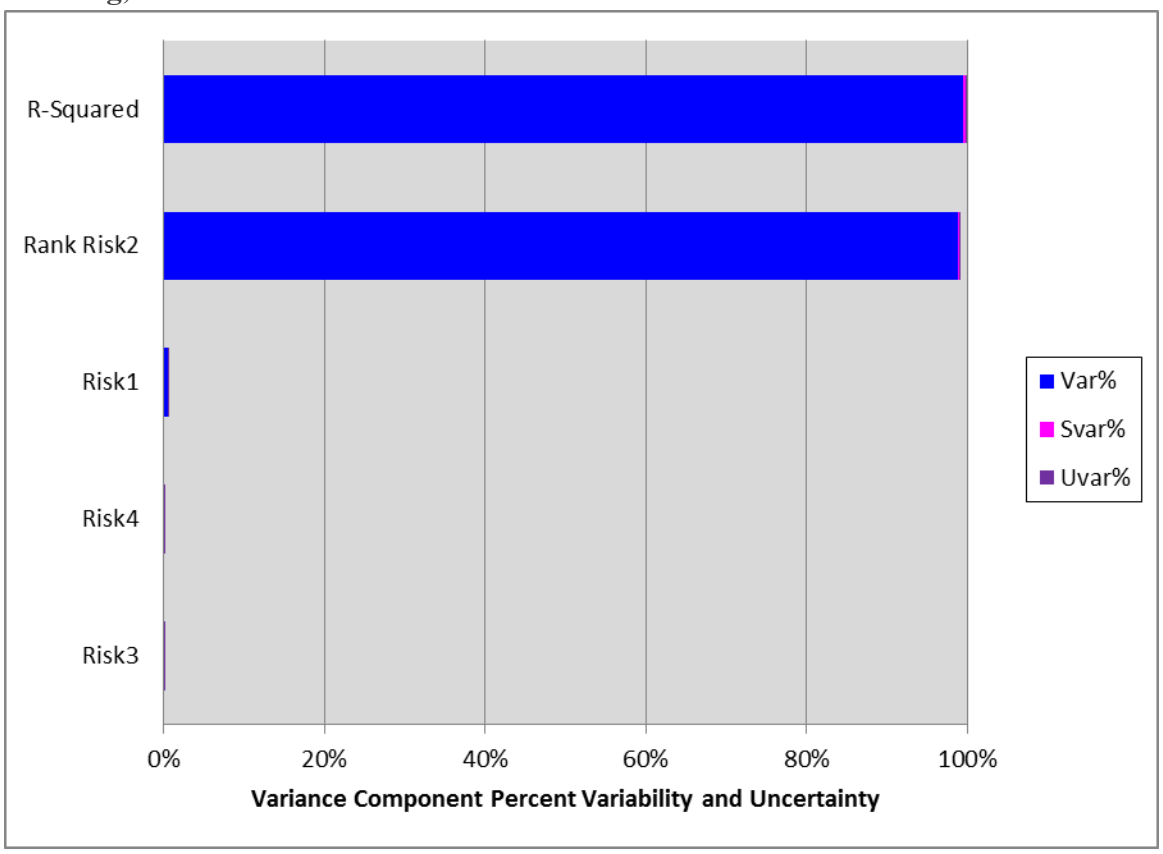
The aggregated two-stage risk factor model is evaluated in this section for uncertainty in the baseline risk ranking. Appendix IX Table 8 shows the rank variance partitioning. The bootstrapped rank regression explains 99.55% of the total variance with 0.45% unexplained by the model. The variance components are all significant so none of the uncertainty components are significant. The variability in the orthogonal regression coefficient variance component explains 0.28% of the variability unexplained by the model leaving 0.17% to the uncertainty components. Appendix IX Figure 5 shows the exact variance partitions that total 100% of the Risk rank variance.
Because each of these risk components also had significant sensitivity in this model, the interpretation is that there is no significant uncertainty associated with the risk rank adjustment components. No model improvement for this part of the establishment *L. monocytogenes* risk ranking algorithm is needed.

Appendix IX. Table 8. Percent Variability and Uncertainty in Two-Stage Adjusted Baseline Risk Ranking for 2006 Dataset

Variable	Var%	Svar%	Uvar%
Rank Risk2	98.90%*	0.16%	0.10%
Risk1	0.47%*	0.11%	0.06%
Risk3	0.05%*	0.01%	0.00%
Risk4	0.12%*	0.01%	0.00%
R-Squared	99.55%*	0.28%	0.17%

*Significant percent variability component

Appendix IX. Figure 5. Percent Variability and Uncertainty in Adjusted Baseline Risk Ranking, 2006 Dataset



Establishment Alternative and RTE Product Production Volume Bootstrap Uncertainty Estimates, 2006 Dataset

Bootstrap estimates for U-estimators were done in parallel with rank regression coefficient estimates, as well as establishment alternative and RTE product production volumes. These estimates provide uncertainty estimates for these variables that show the range of values for each particular distribution that cannot be observed for the static dataset. Appendix IX Table 9 shows the uncertainty in alternatives for the establishment population. Similarly, Appendix IX Table 10 shows the bootstrapped uncertainty for the percent of establishments producing each of the three RTE product categories. Notice that the total percentage is greater than 100% because establishments can produce more than one category of RTE product. Table 10 also shows the percentage uncertainty in the annual volume of production.

Appendix IX. Table 9 Bootstrap Estimates for Percent of 2.493 Establishments in *Lm* Risk Alternatives - 2006 Dataset

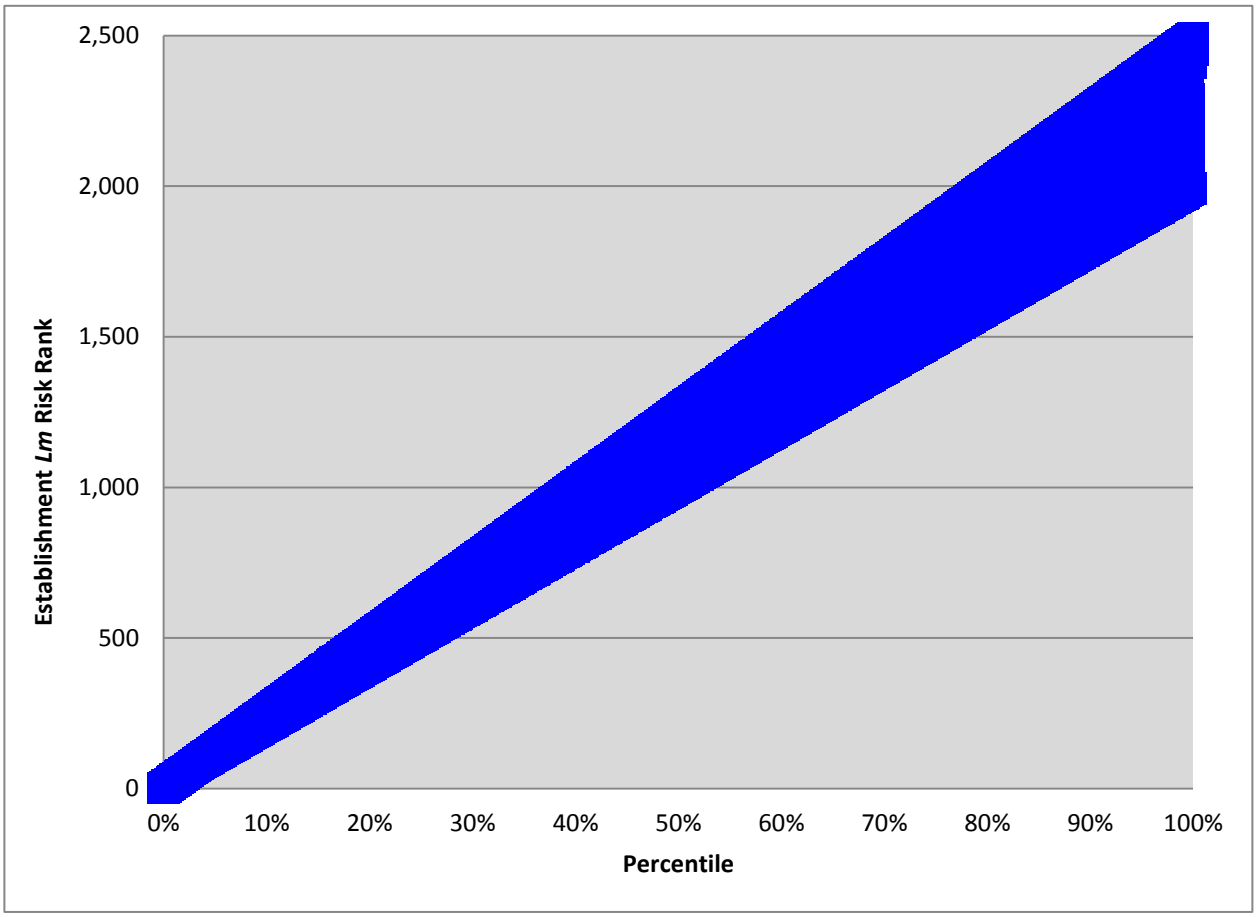
	2006			
Alternative	Average%	Stdev%	Min%	Max%
1	5	0.49	3.38	6.87
2a	12.55	0.74	9.79	15.6
2b	26.25	0.98	22.67	29.88
3	56.2	1.1	52.3	60.22

Appendix IX. Table 10 Bootstrap Estimates for Percent of 1,981out of 2,493 Alternatives from 2,067 Establishments Producing Three Categories of RTE products and Percent of the Total Annual Volume Production – 2006 Dataset

	2006			
%Establishments	Deli Meat	Hot Dog	Other	Total
Average	35.97	19.47	84.15	139.59
Stdev	1.08	0.9	0.81	
%Volume	Deli Meat	Hot Dog	Other	Total
Average	9.39	4.12	86.49	100.00
Stdev	1.33	0.04	0.02	

Appendix IX Figure 6 illustrates the scope of bootstrapping . The linear wedge shape is produced as a percentile plot of the cumulative risk rank distributions beginning on the lower edge with 1,981 ranks and proceeding with increasing slope to the top of the wedge with 2,493 ranks. This plot shows the limits of the uncertainty distributions over all of the possible rank regression models bounded by the upper and lower limits of 1,981 and 2,493 ranks respectively. This figure indicates the unique structure of rank regression uncertainty because the rank distributions are bounded by the variability of the ranks themselves and the uncertainty lies in the permutations of the ranks rather than unbounded limits that may be difficult to estimate.

Appendix IX. Figure 6. Percentiles of the *Lm* Risk Rank Distributions Possible from 2005 through 2006 Bounding Risk Rank Variability and Uncertainty



L. monocytogenes Establishment Risk Ranking Algorithm

Summary of Results

The variability and uncertainty in the establishment *Lm* risk ranking algorithm risk components by dataset used to development versions 2005 and 2006 are shown in Appendix IX Tables 11 and 12. The mean and variance U-statistics produced through bootstrapping are denoted as Var% and SVar% respectively. The bootstrapped and not-bootstrapped estimates are shown for comparison. The not-bootstrapped estimates are found by performing one pass of the algorithm through the entire dataset so there is no resampling. The bootstrapped estimates allow for partitioning of the total risk rank variance into model variability and uncertainty components, but the not-bootstrapped estimates do not allow for partitioning of the component uncertainties. The residual variance is partitioned in the bootstrapped estimates between variability in the risk ranks (Var%) explained by the bootstrapped algorithm models and variability that is still unexplained or uncertain (Uvar%). The uncertainty analysis partitions the total explained rank variance into Var% and the SVar%. Because the total variability is estimable due to the regression on ranks, the remaining unexplained variance UVar% is uncertainty that may be reduced by improving the risk ranking model and thereby increasing the percent of variance explained by the model given by the R-squared statistic. Total uncertainty not explained by the not bootstrapped model can therefore be stated as the sum of SVar% and UVar%.

It is apparent that the two-stage model shows some differences in uncertainty estimates between the algorithm versions. The baseline risk adjustment consistently has the same small amount of uncertainty from 0.5% to 0.9% of the total rank variance. The baseline algorithm uncertainty estimates have a greater range (19% to 24%) but are still acceptable as stated in the respective uncertainty analyses.

Appendix IX. Table 11. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2005 Dataset

2005	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Deli Meat	65.10%	5.90%	Deli Meat	65.02%*	1.51%	5.50%
HotDog	2.40%	5.90%	HotDog	2.39%*	1.81%	6.61%
Other	8.60%	5.90%	Other	8.65%*	1.83%	6.68%
R-squared	76.0%*	24.00%	R-Squared	76.06%*	5.15%	18.79%
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Rank Risk2	97.70%*	0.01%	Rank Risk2	97.69%*	0.01%	0.20%
Risk1	1.55%*	0.01%	Risk1	1.62%*	0.01%	0.17%
Risk3	0.21%*	0.01%	Risk3	0.21%*	0.00%	0.01%
Risk4	0.08%*	0.01%	Risk4	0.08%*	0.00%	0.00%
R-Squared	99.54%*	0.46%	R-Squared	99.60%*	0.03%	0.37%

*Significant percent variability component

Appendix IX. Table 12. Percent Variability and Uncertainty in Baseline and Adjusted Baseline Risk Ranking for 2006 Dataset

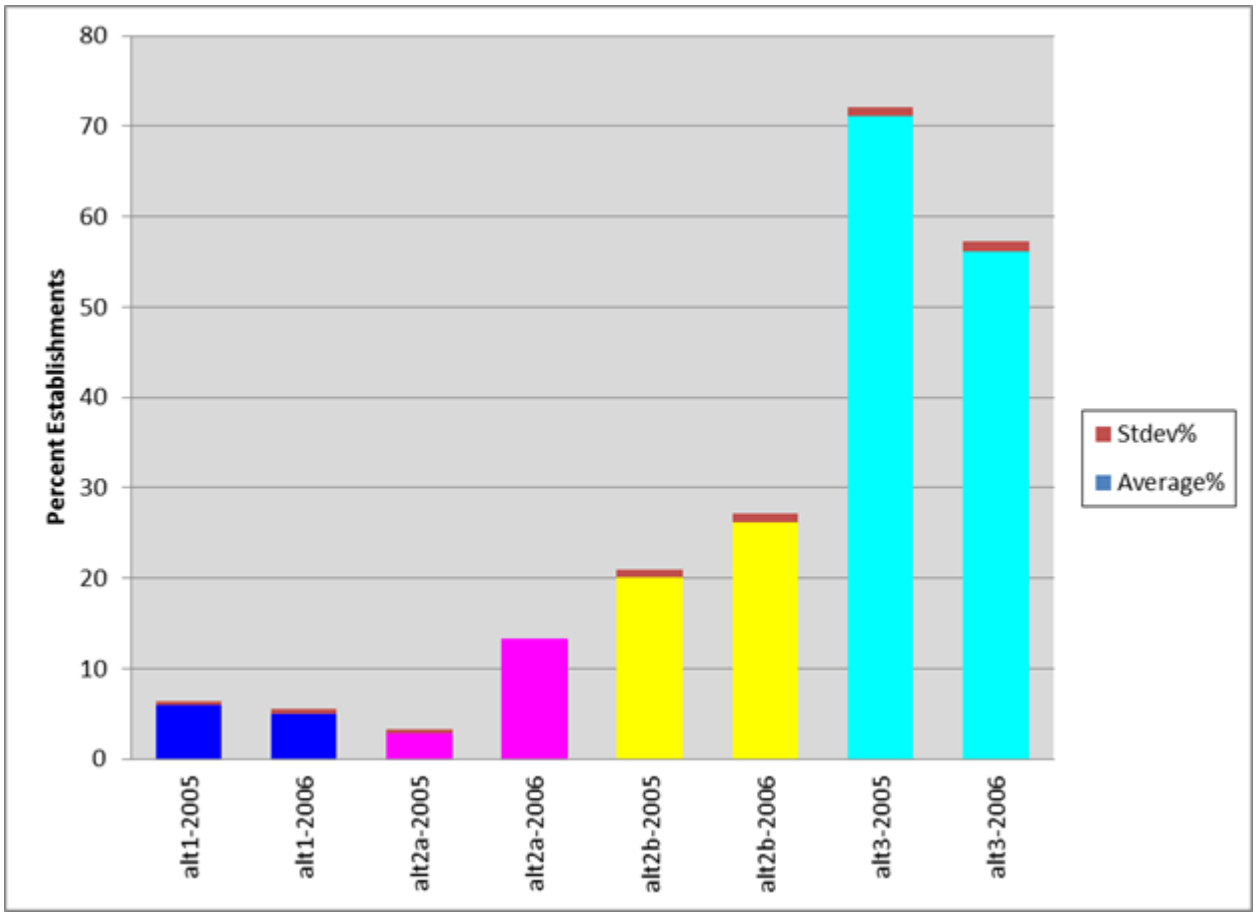
2006	Not-Bootstrapped			Bootstrapped		
Variable	Var%	SVar%	Variable	Var%	SVar%	UVar%
Deli Meat	71.07%*	0.05%	Deli Meat	71.03%*	1.33%	8.82%
Hot Dog	3.26%*	0.05%	Hot Dog	3.30%*	0.52%	3.41%
Other	5.79%*	0.05%	Other	5.81%*	0.76%	5.02%
R-Squared	80.11%*	19.89%	R-Squared	80.14%*	2.61%	17.25%
Variable	Var%	SVar%	Variable	Var%	SVar%	Uvar%
Rank Risk2	98.63%*	0.04%	Rank Risk2	98.90%*	0.16%	0.10%
Risk1	0.36%*	0.04%	Risk1	0.47%*	0.11%	0.06%
Risk3	0.06%	0.04%	Risk3	0.05%*	0.01%	0.00%
Risk4	0.06%	0.04%	Risk4	0.12%*	0.01%	0.00%
R-Squared	99.10%*	0.90%	R-Squared	99.55%*	0.28%	0.17%

*Significant percent variability component

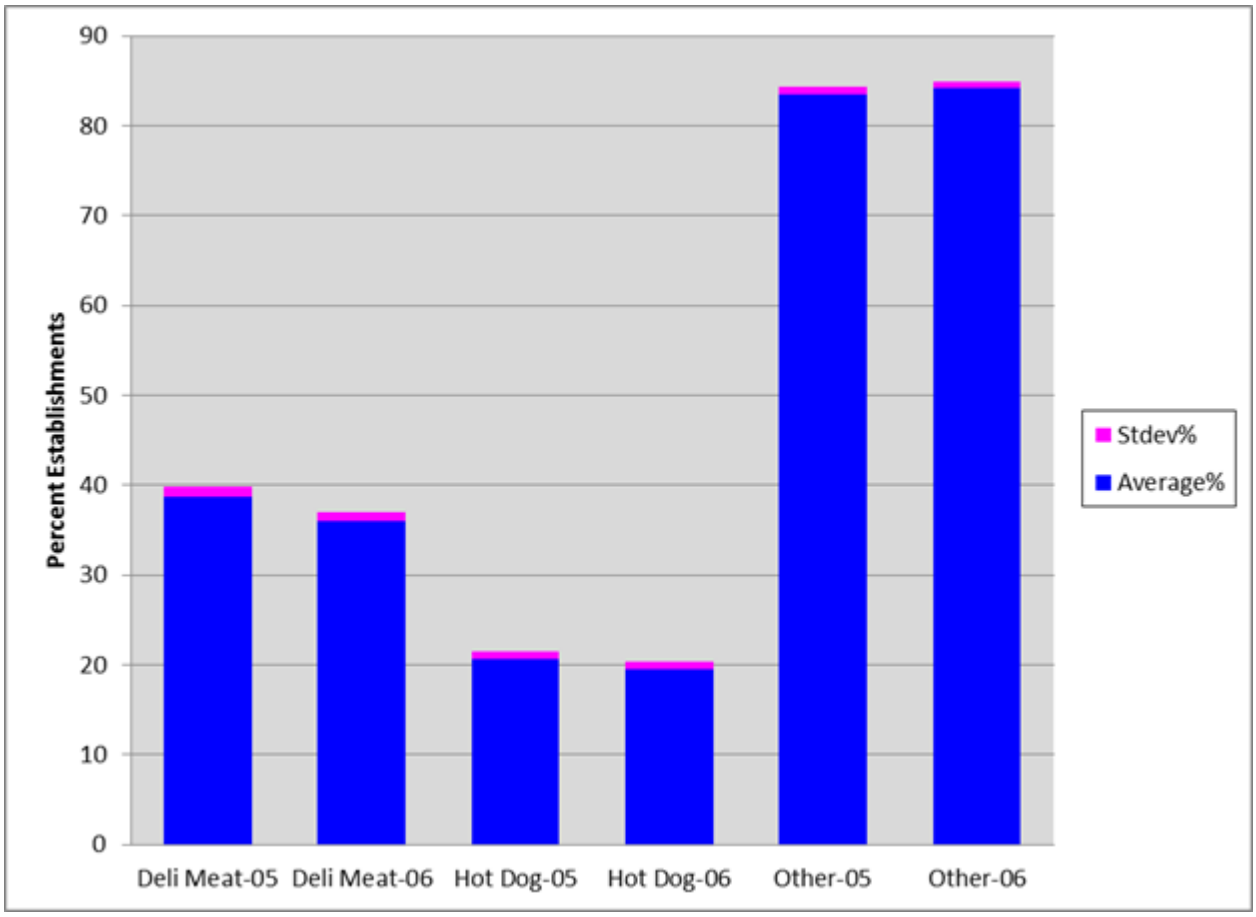
Appendix IX Figure 7 lists the percent of establishments producing post-lethality exposed RTE products which fall into the *Listeria monocytogenes* risk alternatives for each of the datasets. The uncertainty in the estimates shown by Stdev% is the N-weighted U-estimator. The uncertainties are relatively small within each dataset but will be larger if the increase and decrease of each alternative with time is taken into account. Similarly, Appendix IX Figure 8 shows the percent of establishments producing RTE products in the three major categories of deli meats, hot dogs, and other RTE products. There is less of a difference between the averages than with the percent in alternatives but trends are still obvious. Additionally, Appendix IX Figure 9 shows the percent of total annual post-lethality exposed RTE production in the same three RTE product categories where trends in the averages are also obvious. The percent variability for 'other' RTE products is substantially larger than for the other RTE products.

The total variability in each of the datasets used for algorithm development is bracketed by the risk ranks used in modeling the data. The extent of this total variability is shown in Appendix IX Figure 10. The 2005 dataset represents the lower edge of the curved wedge shaped cumulative rank distribution while the 2006 dataset is represented by the upper edge of the distribution (the variances in this figure correspond to the ranks shown before in Appendix IX. Figure 6). Therefore, the risk rank regression model permits reasonable estimates of variability and uncertainty that are fitted to conform to the known limits of the possible rank distributions. The standardized risk component uncertainties are shown in Appendix IX. Figure 11. The first stage deli meat, hot dog, and other RTE product uncertainties are greater than the second stage uncertainties for historical adjustment of the risk ranks. More data will have to be gathered to discern actual trends in the component uncertainty distributions with increasing numbers of ranks because of the observed inconsistent component trends. Appendix IX. Figure 12 shows the overall uncertainty trend seems to be decreasing with increasing numbers of risk ranks but further analysis is required to establish this with certainty.

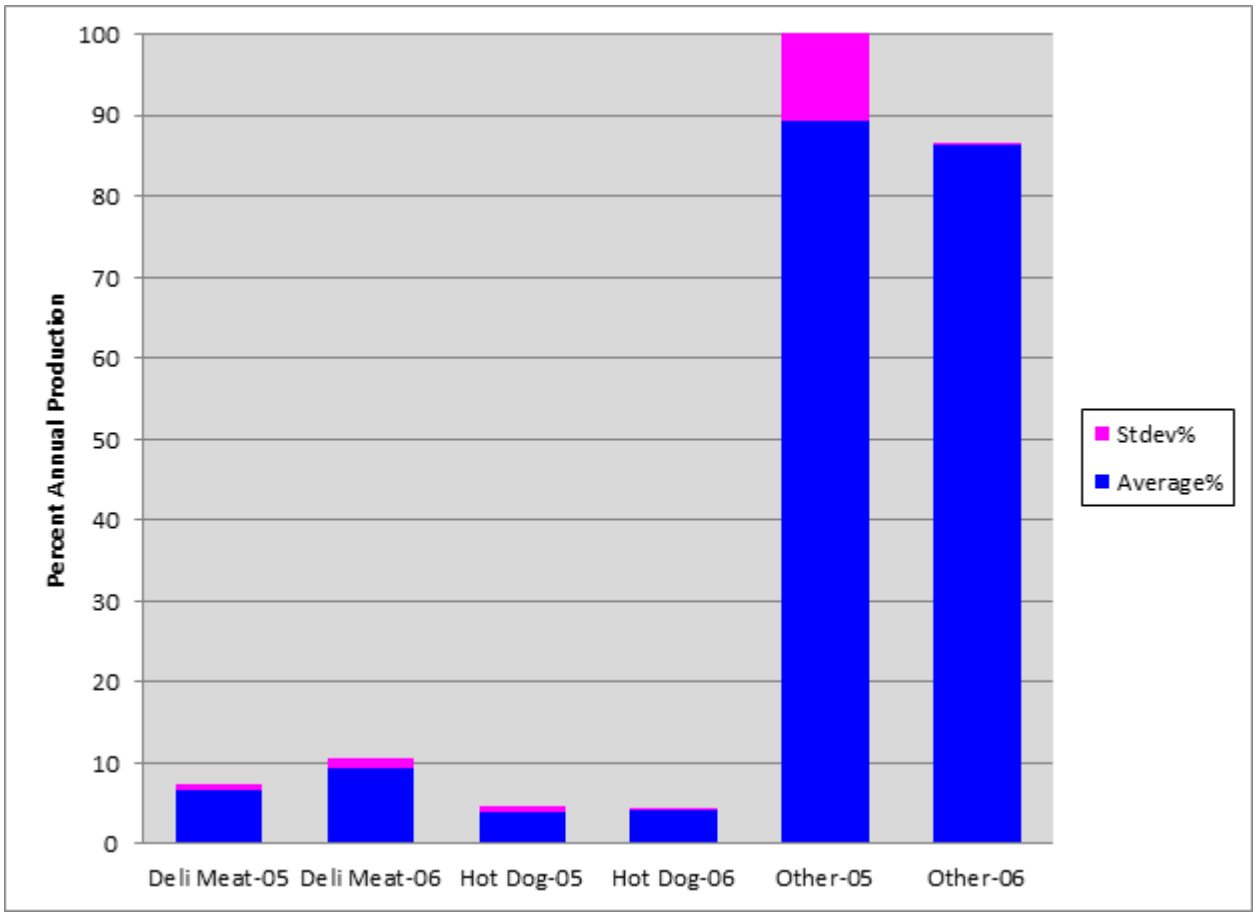
Appendix IX. Figure 7. Percent of Establishment in Lm Risk Alternatives 1, 2a, 2b, and 3 for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005 and 2006)



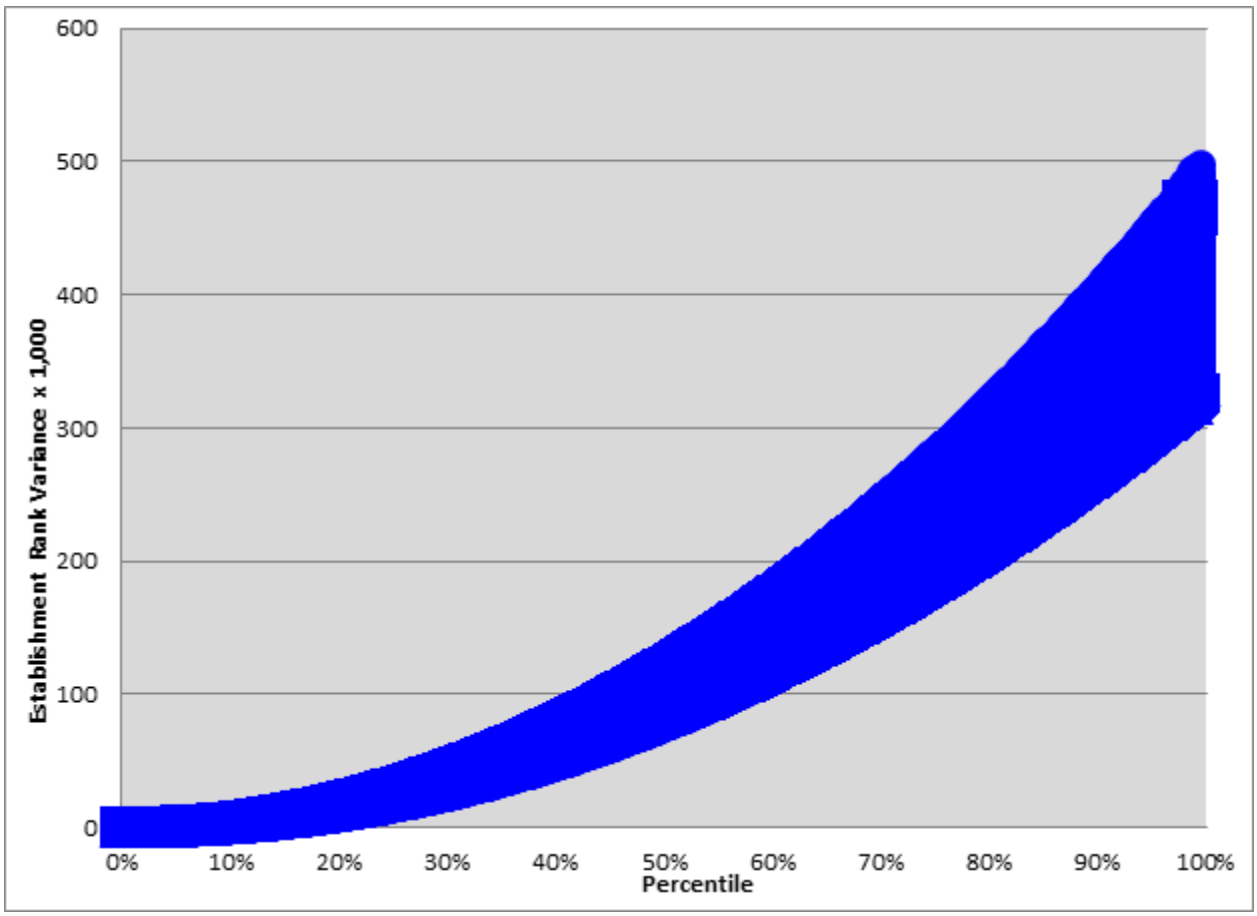
Appendix IX. Figure 8. Percent of Establishments Producing Post-Lethality Exposed RTE Products for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005 and 2006)



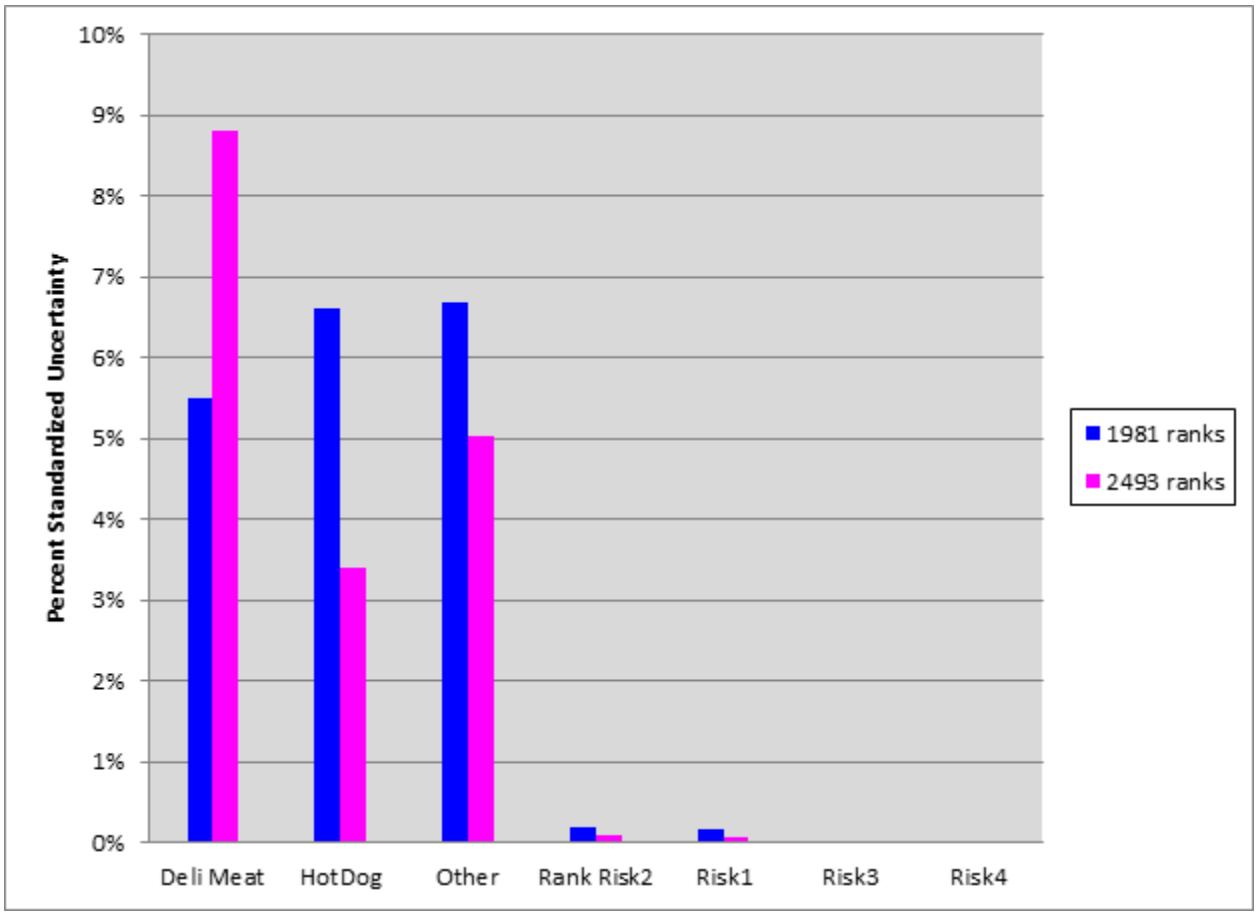
Appendix IX. Figure 9. Percent Annual Post-Lethality Exposed RTE Products Produced for Establishment *Lm* Risk Ranking Algorithm Development Datasets (2005 and 2006)



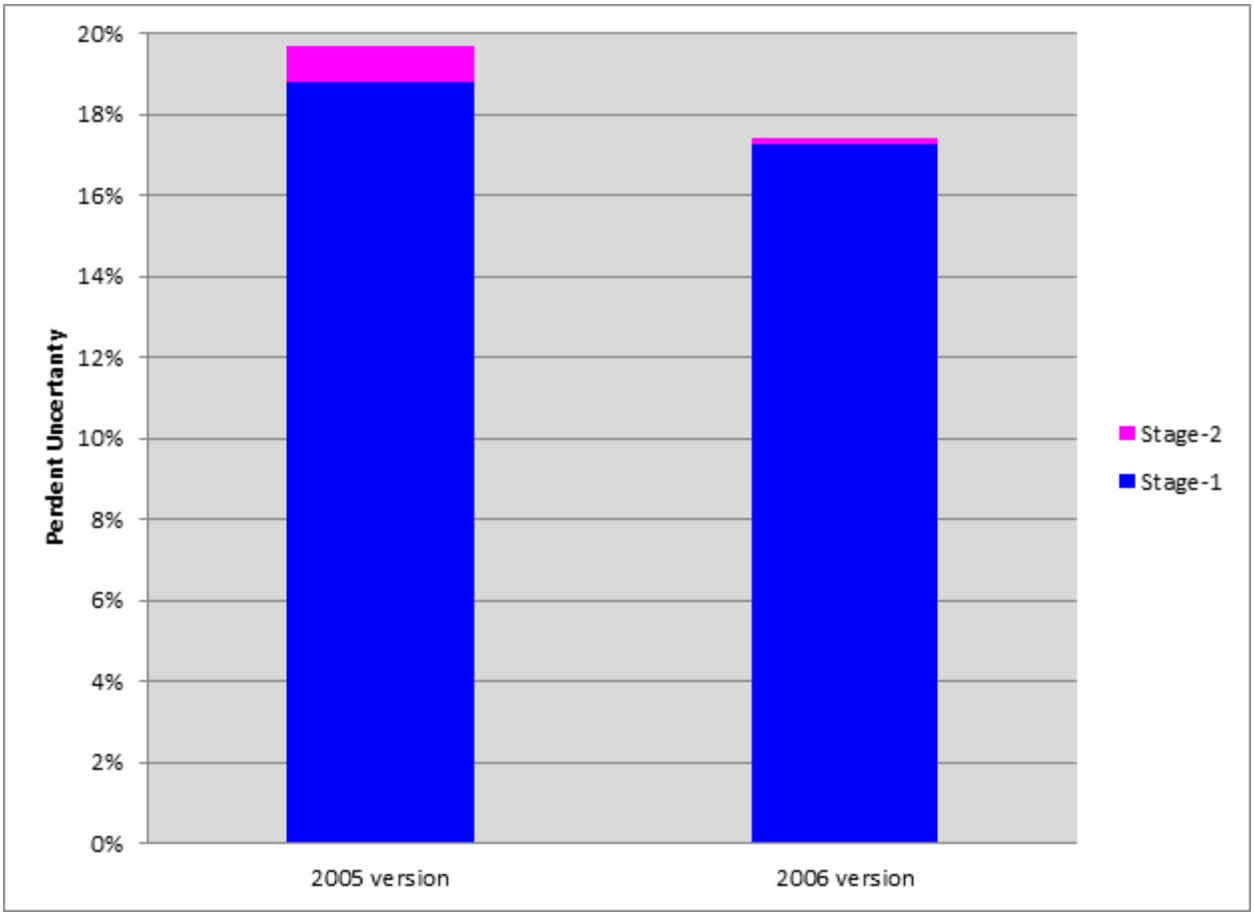
Appendix IX. Figure 10. Percentiles of Minimum and Maximum Rank Variance for 2005 and 2006 Datasets



Appendix IX. Figure 11. Percentages of Standardized Uncertainty by Risk Variable for 2005 and 2006 Datasets



Appendix IX. Figure 12. Decline in Percentages of Standardized Stage 1 and Stage 2 Uncertainties with Increasing Risk Rank Estimated from 2005 and 2006 Datasets



APPENDIX X. *Listeria monocytogenes* Risk-Ranking Algorithm SAS Code and Excel Spreadsheet Examples

This appendix provides information for running the three establishment *Listeria monocytogenes* (*Lm)* risk ranking algorithm for the 2006. The 2005 algorithm is not given since it only differs from the 2006 version by five coefficient values in Risk3. The dataset for the SAS code and example Excel spreadsheets are provided in the companion zip file. The equations used for the 2006 algorithm version is as follows.

Equations used for 2006 Establishment Lm Risk Ranking Algorithm

Risk2 = 1.0000 x Deli Meat x Q80 + 0.0582 x Hot Dog x Q80 + 0.000217 x Other x Q80

Adjusted Risk Rank = 1338 x Risk1 + Rank Risk2 + 334.5 x RR x Risk3 / 7.0116 + 334.5 x Risk4 x (RR- 7.011566 – 1) / 7.011566, conditional on Risk1, Risk3, and Risk4

Risk3 = 0.4614 x month2 + 0.2446 x month3 + 0.1252 x month4 + 0.0861 x month5 + 0.0826 x month6

Risk4 = (month1 + month2 + month3 + month4 + month5 + month6)/17

The following SAS code implements the 2006 algorithm of the establishment *Listeria monocytogenes* risk ranking algorithm incorporating the modifications to the original *Listeria monocytogenes* risk ranking algorithm first developed in Excel spreadsheets in January 2005. These modifications are current as of October 2011. The accompanying example database can be used to study the algorithm input and output. In order to use the code, cut and paste into the SAS editor. Create a SAS library "C:\SAS" for the input and output files. The program will read and write files using the SAS library. The example program was created to obtain the establishment *L. monocytogenes* risk ranks for one month only. The program produces a list of establishment numbers and *L. monocytogenes* risk rankings over all alternatives.

The input dataset "sas_example2006" contains the annual production volumes of 1,000 hypothetical establishments and their intervention alternatives listed by establishment number. The SAS dataset can be created from the Excel file "Excel_Example2006". The variable names are in the following table that corresponds to the Excel_Example dataset.

Appendix X. Table 1. Example Variable Names

Item	Variable	Description
1	Establishment	Establishment ID
2	DeliS	Deli meat-Sliced
3	DeliUS	Deli meat-Unsliced
4	HotDog	Hot Dogs
5	Cooked	Cooked RTE Products
6	Ferm	Fermented RTE Products
7	Dried	Dried RTE Products
8	Cured	Salt-cured RTE Products
9	Frozen	Frozen RTE Products
10	Pate	Pate, Meat Spreads, Deli salads
11	Total_Volume	Total annual RTE Volume in pounds converted to grams
12	EDMV	EDMV-Equivalent Deli Meat Volume in pounds converted to grams
13	Volume	Size Volume - H, M, L
14	Alternative	1=1; 2a=2.1; 2b=2.2; 3=3
15	Q80	80th Quantile of Lm Contamination Distribution
16	RR	Prevalence Relative Risk at Retail
17	AMA	Antimicrobial Agent Effect
18	PosP1	*Lm* Positive in Product- Month1
19	PosP2	*Lm* Positive in Product- Month2

Appendix X. Table 1. Example Variable Names (continued)

Item	Variable	Description
20	PosP3	*Lm* Positive in Product- Month3
21	PosP4	*Lm* Positive in Product- Month4
22	PosP5	*Lm* Positive in Product- Month5
23	PosP6	*Lm* Positive in Product- Month6
24	PosC6	*Lm* Positive on Food Contact Surface- Month6
25	NegP1	*Lm* Negative in Product- Month1
26	NegP2	*Lm* Negative in Product- Month2
27	NegP3	*Lm* Negative in Product- Month3
28	NegP4	*Lm* Negative in Product- Month4
29	NegP5	*Lm* Negative in Product- Month5
30	NegP6	*Lm* Negative in Product- Month6
31	Risk2	Baseline Risk
32	Risk1	Immediate Regulatory Risk
33	Rank Risk2	Baseline Risk Rank
34	Risk3	Increase in Risk Rank for Past Positives
35	Risk4	Decrease in Risk Rank for Past Negatives
36	Adj. Risk2	Adjusted Baseline Risk2 Rank
37	Risk Rank	*Lm* Establishment Risk Rank

Please note: you will need to create a SAS library on your "C" drive labeled "SAS". Place the input file: **"**sas_example2006" in the SAS library folder. The output file will be in the SAS library folder labeled "_2006_Risk_Ranks".

The SAS code for the 2006 Algorithm is:

```
LIBNAME SAS "C:\SAS";
Data sas.data1;
Set sas.sas_example2006;
EDMV=delis+delius+0.058182*hotdog+0.000217*(cooked+ferm+dried+cured);

EDMV=EDMV*1000/2.2;

If Alt = 1 and Vol_Size = "H" Then Risk2=0.000000014*EDMV;
If Alt = 1 and Vol_Size = "M" Then Risk2= 0.0000000125*EDMV;
```

```
If Alt = 1 and Vol_Size = "L" Then Risk2= 0.0000000110*EDMV;
If Alt = 2.1 and Vol_Size = "H" Then Risk2 = 0.0000000820*EDMV;
If Alt = 2.1 and Vol_Size = "M" Then Risk2 = 0.0000000674*EDMV;
If Alt = 2.1 and Vol_Size = "L" Then Risk2 = 0.0000000610*EDMV;
If Alt = 2.2 and Vol_Size = "H" Then Risk2 = 0.00000153*EDMV;
If Alt = 2.2 and Vol_Size = "M" Then Risk2 = 0.00000129*EDMV;
If Alt = 2.2 and Vol_Size = "L" Then Risk2 = 0.00000116*EDMV;
If Alt = 3 and Vol_Size = "H" Then Risk2 = 0.00000724*EDMV;
If Alt = 3 and Vol_Size = "M" Then Risk2 = 0.00000708*EDMV;
If Alt = 3 and Vol_Size = "L" Then Risk2 = 0.00000465*EDMV;

If Alt = 1 and Vol_Size = "H" Then RR = 1.097591;
If Alt = 1 and Vol_Size = "M" Then RR = 1.056208;
If Alt = 1 and Vol_Size = "L" Then RR = 1.000000;
If Alt = 2.1 and Vol_Size = "H" Then RR = 1.902718;
If Alt = 2.1 and Vol_Size = "M" Then RR = 1.881717;
If Alt = 2.1 and Vol_Size = "L" Then RR = 1.808987;
If Alt = 2.2 and Vol_Size = "H" Then RR = 4.794365;
If Alt = 2.2 and Vol_Size = "M" Then RR = 4.590511;
If Alt = 2.2 and Vol_Size = "L" Then RR = 4.361056;
If Alt = 3 and Vol_Size = "H" Then RR = 7.011566;
If Alt = 3 and Vol_Size = "M" Then RR = 6.929975;
If Alt = 3 and Vol_Size = "L" Then RR = 6.795457;
Run;

Proc sort data= sas.data1;
By Risk2;
Run;

data sas.data1;
set sas.data1;
Rank_Risk2=_N_;
run;


Data sas.data2;
set sas.data1;

Risk1=1338*PosP1;
Risk3=0.4614*PosP2+0.2446*PosP3+0.1252*PosP4+0.0861*PosP5+0.0826*PosP6;
Risk4=(NegP1+NegP2+NegP3+NegP4+NegP5+NegP6)/17;

If Risk1 eq 0 and Risk3 gt 0 then Adj_Risk2 = 334.5*RR*Risk3/7.011566 +
Rank_Risk2;
If Risk1 eq 0 and Risk3 eq 0 then Adj_Risk2 = 334.5*Risk4*(RR-7.011566-
1)/7.011566 + Rank_Risk2;
If Risk1 gt 0 then Adj_Risk2 = Risk1 + Rank_Risk2;
Run;

Proc sort data= sas.data2;
By plant;
Run;

Proc Summary data=sas.data2;
By plant;
Var Adj_Risk2;
```

```
Output out=sas.data3 sum(Adj_Risk2)=Risk_Rank;
Run;

Proc Sort data=sas.data3 (keep= plant risk_rank);
By descending Risk_Rank;
Run;

data sas.data4;
set sas.data3;
Rank_Risk_Rank=_N_;
run;

Data sas._2006_Risk_Ranks (keep=plant Ranks_2006);
Set sas.data4;
Ranks_2006 = 1000-Rank_Risk_Rank+1;
Run;
```

This example can be used to illustrate the general sampling plan used for risk-based verification sampling if the number of samples allocated per month is specified and if all establishments are to receive a minimum number of sample requests over a year. Because risk-based sampling requires that the highest risk ranked establishments are sampled each month, lower risk establishments may not be sampled at all. In order to avoid this situation, a random sample of establishments not in the high risk sampled group is taken. This random sample size is based on the number of samples needed to sample every low risk establishment once or twice a year.

Because the number of establishments in the example is 1,000, a monthly allocation of 300 is used for illustration. Of the 300 samples, 250 can be given for high risk establishments and 50 can be given for lower risk establishments.