FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats

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FSIS

FSIS *LISTERIA* RISK ASSESSMENT REPORT

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.[1] In general, the scientific literature indicated that the relationship between the prevalence and level of *Listeria* species in the plant environment (e.g., food contact and non-food contact surfaces) to the prevalence and level of *Listeria monocytogenes* (*L. monocytogenes*) in ready-to-eat (RTE) meat and poultry products is not well understood. To better understand this relationship, FSIS requested public input as part of the proposed rule for RTE meat and poultry products (66 FR 12609). In addition to the public request for data, FSIS initiated the planning and development of this risk assessment to: 1) provide insight into the relationship between *Listeria* species on food contact surface(s) and *L. monocytogenes* in RTE meat and poultry products; and 2) to evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, use of growth inhibitors, and combinations of these interventions to mitigate contamination on RTE meat and poultry products and reduce the subsequent risk of illness or death from *L. monocytogenes*.

This report provides information on the risk assessment model developed, including the sources of data used, underlying assumptions, model equations, and techniques applied, to provide estimates of the number of deaths from *L. monocytogenes* in deli meats in response to specific risk management questions. This report is organized into the following sections:

1. *Public Health Regulatory Context*
2. *Risk Management Questions*
3. *FSIS Listeria Risk Assessment*
   a. Model Overview
   b. Model Parameters
   c. Conceptual Model
   d. FDA/FSIS Risk Ranking Model
   e. In-Plant Dynamic Model
   f. Model Implementation and User Interface
   g. Calibration of the In-Plant Dynamic Model
4. *Listeria Risk Assessment Outputs*
5. *Sensitivity Analysis*

[1] The purpose of risk assessment as a public health tool is to use available data and information in a model to predict outcomes (i.e., effectiveness of an intervention in reducing illnesses) to inform decision-making. Without risk assessment, the public health benefit of selecting one policy intervention over another would be unknown. On the other hand, waiting to have all the data would prevent public health measures from being implemented in a timely manner. The risk assessment methodology is a tool designed to inform decision-makers when all of the data or information are not known. Risk assessment allows there to be scientifically-based informed decision-making.

6. *References*
7. *Appendix A: Revisions to the 2001 FDA/FSIS Risk Ranking Model*
8. *Appendix B: Predicted Growth Between Processing and Retail*
9. *Appendix C: Evaluation of FSIS RTE Survey Data for Volume of Production for Establishments Producing Deli Meats*
10. *Appendix D: Risk Assessment Model Outputs Stratified by High, Medium and Low Production Volume Establishments & Consecutive Positive FCS Samples*.

PUBLIC HEALTH REGULATORY CONTEXT

This section provides background information on the health risks posed by *L. monocytogenes* and the regulatory context for this pathogen in FSIS-regulated RTE meat and poultry products.

Public Health Background

L. monocytogenes is a pathogen that occurs widely in both agricultural (e.g., soil, water, and plants) and food processing environments (e.g., air, drains, floors, machinery) (Ryser 1999). *L. monocytogenes* 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), it can also be present in RTE foods due to post-processing contamination (Mead 1999a, CDC 2000).[2] In 2001, the Food and Drug Administration and the Food Safety and Inspection Service completed a draft risk ranking of RTE foods for *L. monocytogenes* (FDA/FSIS, 2001). Of the 20 RTE food categories evaluated, deli meats posed the highest per annum risk of illness and death from *L. monocytogenes*, while hot dogs (i.e., frankfurters, wieners, etc.) posed a moderate public health risk. Since the release of the FDA/FSIS risk ranking of RTE foods, public comments and additional data have been made available to update the exposure assessment for deli meats[3] and the *L. monocytogenes* dose-response relationship (see Appendix A).

Definition: Ready-to-Eat (RTE)

RTE meat and poultry products are products that are in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, gastronomic, or culinary purposes (9 CFR Part 430).

In general, consumption of food contaminated with *L. monocytogenes* may cause listeriosis, which can result in serious human illness (Ryser 1999). In 1999, the Centers for Disease

[2] In 1991, after a series of outbreaks of human illness associated with the consumption of a variety of foods (e.g., meats, coleslaw, pasteurized milk, soft cheese), the National Advisory Committee for Microbiological Criteria in Foods (NACMCF) recommended control strategies to minimize the presence, survival, and multiplication of *L. monocytogenes* in foods (NACMCF 1991). These control strategies included the development of an effective national surveillance system for listeriosis and inclusion of this pathogen in industry HACCP systems to ensure the safety of foods from production to consumption.

[3] The exposure assessment for hot dogs was also updated based on public comments and additional data since the release of the FDA/FSIS risk ranking of RTE foods.

Control and Prevention (CDC) reported that of all the foodborne pathogens under surveillance in the United States, *L. monocytogenes* had the second highest fatality rate (20%) and the highest hospitalization rate (90%). Those at greatest risk of illness were the elderly (i.e., those 60 years and older), those with suppressed or compromised immune systems (e.g., those who have received a bone marrow transplant, cancer treatment, etc.), and fetuses or newborns (Slutsker and Schuchat 1999).[4] Each year, *L. monocytogenes* causes an estimated 2,500 cases of foodborne listeriosis, including approximately 500 fatalities (Mead 1999a, b).

Policy Context

Prior to initiating this risk assessment, FSIS has taken a number of regulatory steps to protect the public's health, including the following:

Microbiological Testing for L. monocytogenes in RTE Meat and Poultry Products. Since 1987, FSIS has randomly sampled and tested RTE meat and poultry products[5] produced in federally inspected establishments for *L. monocytogenes*. During the 1980s, when *L. monocytogenes* emerged as a public health problem associated with deli meats and other processed foods, FSIS established a "zero tolerance" (e.g., no detectable level of viable pathogens permitted) for *L. monocytogenes* in RTE meat and poultry products. Such products testing positive for *L. monocytogenes* are considered "adulterated" under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA) (21 USC 453(g) or 601(m)).[6] The combination of declaring *L. monocytogenes* in RTE meat and poultry products an adulterant and continued microbiological sampling of these products for *L. monocytogenes* may have contributed to the 44 percent decline from 1989 to 1993 in the rate of illness from *L. monocytogenes*.[7]

PR/HACCP. On July 25, 1996, FSIS published its final rule on Pathogen Reduction and HACCP (PR/HACCP) Systems (61 FR 38806), which established new requirements for establishments producing meat and poultry products to improve food safety. Under HACCP, establishments must analyze their production systems, identify where hazards such as microbial contamination (e.g., *L. monocytogenes*) can occur, and establish controls to prevent or reduce those hazards. For hazards that are considered an adulterant in certain products, a "zero tolerance" is followed, and if the pathogen is detected in product, a recall of product may ensue if the product is in the market place. FSIS also requires establishments to 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) that are exposed to the environment post-lethality treatment, particularly those products that support the growth of this pathogen.

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[4] Perinatal listeriosis results from *in utero* exposure of the pregnant mother, causing fetal infection that leads to fetal death, premature birth, or neonatal illness, or death (Lennon 1984, Souef 1981).

[5] These products include cooked and fermented sausages, cooked corned beef, sliced ham and luncheon meats, beef jerky, cooked uncured poultry, and meat salads and spreads.

[6] Adulterated products are usually recalled voluntarily by the manufacturer.

[7] FSIS believes that while testing approximately 7,000 RTE meat and poultry products for *L. monocytogenes* each year helped to reduce the incidence of listeriosis, improved sampling methods (e.g., sampling design) are needed to effectively prevent illness from RTE meat and poultry products. See current RTE sampling directive: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.3.htm.

FSIS Notice/L. monocytogenes in HACCP Plans. In February 1999, during a large outbreak of listeriosis associated with hot dogs and deli meats, FSIS issued a notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were adequately addressing *L. monocytogenes* (64 FR 27351). FSIS believes that *L. monocytogenes* contamination is reasonably likely to occur in the production of most RTE meat and poultry products.

Food Contact Surface Testing for Listeria Species. FSIS acknowledges that there may be certain processing operations in which *L. monocytogenes* is not a hazard reasonably likely to occur because of control procedures addressed in the Sanitation SOPs and other programs. In these cases, the hazard is, therefore, not addressed in an establishment's HACCP system. In such establishments, verification through microbiological testing of food contact surfaces to ensure the establishment's Sanitation SOP in controlling *Listeria* species may be appropriate.[8] Were an establishment to find *Listeria* species on a food contact surface, that finding may be indicative of a sanitation problem that could cause adulteration of the product (e.g., cross-contamination).[9,10] Establishments may need to take certain actions after food contact surfaces test positive for *Listeria* species (e.g., those defined in its Sanitation SOP according to §416.15).[11]

Proposed RTE Rule. On February 27, 2001 FSIS issued a proposed rule (66 FR 12590) to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food contact surfaces for *Listeria* species after lethality treatment and before final product packaging. Establishments were given the option to avoid testing if they established a critical control point (CCP) addressing possible *L. monocytogenese* contamination after lethality treatment. The focus on the non-pathogenic indicator was made because these organisms would be found more frequently in the environment than *L. monocytogenes* and because test results would be available more quickly. Finding *Listeria* species would be indicative of a sanitation problem even though the contaminant may not be *L. monocytogenes.* The establishment and FSIS would use the test results to verify the efficacy of the establishment's "Sanitation SOPs" in preventing RTE product contamination by *L. monocytogenes.* FSIS also suggested an increased frequency of *Listeria* species testing on food contact surfaces for larger establishments. Since neither the suggested frequency of testing nor the relationship between testing for *Listeria* species on food contact surfaces and *L. monocytogenes* on the product was based on either scientific data or a risk assessment, the agency requested comment from the public regarding this ruling and initiated this risk assessment.

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[8] On January 13, 2000, the Center for Science in the Public Interest (CSPI) requested that FSIS require all RTE meat and poultry processing establishments, including those that address *L. monocytogenes* as part of their HACCP system, to conduct environmental testing for *Listeria spp.* and product testing for *L. monocytogenes.*

[9] Notably, Tompkin et al. (1986) recommended plant-wide environmental testing for a non-pathogenic "indicator" (e.g., *Listeria spp.*) instead of testing for *L. monocytogenes*. An indicator organism is one that occurs frequently in the environment or food and the presence of which is correlated to the pathogen of concern.

[10] Recurring test positives for *Listeria spp.* may indicate that the establishment has a serious sanitation problem, even if *L. monocytogenes* is never found. FSIS enforcement action will vary depending on the establishment's efforts to correct its sanitation and processing problems and its disposition of affected product.

[11] Sanitation SOP corrective actions may include "procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s)." (66 FR 12604).

Technical Public Meetings. On May 15, 2000, FSIS held a public meeting to discuss: current Agency initiatives to prevent human illness from *L. monocytogenes* in RTE meat and poultry products; the use of *Listeria* species as an indicator organism for *L. monocytogenes*; and the efficacy of environmental testing for *Listeria* species.[12] On May 8, 2001, FSIS held a public meeting to discuss scientific research and new technologies relevant to the *L. monocytogenes* in RTE meat and poultry products. At this meeting, FSIS requested data relevant to the proposed regulation regarding frequencies of testing for environmental *Listeria* species and the correlation with volume of production.[13]

Listeria Summit. On November 18, 2002, FSIS held a public meeting to provide a forum for experts from government, academia, industry, and elsewhere to discuss current research and information related to improving the safety of RTE products. The topics discussed included the role of environmental and product testing, decontamination strategies, and consumer behaviors related to RTE foods.

Risk Assessment Public Meeting. On February 26, 2003, FSIS held a public meeting to discuss the FSIS *Listeria* risk assessment model, underlying data and assumptions, and to garner data and information through public input.

RISK MANAGEMENT QUESTIONS

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

1) How effective are various food contact surface[14] testing and sanitation (corrective action) regimes (e.g., vary the frequency of testing by plant size – large, small, and very small plants) on mitigating *L. monocytogenes* contamination in finished RTE product, and reducing the subsequent risk of illness or death?;

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[12] The National Food Processors Association (NFPA) agreed that establishments should implement an environmental monitoring program for an indicator organism such as *Listeria* species. However, NFPA insists that such programs must be highly flexible in order that appropriate actions can be taken by industry. NFPA felt that mandating environmental testing was likely to be counterproductive, as it may discourage establishment efforts to find the *Listeria* species due to concerns of overly severe enforcement and compliance requirements by FSIS. Furthermore, NFPA noted that since there is no available scientific data correlating the frequency of environmental testing for *Listeria* species (and subsequent corrective actions) to reduced prevalence of *L. monocytogenes* in RTE meat and poultry products, establishments should be allowed flexibility in testing and frequency of testing. NFPA supported revision of the FSIS directive for plants operating under a HACCP system to incorporate options for industry testing for environmental *Listeria* species that would be verified by FSIS such that these establishments would be subject to a reduced frequency of product testing for *L. monocytogenes* by FSIS.

[13] In response to this request for input, the National Meat Association (NMA) submitted comments on September 10, 2001, indicating that, because of the absence of evidence, they cannot support a regulation that would require plants to test product contact surfaces for *Listeria* species at prescribed frequencies based on plant size.

[14] In-plant food contact surfaces include conveyor belts, tables, counter tops, machinery (peeler, slicer, packing equipment) that contact product (9 CFR 301, 303). In-plant non-food contact surfaces tested during in-depth verification of establishments associated with *L. monocytogenes* outbreaks or where RTE product was found positive for *L. monocytogenes* during routine monitoring include: (1) air samples; (2) floor surfaces immediately below production lines; (3) machine parts; and (4) walls.

2) How effective are other interventions (e.g., pre- and post-packaging interventions or the use of growth inhibitors) in mitigating *L. monocytogenes* contamination in finished RTE product, and reducing the subsequent risk of illness or death?; and

3) What guidance can be provided on testing and sanitization 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)?[15]

   Note: For purposes of this risk assessment, three different types of testing were considered. The first was environmental testing. This would include air ducts, walls, floor drains, etc. The second was food contact surface testing. This includes tables, rollers, or any other surface that the RTE product comes in contact with after cooking or other lethality treatment. The third type of testing was direct testing of the RTE product itself. Based on these specific risk management questions and the available data, this risk assessment focused on testing of food contact surfaces and considered a few scenarios for testing RTE product.

FSIS *LISTERIA* RISK ASSESSMENT

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 deli meats at retail was developed using currently available data. The outputs of the in-plant model (e.g., concentration of *L. monocytogenes* on deli meat at retail) were used as inputs into the updated FDA/FSIS retail-to-table exposure pathway for deli meats. This output was calibrated to the concentration of *L. monocytogenes* in RTE product at retail in the FDA/FSIS exposure assessment pathway, which included recently available retail survey data (Gombas, 2003). The FDA/FSIS exposure assessment then tracks the level of *L. monocytogenes* in deli meat from retail to table, and provides estimates of the subsequent risk of illness or death from consuming these RTE products. These two connected models – the in-plant model and the updated retail-to-table FDA/FSIS exposure assessment and FDA/FSIS dose-response relationship – comprise the overall FSIS *Listeria* risk assessment model.

The in-plant model is unique in that it is a dynamic model with spatial and temporal components, which track the movement of *Listeria* contamination from food contact surface to RTE product during processing. In general, there are few published studies that discuss microbial contamination within a food processing plant. den Aantrekker *et al.* (2002) develop, but do not actually apply, a detailed model of bacterial recontamination within a food processing environment for different exposure pathways. As a result, the FSIS *Listeria* risk assessment

[15] The efficacy of microbiological testing is unclear in the literature. Brown et al. (2000) argue that, under HAACP, enumeration of indicator organisms is more appropriate that pathogen detection, and that batch testing for pathogens is not an effective method for evaluating food safety. Swanson and Anderson (2000) argue that microbial testing is needed to validate critical control points, but that once this is accomplished microbiological testing is ineffective. Nestle (2003) argues that additional testing would produce safer food. Sugarman (2003), in an interview with Jack in the Box VP for Quality and Logistics David Theno, states that Jack in the Box is currently testing ground beef production every 15 minutes at 3 processing plants ten years after the E. coli O157:H7 outbreak. Theno states that testing can be used to control contamination levels. Given this uncertainty concerning testing effectiveness, the goal of this risk assessment was to quantify the relationship between testing and public health.

model provides a useful tool to evaluate the effectiveness of various interventions to control contamination of RTE product from in-plant sources of *Listeria* and reduce the subsequent risk of illness or death from *L. monocytogenes* on RTE product. By modeling changes in plant practices such as: the frequency of testing and sanitation of food contact surfaces, the effectiveness of pre- and post-packaging interventions[16], the effectiveness of growth inhibitors, effectiveness of enhanced sanitation, as well as combinations of these practices, this risk assessment can provide numerous outputs to address specific risk management questions. The in-plant risk assessment model was also developed with user-friendly interfaces to allow users to change scenario conditions and assumptions. As a result, this risk assessment model can be used as a tool to explore a variety of risk management scenarios beyond those developed for this report.

Note: An implicit assumption in this risk assessment is that all *L. monocytogenes* on RTE product comes from food contact surfaces and not from an inadequate lethality treatment. This assumption is necessary to evaluate the specific risk management question provided by FSIS risk managers. Also, in developing the FSIS *Listeria* risk assessment model, FSIS has generally left unchanged the components of the current FDA/FSIS exposure assessment for deli meats and the FDA/FSIS dose-response relationship for use in this risk assessment.[17]

Model Overview

The 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 FSIS *Listeria* risk assessment, in both the in-plant dynamic model and the FDA/FSIS retail-to-table exposure assessment for deli meats. The inputs for the in-plant dynamic model of the 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

[16] Pre- and post-packaging interventions are those implemented after the potential pathogen transfer from food contact surface to RTE product has occurred.

[17] The FDA/FSIS risk-ranking model has undergone extensive review and public input. As a result, FSIS did not change any of the components of that retail-to-table exposure assessment for deli meats or hot dogs, including the dose-response relationship updated based on public comment.

In the 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 FDA/FSIS retail-to-table exposure assessment for deli meats and the current 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[18]). 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. The model may also be run for hot dogs/frankfurters in the future.

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.

[18] Product reformulation is another process for achieving inhibition of growth and is treated the same as using other growth inhibitors in this model.

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.

Updated FDA/FSIS Risk Ranking Model

The 2001 FDA/FSIS risk ranking model was developed to identify the relative risk of illness or death posed by RTE foods in 20 categories (FDA/FSIS, 2001). This assessment indicated that deli meat posed the greatest public health risk for listeriosis of all the RTE foods. Roughly 80% of all deaths and cases are caused by deli meats according to the FDA/FSIS risk ranking model. This model was originally released for public comment and review in January, 2001. Based on review and comments, the exposure assessment for deli meats (and hot dogs) and the dose-response relationship have been updated.

The current FSIS *Listeria* risk assessment is designed to simulate RTE food production within the processing plant and predicts the *L. monocytogenes* concentrations at retail. It uses the updated FDA/FSIS exposure assessment for deli meats and the updated dose-response relationship to model distributions of the concentration of *L. monocytogenes* on RTE product at retail through consumption and estimates the subsequent annual number of deaths and illnesses.

The 2001 FDA/FSIS risk ranking model is comprised of two major components – an exposure assessment and a dose-response relationship. A separate retail to table exposure assessment pathway was constructed for each of the RTE food categories. Results from all the RTE food categories were then carried forward to the dose-response simulations, where a separate simulation was constructed for each of the three population groups: elderly, intermediate, and perinatal.[19] The exposure assessment for deli meats incorporated new data, including retail survey data from the National Food Processors Association (NFPA) on the prevalence and level of *L. monocytogenes* on RTE products (Gombas, 2003).

A two-dimensional Monte Carlo simulation was used to integrate the components for each of the twenty exposure assessment pathways for each of the RTE food categories, with 100,000

[19] For the purposes of this model: elderly were defined as being 60 years of age or older; the intermediate population were those older than 30 days and less than 60 years old; and the perintal included fetuses and newborns from 16 weeks after fertilization to 30 days after birth (i.e., the pregnancy-associated cases where the mother experiences a foodborne *L. monocytogenes* infection during pregnancy, exposing her fetus to the pathogen).

variability iterations and 300 uncertainty iterations. The end result of each exposure simulation is the fraction of servings that occur at designated dose levels (broken out at half-$\log_{10}$ intervals) for each food category and population group. The conversion to dose bins was necessary in order to integrate the exposure simulation, which evaluated the exposure from individual servings, with the dose-response model, which predicted the number of cases at a population level. For more information on the 2001 FDA/FSIS risk ranking model see: http://www.foodsafety.gov/~dms/lmrisk.html.

The simulation in the FDA/FSIS risk-ranking model was carried out in several steps. First, a two-dimensional Monte Carlo simulation was used to integrate the variability and uncertainty of the initial RTE contamination levels, predicted growth of *L. monocytogenes* per serving, and serving size, with 100,000 model variability iterations and 300 model uncertainty iterations. The variability dimension for the estimated doses was then condensed to half-$\log_{10}$ increments, which ranged from -5 to +10 logs for each of the 300 model uncertainty iterations. Second, a one-dimensional (uncertainty only) dose-response simulation was run by selecting, one of the 300 exposure distributions for each food category, then adjusting these distributions for strain-virulence and host susceptibility factors. The dose-adjusted exposure distributions (i.e., the concentration of *L. monocytogenes* in servings of RTE product) were then integrated with a dose-response function to predict the total number of deaths per annum for each food category. The total number of listeriosis deaths per annum was estimated by summing the deaths across all food categories. On each uncertainty iteration, the dose-response function was adjusted until the total number of listeriosis deaths was equivalent to CDC surveillance estimates.

The dose-response simulations consisted of 4000 model uncertainty iterations. During the model simulation, a dose-response scaling factor was determined to equate the deaths predicted by the dose-response function and the exposure distribution for each of the food categories, with the public health estimates for current annual rates of listeriosis. Since the 2001 FDA/FSIS risk ranking model is calibrated such that the overall predicted incidence of listeriosis is in line with the actual incidence of listeriosis based on CDC surveillance data, an implicit assumption is that the foods encompassed by the food categories account for all cases of foodborne listeriosis.

In order to facilitate scenario comparisons, the same sequence of random numbers were used in different simulations to permit comparisons.

In-plant Dynamic Model

Conceptual Model

A schematic overview of the conceptual model is provided in 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.

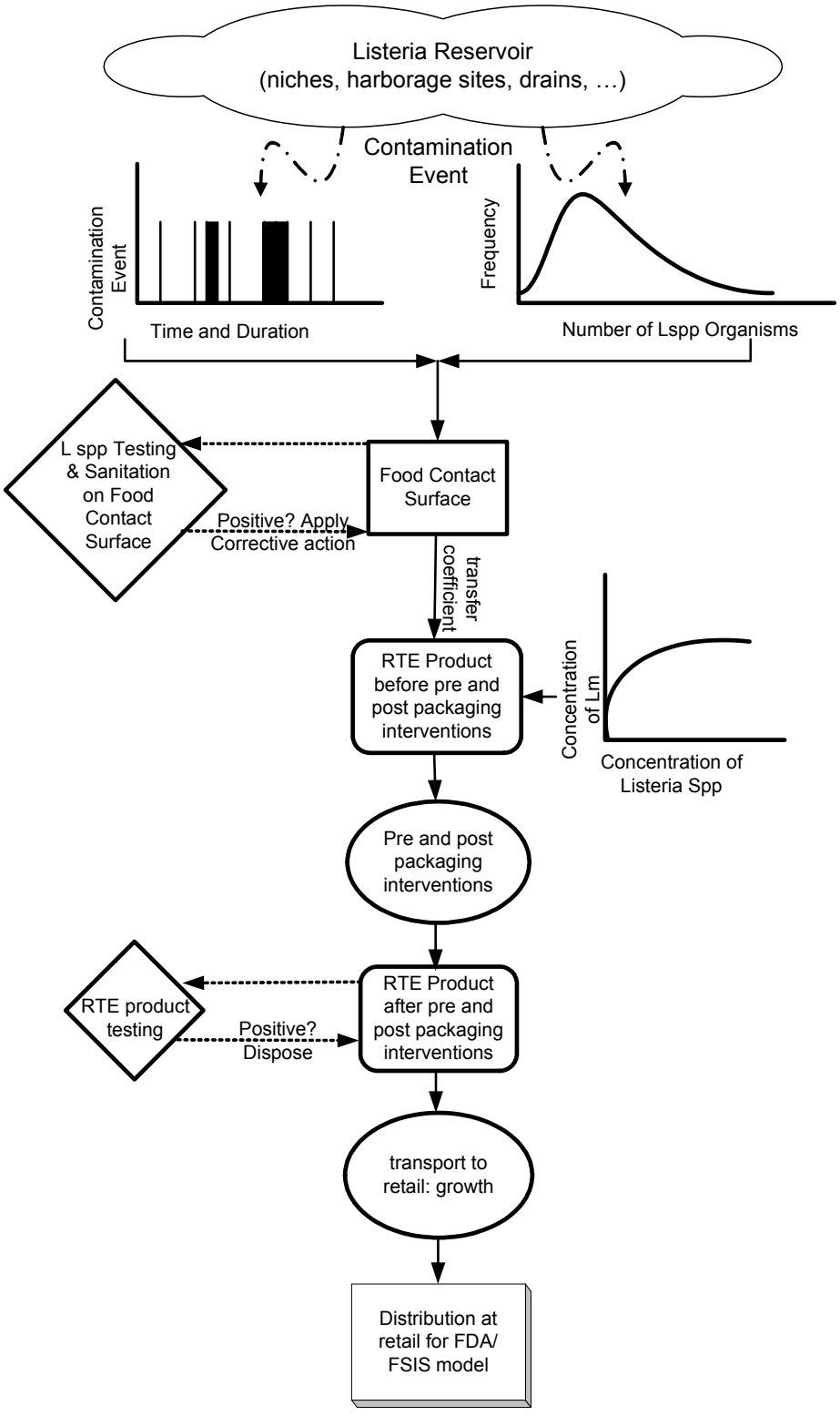


Figure 1. Conceptual Model for the "In-plant" Component of the FSIS *Listeria* Risk Assessment.

The concept of long-term *Listeria* reservoirs (harborage sites) in plants assumed in the FSIS *Listeria* risk assessment is supported by recent studies published in the literature. Lunden *et al.* (2002) described sequential *L. monocytogenes* contamination at three plants as a dicing machine was moved from plant to plant. This study provides an example where food processing equipment can act as long-term harborage sites over a long period of time even while typical sanitation measures are being taken.

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: 1) the time between initialization of events (i.e., How often is a food contact surface contaminated?); 2) the duration of the event (i.e., How long does it last?); and 3) the amount of *Listeria* species transferred from the in-plant reservoir to the food contact surface.

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.[20]

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. 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 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.

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 is transferred to the product lot being processed.

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

[20] Air was tested and not found to be a source of contamination. Inadequate cleaning was also indicated as a reason for contamination.

At this point the product lot can undergo post-lethality treatment (i.e., pre- and post-packaging intervention(s)[21]**,** which will reduce the concentration of *L. monocytogenes*. 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 assumes a lag time of about 3 days. The model also assumes that product lots of RTE product that test positive for *L. monocytogenes* are removed from the food supply. Operationally, this would be accomplished by re-processing the lot for human food, diversion of the lot into products not intended for human consumption, or disposal of the lot.

After pre- and post-packaging interventions and possible additional RTE product testing, the lot proceeds to retail. Using the deli meat component of the updated FDA/FSIS risk ranking model, the growth of *L. monocytogenes* during the transport stage was estimated. A constant logarithmic growth factor is applied in the model (see Appendix B). Because three different plant sizes are modeled, the final step in the model is to select the lots that appear at retail from among the lots produced by each plant size. The resulting distribution of *L. monocytogenes* concentrations on RTE product at retail serves as an input for the updated FDA/FSIS risk ranking model to estimate the public health impacts (illnesses and deaths).

The FSIS *Listeria* risk assessment team considered including additional detail, such as modeling various types of food contact surfaces, additional operational steps based on the type of ready-to-eat product, additional interventions, and pathways of contamination of food contact surface or product from the plant environment. However, the current model was designed specifically to answer the risk management questions posed by FSIS risk managers. The current level of detail in the FSIS Listeria risk assessment is adequate to inform decision-making based on these risk management questions. To incorporate additional operational steps and variability in the FSIS Listeria risk assessment model would require the availability of additional data adequate to provide this level of detail. Such data are not available in the published literature and have not been made available to the Agency.

Sources of Data and Assumptions

Based on the conceptual model for the FSIS *Listeria* risk assessment (Figure 1), a summary of the data and assumptions used in this model are provided below (Table 1).

[21] 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.

Table 1. Available data and assumptions for the "plant to table" FSIS *Listeria* risk assessment.

Model Step	Data Required	Available Data	Assumptions
Occurrence of a "contamination event"[22]	Distribution (mean and shape) for time between contamination events	FSIS in-depth verification investigation – number of food contact surface samples that test positive for *Listeria* spp. over a specified time period	Distribution does not change by size of plant. Interventions do not change time between contamination events.
	Duration of a contamination event	Tompkin (2002) provides table of number of plants with successive weekly positive *Listeria* food contact surfaces.	Duration does not change by size of plant. Intervention does not change duration.
	Number of *Listeria* spp. transferred to food contact surface during each lot production.	None. Levels calibrated to match FDA/FSIS risk exposure assessment concentration distribution for *L. monocytogenes* on deli meat at retail (includes recent NFPA data in FSIS Docket 03-005N).	Distribution assumed log normal. Intervention does not change number transferred.
	Food contact surface area	None.	Assumed to vary by plant size in proportion to mean lot weight.
	Fraction of deli meats produced by plant size.	FSIS RTE survey results (FSIS 2003).	Lot assumed to be 1 shift production per line. Model assumes 2 shifts per day and 30 days per month. Minimum lot weight for any plant size assumed to be 1000 lbs.
Testing of food contact surface	Area swabbed Probability of detecting 1 organism	Area swabbed provided by industry (Dr. Brie Wilson, National Turkey Federation, personal communication, November 2002). Information also provided by Dr. Sharar, FSIS/OPPDE, November 2002.	
Transfer of *Listeria* species from food contact surface to RTE product	Transfer coefficients for the transfer of pathogens from food contact surfaces to RTE products	Scientific literature: Montville et al. (2001); Chen et al. (2001); and Midelet and Carpentier	

[22] A "contamination event" is defined as *Listeria* spp. contaminating a food contact surface from workers hands, through environmental disruption, etc.

		(2002)	
Sanitation of food contact surface	Sanitation timings and effectiveness	The frequency of sanitation and sanitation effectiveness can be input into the model	
Convert food contact surface concentrations for *Listeria* spp. into *L. monocytogenes* surface concentrations on RTE product.	Proportion of *Listeria* spp. (levels) that are *L. monocytogenes* (levels)	Scientific literature: Tompkin, 2002 and 1992	Assume that the prevalence distribution provided by Tompkin are similar to those for concentration
	Lot weight (production volume per line per shift) by plant size	FSIS RTE survey results (FSIS 2003)	
Post Processing	Fraction of industry implementing controls and their effectiveness	(Input provided by FSIS/OPPED, December 2002)	Varied by scenario analyzed
Product testing for *L. monocytogenes*	Sample mass Frequency of testing	Mass from USDA guidelines. Frequency of testing varied by scenario.	
Transportation of RTE product to retail	Growth multiplier	FDA/FSIS exposure assessment for deli meats	Growth multiplier fixed at 1 log unit for all lots.
	Fraction of industry employing growth inhibitors or product reformulation and its effectiveness		Varied by scenario analyzed
L. monocytogenes in RTE product from retail to consumer	None. Model output.	Use the updated FDA/FSIS exposure assessment for deli meats for *L. monocytogenes* in RTE products as calibration values for *Listeria* added during contamination event.	
Public health impacts	No additional data.	Uses the updated FDA/FSIS dose-response model	

Note: Keep in mind that the quality of the assessment of data is distinct from the sufficiency of the available data. While there was limited data for this risk assessment, key uncertainties (e.g., the dose-response relationship developed in the FDA/FSIS risk ranking) are likely to remain for quite some time until additional data becomes available. FSIS used the "best available" data to conduct this risk assessment. The option not to use risk assessment in decision-making was clearly not acceptable to the public based on comments received by the Agency for the Feb. 27, 2001 proposed rule. Moreover, the decision not to make any decision in light of the number of illnesses associated with *L. monocytogenes*, particularly from deli meats, which compromise about 80% of cases based on the FDA/FSIS risk ranking of illnesses/deaths associated with RTE products, is not acceptable in light of Healthy People 2010 goals. Risk assessment organizes data into a systematic framework to evaluate the marginal public health benefits (e.g., lives saved

or deaths prevented) associated with a potential intervention relative to the decision to maintain the status quo. Such information was deemed useful for risk management decision-making.

Model Calculations and Base Values

This type of risk assessment model is a dynamic model and has spatial and temporal interactions that make it somewhat difficult to present as pure mathematical equations. However, the major equations and base values are provided below. The justifications for the base values are provided later.

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 below. 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:

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

where

Table 2. Variables and Base Values for *Listeria* Concentration on Food Contact Surface.

Variable	Definition	Type	Base Value*
LSj	Listeria spp concentration on food contact surface at end of lot j (cfu/cm^2)	stochastic, calculated	NA
TCj	transfer coefficient for lot j (dimensionless)	stochastic, input	LN(-0.14, 1), truncated to between 0 and 1
δ(j)	added Listeria spp. concentration added to the food contact surface if a contamination event is ongoing (cfu/cm^2) $\delta(j) = \begin{cases} 0 & \text{if not during contamination event} \\ RN \sim LN(-6,3.5) & \text{if during contamination event} \end{cases}$	stochastic, input	LN(-6, 3.5)
s_j	Sanitation effectiveness	calculated	See below

*LN indicates log10 normal distribution with mean and standard deviation given on the log10 scale

The sanitation effectiveness s_j for each time period (or lot produced) is

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

where

Table 3. Variables and Base Values for Sanitation of Food Contact Surface.

Variable	Definition	Type	Base Value
s_j	sanitation effectiveness for lot j (dimensionless)	calculated	NA
s_{wipe}	between-lot sanitation effectiveness (dimensionless)	fixed, input	0.50
s_{sop}	end of day sanitation effectiveness (dimensionless)	fixed, input	0.75
s_{enhan}	enhanced sanitation effectiveness if a previous FCS was tested, found positive, and the enhanced sanitation option is selected (dimensionless)	fixed, input	0.95
s_{lag}	s_{lag} = FCS report lag in days * number of lots produced per day (lot units, i.e. time)	fixed, input	6 (3 days * 2 lots per day)

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

Table 4. Variables and Base Values for the Concentration of *L. monocytogenes* in a RTE Product Lot Produced in the Plant.

Variable	Definition	Type	Base Value*
LM_j	*L. monocytogenes* concentration in RTE product lot j (cfu/g)	stochastic, calculated	NA
A_j^*	food contact surface area at lot j , stochastic (* only varies for new contamination event) (cm)	stochastic, input	U(100000, 1000000)
M_j	mass of lot j (lb, internally	stochastic, input	varies by plant size large: N(19371,

	converted to g)		14000) small: N(7100, 10600) very small: N(2800, 9500)
R_j	*L. monocytogenes* / *Listeria* spp ratio for lot j (dimensionless)	stochastic, input	N(0.52, 0.26), truncated to between 0 and 1

* U() represents a uniform distribution with minimum and maximum given
N() represents a normal distribution with mean and standard deviation given

Post processing interventions are then applied which can reduce the concentration of *L. monocytogenes* in the RTE lot.

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

where

Table 5. Variables and Base Values for the Concentration of *L. monocytogenes* in a RTE Product Lot With Consideration of Post-Processing Interventions.

Variable	Definition	Type	Base Value
$LMPP_j$	*L. monocytogenes* concentration in RTE lot j after post processing interventions (cfu/g)	stochastic, calculated	NA
PP_k	Post processing intervention effectiveness for plant size k (dimensionless)	Stochastic, input	0 $U(PP_{min}, PP_{max})$ when applied
FPP_k	Fraction of lots for plant size k that undergo post processing interventions (dimensionless)	Fixed, Input	0
RN_j	Uniform random number used to test if lot j should undergo post processing	Stochastic, calculated	U(0,1)

Post processing interventions were not modeled for the base run. The different plant sizes were allowed to have different minimum and maximum values. Note: 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.

During the transport from the processing plant to retail, bacterial growth could occur which increased the concentration of *L. monocytogenes*. The product or packaging could be formulated to reduce the growth.

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

where

Table 6. Variables and Base Values for Modeling Growth of *L. monocytogenes* in Product.

Variable	Definition	Type	Base Value
$LMGI_j$	*L. monocytogenes* concentration in lot j after growth and growth inhibition during transport to retail (cfu/g)	Stochastic, calculated	NA
GF	Growth factor applied to all lots	Fixed, input	1
GI	Growth inhibition factor	Stochastic, input	0 $UN(GI_{min}, GI_{max})$ when applied
FGI_k	Fraction of lots for plant size k that undergo growth inhibition (dimensionless)	Fixed, Input	0
RN_j	Uniform random number used to test if lot j should undergo growth inhibition	Stochastic, calculated	U(0,1)

Growth inhibition was not modeled for the base run. Note that, based on the values of GF and GI, it was possible for growth inhibition to actually reduce the concentration of *L. monocytogenes* in the lot.

The model actually generates the requested number of lots for each plant size, and then selects a continuous run to combine for the retail distribution. The number of lots in the run is determined by the fraction of production for each plant size.

$$LMComb_i = \begin{cases} LMGI_k^{large} & \forall\ k = start, FP_{large} * NSim \quad \cup \\ LMGI_k^{small} & \forall\ k = start, FP_{small} * NSim \quad \cup \\ LMGI_k^{verysmall} & \forall\ k = start, FP_{verysmall} * NSim \end{cases}$$

where

Table 7. Variables and Base Values for Modeling Retail Concentration of *L. monocytogenes* in a Product Lot.

Variable	Definition	Type	Base Value
LMCombi	*L. monocytogenes* concentration in lot i after combining lots from different plant sizes (cfu/g)	Stochastic, calculated	NA
start	Starting lot number for run	Fixed, built-in	100
FPk	Fraction of pounds produced by each plant size k (dimensionless)	Fixed, input	Large = 0.48 Small = 0.48 Very small = 0.04
NSim	Number of lots to simulate for each	Fixed, input	1000000

	plant size		

The first lot produced assumed that the FCS Listeria concentration is 0 cfu/gram. To prevent this initial value from biasing the final results, the first 100 lots simulated for each plant size are excluded from further consideration. In effect, this seeds the starting FCS concentration.

The final retail distribution is based upon the combined distribution but filtered depending on whether the lot was tested and the corresponding result. Any lot that was not tested and any lot that was tested and returned a negative passes on to retail. Any lot that was tested and found positive is removed.

$$LM\text{Retail}_i = LMComb_i \mid_{\text{i not tested}} \cup LMComb_i \mid_{\text{i tested negative}}$$

FCS and RTE Lot Testing

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):

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

The RTE lot sample is judged positive by

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

where

Table 8. Variables and Base Values for Testing for *L. monocytogenes* in Product.

Variable	Definition	Type	Base Value
$\mathrm{LM}_{\text{sample j}}$	total *L. monocytogenes* cfu in test sample j (cfu)	stochastic, calculated	NA
pDLM	probability of detecting 1 *L. monocytogenes* cfu in test if present (dimensionless)	fixed, input	0.75
$\mathrm{U}(0,1)_{\text{j}}$	uniform random number between 0 and 1 (dimensionless)	stochastic, calculated	NA
$\mathrm{LMR}_{\text{sample j}}$	*L. monocytogenes* test result for lot j (positive or negative)	stochastic, calculated	NA

The testing procedure for food contact surfaces was similar, with the relevant substitutions.

$$LS_{sample\ j} = Poisson\left(A_{swab\ j} * LS_j\right)$$

The FCS sample is judged positive by

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

where

Table 9. Variables and Base Values for Testing for *Listeria* on Food Contact Surface.

Variable	Definition	Type	Base Value
$LS_{sample\ j}$	total Listeria species cfu in test sample j (cfu)	stochastic, calculated	NA
pDLS	probability of detecting 1 Listeria species cfu in test if present (dimensionless)	fixed, input	0.75
$U(0,1)_j$	uniform random number between 0 and 1 (dimensionless)	stochastic, calculated	NA
$LSR_{sample\ j}$	LS test result for lot j (positive or negative)	stochastic, calculated	NA

Parameter Descriptions and Baseline Values

1) Frequency of a Contamination Event [How often does a 'contamination event' occur?]

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). These data are shown in Table 10, and summarized in Table 11. The data were analyzed using survival analysis and distribution fitting using NCSS[23] statistical software (Hintz, 2001)**.** Several distributions were compared, and the $\log_{10}$ normal distribution had the greatest likelihood (Table 12). 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. Figure 2 shows the resulting fit.

This analysis should be considered as an estimate only. Samples were not taken on a daily basis, and in some cases a considerable number of days passed between samples. Nor does the data provide sufficient sampling evidence to estimate the duration of contamination in comparison to

[23] Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute endorsement or imply its endorsement, recommendation, or favoring by the United States Government.

other data (i.e., Tompkin, 2002). Finally, these data were taken at a plant associated with an *L. monocytogenes* outbreak. How representative this plant's data are compared to other plants is not known.

Table 10. FSIS in-depth verification time series data for estimating time between contamination events (Hynes 2000).

Day	Sequential Number Positive	Line	Days Between Positives	Censor* Type
12	2	1	11	F
16	3	1	4	F
31	4	1	15	F
49		1	18	R
3	2	2	2	F
11	3	2	8	F
19	4	2	8	F
44	5	2	25	F
57		2	13	R
5	2	4	4	F
16		4	11	R
18	2	5	17	F
95	3	5	77	F
97	4	5	2	F
117	5	5	20	F
124	6	5	7	F
138		5	14	R

* Censoring refers to the type of observation that was made. An F or failed observation is one in which the time until the terminal event was measured exactly. An R or right censored observation provides a lower bound for the actual failure time. An L or left censored observation provides an upper bound for the actual failure time. An I or interval censored observation is one in which we know that the failure occurred between two time values, but we do not know exactly when (Hintz, 2001).

Table 11. Summary of Mean Time Between Start of Contamination Events

Type of Observation	**Count**	**Minimum (days between)**	**Maximum (days between)**
Failed	13	2	77
Right Censored	4	11	18
Left Censored	0		
Interval Censored	0		
Total	17	2	77

Table 12. Maximum Likelihood Fits to Mean Time Between Contamination Events for Various Distributions

Distribution	**Likelihood**	**Shape**	**Scale**	**Threshold**
Lognormal10	-50.89	1.08	0.46	0.0

Lognormal	-50.89	2.50	1.06	0.0
Loglogistic	-51.19	2.50	0.62	0.0
Weibull	-51.71	1.05	19.85	0.0
Exponential	-51.74	1	19.69	0.0
Logistic	-57.21	14.82	8.23	0.0
Normal	-59.05	19.10	18.97	0.0
Extreme Value	-63.73	32.23	25.68	0.0

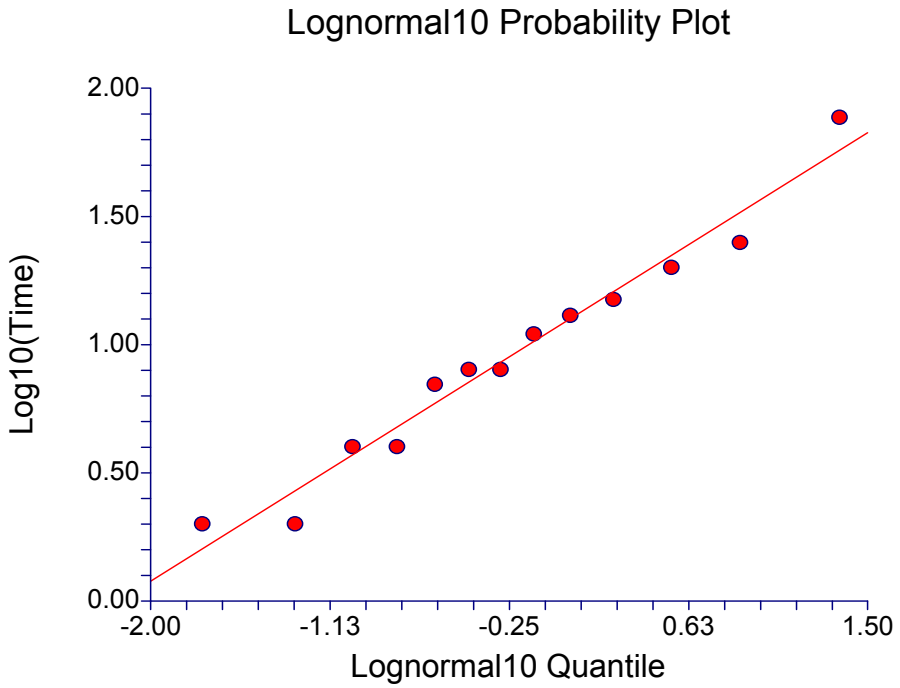


Figure 2. Fit of mean time between contamination events to log normal distribution.

FSIS selected input distributions based on a maximum likelihood fit and a visual fit of data. Given the shortcomings of goodness of fit tests, this approach was considered reasonable for ascertaining the adequacy of fit. Frey (1999) pointed out that the most important approach for ascertaining the adequacy of fit due to the shortcomings of goodness of fit is to consider the visual fit of the data. FSIS believes that its selection of input distributions was reasoned, transparent, and reproducible.

The available data to estimate the time between contamination events came from an in-depth verification investigation of an establishment producing ready-to-eat meat and poultry product associated with an outbreak of *L. monocytogenes*. This was the only data available for this model parameter. Besides the log normal distribution, an exponential distribution is often used to model a mean time between failure, and this theoretical approach was considered.

To compare the two approaches, 10000 random numbers were generated using the best fit parameters for both the log normal distribution and the exponential distribution. The summary statistics comparing the distributions are shown in Table 13 below.

Table 13. Selection of a Distribution for the Time Between Contamination Events.

Parameter	Log normal deviates	Exponential deviates
minimum	0.22	0.000117
Q25	5.88	5.40
Q50 (median)	12.05	13.25
mean	20.56	19.49
Q75	23.61	26.93
maximum	717.40	197.00

The values within the middle quartile range are quite similar. The distributions differ most in the tails. A quantile-quantile plot comparison of the two approaches is shown in Figure 3. Clearly, the log normal distribution is much more right skewed than the exponential. This implies that, at times, the random number generated will mean that several years can pass between contamination events if the log normal distribution is used, but not if the exponential distribution is used. Because the observed data fall much nearer the central value of the distribution, it is difficult to use the data alone to decide. Discussions with deli meat producers suggest that fairly long time between contamination events are possible for some plants. Thus it seemed appropriate to use a log normal distribution for this parameter.

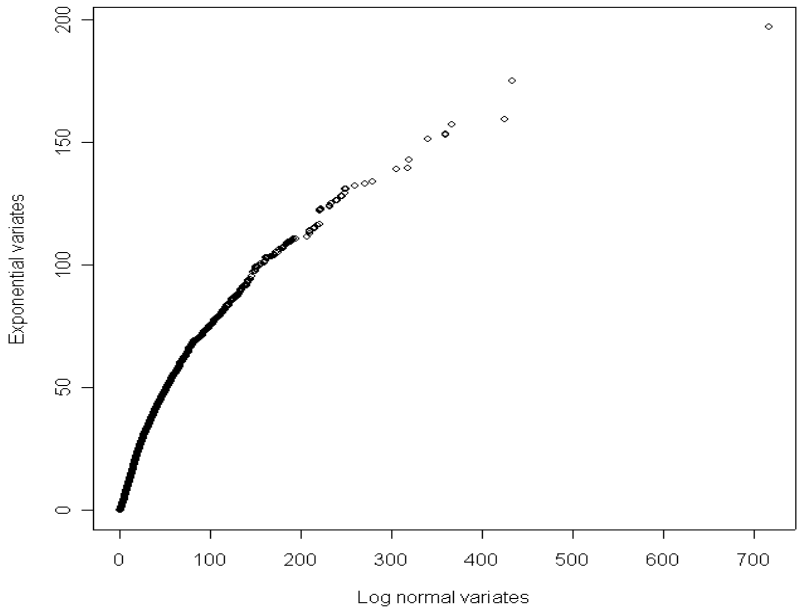


Figure 3. Quantile-Quantile Plot Comparison of the Lognormal and Exponental Distributions for the Time Between Contamination Events.

The selection of the most appropriate distribution has been discussed at length in the agency and the lognormal distribution was selected because it was considered to be biologically more

plausible. That is, it is conceivable that the movement of Listeria contamination from a biofilm in the in-plant environment is a multi-step process and that the probability of this movement occurring increases over time as the biofilm accumulates. This process would be better represented by the lognormal distribution rather than an exponential distribution.

2) Duration of a Contamination Event [How long does a contamination event last?]

Tompkin (2002) provided a table of sequential weekly *Listeria* species testing results and the number of weeks that *Listeria* species positives persisted. While the data available to estimate this parameter was limited, the Tompkin (2002) data was peer-reviewed, represented industry data, and was likely more representative than targeted environmental sampling data. Therefore, FSIS concludes that its reliance on these data was appropriate. These data were analyzed using survival analysis and distribution fitting with NCSS (Hintz 2001). Table 14 shows the data and Table 15 summarizes it. Table 16 provides the maximum likelihoods estimates for a variety of parameters. The $\log_{10}$ normal distribution had the second greatest likelihood (behind the log logistic). On the basis of consistency, ease of interpretation and ease of implementation, the lognormal distribution was used during the simulation. 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. Figure 4 illustrates the fit

Table 14. Data for Contamination Event Duration Analysis. (Adapted from Tompkin 2002)

Number of Weekly Tests	Time (Days)	Start Time (Days)	Censor Type
483	7	0	L
136	14	7	I
36	21	14	I
32	28	21	I
44	35	28	R

Table 15. Summary of Duration of Contamination Event

Type of Observation	Count	Minimum (days)	Maximum (days)
Failed	0		
Right Censored	44	35	35
Left Censored	483	7	7
Interval Censored	204	7	28
Total	731	7	35

Table 16. Maximum Likelihood Fit to Distributions for Contamination Event Duration

Distribution	Likelihood	Shape	Scale	Threshold
Loglogistic	-777.5997	1.455336	0.7245711	0.0
Lognormal10	-780.1027	0.6019546	0.5728621	0.0
Lognormal	-780.1027	1.386052	1.319064	0.0

Weibull	-785.0569	0.6291547	5.966346	0.0
Logistic	-805.0837	-0.5512639	10.47769	0.0
Normal	-815.7148	-2.161562	20.28963	0.0
Exponential	-828.398	1	8.356113	0.0
Extreme Value	-830.9927	3.349459	26.03331	0.0

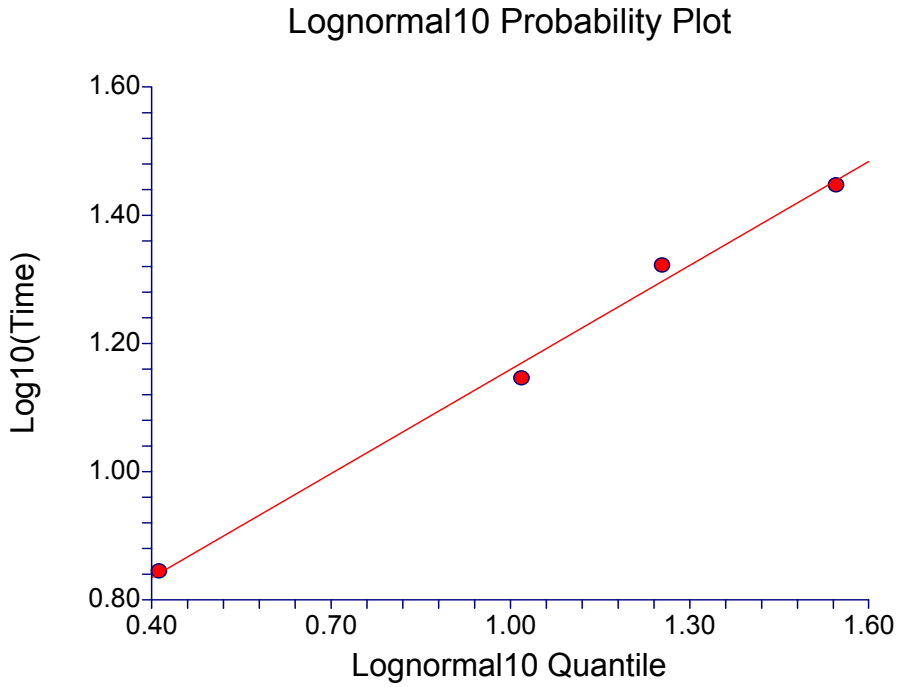


Figure 4. Log normal distribution fit for duration of contamination event.

3) *Listeria* spp. added to FCS during a contamination event

There was no reported literature available to estimate this parameter. The FSIS *Listeria* risk assessment team decided that calibration of the model to obtain this input was preferable to other options (e.g., expert elicitation where the there is no knowledge, expert or otherwise, to estimate the level of L. monocytogenes transferred from a harborage site to food contact surface).

Model calibration consists of changing values of model input parameters in an attempt to match the model's output with independently derived values within some acceptable criteria. Calibration has been used for decades as a standard step in the modeling process, particularly when specific parameter values are unknown and relevant data do not exist. Calibration is well-founded in the scientific literature. While it would be desirable to have data regarding, for example, the concentration of *Listeria* spp. on food contact surfaces, such data do not exist. In this case, it was entirely appropriate to use calibration methods to estimate the distribution of the concentration of *Listeria* spp. on food contact surfaces by matching the model's output with the FDA/FSIS risk ranking model's estimated input for *L. monocytogenes* contamination at retail.

The FDA/FSIS risk ranking model is calibrated, or "anchored" on human health surveillance data that currently provide the best estimate of the magnitude of the public health problem associated with L. monocytogenes in food. Taking the FDA/FSIS risk ranking model as a given,

the FSIS calibration procedure used to infer the initial concentration distribution makes good use of the available scientific information. Ideally, additional information on the initial L. monocytogenes levels would be useful, but the very low concentrations estimated for the vast majority of RTE product would frustrate additional efforts to collect better data at this point in the production process. Ideally, risk assessment models would be validated against independent observed data, but this is often not practicable. Model calibration or "anchoring" is a generally accepted practice in health risk assessment and environmental modeling (National Academy of Sciences 2002). The practice is most appropriate when the primary objective of the risk assessment is, as in this case, to provide a risk management tool for analyzing how to mitigate risk rather than to predict risk. Model calibration has been employed in one fashion or another in the prior USDA microbiological food safety risk assessments (Salmonella Enteriditis and Escherichia coli O157:H7), as well as the Joint Food and Agriculture Organization/World Health Organization risk assessments of Vibrio species (FAO/WHO 2001) and Salmonella (FAO/WHO 2002). There is a trade-off, however, since data used to calibrate the model are unavailable for independent model validation. In the future, it may be possible to use a portion of surveillance data for model calibration and withhold a portion for model validation.[24]

4) Sanitation Effectiveness

Clean-up effectiveness measures the proportion of bacteria on the food contact surface that is removed through sanitation procedures. The model assumes the effectiveness of clean-up between lots is 50% and end of day clean-up is 75%. Therefore, total effectiveness of routine cleaning is actually 1-[(1-50%)*(1-75%)]=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). While some plants may achieve greater log reductions from their cleaning practices, the effectiveness levels assumed in this risk assessment seem reasonable as averages across the entire industry.

Regarding enhanced cleaning, it seems unreasonable to assume an infinite log reduction. Such a level of effectiveness could never be proven experimentally. Nevertheless, an analysis of these inputs suggests the model is insensitive to higher effectiveness levels because much of the contamination on food contact surfaces is transferred to RTE deli meats during the time of processing.

5) Transfer of *Listeria* species from Food Contact Surface to RTE Product

[24] Note that model calibration is distinct from model validation. Model validation is a process for assessing how accurately the model predicts actual phenomena in nature. Validation involves the comparison of model predictions with empirical data not used in developing the model. See Law and Kelton (1991) for a further discussion of the distinction between calibration and validation. Given the limited data available to develop this risk assessment model, validation was not accomplished. Nevertheless, because annual mortality from *L. monocytogenes* in RTE foods is expected to be reasonably constant from year to year (absent some purposeful intervention to prevent such mortality), this model's predictions about annual mortality are expected to be reasonably consistent with estimates from future public health surveillance data. Such consistency provides a limited validation of this model.

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. The resulting *L. monocytogenes* surface concentrations were estimated in the range $10^{6.1}$ cfu/cm2 for stainless steel to $10^{6.4}$ cfu/cm2 for PVC. Twelve sequential contacts with beef were then conducted. After 12 contacts, the study results suggested that approximately

a) log 6.1 transferred from log 6.1 initial population for stainless steel, for a transfer coefficient of 1

b) log 6.45 transferred from log 6.8 initial population for PU for a transfer coefficient of 0.45

c) log 6.25 transferred from log 6.4 initial population for PVC for a transfer coefficient of 0.71

The mean transfer coefficient used was 0.72, which is equivalent to a mean log transfer coefficient of -0.14. The standard deviation reported from Montville et al. (2001) and Chen et al. (2001) is assumed to apply for this input. Variability about the transfer coefficient, therefore, was assumed to be log normally distributed (normally distributed on the log scale) with the mean of –0.14 and a standard deviation of 1. Values generated above 0 (i.e. 100% transfer) were simply truncated to 0. These values imply that the majority of the *Listeria* species on food contact surfaces readily transfer to product.

Estimations for the three different materials were used in the Midelet and Carpentier (2002) paper. Because in the risk assessment the food contact surface was modeled as a single representative surface, a stochastic transfer coefficient varied from lot to lot based on these estimates was deemed appropriate.

Although the distribution is truncated at 100% transfer, the actual approach used does not result in a two-peaked distribution to any noticeable extent. It is certainly true that because of the truncation in the generation of the transfer coefficients, the resulting distribution is not normal on the log scale. Figure 5 presents a histogram of 10000 simulations for the transfer coefficient using the approach in this risk assessment. There is no evidence of a bimodal distribution.

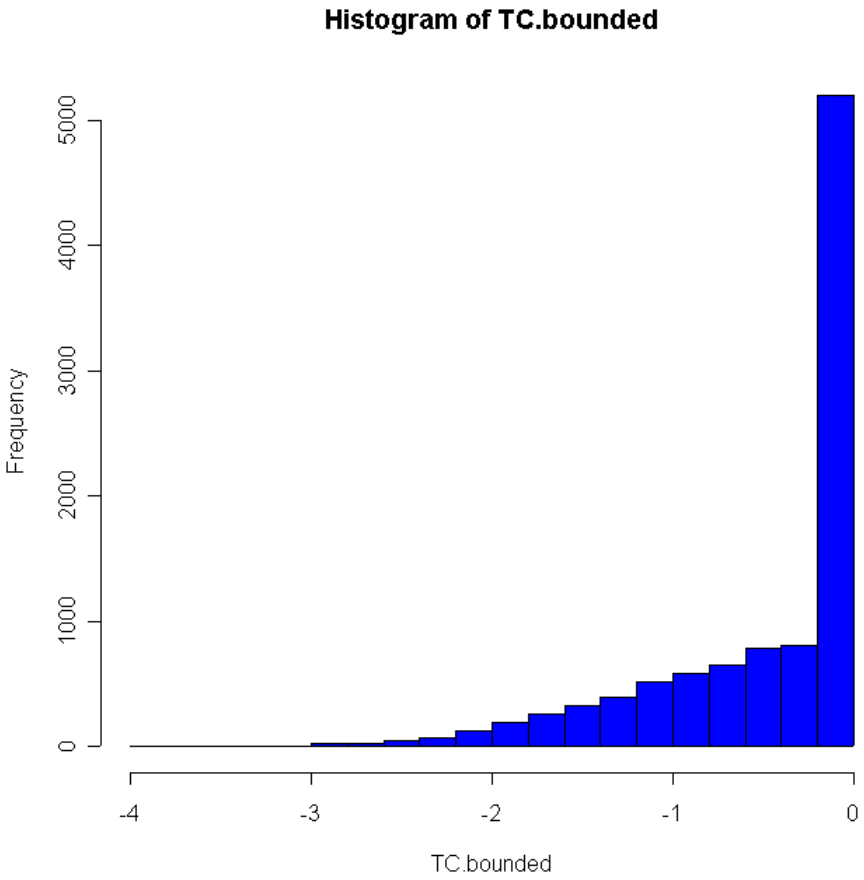


Figure 5. Histogram for the fit of the transfer coefficient data.

An alternative approach was considered – to simply draw with replacement from the three transfer coefficient values provided by Midelet and Carpentier (2002). The empirical cumulative density functions for both approaches are shown below (Figure 6). In both cases, 10000 values for the transfer coefficient were generated. The black curve (below) represents the algorithm selected for this risk assessment. The impact of the truncation can be seen in the jump at a log transfer coefficient of 0. Approximately 45% of the log values are set to 0. Twenty percent of the values are less than –1. The alternative approach is shown in red. Only 3 values are available, so the resulting curve resembles a step function. Using this approach, 33% of the data have a log transfer coefficient of 0, 33% have a value of –0.14, and 33% have a value of –0.34.

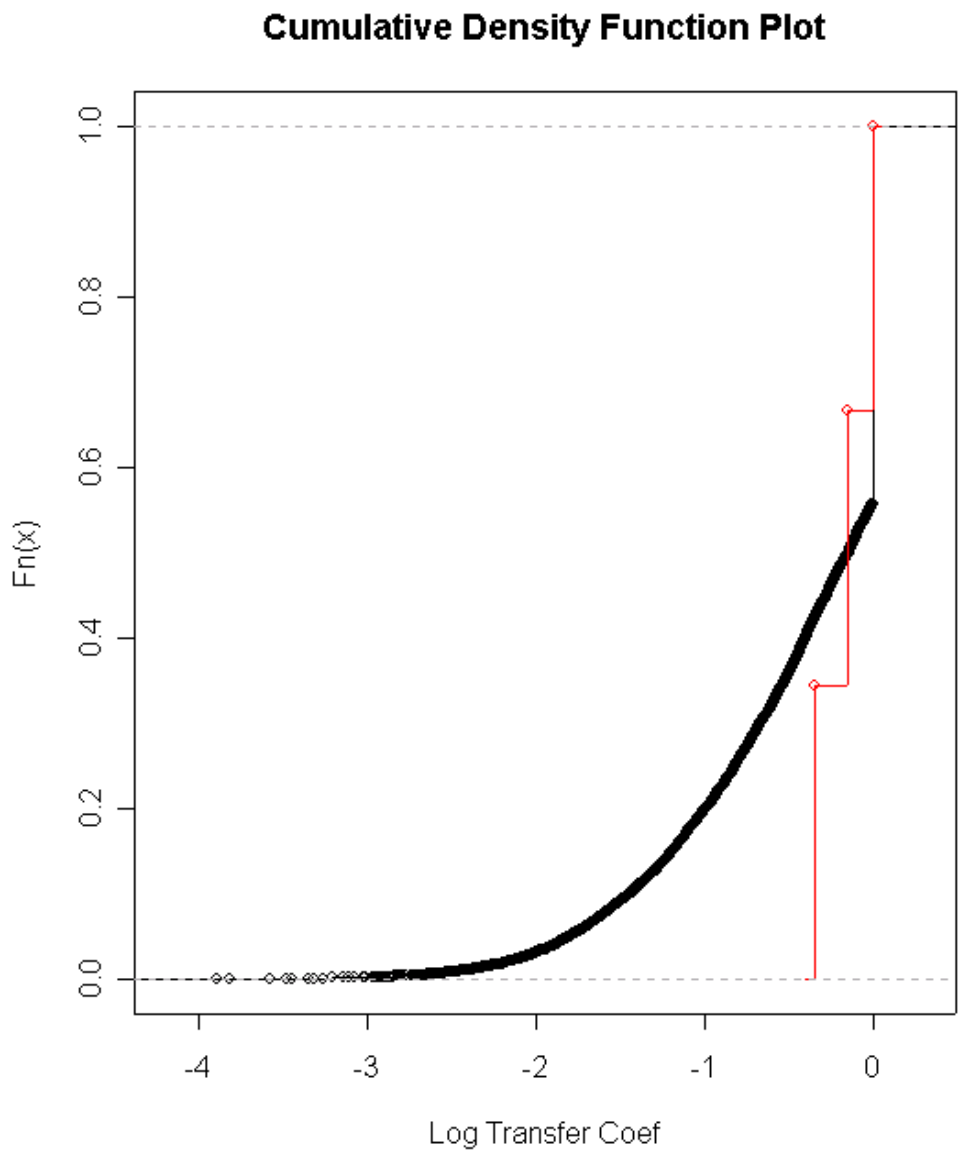


Figure 6. Empirical Cumulative Density Distribution for the Transfer Coefficient.

Obviously, the method chosen results in more variable transfer coefficients, with the possibility of much lower values than available from the alternative approach. This seemed an appropriate approach given the limited data.

There is often a great deal of confusion about the use of prevalence data in estimating transfer coefficients. There are some studies available that examine transfer from food contact surface to RTE product, and these were considered for this risk assessment. However, they are based on prevalence rather than concentrations, and so are of limited usefulness. For example, Deaver (2002) evaluated transfer from inoculated equipment to RTE product, but little useful data could be obtained in estimating a transfer coefficient for this risk assessment. There are two reasons for this. The first is that the study was conducted at the package level, not a lot level as used in

the risk assessment. The second and more important reason is that only prevalence was examined, making it impossible to calculate a transfer coefficient.

The following examples illustrate this point. They are based on Day 1 25-gram sampling for Trial 2, but similar examples could be constructed for any of the results. The slicer was inoculated with 1080 cfu L. monocytogenes. Ten of the 100 samples tested positive for Lm. The table below presents 3 possible scenarios consistent with the data, assuming that 10 cfu transferred to the package would be sufficient to find the sample positive. (This number is probably higher than needed, but only affects the minimum transfer coefficient calculated.)

In Case A, the minimum number of cfu is transferred to each sample. The vast majority of the cfu's remain on the slicer, for an overall transfer coefficient of 0.09. In Case B, all the cfu's are transferred to the samples, leaving none on the slicer and resulting in a transfer coefficient of 1.0.

Table 17. Examples Illustrating Why Prevalence Data is Insufficient for Constructing a Transfer Coefficient for the FSIS *Listeria* Risk Assessment

	Case A		Case B	
Package #	**Lm Slicer**	**Lm Package**	**Lm Slicer**	**Lm Package**
Inoculum	1080		1080	
1	1070	10	90	990
3	1060	10	80	10
5	1050	10	70	10
7	1040	10	60	10
9	1030	10	50	10
39	1020	10	40	10
117	1010	10	30	10
195	1000	10	20	10
197	990	10	10	10
199	980	10	0	10
Transfer Coef	0.09		1.00	

The observed prevalence of 10% (i.e. 10 packages out of 100 positive) are consistent with a transfer coefficient that ranges from 0.09 to 1.00. Thus, prevalence data cannot be used to impute a transfer coefficient. Because of this range, the study was not used directly in the risk assessment, especially since a relevant quantitative study was available in the peer-reviewed literature.

A prevalence of 0 can still imply a non-zero transfer coefficient if the number of organisms transferred to each package is below the detection limit. A prevalence of 100% can still imply a transfer coefficient near 1 if only a small number of organisms are transferred to each package. Thus, the Deaver (2002) study had little relevance to this risk assessment.

5) Ratio of *Listeria monocytogenes* to *Listeria* species

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). Table 18 summarizes these values.

Table 18. Prevalence Data for *L. monocytogenes* to *Listeria* species Ratios

Number of Samples Positive for *Listeria* species	Percent of Samples also Positive for *L. monocytogenes*
1	100
115	96
11	82
90	71
142	71
128	62
328	57
237	54
204	47
46	41
85	38
90	34
3	33
219	27
241	23
318	5

These data concerning the ratios for *Listeria* species to *L. monocytogenes* were tested and found not to be significantly different from a normal distribution. Therefore, this input was modeled as a variability distribution. The distribution fit was not weighted by the number of samples. Each ratio in the table above was given equal weight. The mean was 52% and the standard deviation was 26%. Values outside 0-100% were rounded to 0% or 100% appropriately.

The model uses this ratio of *Listeria* species/*L. monocytogenes* prevalence and applies it to *Listeria* species/*L. monocytogenes* concentration ratios. Given the lack of more specific data, the assumption that the ratio of *L. monocytogenes* to *Listeria* species prevalence applies to the ratio of the concentrations is a reasonable use of available data. Given a random distribution of *L. monocytogenes* amongst all *Listeria* species, and the expectation that all *Listeria* behave in a roughly similar manner, this assumption is a reasonable default in the absence of specific information to the contrary. Moreover, in a peer review of this risk assessment, it was found that the truncated normal (52%, 26%) distribution of the species prevalence ratio values assumed in the risk assessment, compared to a non-parametric empirical cumulative distribution of such prevalence data, provides a reasonable fit (ORACBA 2003).

6) Probability of detecting 1cfu in a sample

This probability of detecting 1 cfu in a RTE sample or FCS swab sample is different from the test sensitivity. Test sensitivity is the probability that a contaminated sample tests positive. A contaminated sample may contain anywhere from one organism to a very large number of organisms. To calculate a test sensitivity would require consideration of the population of contaminated samples. Therefore, test sensitivity is density dependent and differs from the probability of the test successfully detecting 1 cfu. Specificity is the probability that a non-

contaminated sample tests negative and would be estimated at <100% if laboratory error information were available and could be considered.

For both contact surface testing and product testing, the modeled concentration of the organism was multiplied by the sample size to estimate the mean of a Poisson distribution -- a probability distribution that is appropriate for modeling such concentrations. (For food contact surfaces, the concentration is measured in cfu/cm^2 and the sample size is measured in cm^2. For RTE product, the sample size is measured in cfu/gram, and the sample size in grams.) A random number was generated from this distribution that represented the number of cfu's in the sample itself.

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. The Agency did this by using the following expression:

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

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.

As for the limit of detection, the value for this input was obtained from the FSIS Microbiological Laboratory Guidebook (http://www.fsis.usda.gov/OPHS/microlab/mlg8.03.pdf), which reports the detection limit for *L. monocytogenes* testing as better than 1 cfu in a 25-gram sample. Thus, the p value should be fairly high for *L. monocytogenes* testing, conceptually near 1, because the base data set assumed a 25-gram sample.

Moreover, a study by Hayes *et al.* (1992) reported that the USDA method for *L. monocytogenes* had an overall sensitivity of 74%, with a sensitivity of 75% for the luncheon meat subcategory. While the Hayes *et al.* work is reporting test sensitivity, many of the foods included in their analysis had concentrations below the limit of detection for MPN method (<0.3 CFU per gram). Nevertheless, these samples were at or above the limit of detection for the qualitative culturing methods (i.e.., 0.04 CFU per gram or 1 CFU per 25 grams). It is reasonable to argue that these results are mostly indicative of the likelihood of detecting samples containing very few (or even a single) organisms.

Assuming that the concentration of *L. monocytogenes* in RTE product at processing is distributed as 10^Normal(-9, 3.5) cfu/gram, the levels in 50,000 25-gram samples were simulated as a random Poisson process (Haas et al. 1999). Approximately 2% of the simulated 25-gram samples were contaminated with one or more cfu of *L. monocytogenes*, and, as illustrated in Figure 7, approximately 70% of the simulated contaminated 25-gram test samples contained more than 1 cfu of *L. monocytogenes*.

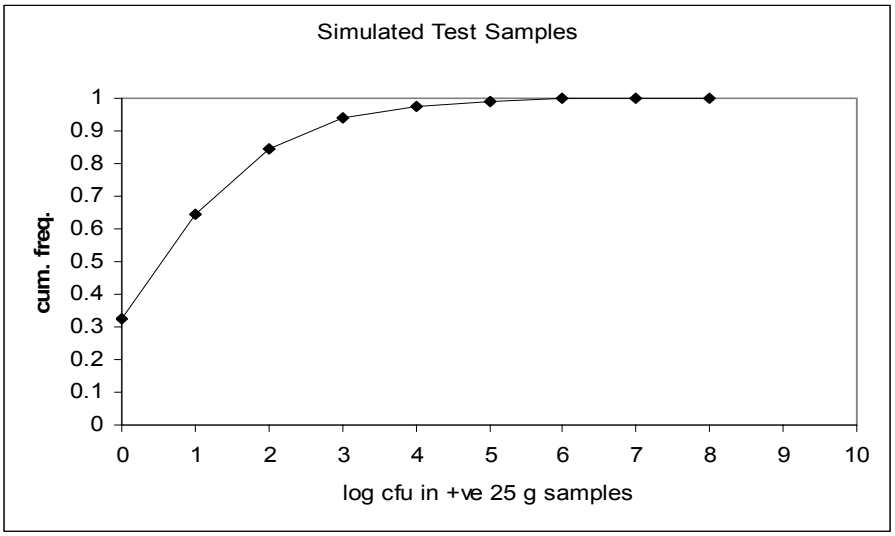


Figure 7. Levels of *L. monocytogenes* in 25-gram samples of RTE product.

As shown in Figure 8, for the roughly 2% of simulated test samples that were contaminated, the mean likelihood of detection exceeds 80% for pdetect 1 values between 0.5 and 0.95. This suggests that given its presence in a 25-gram sample, there is a reasonable likelihood that *L. monocytogenes* would be present at levels sufficiently high to make the probability of detecting a single organism of minor importance. This is due to the fact that the likelihood of detection becomes insensitive to this probability as the numbers of *L. monocytogenes* in the sample increase: likelihood(detection, given presence at level of n) = $1-(1-\text{pdetect}_1)^n$.

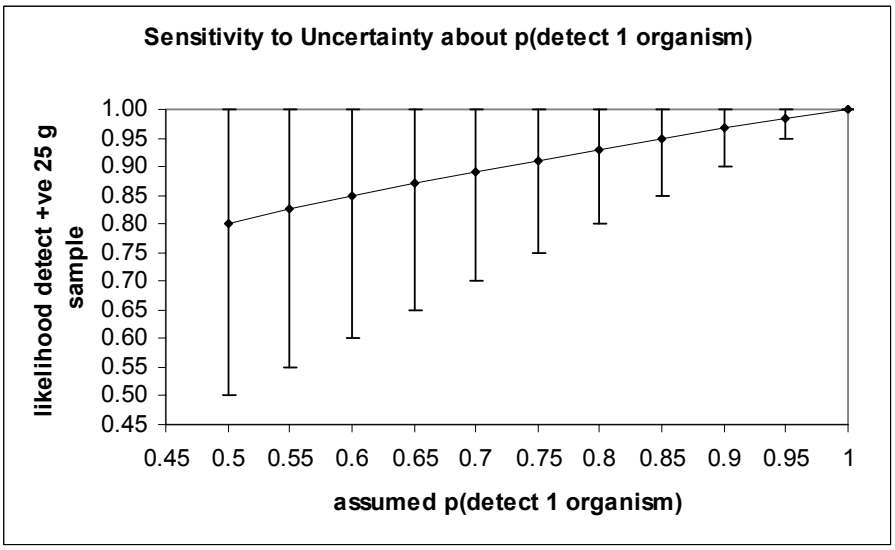


Figure 8. Likelihood of detecting *L. monocytogenes*-positive samples.

A baseline value of 75% probability was used for both FCS sampling and RTE lot sampling.

7) Homogeneity of *L. monocytogenes* within a RTE Product Lot and on FCS

Homogeneity of contamination is a reasonable default assumption often used within the field of microbial and environmental risk assessment. The degree of spatial cluster is unknown and selection of the extent of cluster would be arbitrary. Furthermore, an assumption of clustering should be coordinated with assumptions of sampling design strategies. For example, if we know the agent is limited to a specific fraction of the food contact surface area, sampling strategies might be designed to ensure at least sampling of that area. It should be recognized that a clustered distribution assumption would require recalibration of the concentration distribution and result in higher concentrations in the contaminated area. This heightens the likelihood of detection if any portion of this contaminated region is sampled. A sampling plan with many composited samples each over a very small sampled area, would compensate for the clustering.

The nature of the potential clustering in RTE product is more complicated than it might initially appear. Chae and Schraft (2000) found that *L. monocytogenes* biofilms grown under static conditions occur in two distinct layers. Different *L. monocytogenes* strains also exhibited different biofilm growth rates and different adhesion strengths. Deaver (2002) studied transfer coefficients from an inoculated slicer to RTE product. The slicer was inoculated with 10^3 cfu *L. monocytogenes* on 1 square inch of the slicer blade and allowed to air dry for 20 minutes, and 200 packages were then processed. The entire package (~125 g) and 25 g samples were then analyzed for *L. monocytogenes*, and the prevalence reported. Odd number samples were tested on day 1. (The even number samples were tested on day 30. These results are not shown.) Figure 9 depicts the results for 25-gram samples of salami and turkey. As might be expected, both show that samples from packages processed early were often positive. However, positives were also detected during the middle of the 200 package run. Strangely, both products also had one or more positive samples at the end of the 200 package run. These results suggest that no simple approach to clustering will be valid. Because only prevalence was reported, it is not known if the concentration of *L. monocytogenes* in the "negative" samples was truly zero, or merely below detection.

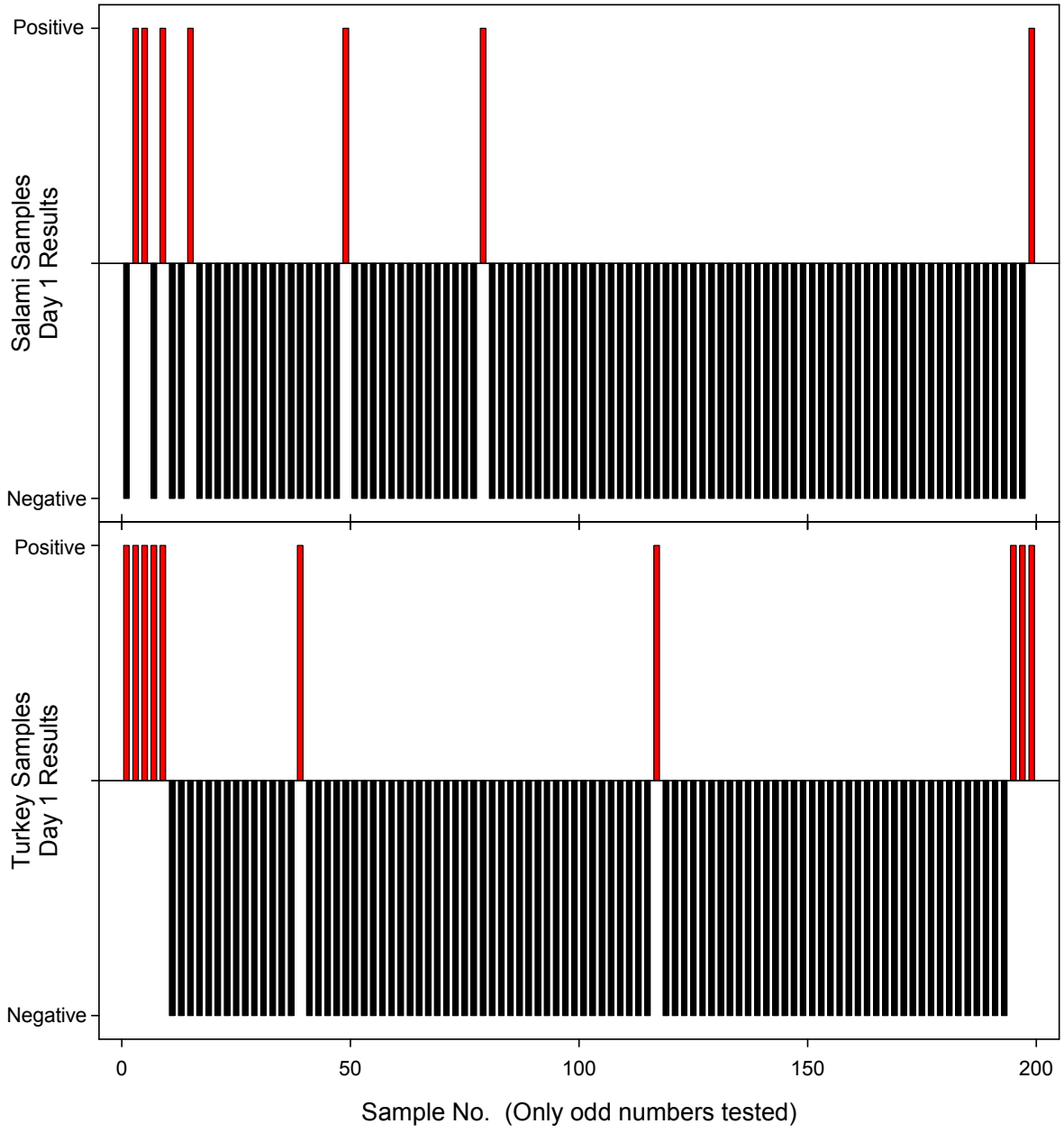


Figure 9. *L. monocytogenes* contamination on samples of RTE product to evaluate the effect assumption of clustering or homogeneity of contamination in a product lot.

The second aspect of clustering that must be considered is the dynamic nature of the contamination event. Contamination events which occur over a very short time frame are more likely to produce clustering in the RTE product. Contamination events which occur over longer time frames are more likely to produce a more uniform concentration distribution. Based on the available data for the duration of a contamination event, this risk assessment model uses contamination events that occur over several days duration.

Yet a third consideration is the possibility that after some portion of a lot becomes contaminated, the RTE product may transfer the bacteria to a food contact surface further down the production line. These bacteria can then move to a later portion of the lot. In effect, cross-contamination between the product and the entire food production chain would likely disperse the bacterial contamination among the lot more than the initial contamination location might imply.

8) Growth of *L. monocytogenes* on RTE Product During Distribution from Plant to Retail

The 2001 FDA/FSIS *Listeria* risk ranking model includes an option for growth from the plant to retail for FSIS-regulated products (e.g., deli meats). Based on a time-temperature sub-model, a growth of 1.9 log units (a multiplier of about 79) was applied to deli meats based on plant monitoring data. While the sub-model itself was stochastic, the final multiplier applied to appropriate data sets was a constant.

Levine et al. (2001) report 1999 prevalence levels of *L. monocytogenes* in various deli meat products at the processing plant: these levels were 2.71% for cooked, roast and corned beef, and 4.58% in sliced ham and other pork luncheon meats. The National Food Processors Association (NFPA) survey of RTE deli meats at retail found an *L. monocytogenes* prevalence of 0.9%. Although these *L. monocytogenese* prevalence levels in deli meats are not directly comparable, these values were used to justify a lowering of the growth factor in this risk assessment. A growth of 1.0 log units (i.e., a factor of 10) was used for all lots, rather than the 1.9 used in the FDA/FSIS risk ranking model (see Appendix B for further discussion).

Note that the limited understanding of growth during shipment to retail, and the non-stochastic nature of the growth model used in this analysis increases the uncertainty of the risk assessment outputs regarding the effectiveness or the use of growth inhibitors or reformulating product.

9) Line production

FSIS (2003) reports 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 is shown in Table 19.

[Note: The data from the FSIS survey of RTE processors of deli meats was also used to stratify establishments according to those that produce a high (upper 25^{th} percentile of industry), medium (50^{th}-75^{th} percentile), or low (lower 50^{th} percentile) volume of product. Analysis of this data and risk estimates by plant production volume are provided in Appendixes C and D.]

Table 19. Lot (per line per shift) weight by plant size.

Plant size	Lot weight (lbs)	Lot standard deviation (lbs)
Large	19371	14000

Small	7100	10600
Very Small	2800	9500

Lot weights (i.e., pounds of deli meat per line per shift) were varied stochastically from lot to lot. These distributions were assumed to be normal. 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. But 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.

No survey data of plant characteristics (e.g., line configuration, *Listeria* control program implementation, and packaging technology) or corresponding data on the prevalence and/or level of *Listeria* species in the establishment was provided to the Agency. Therefore, these factors cannot be further evaluated at this time. As already noted, however, data on production volume from the FSIS survey on processors of deli meats was analyzed and risk estimates provided in Appendixes C and D.

10) Post Processing and Growth Inhibition

Neither post processing interventions nor growth inhibition product formulation and packaging were considered for the base run. However, their impact was evaluated during the different scenarios in the same manner as different FCS testing frequencies. The default assumptions regarding efficacy of post-processing interventions used in the model may very well be lower than efficacies observed in plants or laboratories. Simulating a higher efficacy will illustrate greater benefits for these interventions. The current model settings, therefore, are conservative. For example, the current model predicts that post-processing interventions are at least as effective as a testing program that tests every lot of product. Therefore, the model already gives Agency decision makers the useful information that post-processing interventions that are 90% to 95% efficacious are as effective as, or more effective than, testing.

Data on interventions, such as the use of lactate and diacetate to prevent growth during distribution, which has been published (Seman et al., 2002) were reviewed during the development of the risk assessment. However, since the risk management questions that were presented to the risk assessors at the outset of the assessment did not deal with specific product formulations, the risk assessors decided to model growth inhibition in a manner that could easily be applied to any product reformulation or packaging. Moreover, as mentioned previously in the context of post-processing controls, the efficacy of growth inhibitors assumed in the risk assessment model may be conservative. Nevertheless, FSIS risk managers can conclude from this model's results that growth inhibitors are as effective as, or more effective than, testing food contact surfaces. Simulating higher efficacy from growth inhibitors only serves to reinforce this conclusion. In addition, greater percent reductions were modeled as part of the sensitivity analysis and did show greater public health impacts.

Model Implementation and User Interface

The FSIS *Listeria* risk assessment in-plant dynamic model was written in Microsoft Visual Basic 6.0. Three additional third-party add-ons were used and are necessary to recompile the model: Videosoft vsFlex 6.0, Videosoft vsOCX 6.0, and Graphic Server 5 for Windows. In addition, several subroutines from Numerical Recipes (Press *et al.* 1992) were used. The model is designed so that almost all the required data are entered through the graphical user interface and can be easily changed by the user. Tabs separate the major data entry screens. Each data entry or result screen is described below.

Several portions of the model not directly related to the risk assessment have not yet been completed. These include the printing and help functions.

The Project Data screen shown in Figure 10 is used to store information about the specific model run. None of the data are used within the simulation itself.

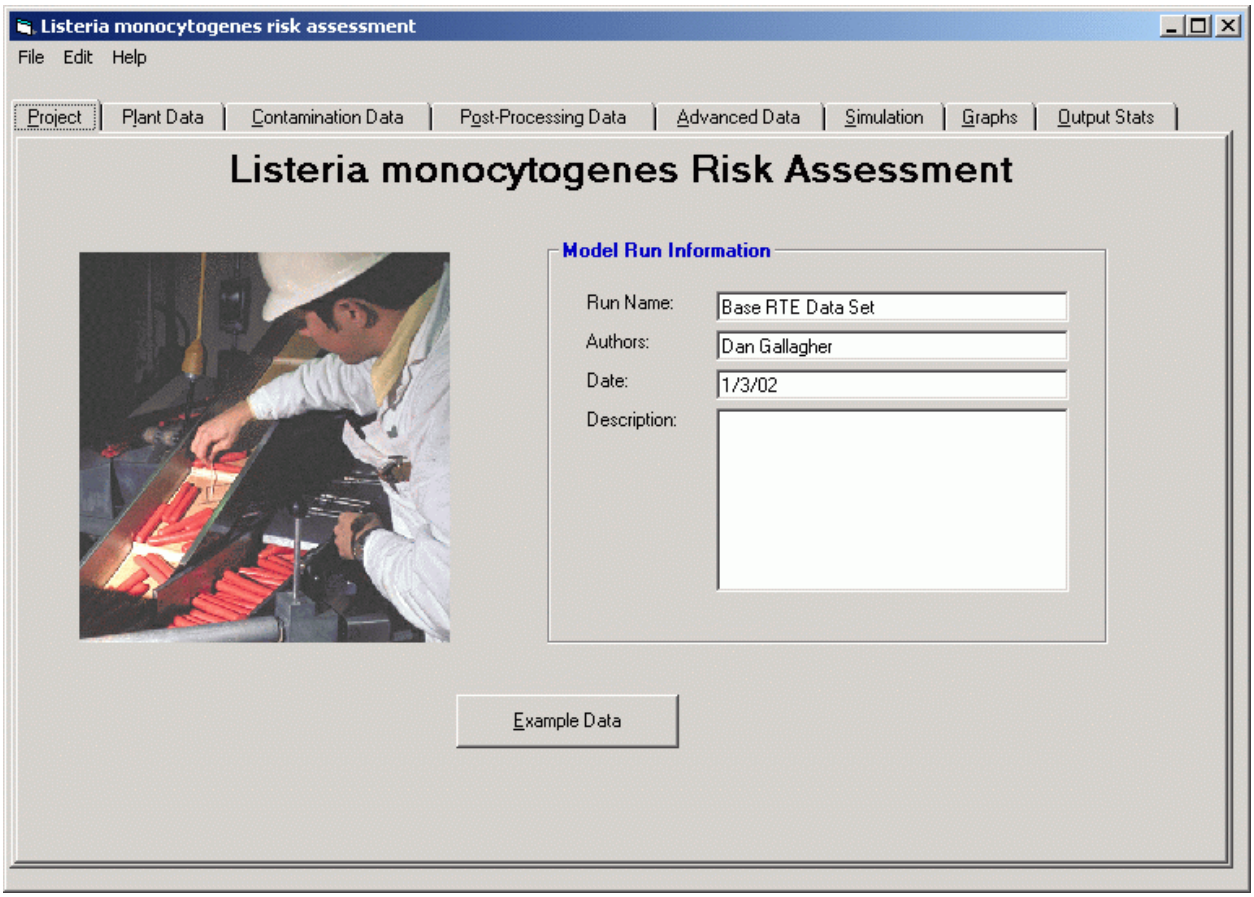


Figure 10. Project Data Entry Screen.

The Plant Data screen shown in Figure 11 is used to enter information on plant production, lot size, sanitation and testing controls. All of these inputs can be modified to perform sensitivity analysis or update the model with more recent data.

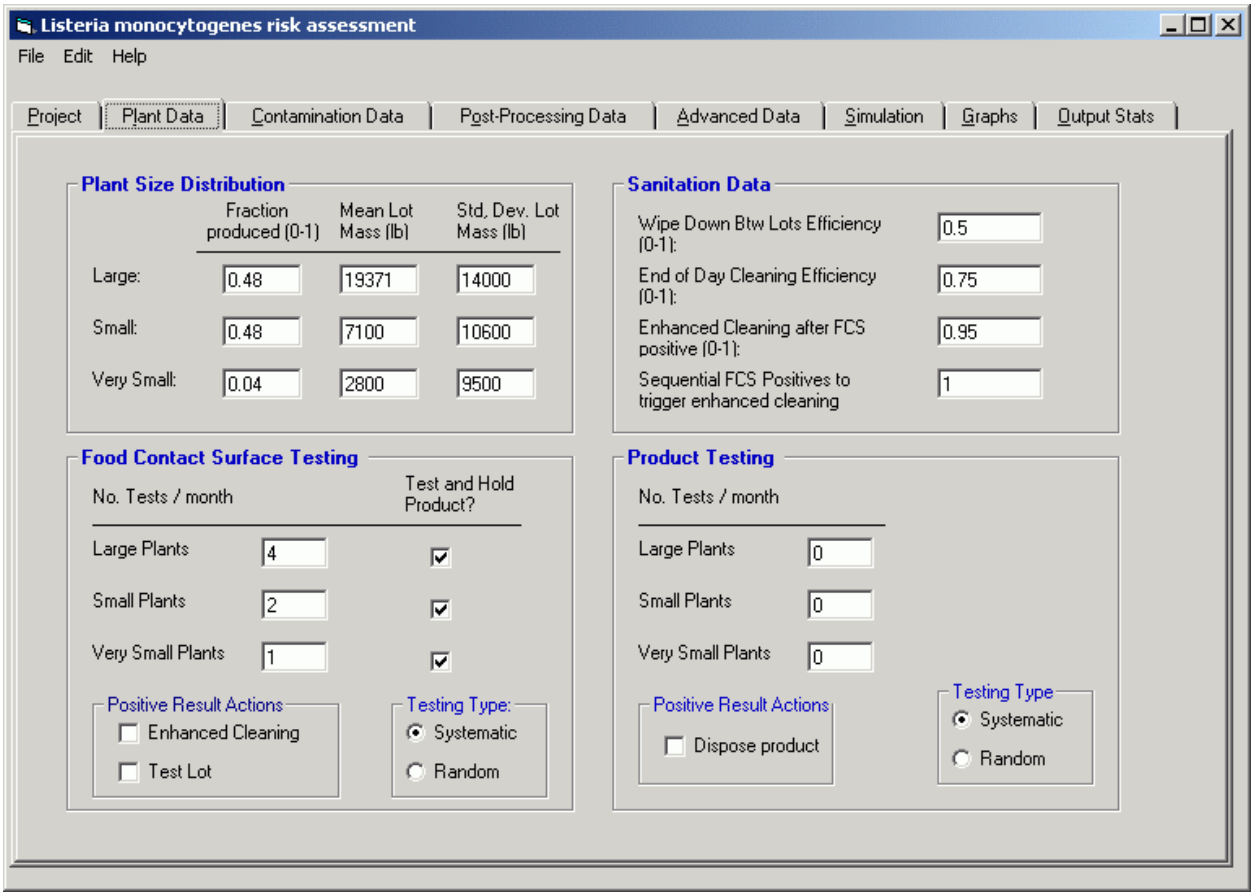


Figure 11. Plant Data Entry Screen

There was little available data on the effectiveness of sanitation in reducing the level of *Listeria* species on food contact surfaces. The base model assumes a brief cleaning or wipe down between the first lot of the day with an efficiency of 50%, i.e. 50% of the *Listeria* species remaining on the food contact surface at the end of the lot production are removed by sanitation controls. The base model assumes greater sanitation effectiveness after the 2nd lot production, since many plants run a 3rd shift as a sanitation shift. The end of day sanitation efficiency was assumed to be 75% in the base model. Therefore, overall effectiveness of routine cleaning is assumed to be 87.5% (i.e., `1-[(1-50%)*(1-75%)]`).

Finally, if a food contact surface was found positive for *Listeria* species, the base model assumes that the plant would conduct a more effective or enhanced cleaning to remove the bacterial contamination. 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 frequency of food contact surface testing for *Listeria* species varied depending on the scenario being analyzed. Different frequencies were allowed for different plant sizes (i.e., for large, small, and very small establishments). Two interventions based on testing results were allowed. First, if a food contact surface tests positive for *Listeria* species, then the RTE product lot would be tested for *L. monocytogenes*. If the RTE product lot was positive for *L.*

monocytogenes, then this lot is disposed of and not used for human consumption. Second, if a food contact surface tested positive for *Listeria* species, then the food contact surface would undergo enhanced cleaning. The base model runs had both options selected.

The model also allowed for the simulation of a test-and-hold procedure for the RTE product lot. If this was selected and a food contact surface was found to be positive for *Listeria* species, the product lot that was produced at the same time the food contact surface was sampled and later found positive for *Listeria* species would be tested for *L. monocytogenes*. If the test-and-hold option was not selected, then the RTE product lot that would be tested for *L. monocytogenes* would be one that was produced after the results from the food contact surface sampled earlier were obtained.

RTE product lot testing for *L. monocytogenes* was similar in concept. Only one intervention was considered: disposal of a product lot found to be *L. monocytogenes* positive. Disposal implies that the lot was removed from the food supply, but could include reprocessing the affected RTE product lot. The base model always had this option selected.

Note that the total number of lots produced per line is fixed at 60 per month (2 lots per day per line multiplied by 30 days per month) within the model. Thus the maximum testing frequency for any size plant is 60 per month.

The model allows for food contact surface testing and lot testing to be performed either randomly or systematically. Random testing would randomly select the specified number of lots to be tested from among the 60 available that month. Systematic testing would keep a constant time interval between the lots being tested, with a random start. For example, a systematic sample might take the first lot produced each Tuesday to obtain 4 lots per month. The base model assumed systematic sampling. Note that systematic sampling has implications for use of test-and-hold procedures. At 16 samples per month, the timing between systematic samples matched the lag between sample analysis and reporting, and simultaneous sampling of food contact surfaces and lots took place even if the test-and-hold option was not selected.

The Contamination Data screen, shown in Figure 12, is used to enter data relating to contamination event timing, duration, levels, transfer coefficients, area swabbed, and product lot mass sampled. Most of these data have been described previously. The “number of composites” was not implemented in this version of the model.

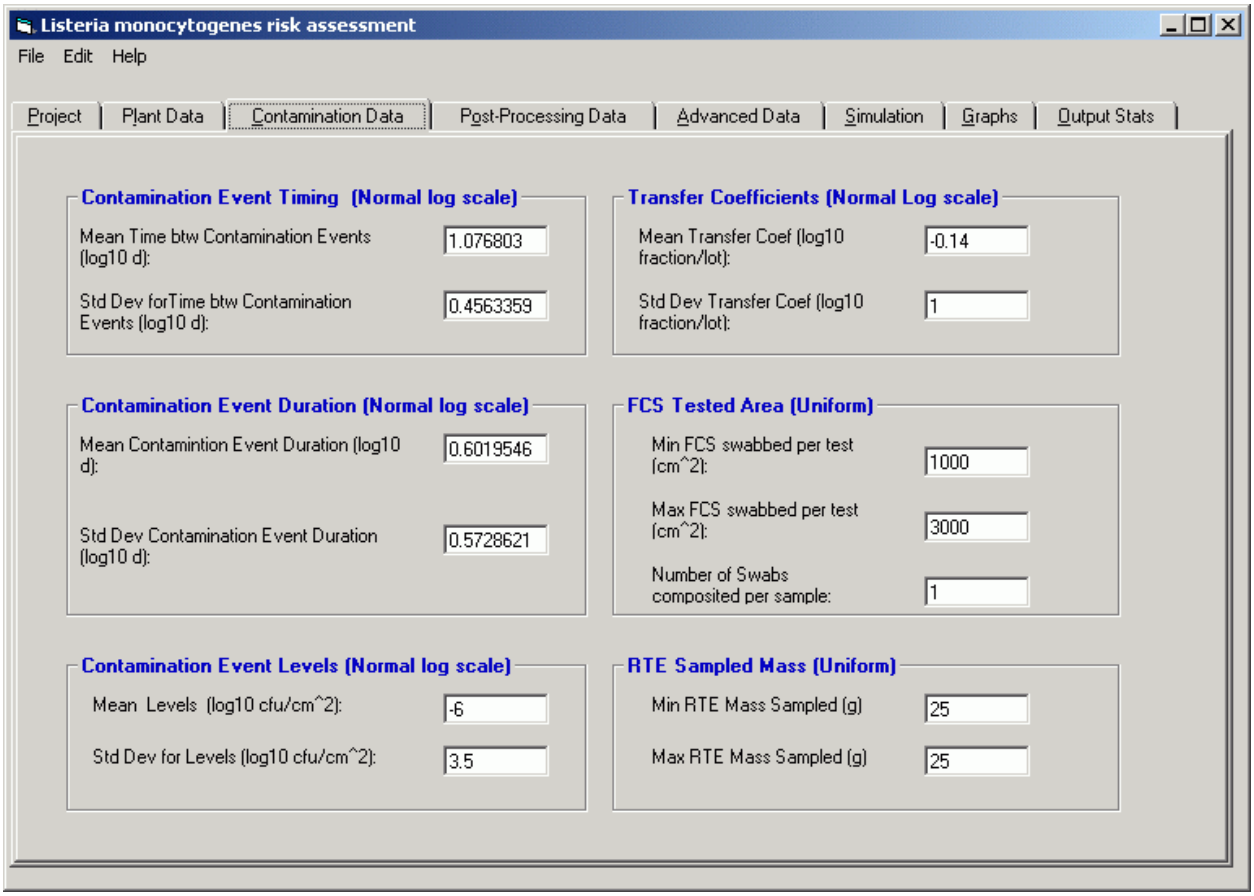


Figure 12. Contamination Data Entry Screen

The Post-Processing Data screen shown in Figure 13 is used to enter data relating to product pre- and post-packaging interventions, growth inhibitors, and product reformulation. A variety of these interventions have been studied. Example of interventions include: addition of sodium lactate or sodium diacetate in frankfurter formulations. (Bedie et al. 2001, Glass et al. 2002), steam/hot water pasteurization (Murphy and Berrang 2002), vacuum-steam-vacuum (Kozempel et al. 2000, Sommer et al. 2002), high pressure technology (Avure Technologies studies), and antimicrobial packaging (Cagri et al. 2002).

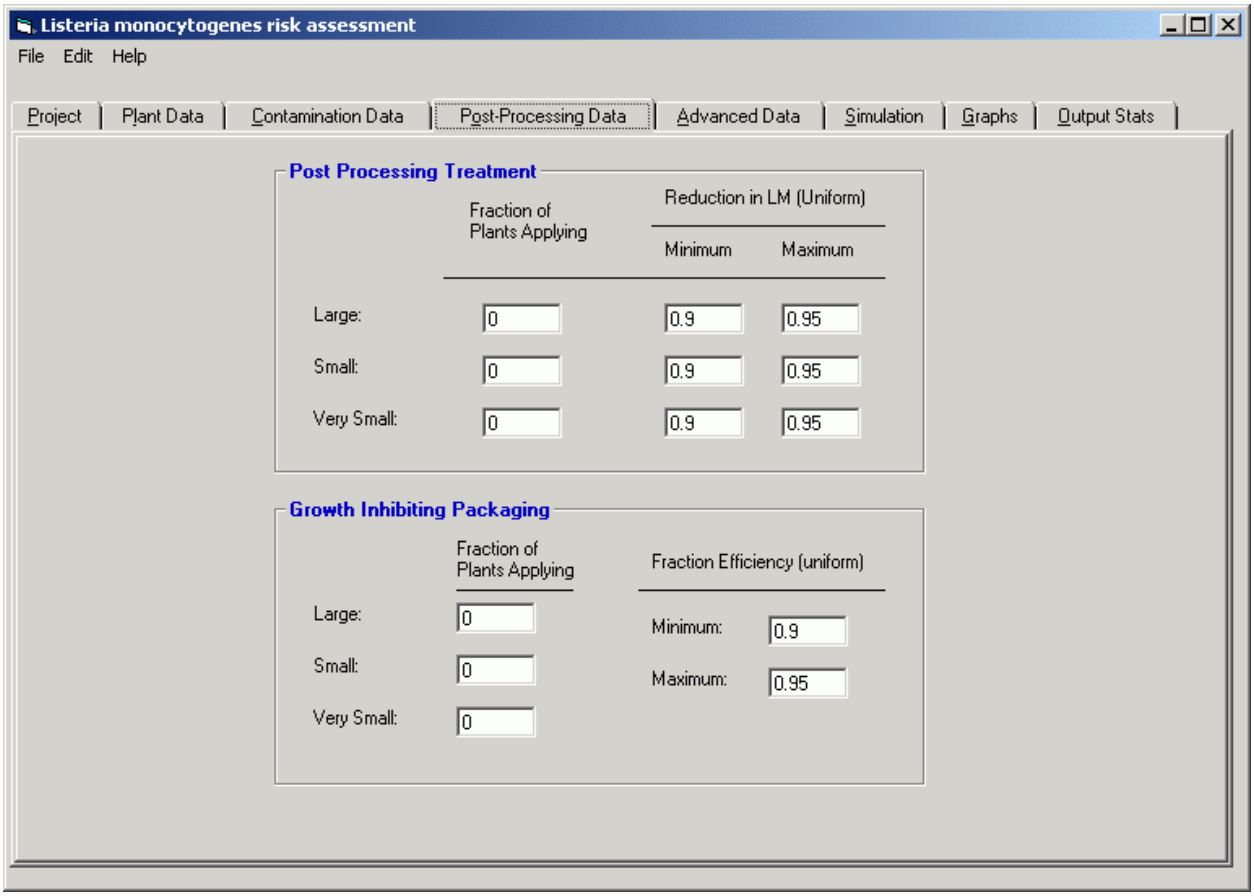


Figure 13. Post Processing Data Entry Screen

For this risk assessment model, the specific pre- and post-packaging interventions are not required. The fraction of production by plant size and the effectiveness of these interventions are required inputs. The effectiveness of a pre- and post-packaging intervention is treated as a uniform random number between the ranges given and reduces the arithmetic scale concentration of *L. monocytogenes* in product by that amount. The effectiveness of growth-inhibitors is also a uniform random number between the specified ranges and is used to adjust the exponential growth predicted between processing and retail.

The base model assumed that none of these measures are used by the industry. Scenarios were run where the impact of these measures were evaluated.

The Advanced Data tab shown in Figure 14 is used to enter data that should not be changed during most scenarios. These include testing lags and detection limits, *L. monocytogenes* to *Listeria* species ratios, food contact surface areas, and growth of *L. monocytogenes* from the processing plant to retail. The model requires the probability of detecting 1 cfu of *Listeria* species for food contact surface testing and 1 cfu of *L. monocytogenes* for product testing. The total number of cfu's in the sample provided are generated as a Poisson random number with the mean of *Listeria* species concentration multiplied by the total area swabbed for food contact surface tests or *L. monocytogenes* concentration multiplied by sample mass for product testing. This sampled cfu number is then used to determine if the sample tests

positive or negative based on the probability of the test successfully detecting 1 cfu. For the base runs, both probabilities were set at 75%.

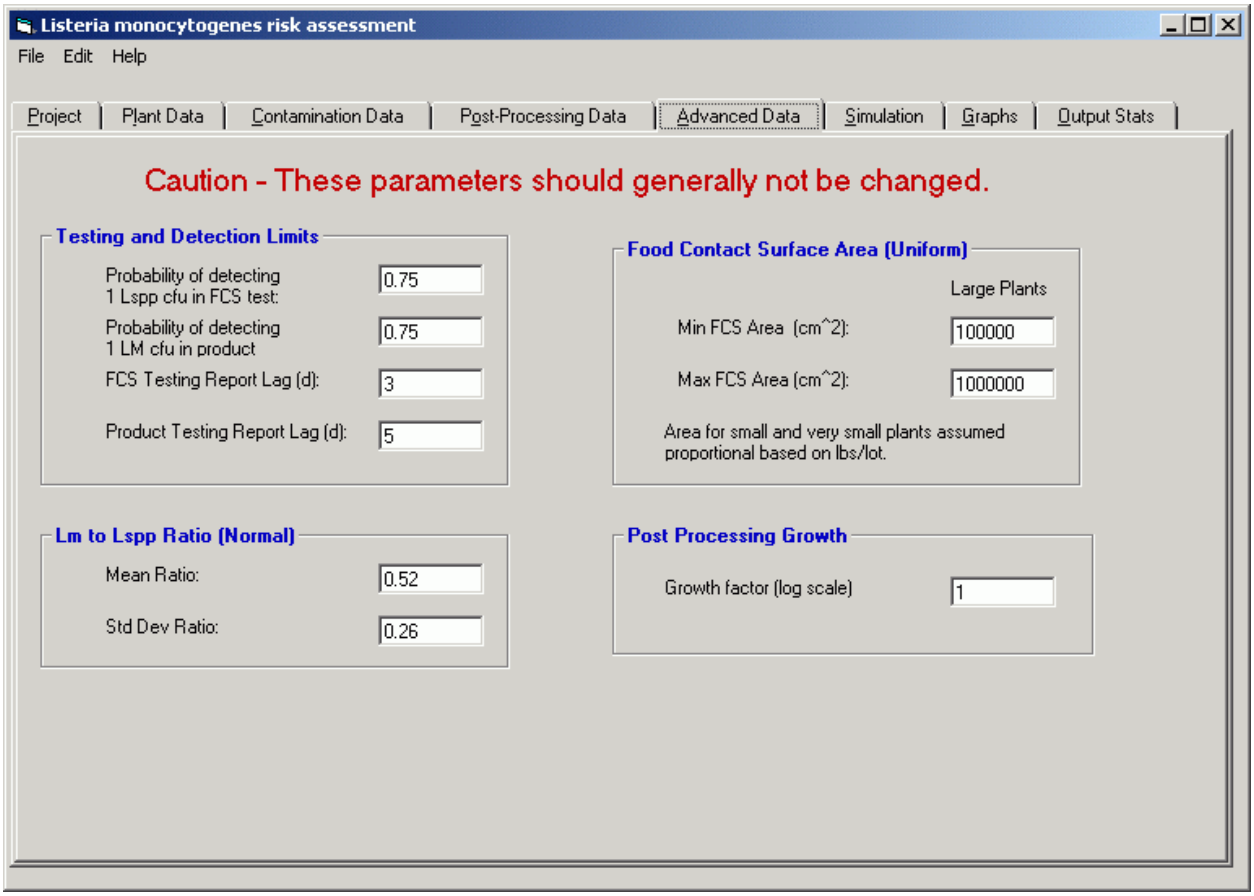


Figure 14. Advanced Data Entry Screen

The *L. monocytogenes* to *Listeria* species ratio has been described above. The model assumed that the distribution was normally distributed but truncated to fall between 0% and 100%.

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.

The Simulation screen shown in Figure 15 is where the model is actually run. The number of product lots to be simulated is the only required input. Results are based on a run of 1,000,000 lots, although early calibration runs were based on fewer lots. The current implementation of the model is rather inefficient in that the model actually simulates the number of lots for each of the 3 plant sizes, then randomly selects the lots to go to retail based on the percentage of the food supply provided by each plant size. The user can

optionally request that all the information for each lot simulated be output to a comma-delimited file that can be read by a spreadsheet or database. Note that these output files can become quite large.

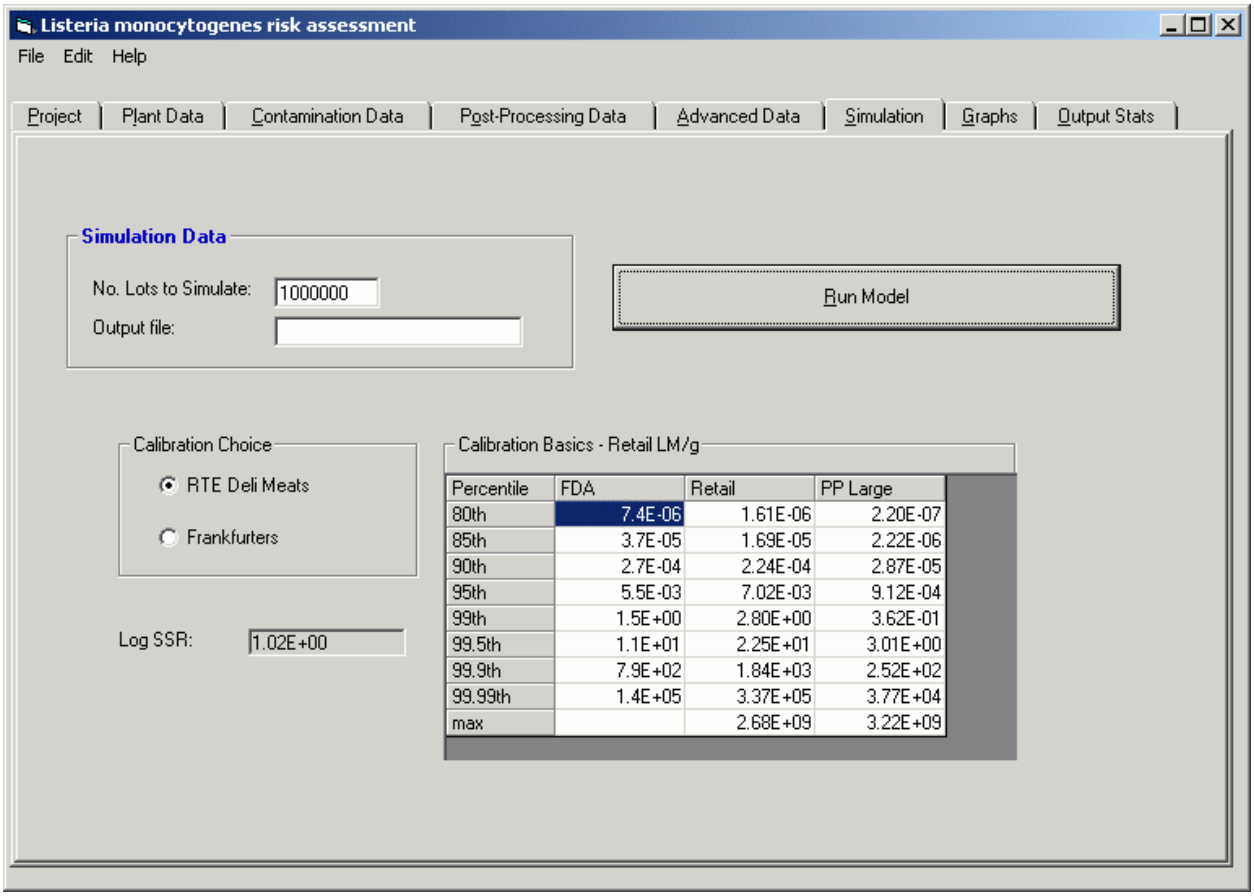


Figure 15. Simulation Screen

The percentiles of the *L. monocytogenes* concentrations at retail and after pre- and post-packaging interventions are provided in conjunction with the updated FDA/FSIS exposure assessment levels for *L. monocytogenes* in deli meats at retail. This portion of the model was used primarily during calibration. The mean and standard deviation of the *Listeria* species levels added to the food contact surface were varied in order to match the levels of *L. monocytogenes* in deli meats observed in the updated FDA/FSIS exposure assessment.

Empirical cumulative density functions are provided as part of the output on the Graphs tab shown in Figure 16 for either the *L. monocytogenes* concentration in product at retail or the *Listeria* species concentration on food contact surfaces. These graphs were used primarily during the calibration phase. The option box selection controls which graph is displayed. Only the non-zero concentrations are shown on either plot. The graph software can only display about 32,000 points, and therefore the graphs are not available if a large number of lots are simulated.

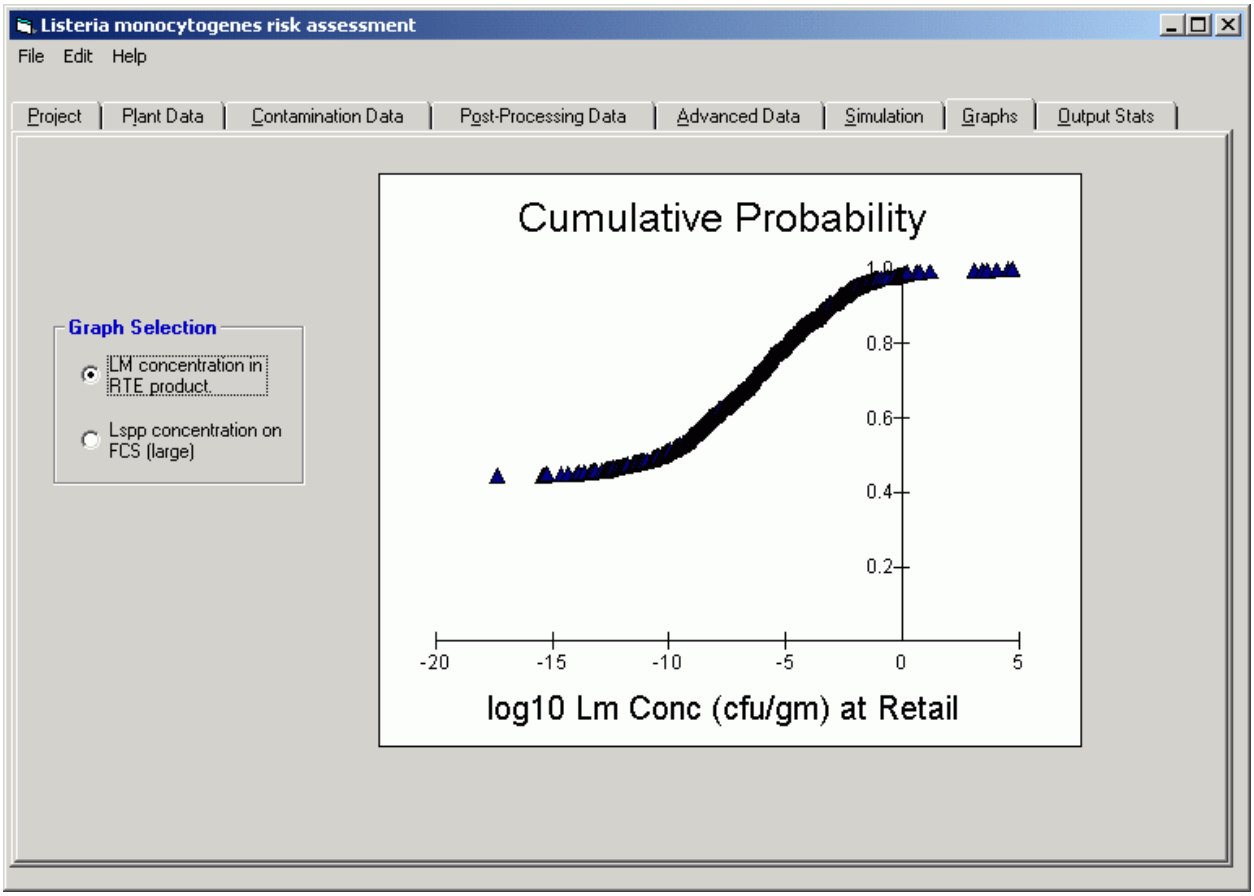
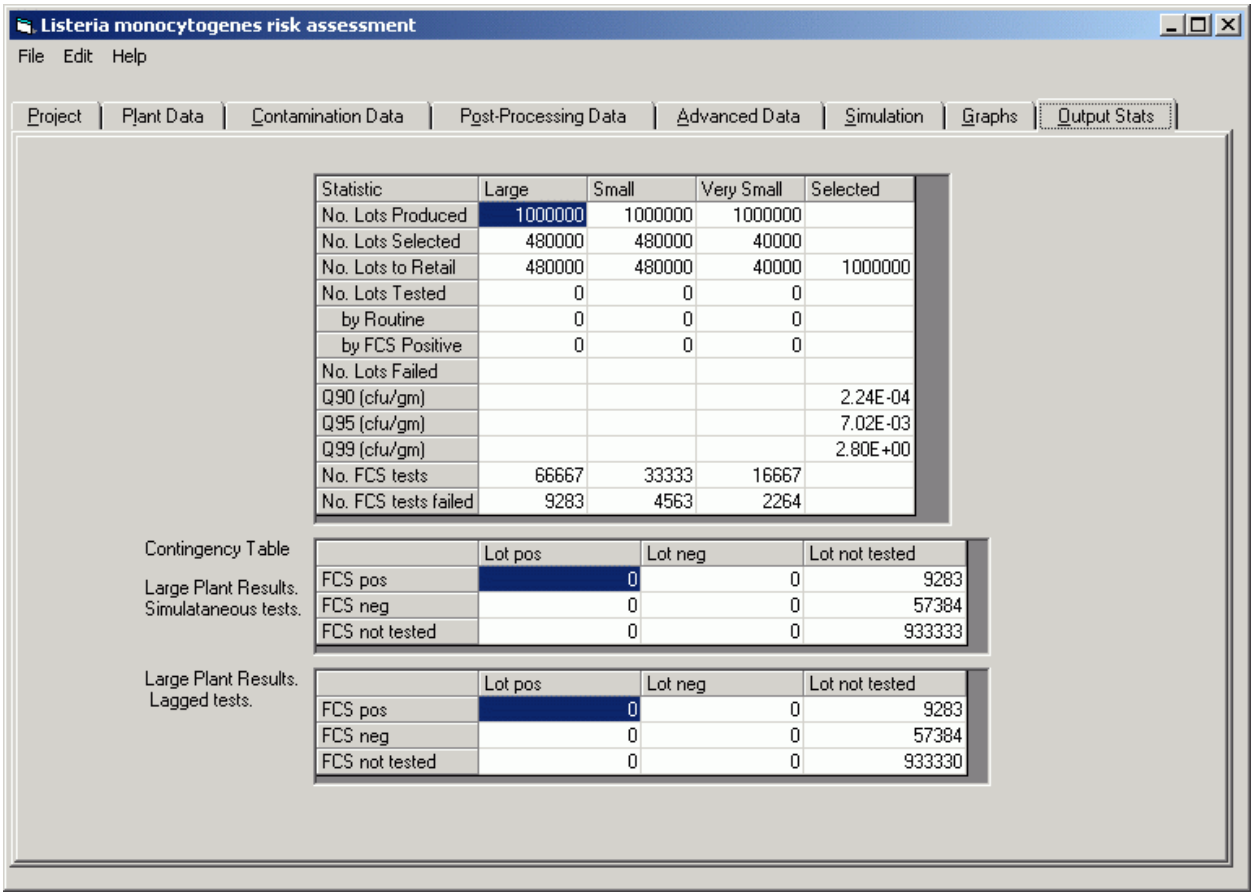


Figure 16. Graph Output Screen

The Output Stats screen shown in Figure 17 summarizes the testing results. It provides the numbers of RTE product lots simulated for each plant size, the number chosen for retail, the number of food contact surfaces and lots tested and the number that failed. Some of the quantiles from the Simulation tab are also given. Finally, two contingency tables are provided to summarize the testing results. The contingency tables shown n Figure 17 break down the food contact surface and RTE product lot testing in a 2 dimensional matrix, and are used to estimate the overall prevalence of food contact surface samples positives for *Listeria* species, RTE product lots positive for *L. monocytogenes*, and the likelihood of finding a RTE product lot positive for *L. monocytogenes* if the corresponding food contact surface sample is positive for *Listeria* species. The first of the contingency tables is used when the test-and-hold procedure is in place, and the RTE product lot tested for *L. monocytogenes* is the one that is produced at the same time the food contact surface is tested for *Listeria* species. The second contingency table is the results for the likelihood of detection of *L. monocytogenes* in a RTE product lot when a food contact surface tests positive for *Listeria* species when the test-and-hold procedure is not in place (i.e., this option was not selected in the model). Again, when the test-and-hold procedure is not in place, the RTE product lot tested is one that lagged in time after the food contact surface was tested for *Listeria* species and later found to be positive (i.e., once the test results are obtained from the laboratory).



Statistic	Large	Small	Very Small	Selected
No. Lots Produced	1000000	1000000	1000000	
No. Lots Selected	480000	480000	40000	
No. Lots to Retail	480000	480000	40000	1000000
No. Lots Tested	0	0	0	
by Routine	0	0	0	
by FCS Positive	0	0	0	
No. Lots Failed				
Q90 (cfu/gm)				2.24E-04
Q95 (cfu/gm)				7.02E-03
Q99 (cfu/gm)				2.80E+00
No. FCS tests	66667	33333	16667	
No. FCS tests failed	9283	4563	2264	

	Lot pos	Lot neg	Lot not tested
FCS pos	0	0	9283
FCS neg	0	0	57384
FCS not tested	0	0	933333

	Lot pos	Lot neg	Lot not tested
FCS pos	0	0	9283
FCS neg	0	0	57384
FCS not tested	0	0	933330

Figure 17. Output Statistics Screen

Calibration of the In-plant Dynamic Model

As described earlier, the values for the mean and standard deviation of the number of *Listeria* species transferred to food contact surfaces at the beginning of lot production, while a contamination event is ongoing, are unknown. The distribution was assumed to be log-normal. Values were initially selected for these parameters and the resulting simulated distribution of the concentration of *L. monocytogenes* in deli meat at retail was compared to the updated FDA/FSIS exposure assessment values for the concentration of *L. monocytogenes* in deli meats at retail. The updated FDA/FSIS exposure assessment model for deli meats actually estimates 300 plausible lognormal distributions (one for each iteration of the model) for *L. monocytogenes* contamination in deli meats at retail. A single set of parameters was estimated by calculating the average of the mean and standard deviation across the 300 sets of parameters.

By comparing the distribution for the concentration of *L. monocytogenes* in deli meats at retail predicted by the FSIS in-plant model to the distribution estimated by the updated FDA/FSIS exposure assessment values for deli meats at retail, the two parameters for the input distribution (i.e., number of *Listeria* species transferred to the food contact surface)

were changed on a iterative basis until the two distributions were deemed sufficiently close. Figure 18 provides the comparison of the final FSIS in-plant model calibration distribution with the updated FDA/FSIS exposure assessment concentration of *L. monocytogenes* in deli meats at retail. Note that only two parameters were treated as unknowns. All other model parameters were kept at their base values. The final estimates of the organisms transferred had a mean on the $\log_{10}$ scale of – 6 cfu/cm^2 and a standard deviation on the log scale of 3.5 cfu/cm^2.

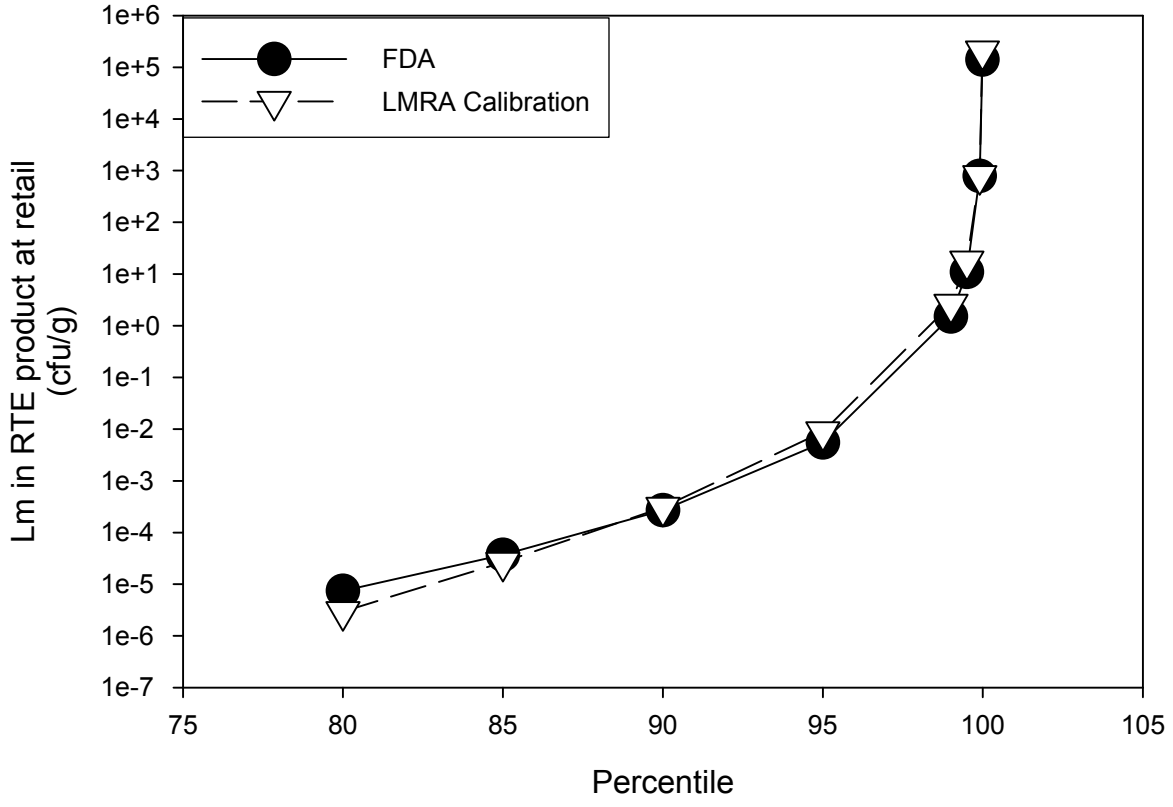


Figure 18. Final FSIS *Listeria* Risk Assessment In-plant Model Calibration to the Updated FDA/FSIS Exposure Assessment Concentrations of *L. monocytogenes* in Deli Meats at Retail. The mean and standard deviation of the log number of *Listeria* species transferred to the food contact surface at the beginning of each lot production during a contamination event were used to fit this distribution.

Model Stability

Twenty separate runs were made using the 4-2-1 scenario.

"4-2-1" means that food contact surfaces are tested for *Listeria* species at one of the following frequencies, depending on establishment size:

- If the plant is large, at least four tests, per line, per month;
- If the plant is small, at least two tests, per line, per month;
- If the plant is very small, at least one test, per line, per month.

The variability of the quantiles is shown in Figure 19 below as a box plot. The interquatile range is shown as a rectangular box, with the median value as a line within the box. The 95th percentiles are shown as vertical lines extending from the box. These graphs then indicate central tendency (the median), spread (both the interquartile range and the 95th percentiles), and an indication of symmetry/skewness (the location of the median within the box.) The results indicate very little spread among the 20 replicate model runs. As expected, the 99.99th quantile exhibited more variability than the lower quantiles. Overall however, the variability appears small among replicate simulations.

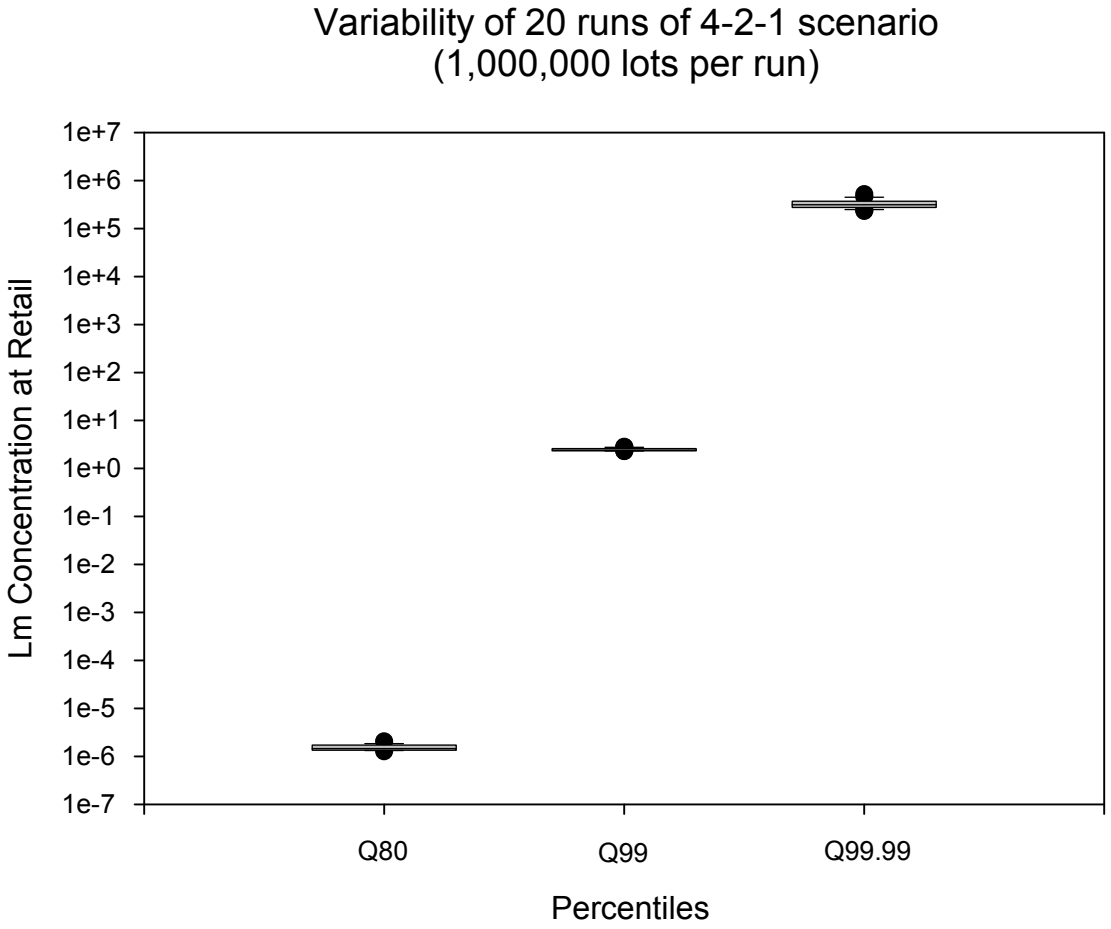


Figure 19. Stability of the FSIS *Listeria* risk assessment model simulated quantiles based on 20 runs of the 4-2-1 scenario.

FSIS *LISTERIA* RISK ASSESSMENT OUTPUTS

The FSIS *Listeria* risk assessment outputs provided in this report are only those that inform risk management decision-making in regards to the following policy questions:

1) 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 *L. monocytogenes* contamination in finished RTE product, and reducing the subsequent risk of illness or death?;

2) How effective are other interventions (e.g., pre- and post-packaging interventions or the use of growth inhibitors) in mitigating *L. monocytogenes* contamination in finished RTE product, and reducing the subsequent risk of illness or death?; and

3) What guidance can be provided on testing and sanitization 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 monocytogenes concentrations at retail (outputs of the FSIS Risk Assessment in-plant model).'

Figure 20 below shows 3 quantile (i.e., the 80th, 99th, and 99.99th percentiles) concentrations of *L. monocytogenes* in deli meats at retail for the scenarios analyzed. Test and hold was used for all food contact surface testing and if a lot tested positive for *L. monocytogenes* it was assumed not to be sold for retail.

Most of the scenarios are given as triplet numbers, e.g. 4-2-1, and represent the number of monthly food contact surface samples per line for large, small, and very small plants.

The "60-60-60" triplet represents testing the food contact surface for every lot that is produced, because the model assumes that each line produces 60 lots per month. The "60-60-60 Lot" scenario represents testing every lot produced for *L. monocytogenes*, rather than a food contact surface for *Listeria* species. "PP" represents post-processing intervention/control, assuming that 100% of the industry incorporates some form of post-processing that is 90-95% effective. The "GIP" represents that 100% of the industry incorporates growth inhibiting packaging or product reformulation that is 90-95% effective. Finally, the "PP&GIP" scenario represents a combination of the previous two scenarios: 100% of the industry incorporates both post-processing and some form of growth inhibition, each of which is 90-95% effective.

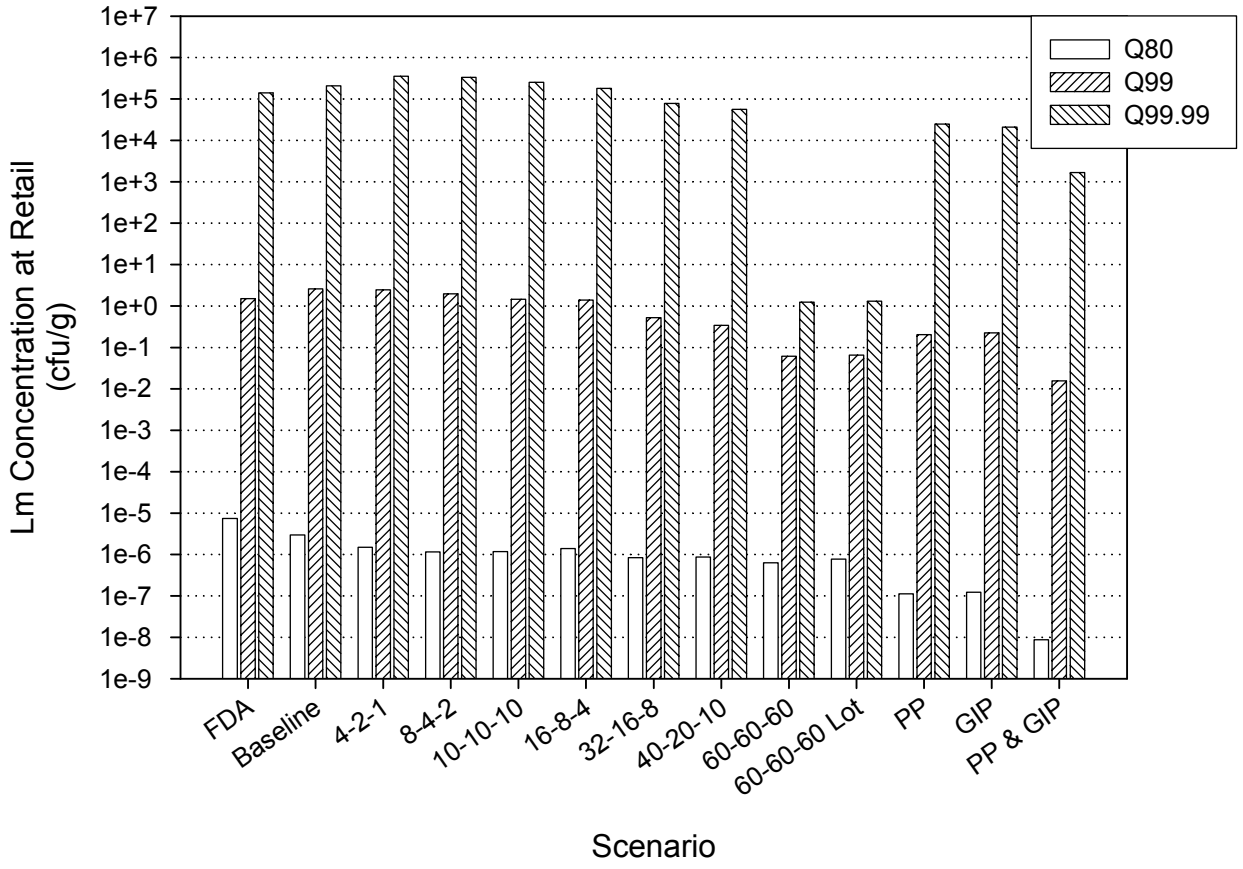


Figure 20. Quantiles of *L. monocytogenes* at Retail for Various Scenarios Tested.

The data generally show a decline in the *L. monocytogenes* concentration in RTE product at retail as the food contact surface testing and sanitation effort increases. The decline is more noticeable for the 80th and 99th percent quantiles. As previously described, the 99.99th percent quantile is more variable. Note the slight drop in the 80th percent quantile from the baseline to the initially proposed 4-2-1 testing level. Also note that testing and corresponding sanitation alone is not sufficient to effect a complete removal of *L. monocytogenes* from retail deli meats. Testing either every RTE lot that is produced or the food contact surface (along with corresponding sanitation) for every lot that is produced greatly reduces the extreme tail of the distribution (Q99.99) but has little impact on the 80th percent quantile. Post-processing interventions and growth inhibition (e.g., via the use of growth inhibitors/product reformulation) each have lower 80th percent quantiles than complete testing (i.e., testing every single lot of RTE product; 60-60-60 testing). In particular, note the decrease in the 80th percent quantile when post-processing and growth inhibition are combined. Reminder: that these scenarios assume that 100% of the industry adopts such practices.

Public Health Impacts

Figure 21 depicts estimated numbers of deaths among the elderly for the scenarios tested. For the proposed minimal amount of food contact surface testing (i.e., the 4-2-1 scenario ; FSIS, 66 FR 12589, February 27, 2001), the estimated median number of deaths among the elderly is reduced by about 20 per year.

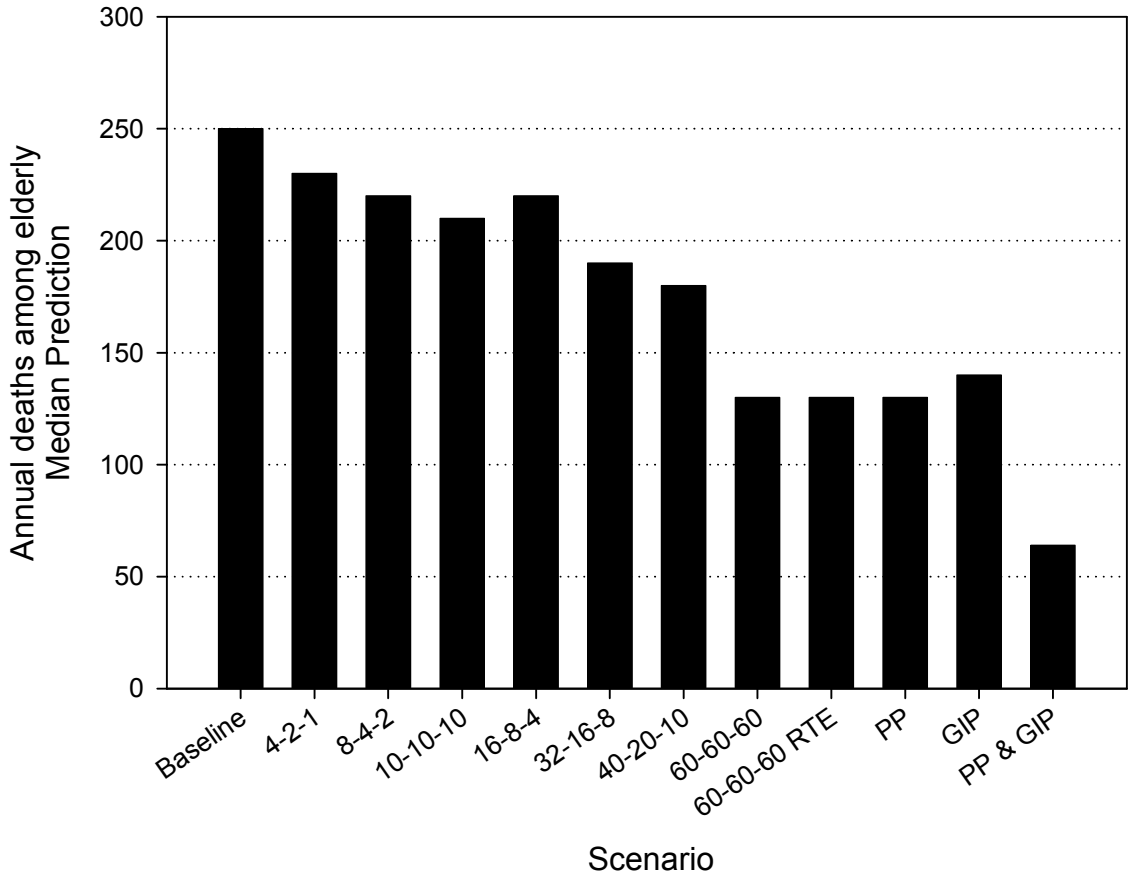


Figure 21. Estimated number of deaths among the elderly for the various scenarios tested.

Tables 20-23 provides the estimated retail concentration of *L. monocytogenes* in deli meats and the resulting number of deaths in the U.S. population among the elderly, intermediate age, and neonatal populations. The combination of post-processing and growth inhibitors is the only scenario tested where the total estimated number of deaths falls below 100 per year at the median of the uncertainty distribution.

The FDA/FSIS results in Tables 20-23 include uncertainty about the retail concentration distribution which the FSIS baseline predictions do not. This reduced uncertainty is not substantial but is the result of the in-plant model being calibrated to a singular, average, distribution predicted by the updated version of the 2001 FDA/FSIS risk ranking model.

Table 20. Quantiles of *L. monocytogenes* Concentrations in Deli Meat at Retail for Scenarios Tested

%	FDA/FSIS exposure assessment Model	FSIS Baseline Model	4-2-1	8-4-2	16-8-4	32-16-8	40-20-10	60-60-60	60-60-60 Lot	PP	GIP	PP&GIP
80.00	7.40E-06	2.95E-06	1.50E-06	1.15E-06	1.39E-06	8.38E-07	8.68E-07	6.29E-07	7.67E-07	1.12E-07	1.22E-07	8.67E-09
85.00	3.70E-05	2.66E-05	1.57E-05	1.25E-05	1.41E-05	8.98E-06	9.02E-06	6.13E-06	7.52E-06	1.18E-06	1.25E-06	9.06E-08
90.00	2.70E-04	3.06E-04	2.07E-04	1.70E-04	1.81E-04	1.18E-04	1.09E-04	6.88E-05	8.34E-05	1.59E-05	1.69E-05	1.23E-06
95.00	5.50E-03	8.86E-03	6.47E-03	5.34E-03	5.05E-03	3.19E-03	2.71E-03	1.35E-03	1.53E-03	5.22E-04	5.60E-04	3.93E-05
99.00	1.50E+00	2.60E+00	2.47E+00	1.98E+00	1.40E+00	5.26E-01	3.42E-01	6.10E-02	6.51E-02	2.03E-01	2.24E-01	1.56E-02
99.50	1.10E+01	1.78E+01	2.20E+01	1.70E+01	1.27E+01	4.50E+00	2.61E+00	1.47E-01	1.54E-01	1.70E+00	1.90E+00	1.32E-01
99.90	7.90E+02	8.04E+02	1.70E+03	1.24E+03	1.01E+03	4.52E+02	3.02E+02	5.04E-01	5.08E-01	1.39E+02	1.47E+02	1.08E+01
99.99	1.40E+05	2.06E+05	3.53E+05	3.31E+05	1.80E+05	7.76E+04	5.62E+04	1.25E+00	1.31E+00	2.47E+04	2.09E+04	1.67E+03

Table 21. Estimated Uncertainty in Annual Deaths Among the Elderly Population (> 60 years of age) for Scenarios Tested*

Percentile	FDA/FSIS dose-response Model	FSIS Baseline Model	4-2-1	8-4-2	16-8-4	32-16-8	40-20-10	60-60-60	60-60-60 Lot	PP	GIP	PP&GIP
5%	44	79	73	70	69	61	58	42	43	43	43	21
50%	230	250	230	220	220	190	180	130	130	130	140	64
95%	300	290	270	260	260	230	210	150	160	160	160	76
Average	200	220	210	200	200	170	170	120	120	120	120	59

Table 22. Estimated Uncertainty in Annual Deaths Among the Intermediate Age Population (> 30 days old and less than or equal to 60 years of age) for Scenarios Tested*

Percentile	FDA/FSIS dose-response Model	FSIS Baseline Model	4-2-1	8-4-2	16-8-4	32-16-8	40-20-10	60-60-60	60-60-60 Lot	PP	GIP	PP&GIP
5%	11	19	17	N/A	N/A	N/A	14	10	11	10	10	5
50%	53	56	52	N/A	N/A	N/A	41	29	30	30	31	15
95%	65	64	60	N/A	N/A	N/A	47	34	35	35	36	17
Average	47	51	48	N/A	N/A	N/A	37	27	28	28	28	13

Table 23. Estimated Uncertainty in Annual Deaths Among "Perinatal" Population (between 16 weeks before delivery and up to 30 days after birth) for Scenarios Tested.*

Percentile	FDA/FSIS dose-response Model	FSIS Baseline Model	4-2-1	8-4-2	16-8-4	32-16-8	40-20-10	60-60-60	60-60-60 Lot	PP	GIP	PP&GIP

	5%	3.7	6.4	6	N/A	N/A	N/A	4.7	3.3	3.4	N/A	3.5	1.7
	50%	13	14	13	N/A	N/A	N/A	10	7	7.3	N/A	7.6	3.5
	95%	16	15	14	N/A	N/A	N/A	11	8	8.3	N/A	8.5	4
Average		12	13	12	N/A	N/A	N/A	9.3	6.6	6.8	N/A	7.1	3.3

*Baseline model calibrated to 310 deaths per year among the elderly, 67 intermediate age deaths per year, and 16 neonatal/newborn deaths per year in the U.S. population.

Table 24 summarizes the predicted median lives saved per year for each of the age groups for the difference testing and pre and post packaging interventions analyzed.

Table 24. Summary of predicted median lives saved relative to baseline

Scenario	Elderly	Intermediate	Neonates/Newborns	Total
4-2-1	20	4	1	25
8-4-2	30	NA	NA	≥30
10-10-10	40	NA	NA	≥40
16-8-4	30	NA	NA	≥30
32-16-8	60	NA	NA	≥60
40-20-10	70	15	4	89
60-60-60	120	27	7	154
60-60-60 RTE	120	26	7	153
PP-95%	120	26	NA	≥146
PP-99%	173	39	10	221
GIP	110	25	NA	≥135
PP-95% & GIP	186	41	11	238

NA – not available.

Based on a monotonic Kendall tau statistical test for trend, the increase in the number of lives saved with increasing frequency of testing is statistically significant at the 99% significance level. (tau=0.88, p=0.0028).

Lot and Food Contact Surface Prevalence: Likelihood of Detection

Table 25 illustrates the contingency results of a sample run of 1,000,000 lots tested with 60 food contact surface tests per month and 60 lot tests per month, i.e. all possible tests of both the food contact surface and the product was conducted. Test and hold was used, but no other interventions were implemented.

Table 25. RTE Product Lot and Food Contact Surface Prevalences

	Lot positive	Lot negative	Sum
FCS positive	21635	115940	137575
FCS negative	8	862417	862425
Sum	21643	978357	1000000

This implies an overall RTE product lot prevalence for *L. monocytogenes* is 21643/1000000 or approximately 2.2%. The food contact surface prevalence for *Listeria* species is 137575/1000000 or approximately 13.7%. The lot prevalence when the food contact surface is positive is 21635/137575 or approximately 15.7%. Thus, knowing that the food contact surface is positive increases the likelihood of finding a positive lot by a factor of 7.

Test and Hold Effectiveness

Table 26 below provides data for evaluating the effectiveness of test and hold at various testing frequency. Figure 22 provides a graphical comparison. Clearly, there is only a small impact at

lower testing frequencies such as 4-2-1. At higher testing frequencies, test and hold greatly reduces the concentrations at retail.

Table 26. Effectiveness of Test and Hold of RTE Product Lot

Description	Q80	Q85	Q90	Q95	Q99	Q99.5	Q99.9	Q99.99
4-2-1	1.50E-06	1.57E-05	2.07E-04	6.47E-03	2.47E+00	2.20E+01	1.70E+03	3.53E+05
4-2-1 no test and hold	1.40E-06	1.50E-05	2.04E-04	6.63E-03	2.74E+00	2.28E+01	1.92E+03	4.04E+05
8-4-2	1.15E-06	1.25E-05	1.70E-04	5.34E-03	1.98E+00	1.70E+01	1.24E+03	3.31E+05
8-4-2 no test and hold	1.21E-06	1.32E-05	1.82E-04	6.00E-03	2.31E+00	1.90E+01	1.80E+03	3.18E+05
16-8-4	1.39E-06	1.41E-05	1.81E-04	5.05E-03	1.40E+00	1.27E+01	1.01E+03	1.80E+05
16-8-4 no test and hold	2.04E-06	1.97E-05	2.41E-04	7.03E-03	2.54E+00	2.12E+01	1.76E+03	2.42E+05
32-16-8	8.38E-07	8.98E-06	1.18E-04	3.19E-03	5.26E-01	4.50E+00	4.52E+02	7.76E+04
32-16-8 no test and hold	1.07E-06	1.15E-05	1.59E-04	4.88E-03	1.75E+00	1.51E+01	1.31E+03	2.69E+05
60-60-60	6.29E-07	6.13E-06	6.88E-05	1.35E-03	6.10E-02	1.47E-01	5.04E-01	1.25E+00
60-60-60 no test and hold	1.28E-06	1.24E-05	1.53E-04	4.11E-03	9.62E-01	8.74E+00	8.02E+02	1.29E+05

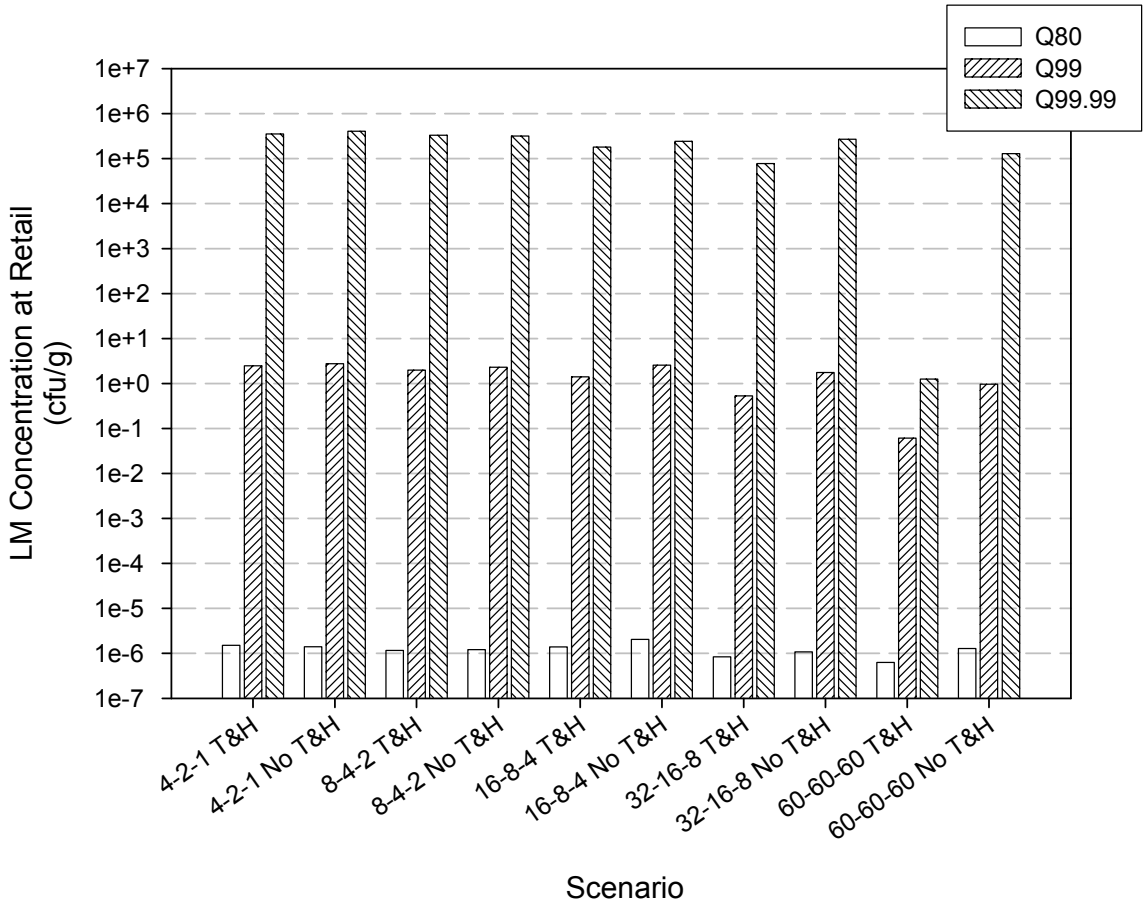


Figure 22. Comparison of Test and Hold Effectiveness for Difference Testing Frequencies.

This changing impact can be best illustrated in Table 27, which shows the comparison of the percentage of food contact surface positives and the lot positives for 2 sampling frequencies with and without test and hold.

Table 27: Example comparison of % food contact surface positives and lot positives under different test and hold scenarios

FCS Sample Frequency	Test and Hold?	FCS Tests	FCS Positives	Lot Tests	Lot Positives	% FCS Positives	% Lot Positives
4	Yes	66667	9171	9171	1432	13.8	15.6
4	No	66666	9442	9442	422	14.2	4.5
60	Yes	1000000	132914	132914	20560	13.3	15.5
60	No	1000000	131867	131867	5268	13.2	4.0

The percentage of food contact surface positives is approximately constant at about 13-14% regardless of the test and hold option. The percent of positive lots varies significantly depending on whether or not test and hold is implemented. When test and hold is implemented, positive lots occur approximately 15-16% of the time. When test and hold is not implemented, the lot percentage drops to 4-5 %. This decrease is caused by not being able to sample the lot during a period of known food contact surface contamination. The 3 day lag before a lot test is conducted greatly reduces the probability of finding a contaminated lot. These prevalence levels can also be compared to the overall lot prevalence described earlier, which was about 2.2%. The 4% prevalence when test and hold is not implemented is still almost twice what the overall lot prevalence is. In other words, knowing that the food contact surface was positive 3 days prior doubles the likelihood of finding a positive lot.

With test and hold enabled, for the smaller testing frequency, only 1432/1000000 lots (0.14%) tested positive and were removed from the food supply. For the more frequent testing, 20560/1000000 lots (2%) tested positive and were removed. The higher percentage removal leads to lower values for the given percentiles at retail.

SENSITIVITY ANALYSIS

A sensitivity analysis involves varying parameter inputs and assumptions to determine how they affect the estimated risk of illness. A preliminary sensitivity analysis of the FSIS *Listeria* risk assessment model has been conducted and the initial results are presented below.

Figure 23 evaluates the model results for a variety of pre and post packaging intervention level. The *L. monocytogenes* concentrations in deli meat at retail for different industry participation and intervention effectiveness are graphed. As expected, the retail concentrations decrease as both participation and effectiveness increase.

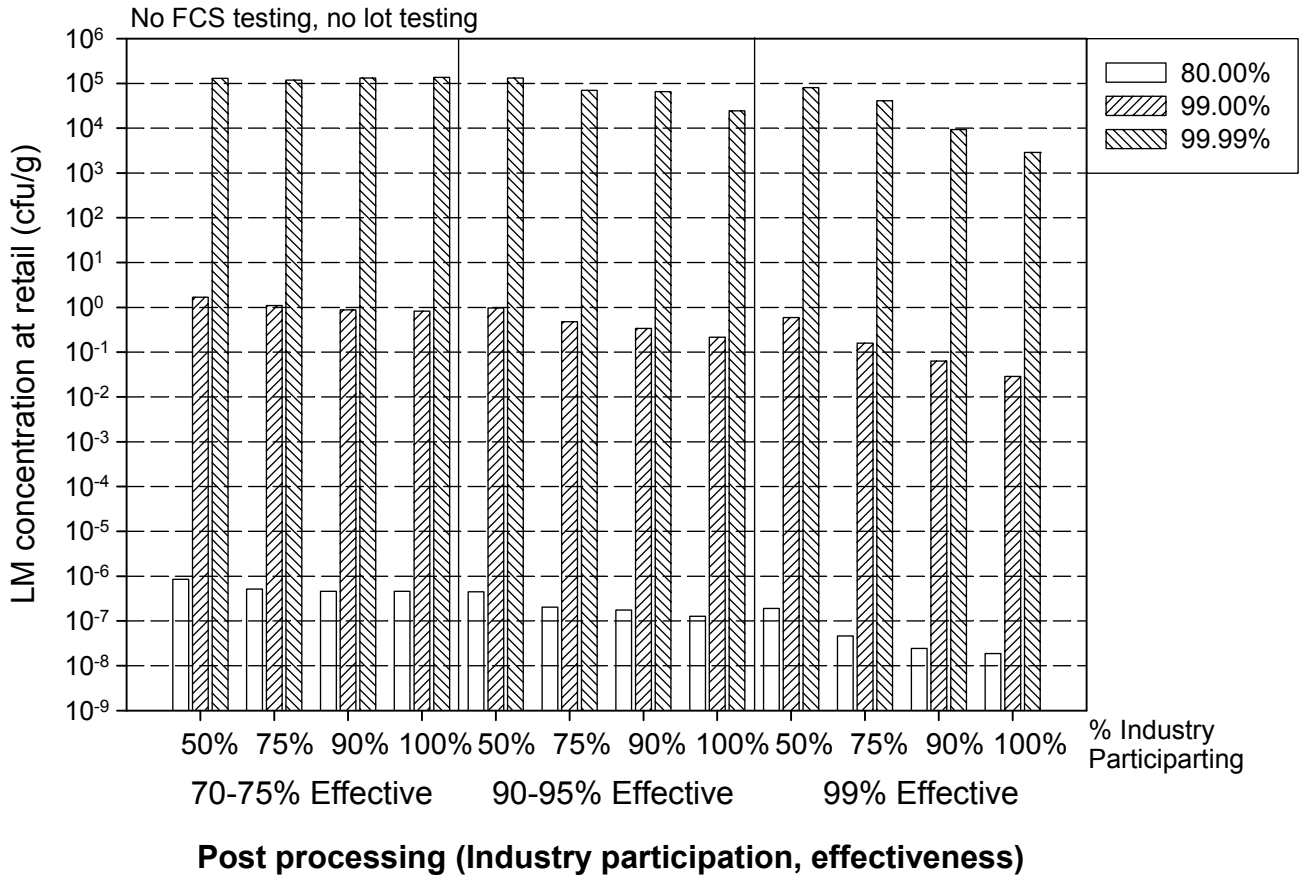


Figure 23. Sensitivity to Pre and Post Packaging Interventions**.**

Figure 24 presents the changes in retail *L. monocytogenes* concentrations for different sample masses used for RTE product lot testing. The concentrations decrease over all the sample masses tested, and the percent of positive lots increases. The change in the lot prevalence emphasizes that prevalence data is tied to detection limits.

In practice, 25 grams is consistently used for the sample mass, and the largest sample mass that can easily be used is about 100 grams. Multiple samples, at greater cost, would have to be analyzed to achieve the same effect as the larger RTE product lot sample masses modeled.

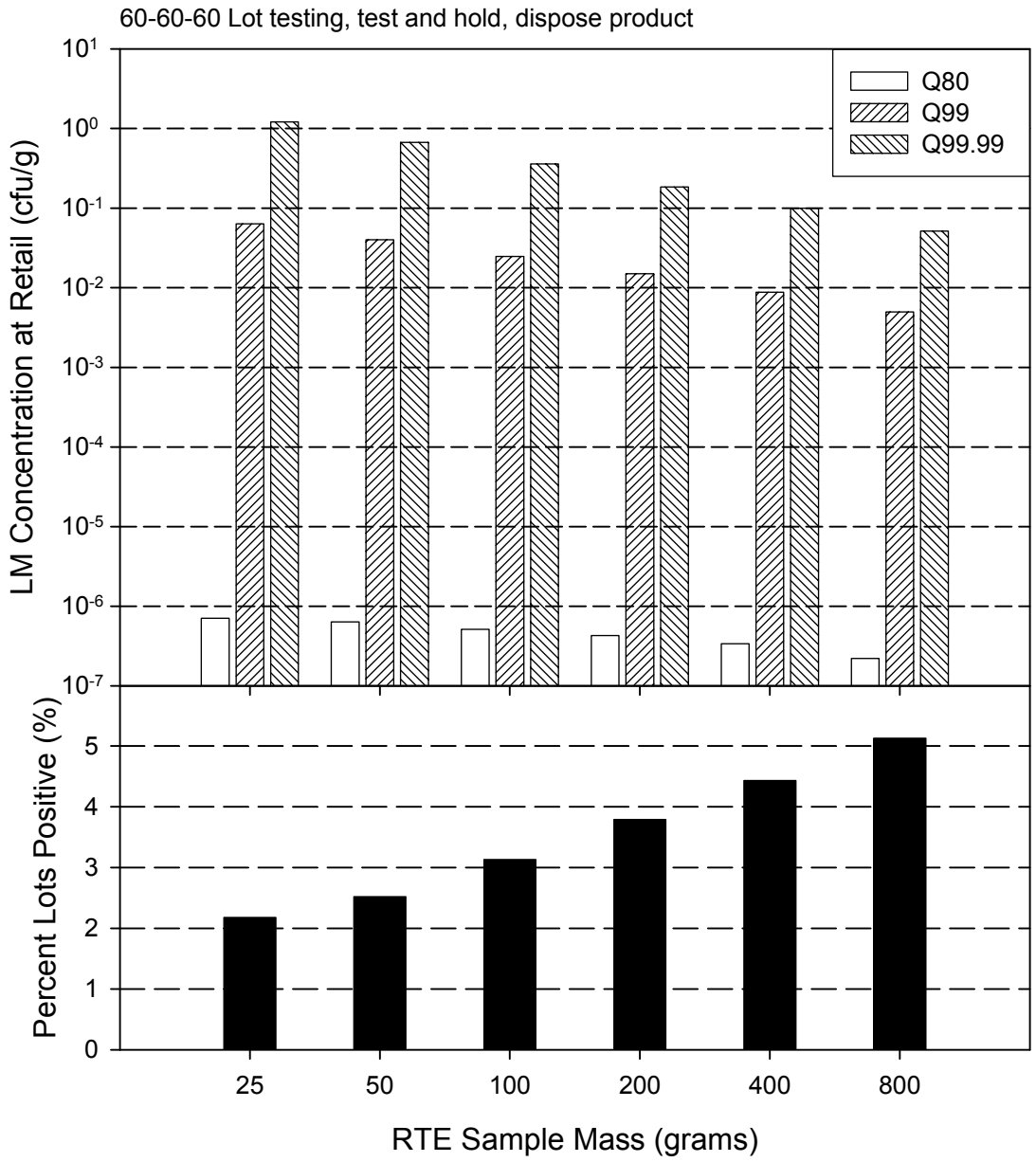


Figure 24. Sensitivity to RTE mass sampled.

Figures 25 and 26 show the impacts of varying the surface area swabbed during food contact surface testing. The retail concentrations initially decrease as larger areas are swabbed, but this effect levels off when 100-1000 cm^2 are sampled. Larger areas do not provide additional benefits. This is confirmed in Figure 26. The total number of positive lots found reaches its maximum when about 100 cm^2 is sampled, at about 2% of all the lots produced. This is the same as the overall lot prevalence. In other words, this area is sufficient to identify all the positive lots that are present. Sampling larger areas increases the percentage of food contact surface positives, but does not change the number or percentage of positive lots.

It is important to keep in mind that these conclusions are based on the assumption that *Listeria* species contamination is uniformly spread across the entire food contact surface. In practice, there is likely to be spatial variability, which might change the results.

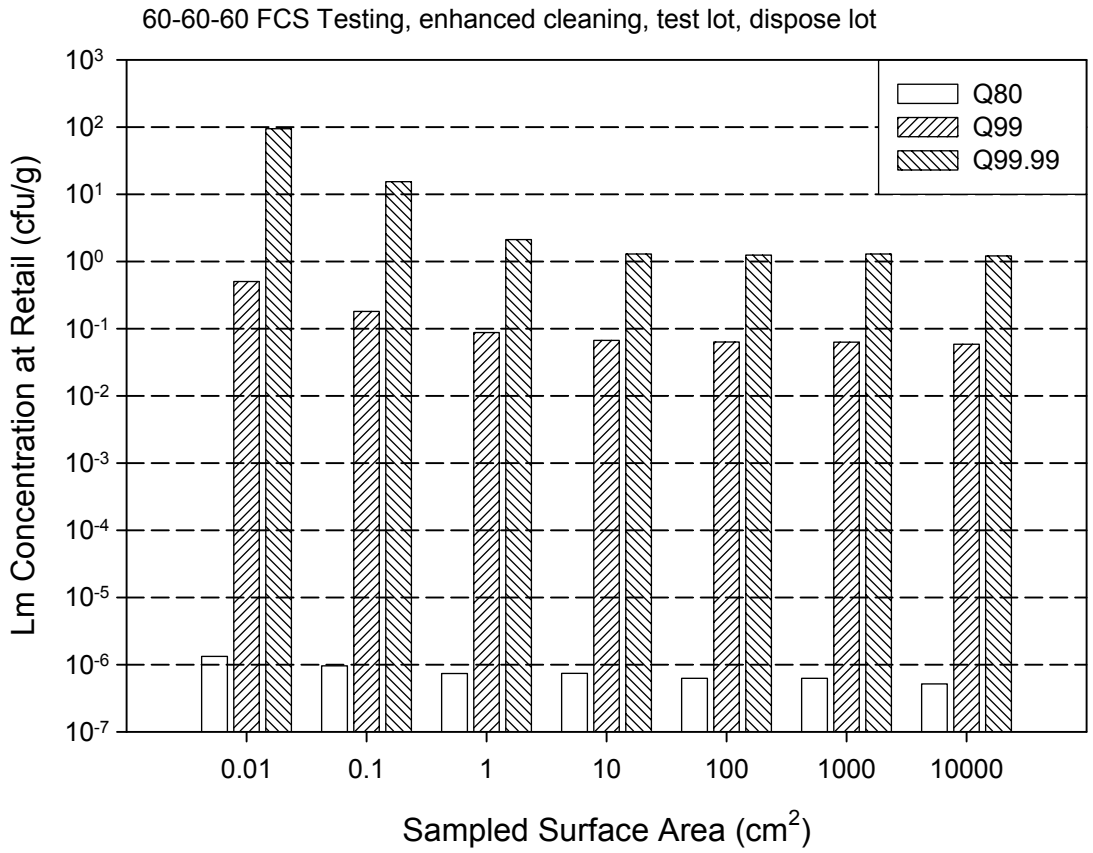


Figure 25. Retail *L. monocytogenes* concentrations in deli meats for different food contact surface area tested.

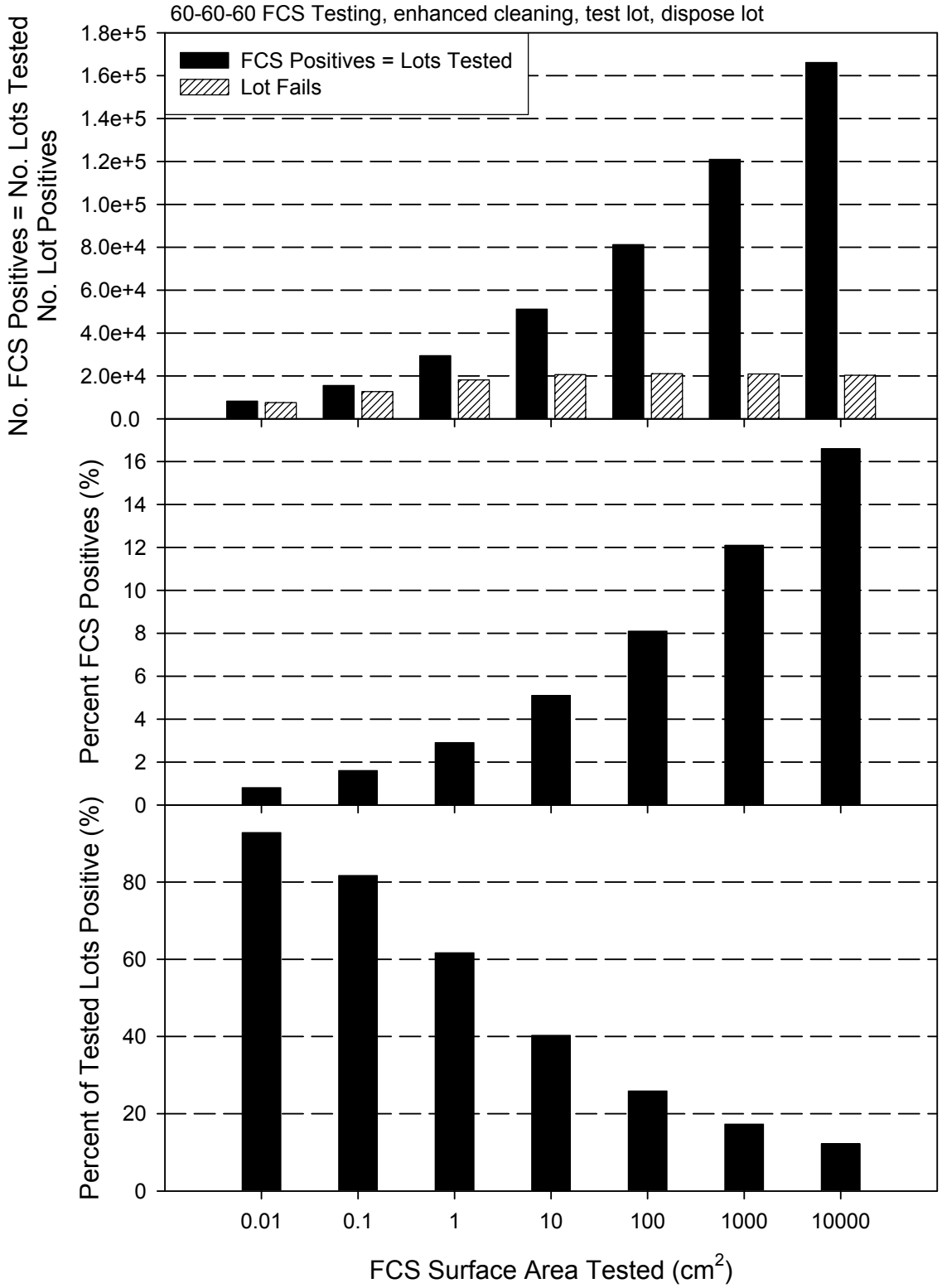


Figure 26. Sensitivity of positive RTE product lots and food contact surface area found to be positive based on the area of food contact surface tested.

L monocytogenes to *Listeria* species ratio

A very preliminary evaluation of the FSIS risk assessment model results to changes in the *L. monocytogenes* to *Listeria* species ratio is presented in Table 28.

Table 28. Evaluation of the concentration of *Listeria* species added to food contact surface and the prevalence of *Listeria* species on food contact surface or *L. monocytogenes* in RTE product lots as a function of different *L. monocytogenes (Lm)*/ *Listeria* species (Listeria species) ratios

Parameter	Low Ratio	Baseline	High Ratio
Mean Lm/Listeria species ratio	0.052	0.52	0.95
Std dev Lm/Listeria species ratio	0.026	0.26	0.026
Mean Listeria species/cm^2 added during contamination event (log scale)	-5	-6	-6.4
Std dev Listeria species/cm^2 added	3.5	3.5	3.5
overall lot prevalence (%)	2.2	2.2	2.0
overall FCS prevalence (%)	18.7	13.8	12.0
contingent lot prevalence when FCS is positive (%)	11.7	15.7	17.0
Improvement	5.3	7.1	8.5

Each column in the table requires a separate calibration of the level of *Listeria* species added to the food contact surface during a contamination event, and except for the baseline, the results are from initial calibrations only.

The overall lot prevalence, whether the mean ratio is 5%, 52%, or 95% is relatively constant at about 2%. This is consistent with the fact that all 3 simulations need to meet the same observed prevalence of *L. monocytogenes* at retail. The food contact surface prevalence changes however, with higher prevalences found for lower ratios. This result is because lower ratios require more *Listeria* species added to the food contact surface to match observed Lm concentrations. A ratio of 5% implies that approximately 10 times as many *Listeria* species are added to the contact surfaces compared to the baseline case. The contingent lot prevalence, i.e. the prevalence of positive lots when the food contact surface is positive increases as the ratio increases. As more of the organisms on the food contact surface are Lm, a positive food contact surface is more indicative of a positive lot. The improvement over the baseline lot prevalence (i.e. the ratio of contingent lot prevalence to overall lot prevalence) also increases as the ratio increases. At very low ratios, lot testing is 5 times more likely to find a positive lot if the food contact surface was positive. At very high ratios, lot testing is 8.5 times more likely to find positive lots.

The baseline ratio is based on prevalence data, not actual concentration data. The model has simply made this assumption in the lack of any better data. A concentration ratio of 5% is possible, however a concentration ratio of 95% seems unlikely when almost half of samples collected contain only *Listeria* species other than Lm.

The efficacy of food contact surface increases with higher ratios. However, even at very low ratios there is still a marked improvement achieved in sampling efficiency by knowing the results of the food contact surface test.

Uncertainty versus Variability

The in-plant model only considers variability, while the FDA/FSIS model considers both uncertainty and variability. Figure 27 depicts the 5th, 50th, and 95th percentile values for annual deaths in the elderly population are represented for four scenarios. These ranges reflect the uncertainty about the true number of deaths per annum. The first scenario is the prediction using the FDA/FSIS risk ranking model without any modification. For this scenario the 5th and 95th percentile values are about 50 and 300, respectively. The second scenario replaces the uncertainty about the concentration of *L. monocytogenes* per gram at retail in the FDA/FSIS risk ranking model with a single distribution that only describes variability. This variability distribution was calculated as the average distribution among 300 uncertain choices. For this scenario, the 5th and 95th percentiles are about 75 and 290, respectively. Therefore, removing the uncertainty about the concentration of *L. monocytogenes* per gram at retail has slightly reduced the uncertainty implied by the model. It has also increased the median value from about 230 deaths per annum to about 250 deaths per annum. The third and fourth scenarios use the in-plant model predictions for the variability in concentration of *L. monocytogenes* per gram at retail. The variability distributions for *L. monocytogenes* concentration per gram predicted by the in-plant model were calibrated to the average distribution calculated from the FDA/FSIS risk ranking model. These final two scenarios suggest that the predicted uncertainty in deaths per annum is not affected by the choice of a particular baseline from the in-plant model.

Although the baseline median value changes from 230 to 250 by not including uncertainty in the *L. monocytogenes* concentration per gram at retail, this effect is not substantial. The primary quantitative output of the risk assessment is the predicted deaths averted by interventions relative to the baseline. This marginal effect should be equivalent for baseline median of 230 or 250.

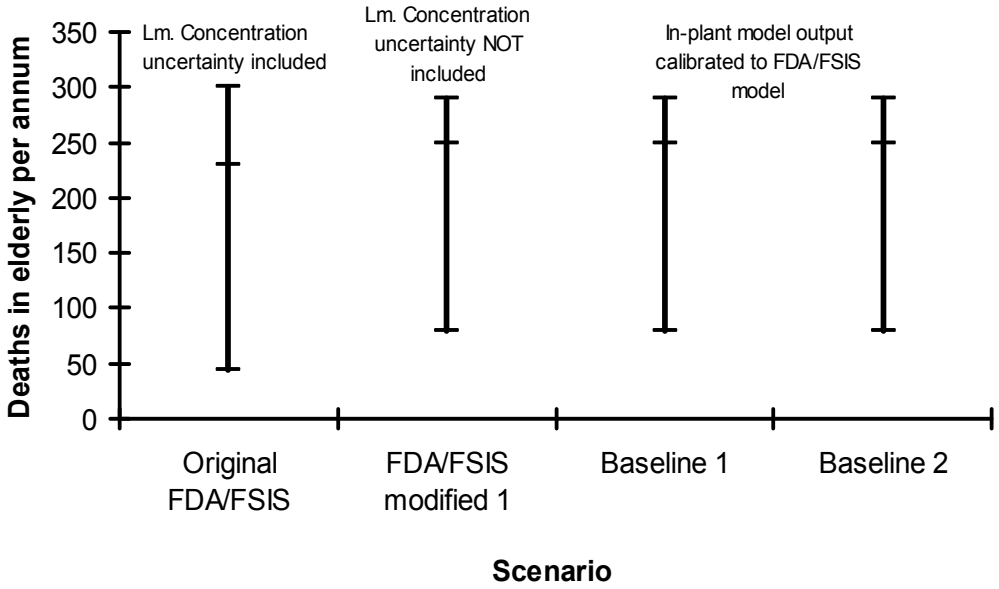


Figure 27. Per Annum Deaths Among the Elderly – A Comparison of FDA/FSIS Model Estimates with the FSIS *Listeria* Risk Assessment Baseline.

Model Validation

Although the data are not available to formally validate the model, the prevalence under the base model run was compared to preliminary USDA surveillance data. Prevalence was not used as part of the calibration process. Based on HAACP code 03G, which represents fully cooked, not shelf stable product that is sliced, diced or shredded, 23 out of 997 samples were positive for *L. monocytogenes*. This represents a prevalence of 2.3%. The base model's prevalence for *L. monocytogenes* in deli meats was 2.2%.

Several caveats apply to this comparison. The product categories do not overlap exactly. The O3F category includes products like diced chicken that would not be considered a RTE deli meat. The USDA values are still undergoing QA/QC and can only be considered preliminary. The Gombas *et al.* study (2003) found a lower average prevalence in deli meats of 0.9% then the USDA surveillance. Finally, the agreement between simulated and measured prevalence may be more of an indication that the upper tail of the FDA retail distribution , which the risk assessment match well during calibration, agrees with the observed USDA prevalence. Nonetheless, the agreement is supportive of the risk assessment model.

SUMMARY

- Food contact surfaces found to be positive for *Listeria* species greatly increased the likelihood of finding RTE product lots positive for *L. monocytogenes*.
- Frequency of contamination of food contact surfaces with *Listeria* species encompasses a broad timeframe, and the duration of a contamination event lasts approximately a week.
- The proposed minimal frequency of testing and sanitation of food contact surfaces, as presented in the proposed rule (66 FR 12569, February 27, 2001), is estimated to result in a small reduction in the levels of *L. monocytogenes* on deli meats at retail
- Increased frequency of food contact surface testing and sanitation is estimated to lead to a proportionally lower risk of listeriosis.
- Combinations of interventions (e.g., testing and sanitation of food contact surfaces, pre- and post-packaging interventions, and the use of growth inhibitors/product reformulation) appear to be much more effective than any single intervention in mitigating the potential contamination of RTE product with *L. monocytogenes* and reducing the subsequent risk of illness or death.
- The FSIS Listeria risk assessment clearly provides information important for comparing the relative effectiveness of interventions (e.g., testing and sanitation, post-lethality interventions, use of growth inhibitors, and combinations of these interventions; see Tables 10-14).

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[25] Note: This relative risk ranking has been received public review and comment. As a result, the model has been updated with additional data supplied by industry and other stakeholders. The FSIS *Listeria* risk assessment used components of the updated version of the 2001 FDA/FSIS risk ranking of RTE foods (i.e., those pertaining to deli meats and hot dogs/frankfurters).

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Appendix A. Revisions to the 2001 FDA/FSIS Risk Ranking Model

The exposure assessments for deli meats and hot dogs and the dose-response relationship of the January 2001 draft FDA/FSIS risk ranking model (see http://www.foodsafety.gov/~dms/lmrisk.html) was updated in response to public comments and the availability of additional data. Below is a list of the changes made to the exposure assessments for deli meats and hot dogs and the dose-response relationship. The updated FDA/FSIS exposure assessment for deli meats and updated dose-response relationship was used in the FSIS *Listeria* risk assessment.

Food Category Changes

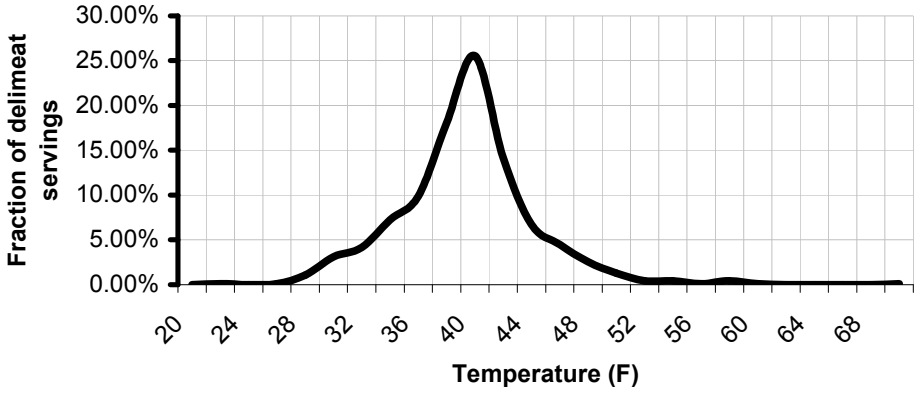
- Split frankfurters into two categories: not reheated and reheated.

Contamination Data Changes

- Additional contamination data for deli meats from published studies (see the table on p. 48).
- New contamination data was incorporated. This included: updated FSIS data (meats and meat products; included in Docket 03-005N), and the NFPA *L. monocytogenes* retail data for deli meats (also included in Docket 03-005N).
- Percent hot dogs eaten uncooked was modeled using a triangle distribution (4, 7, 10) based in part on information provided in the America Meat Institute (AMI) survey. The AMI data has been submitted to the Listeria docket (Docket 03-005N).

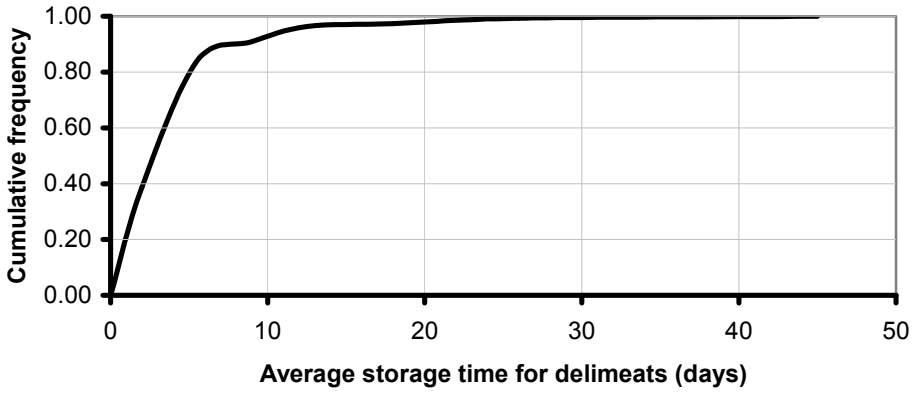
Growth Data Changes

- Frankfurters that are frozen before consumption were considered by excluding growth of *L. monocytogenese* during consumer handling for this portion of the frankfurters. A uniform distribution (3, 8.7) was used based information provided in the AMI survey and the FDA Food Safety Survey.
- The storage temperature distribution applicable to deli meats is shown below. This data was developed from Audits International surveys (see: http://www.foodriskclearinghouse.umd.edu/pversion/Audits-FDA_temp_study.htm).



Post-retail Storage Duration Changes

- Frankfurter and deli meats food categories. A survey sponsored by AMI provided data allowing the use of a semi-empirical distribution. Inter-household variation was based on the AMI data (they asked average storage time). These results are shown below (also included in Docket 03-005N).



A log normal distribution was applied at the empirical data points to introduce intra-household variation. The magnitude of the intra-household variation, expressed as the Geometric Standard Deviation (GSD) ranged from 0.4 to 0.6 to be consistent with the 'last storage time' data from the FSIS hotline study.

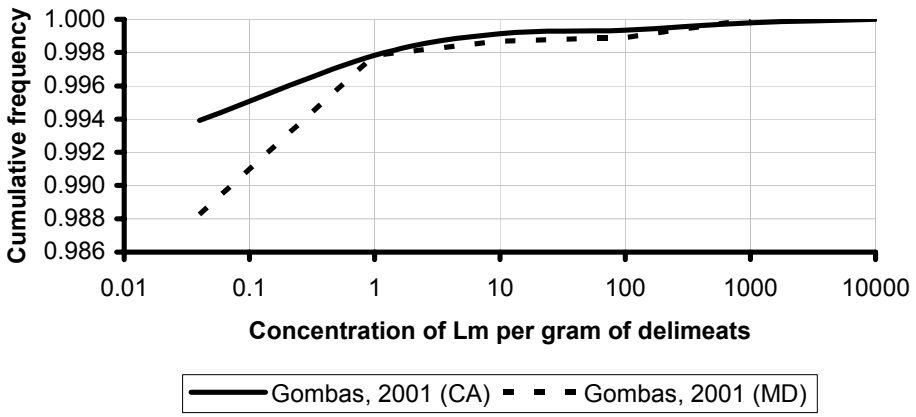
Changes to Modeling L. monocytogenes Levels in Food at Retail

- The models were fit to log dose (log cfu) instead of dose (cfu). A normal distribution was used exclusively; a range of parameters was used to represent the uncertainty.

- The algorithm used to calculate percentiles by ParamFit (used to develop the Log-Growth models) is (x-0.5)/n instead of (x-l)/(n-1).

- Quantitative modeling of *Listeria* distributions was applied to individual studies. Only studies with 10 or more enumerated samples were modeled. Group-specific generalizations about the shape of the *L. monocytogenes* concentration distributions (i.e. the geometric standard deviation with an uncertain range) were based on these analyses.

  The NFPA survey data (see *Listeria* Docket 03-05N) were used for deli meats. These results are summarized below.



- The geometric means used to produce an estimate were based on the prevalence value from a randomly selected individual study and a randomly selected geometric standard deviation. The probability interval assigned to each study was proportional to its weight, which was a function of the number of observations, the date of the study, and the geographic area of the study.

  Prevalence data used for deli meats are summarized below.

REFERENCE	Country	Total samples	% Positive
Aguado et al., 2001	Spain	369	9.2%
Baek et al., 2000	Korea	50	0.0%
Bersot et al, 2001	Brazil	30	26.7%
Daley et al., 1999	Canada	19	5.3%
Gillespie et al., 2000	UK	3455	0.4%
Gombas, 2001 NFPA-CA	USA	4600	0.6%
Gombas, 2001 NFPA-MD	USA	4599	1.2%
Gomez-Campillo et al., 1999	Spain	20	0.0%
Kamat and Nair, 1994	India	2	0.0%
Lahellec et al., 1996	France	45	2.2%
Levine, 2000	USA	9864	2.3%
Levine, 2001	USA	9037	1.9%
Miettinen, M., et al., 2001	Finland	25	0.0%
Ng and Seah, 1995	Singapore	17	17.6%
Ojeniyi, et al 2000	Denmark	55	7.3%
Oregon State Dept of Agriculture, 2001	USA	451	1.1%
Qvist and Liberski, 1991		240	14.2%
Samelis and Metaxopoulos, 1999	Greece	52	5.8%
Soriano et al.,2001	Spain	15	0.0%
Uyttendaele et al., 1999	Belgium	879	7.1%

- Data from geographic areas outside the United States were weighted to predict *L. monocytogenes* concentrations in foods in the United States. Group 1: North America

including US, Canada and Mexico; EU countries, Japan; Australia and New Zealand. Data from other countries will also be included in group 1 if they an important source for the food in the study. Weight =1. Group 2: All remaining data. Weight = 0.3. The decision of whether a country was an important import source depended on the level of imported product and the level of US consumption of the product. This decision was made on a case-by-case basis for each food category but general criteria for identifying an important import source is at least 1000 MT or $1 million/year.

- Data from older studies was weighted. A step-wise weighting was used for three time periods: pre-1993 to 1993, 1994 to 1998, and 1999 to current. The weighting for the step-wise approach will be 0.4, 0.7, and 1.0, respectively.

- Analogies about *L. monocytogenes* distribution shape was drawn from one food category to another, if there are no significant differences in distribution shapes among foods.

- The impact of truncating the contamination distribution prior to the growth model at the low (cold) end of the maximum growth values (i.e., at approximately 10^5) was evaluated.

Changes to Dose-response Modeling

- Instead of targeting the median value that is the result of multiple simulations, the dose-response adjustment factor was individually generated for each of the uncertainty iterations.
- The hospitalization /mortality ratios were calculated separately for each population group.

General Model Change

Although the model still uses Excel worksheet functions (e.g., statistical distribution functions, data indexing functions), it has been completely rewritten in Visual Basic for Applications (VBA).

Appendix B. Predicted growth between processing and retail

In the 2001 FDA/FSIS risk-ranking model exposure assessment for deli meats, prevalence data from processing plants were adjusted to account for growth in *L. monocytogenes* between the processing plant and the retail outlet. Based on simulated growth predictions, an adjustment of 1.9 logs (a multiplier of roughly 79) was assumed.

The available sampling evidence at processing and retail creates some confusion as to what is actually occurring between these two points in time and space. For example, FSIS reports a prevalence of 1%-3% *L. monocytogenes*-positive 25 gram samples at deli meat processors. In contrast, a large survey of deli meats at retail completed by NFPA found 0.9% of 25 gram samples positive for *L. monocytogenes*. Because the sampling and culturing methods were the same for both surveys, these results suggest that fewer servings are contaminated at retail than at processing. Seemingly, instead of growth making the problem worse between processing and retail, these data imply that the situation is better at retail than processing. This conclusion, however, is highly counterintuitive. Given the capacity of *L. monocytogenes* to survive and grow even at low temperatures, it is difficult to argue that there is no growth, or a reduction, in the numbers of *L. monocytogenes* in servings between processing and retail. As the 2001 FDA/FSIS risk ranking model predicts, this amount of growth is predicted to be, on average, 1.9 logs.

The FDA/FSIS exposure assessment for deli meats used both the FSIS and NFPA data in estimating the distribution for concentration of *L. monocytogenes* at retail. The conflicting effects of these data, however, are subsumed in the uncertainty about this distribution. This uncertainty is ignored in calibrating the in-plant model and, therefore, the effect of growth is more explicit for the in-plant model. This creates a problem that must be addressed.

To illustrate the problem, a series of three examples are presented. These examples are based on the following assumptions.

The log concentration of *L. monocytogenes* at retail is the sum of the log concentration at processing and the log of growth.

$$(1.1)\ \text{Retail}_{\text{Log(Lm per gram)}} = \text{Processing}_{\text{Log(Lm per gram)}} + \text{Growth}_{\text{Log(Growth multiplier)}}$$

The retail concentration distribution is assumed in the FDA/FSIS risk ranking to be a lognormal. Therefore, the log of concentration is normally distributed. The logs of the processing and growth distributions are also assumed to be normal distributions for these examples. Consequently, the following equation results.

$$(1.2)\ \text{Normal}_{\text{retail}}(\mu_1+\mu_2, \sqrt{\sigma^2{}_1+\sigma^2{}_2}) = \text{Normal}_{\text{process}}(\mu_1,\sigma_1) + \text{Normal}_{\text{growth}}(\mu_2,\sigma_2)$$

The FDA/FSIS exposure assessment model for deli meats provides the parameters for the $\text{Normal}_{\text{retail}}$ distribution. The mean is approximately -8 and the standard deviation is about 3.5. Given these parameters, the parameters of the $\text{Normal}_{\text{process}}$ distribution are calculated for different cases of growth. These cases are defined by assuming different parameters for the $\text{Normal}_{\text{growth}}$ distribution.

As assumed in the FDA/FSIS exposure assessment for deli meats, a threshold concentration of one *L. monocytogenes* in 25 grams is needed for a test to be positive. This concentration is equivalent to -1.4 logs. The proportion of the retail and processing distributions above this threshold provides an estimate of the prevalence of positive samples at each of these locations.

Case 1

The 2001 FDA/FSIS exposure assessment model for deli meats predicts an average growth of 1.9 logs with a standard deviation of 1.4 logs. Figure A-1 illustrates the outcome in this case. The grey line shows the threshold above which any sample would be positive. In this case, although 3% of samples would be positive at retail, only 0.3% of samples would be positive at processing.

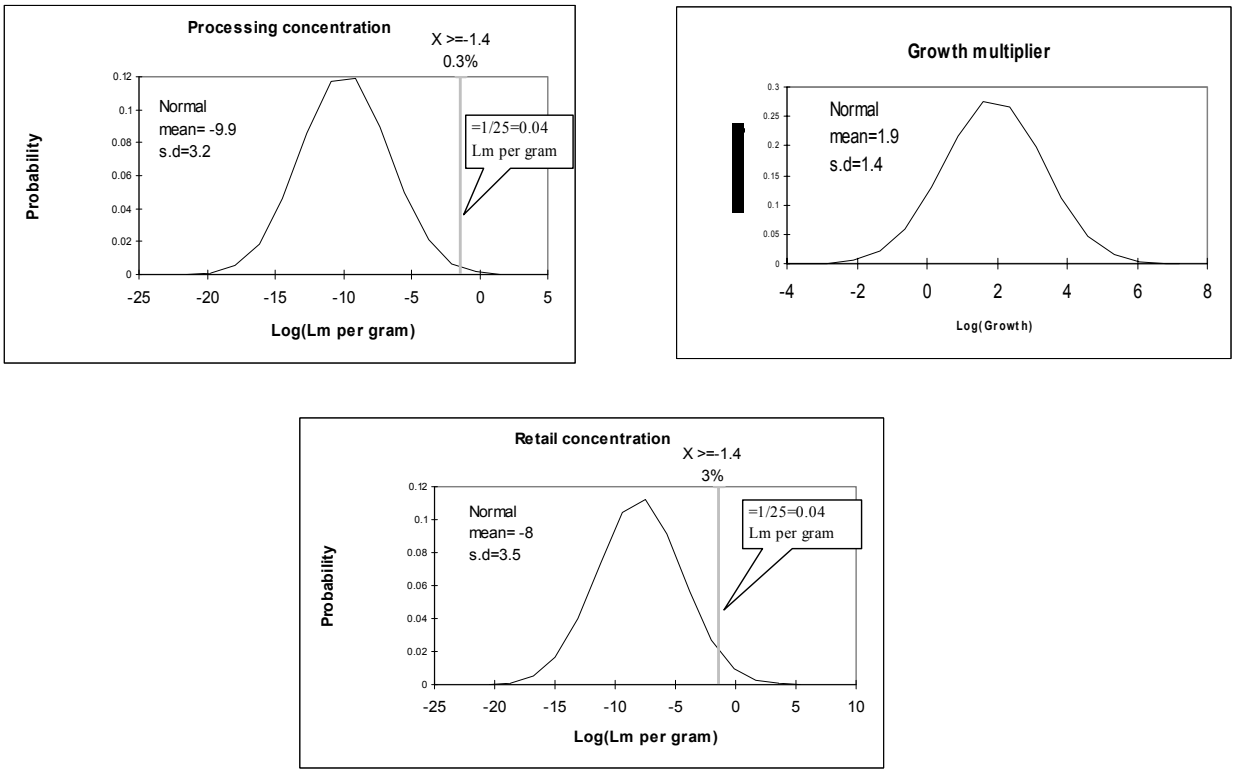


Figure A-1. Case 1 example where growth multiplier is assumed to be a normal distribution with a mean and standard deviation consistent with those predicted by the growth model in the 2001 FDA/FSIS exposure assessment model for deli meats.

Case 2

While the 2001 FDA/FSIS exposure assessment model for deli meats predicts a distribution of growth (mean = 1.9 logs and s.d.= 1.4 logs), the model only uses the central tendency value when predicting growth between processing and retail. Figure A-2 illustrates the outcome when

growth is a scalar adjustment. In this case, 3% of samples would be positive at retail and 0.8% of samples would be positive at processing.

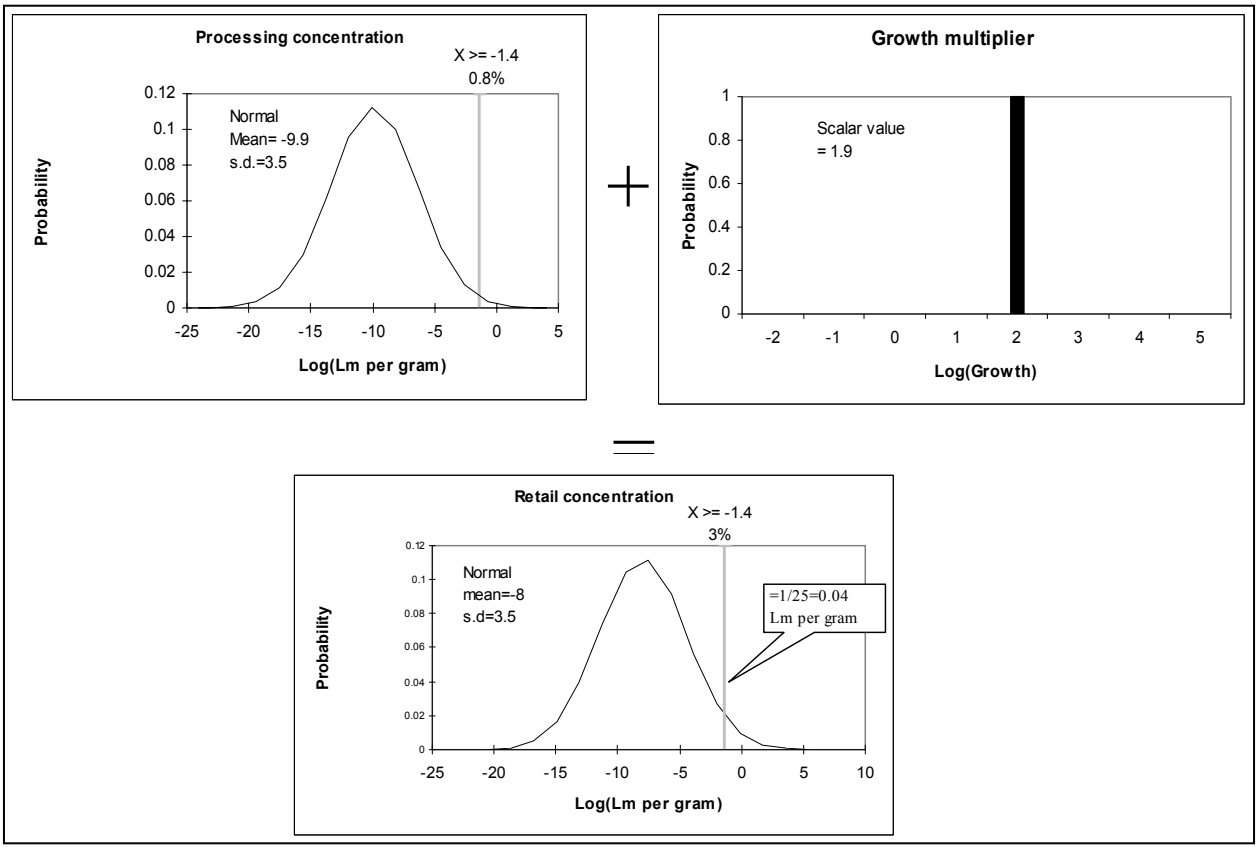


Figure A-2. Case 2 example where growth multiplier is a constant value of 1.9 logs. This is the assumption made when accounting for growth in the FDA/FSIS exposure assessment model for deli meats.

Case 3

Instead of a 1.9 logs scalar adjustment for growth, a 1 log adjustment is considered. Figure A-3 illustrates the outcome for this case in which 1.5% of samples would be positive at processing.

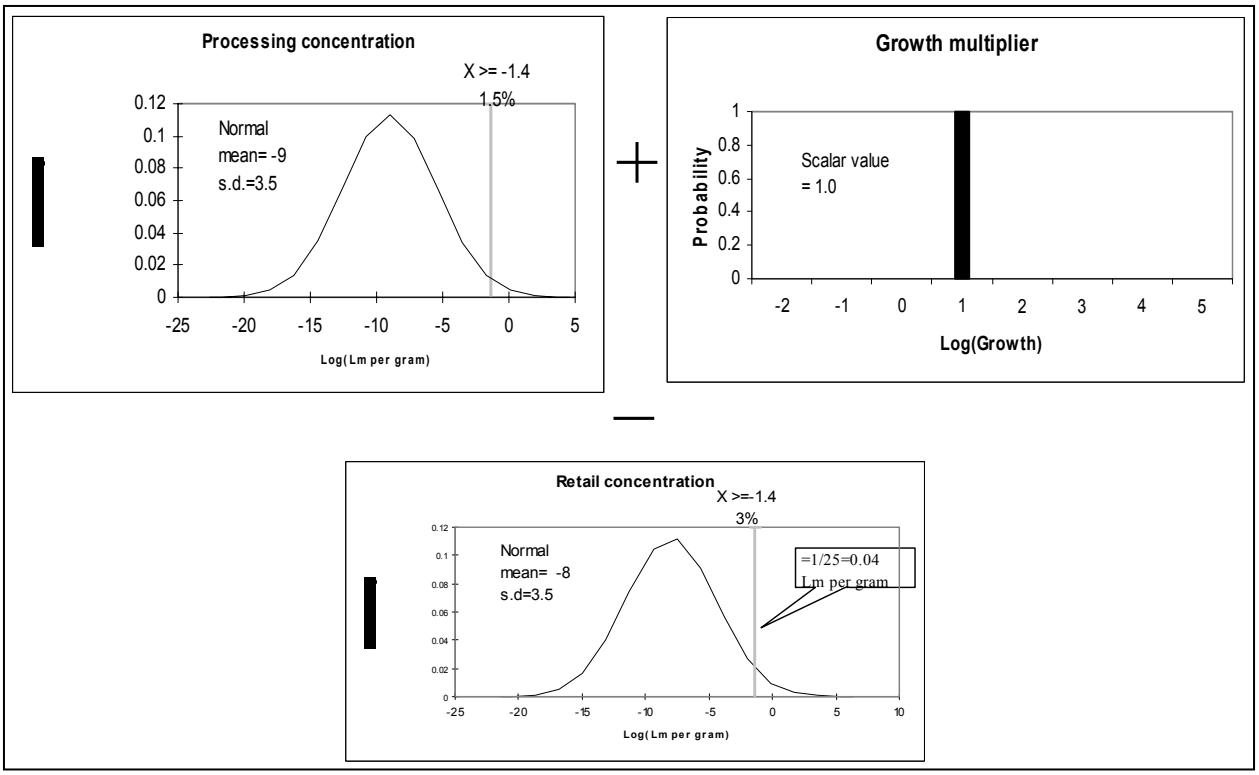


Figure A-3. Case 3 example where growth multiplier is a constant 1 log. This is the assumption used in the in-plant model.

Of the three cases considered, Case 3 is most consistent with the 1%-3% prevalence of positive samples found by FSIS at processing. In both Cases 1 and 2, the prevalence of positive samples at processing are below this observed range. None of the cases match the NFPA results of 0.9% positive samples at retail, but these results are included in the algorithm for estimating the *L. monocytogenes* concentration distribution for deli meats at retail in the FDA/FSIS exposure assessment model.

For the in-plant model, the scenario presented for Case 3 is used. A one log adjustment for growth seems most consistent with the available data at processing, as well as the *L. monocytogenes* concentration distribution in deli meats at retail estimated in the FDA/FSIS exposure assessment model for deli meats.

Appendix C. Evaluation of FSIS RTE Survey Data for Volume of Production for Establishments Producing Deli Meats

Purpose

The purpose of this analysis is to estimate probability distributions of product mass per line per shift for plants categorized as large, medium, and small volume plants. These three probability distributions are necessary inputs to the in-plant FSIS *Listeria* risk assessment model.

Data

The data were collected during a November 2002 survey of RTE processors. A total of 1139 processing establishments provided responses to this survey. While the survey included questions about hot dog production, this analysis only focuses on production of deli products. There were four classes of deli products considered:

1. **Unpeeled other sausage type product**
   Examples: bologna, mortadella, cooked salami

2. **Large mass chopped and formed type product**
   Examples: turkey roll, pickle & pimento loaf, cooked ham (sectioned and formed)

3. **Large mass whole muscle type product**
   Examples: cooked roast beef, cooked whole birds, cooked corned beef, whole cooked turkey ***breast, cooked whole ham***

4. **Sliced type product**
   Examples: sliced ham/bologna/chicken or turkey breast/olive loaf

Regarding production amounts, the survey asked processors to estimate production per shift of operation. One shift is assumed to refer to the time of production between clean-up in a processing plant. A single day in a large processing plant may comprise two shifts; the first two occurring between 6 am and 12 pm, and the second between 1 pm and 6 pm. These shifts are separated by work stoppage, cleaning of equipment, and a lunch break for personnel. Nevertheless, a shift may represent the continuous production of a specific deli product on one or more lines in the processing plant. Therefore, the survey also asked processors for the number of lines simultaneously operating in the processing plant.

To estimate total annual production, the survey also asked processors to provide the number of shifts per week, and weeks per year, the plant was producing a particular deli product.

PRODUCTION PER SHIFT

Each processing plant completed production per shift questions for each deli product it produces. Responders selected one of the following choices to signify production per shift for each deli product they produced.

a. < or = 1,000 lbs

b. 1,000 – 10,000
c. >10,000-50,000
d. >50,000-100,000
e. >or =100,000
does not produce → *skip to next row*

For the purposes of analysis, the responses were converted into point estimates by assuming the median value of intervals. For choice e (≥ 100,000 pounds per shift), a value of 100,000 was assumed. Therefore, the following values were entered into the database for the selected choice.

a. 500 lbs
b. 5500 lbs
c. 30,000 lbs
d. 75,000 lbs
e. 100,000 lbs

LINES PER SHIFT

For each deli product, responders indicated the number of lines producing this product per shift.

Number of lines
producing this product per shift:
(select one)
a. 1
b. 2
c. 3
d. 4
e. > or = 5

In this case, responders who selected choice e (≥5) were assumed to have 5 lines per shift.

SHIFTS PER WEEK

For each deli product, responders indicated the number of shifts that produced this product per week.

Number of
shifts per week:
(select one)
a. 1-3
b. 4-5
c. 6-8
d. 9-10
e. >or = 11

The midpoint value of each interval was selected as a point estimate for the database. Therefore, the following values were assumed.

Number of
shifts per week:
(select one)
a. 2
b. 4.5
c. 7
d. 9.5
e. 11

NUMBER OF WEEKS OF PRODUCTION

For each deli product, responders indicated the number of weeks that this product was produced each year.

Number of production weeks per year:
(select one)
a. < or = 12 weeks
b. 13 – 24
c. 25 – 42
d. 43 – 51
e. 52 weeks

The midpoint value of each interval was selected as a point estimate for a database entry. Therefore, the following values were assumed.

Number of production weeks per year:
(select one)
a. 6 weeks
b. 18.5 weeks
c. 33.5 weeks
d. 47 weeks
e. 52 weeks

Methods

The analysis began by estimating each processing plant's total annual production of all deli products. The plants were then ranked and categorized into large, medium, and small volume processors based on this total annual production.

For each volume category, the production per line per shift was initially characterized for each deli product. The production per line per shift for the entire volume category was then estimated by combining the deli products within the category.

TOTAL ANNUAL PRODUCTION PER PROCESSING PLANT

Responding processing plants were ranked by their estimated total annual production of all deli products. For each deli product produced in a processing plant, the total annual production was estimated as;

Production per shift x Shifts per week x Weeks per year

The total annual production per processing plant was estimated as the sum of the annual production for all deli products produced in that processing plant.

CATEGORIZING LARGE, MEDIUM, AND SMALL VOLUME PROCESSING PLANTS

Responding plants were ranked by their total annual production of all deli products and assigned to large, medium of small volume plant categories. Definitions for the categories were provided by OPPD. Large volume plants were defined as those whose total annual production of all deli products was within the top quartile of plants ($\geq$ 75th percentile). Medium volume plants were defined as those whose total annual production of all deli products was between the 50th percentile and the 75th percentile. Small volume plants were defined as those whose total annual production of all deli products was less than the 50th percentile.

ESTIMATING PRODUCTION PER LINE PER SHIFT

The in-plant *Listeria monocytogenes* risk assessment model randomly selects a production line during a shift and characterizes the production of deli product in terms of lots. Therefore, a lot is the mass of deli product produced by a single line during one shift. Because the lot is the unit modeled in the risk assessment, the survey data were analyzed to estimate the distribution of production per line per shift by volume category.

For each deli product produced in a processing plant, the production per line per shift was estimated as:

$$\frac{\text{Production per shift}}{\text{Lines per shift}}$$

For each volume category, various distributions were fit to the (non-zero) production per line per shift estimates for each of the deli products. Fitting of continuous probability distributions to the data was accomplished using the maximum likelihood estimation algorithm in BestFit. The choice of distributions was limited by forcing the distributions to have non-negative domains.

In each volume category, the selected distributions for the four deli products were combined using Monte Carlo simulation. On each iteration of a simulation, one distribution was randomly selected according to the percent of total annual production represented by the deli product (Table x), and a value from the selected distribution was randomly selected. At 10,000 iterations per simulation, the mean and standard deviation converged sufficiently so that there was <1% change in these parameters.

The 10,000 values, or pseudo-data, generated from each simulation (one each for large, medium, and small volume plants) were then entered into BestFit and several plausible

distributions were fit to the data. Chi-square, Anderson-Darling (AD), and Kolmogorov-Smirnov (KS) goodness of fit statistics were also calculated.

Table C-1. Estimated annual production (pounds) for four deli products within three volume categories.

Volume Category	Deli-1	Deli-2	Deli-3	Deli-4	Total
Large	591,002,625	1,499,120,250	2,002,267,375	2,091,023,125	6,183,413,375
(%)	9.6%	24.2%	32.4%	33.8%	
Medium	35,188,375	31,824,250	69,002,125	52,759,000	188,773,750
(%)	18.6%	16.9%	36.6%	27.9%	
Small	7,282,125	5,118,000	9,495,375	12,223,000	34,118,500
(%)	21.3%	15.0%	27.8%	35.8%	

Results

The results of this analysis summarize the total annual production for all processing plants, the statistical fitting of probability distributions to the deli product classes within each production volume category, and the statistical fitting of probability distributions to the combined data within volume categories.

TOTAL ANNUAL PRODUCTION ACROSS ALL PLANTS

After ranking processing plants from largest to smallest total annual production of deli products, it was noted that processors in the upper 25th percentile of production are responsible for >95% of total annual production (Figure C-1). In other words, 285 (25%) of the 1139 processors surveyed produced a total of 6.2 billion (96%) of the 6.4 billion pounds all processors were estimated to produce in a year. It is also notable that the top 10% of processors are responsible for about 85% of total annual production of deli meats.

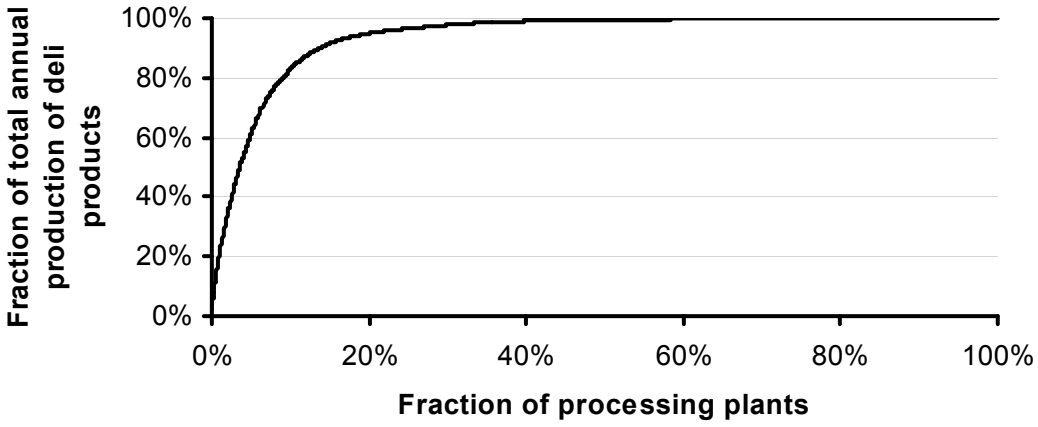


Figure C-1. Relationship between the fraction of processing plants and the cumulative total annual production of deli products by the processing plants.

INITIAL FITTING OF DISTRIBUTIONS TO DATA BY DELI PRODUCT CLASSES WITHIN VOLUME CATEGORIES

Statistical fits of lognormal distributions to the data from each of the four deli products within each processing plant volume category suggested substantial differences in the average pounds of production per line per shift (Table C-2). For example, the average production per line per shift of deli product category 1 is 12,637 pounds from large volume plants, 1,251 pounds from medium volume plants, and 532 pounds from small volume plants. Similar patterns are noted for the other deli product categories.

Goodness of fit tests did not support a conclusion that the production per line per shift data originated from any of the parametric distributions tested, including the lognormal. Such a finding is not surprising given the nature of the data. Figures C-2 and C-3 are examples of estimated lognormal distributions and empirical cumulative frequency distributions based on the survey data. The empirical distributions shown in these graphs are not characteristic of any smooth cumulative function. Instead, these distributions suggest a "lumpy" pattern of data points. This clustering of data points is a result of the ordinal, multiple choice format of the survey. There were only 5 choices for production per shift – and 5 choices for lines per shift – available to those surveyed. Therefore, only a total of 25 data points were possible. This limitation of the data is responsible for the stair-stepping pattern evident in the empirical cumulative distribution. Such a pattern would be very difficult for any smooth, well-behaved function to statistically fit, yet the lack of fit does not necessarily rule out the hypothesis that the data originated from a lognormal distribution. For the purposes of this analysis, the lognormal distribution was selected for ease of implementation and plausibility relative to other parametric distributions available from BestFit, e.g., loglogistic, Inverse Gaussian, Weibull, gamma, or exponential.

Table C-2. Maximum likelihood estimates of lognormal distribution parameters for production per line per shift. Large, medium, and small volume processors are defined based on total annual production of all deli products

	Deli category 1	Deli category 2	Deli category 3	Deli category 4
Large volume				
mean	12,637	19,384	23,766	12,501
s.d.	28,468	49,396	49,470	29,710
Medium volume				
mean	1,251	1,041	2,087	1,303
s.d.	1,580	1,137	3,409	1,672
Small volume				
mean	532	560	639	555
s.d.	162	219	355	220

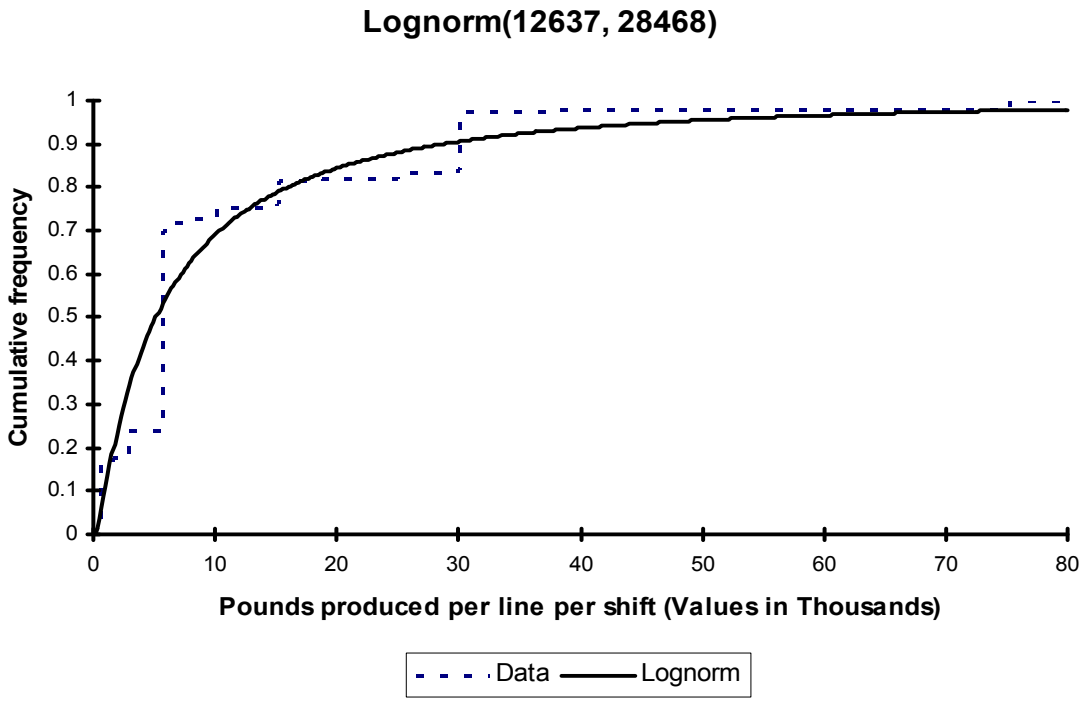


Figure C-2. Comparison of lognormal distribution to data on production per line per shift from large volume processing plants' production of deli product category 1.

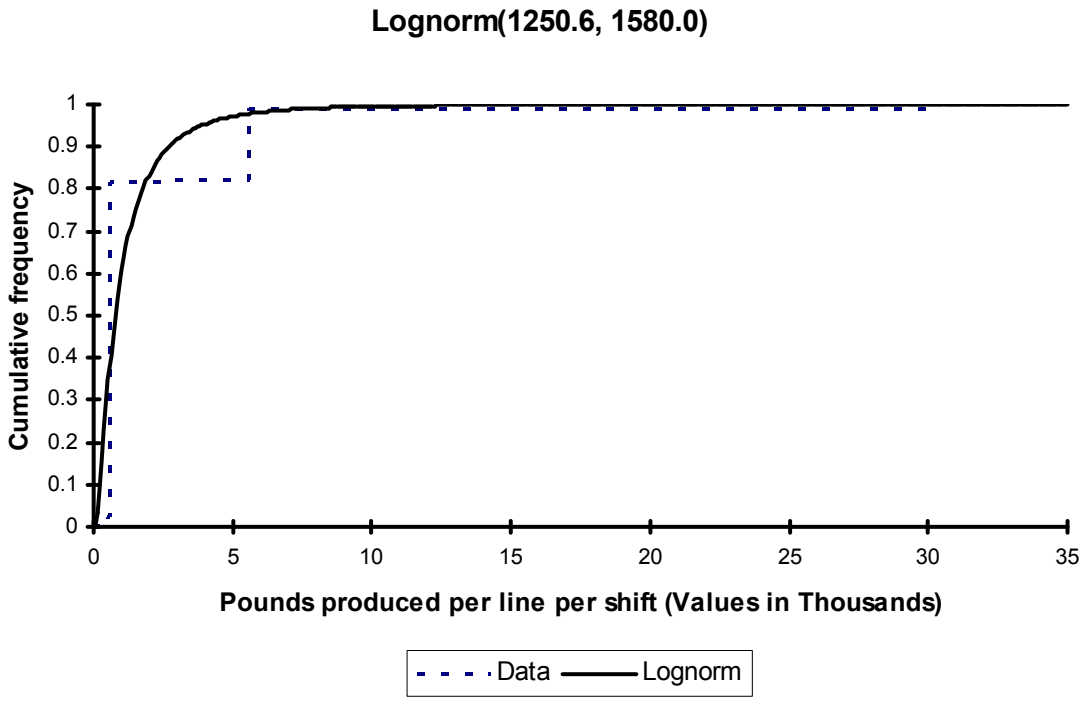


Figure C-3. Comparison of lognormal distribution to data on production per line per shift from medium volume processing plants' production of deli product category 1.

STA*TISTICAL FITTING OF DISTRIBUTIONS TO COMBINED VOLUME CATEGORY DATA*

Following the combining of the four deli product distributions within each volume category by Monte Carlo simulations, the resulting pseudo-data were entered into BestFit to determine plausible distributions. *A priori*, it could not be determined what distribution would describe each volume categories' production per line per shift. Nevertheless, the lognormal distribution best fit the data from the large and medium volume categories, and was the second best-fitting distribution in the small volume category (Tables C-3 – C-5). The lognormal distribution was a statistically significant fit (P=0.58) in the large volume category, but none of the distributions' fits were significant for the medium and small volume categories.

Because the lognormal distribution was the only statistically significant fit, and this distribution could be readily implemented in the *Listeria monocytogenes* risk assessment model, this distribution was assumed applicable for the three volume categories. The lognormal parameters shown in Tables C-3 – C-5 were used. Nevertheless, it should be noted that uncertainty about the true distribution type and the parameters of the lognormal could influence the results of the in-plant model.

Table C-3. MLE parameters for production per line per shift in large volume plants. Parameters and goodness of fit statistics were generated from analysis of pseudo-data resulting from combining four deli product categories in large volume category of plants.

MLE's	**Lognormal**	**LogLogistic**	**Inverse Gaussian**	**Weibull**	**Exponential**
parameter 1	18,420.35	0.00	18,067.37	0.72	18,067.37
parameter 2	45,155.71	6,982.84	3,106.66	13,963.21	
parameter 3		1.25			
Goodness of fit					
Chi-sqr value	69.80	213.69	963.57	1,077.15	2,843.44
p-value	0.58	0.00	0.00	0.00	0.00
AD value	0.35	7.77	196.25	108.55	Infinity
p-value	N/A	N/A	N/A	< 0.01	< 0.001
KS value	0.01	0.02	0.10	0.06	0.18
p-value	N/A	N/A	N/A	< 0.01	< 0.01

Table C-4. MLE parameters for production per line per shift in medium volume plants. Parameters and goodness of fit statistics were generated from analysis of pseudo-data resulting from combining four deli product categories in the medium volume category of plants.

MLE's	**Lognormal**	**LogLogistic**	**Inverse Gaussian**	**Weibull**	**Exponential**
parameter 1	1,487.93	0.00	1,532.48	0.92	1,532.48
parameter 2	2,115.42	846.98	744.94	1,455.15	
parameter 3		1.67			
Goodness of fit					
Chi-sqr value	99.43	175.28	288.81	1,428.84	1,500.43
p-value	0.02	0.00	0.00	0.00	0.00
AD value	1.89	5.98	28.26	Infinity	Infinity
p-value	N/A	N/A	N/A	< 0.01	< 0.001

KS value	0.01	0.01	0.04	0.07	0.09
p-value	N/A	N/A	N/A	< 0.01	< 0.01

Table C-5. MLE parameters for production per line per shift in small volume plants. Parameters and goodness of fit statistics were generated from analysis of pseudo-data resulting from combining four deli product categories in the small volume category of plants.

MLE's	**LogLogistic**	**Lognormal**	**Inverse Gaussian**	**Gamma**	**Weibull**
parameter 1	0.00	573.46	574.52	5.74	2.25
parameter 2	523.58	251.29	2,971.02	100.14	648.76
parameter 3	4.24				
Goodness of fit					
Chi-sqr value	121.02	126.09	159.89	454.54	1,590.99
p-value	0.00	0.00	0.00	0.00	0.00
AD value	2.27	4.51	7.67	36.67	Infinity
p-value	N/A	N/A	N/A	< 0.005	< 0.01
KS value	0.01	0.02	0.02	0.04	0.08
p-value	N/A	N/A	N/A	N/A	< 0.01

Conclusions

- Large volume processing plants – the upper quartile of all plants – are responsible for >95% of all deli meat produced per year.
- Deli product classes 3 and 4 – large mass whole muscle and sliced meats – comprise the largest share of deli products produced by all processing plants.
- While large volume processors produce the greatest total product per year, these plants also have a much larger average production per line per shift than medium and small volume processors.
- After combining the four deli products, the resulting production per line per shift distribution can be modeled as a lognormal for each of the volume categories.

Appendix D
Volume Based Testing and Lot Testing Based on Sequential Positive Food Contact Surface Results

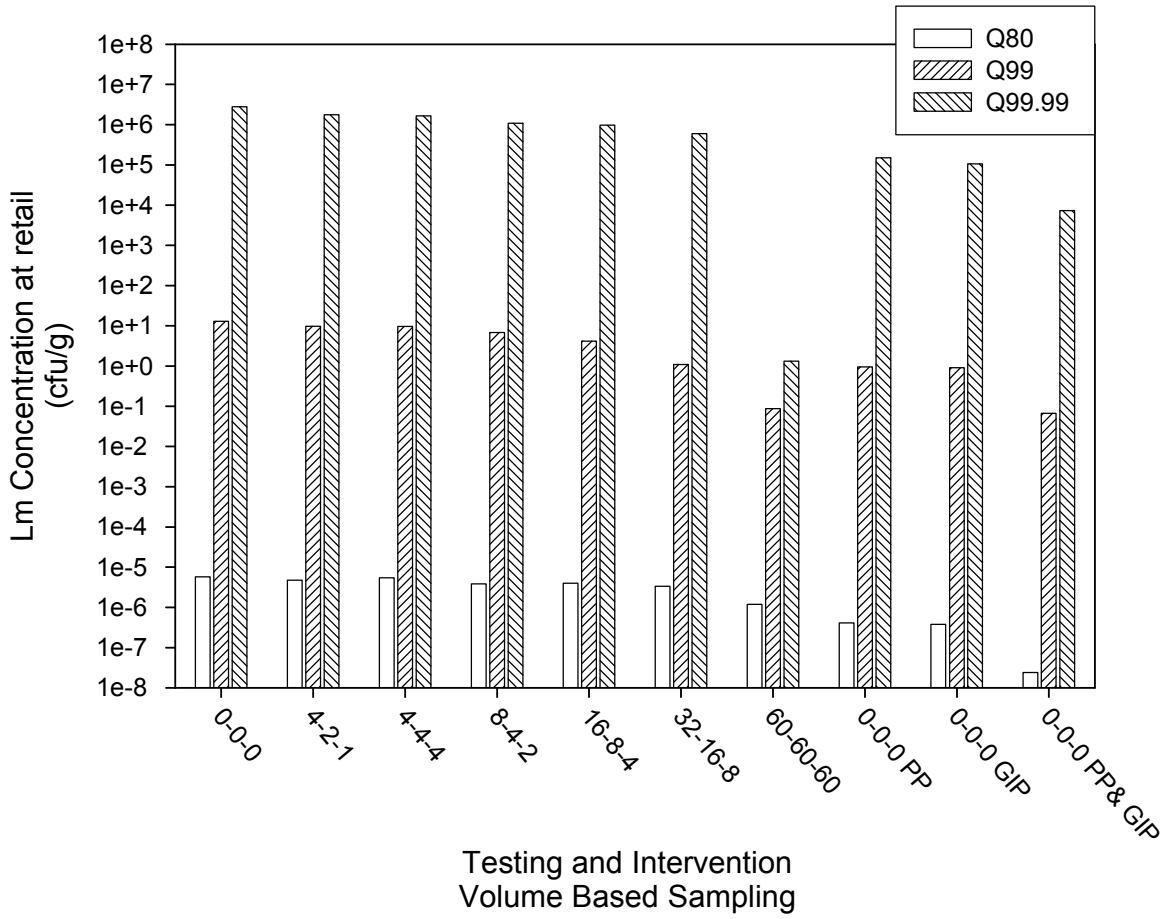
1) VOLUME BASED TESTING

Using the results from Appedix C above, the in-plant model was rerun. Because the probability distribution used to generate lot masses changed from a normal to a log10 normal, no direct comparison between the volume based sampling and the HAACP based sampling is possible without a model recalibration, which was not performed. Although the mean lot mass increased based on the volume classification, the median lot mass actually decreased. Because of this, the Lm concentrations at retail are higher than the baseline in the HAACP classification approach. A recalibration would be need to reduce these concentrations back to the FDA distributions. Because of this, comparisons should only be made within the same classification strategy (volume based or HAACP based).

The classification strategy only makes a difference if there is a differential testing frequency among the categories. For example, a 4-2-1 testing frequency requires more tests of the larger category, and the retail concentrations and public health impacts can change depending on how the categories are defined. A 4-4-4 testing frequency tests all producers at the same frequency, and the category definition is immaterial.

The survey analysis in Appendix C found that over 96% of servings were produced by the top 25% of production facilities. The HAACP category of large plants found that 48% of servings were produced by the large HAACP category. Switching to volume based testing (with equivalent testing frequencies for the "large" category) implies that more servings are tested at a higher frequency under the volume based approach than under the HAACP based approach. The earlier risk assessment found that increased testing frequency was statistically significantly correlated with greater number of lives saved. Thus, switch to volume based sampling categories would have a corresponding benefit for the number of lives saved.

Figure D-1 illustrates the Lm concentrations at retail from a volume based categorization under different FCS sampling frequencies and interventions. The trends are similar to the HAACP based results. Increased FCS testing results in lowered Lm concentrations at retail, particularly among the highest quantiles. Post-processing and growth inhibiting formulation and packaging decrease the lower quantiles, and the combination has the greatest impact overall.



2) LOT TESTING BASED ON SEQUENTIAL POSITIVE FOOD CONTACT SURFACE RESULTS

Description of Lot Testing Based on Sequential Positive Food Contact Surface

Take FCS samples on a regular basis. Upon notification that a FCS was positive for Lspp, immediately take a second FCS sample. Anytime two reported FCS samples are positive (regardless of the time between samples):

a) take corrective sanitation action,
b) immediately take a lot sample,
c) take FCS samples continuously until a negative is reported
d) hold any additional lots until the FCS sample result is available. If the FCS result is reported as positive, release held product lots. If the FCS sample is positive, test all product lots being held.

Note that product lot testing is triggered by FCS positives, not by any product lot results. The timing between FCS samples can vary because sequential positives can trigger additional FCS testing. Two examples are shown below.

Below is part of the run with the interpretation of what sequential means in terms of the actual actions undertaken. The model assumes that 6 lot production before a result is returned (3 days reporting lag * 2 lots per day).

Abbreviations:
"h,y": initially held, then tested based on a later FCS positive result
"h,n", initially held, then released without testing based on a later negative FCS result

Table D-1: Simple Consecutive Positive Example

Lot	FCS Sampled?	Result Reported from FCS Test 6 lots previous	Consecutive positive count	Action	Lot test?
625	n				n
626	y				n
627	n				n
728	n				n
629	n				n
630	n				n
631	n				n
632	y	pos	1	take additional FCS sample	n
633	n				n
634	n				n
635	n				n
636	n				n
637	n				n
638	y	pos	2	trigger lot test trigger FCS test until result available	y
639	y			hold lot	h,n
640	y			hold lot	h,n
641	y			hold lot	h,n

642	y			hold lot	h,n
643	y			hold lot	h,n
644	n	neg	0	release held lots	n
645	n	neg	0		n
646	y	pos	1	take additional FCS sample	n
647	n	neg	0		n
648		neg	0		n
649		neg			n
650					n
651					n
652		neg	0		n
653					n

Table D-2: Complex Consecutive Positive Example

Lot	FCS Sampled?	Result Reported from FCS Test 6 lots previous	Consecutive positive count	Action	Lot test?
896	n				n
897	y				n
898	n				n
899	n				n
900	n				n
901	n				n
902	n				n
903	y	pos	1	take additional FCS sample	n
904	n				n
905	n				n
906	n				n
907	n				n
908	n				n
909	y	pos	2	trigger lot test, trigger FCS until result	y

				available	
910	y			hold lot	h,y
911	y			hold lot	h,y
912	y			hold lot	h,y
913	y			hold lot	h,y
914	y			hold lot	h,y
915	y	pos	3	test held lots test current lot	y
916	n	neg	0		n
917	n	neg	0		n
918	y	pos	1	take additional FCS sample	n
919	y	pos	2	trigger lot test trigger FCS until result available	y
920	y	pos	3	test lot	y
921	y	pos	4	test lot	y
922	y			hold lot	h,y
923	y			hold let	h,y
924	y	pos	5	test held lots test current lot	y
925	n	neg	0		n
926	n	neg	0		n
927	n	neg	0		n
928		neg	0		n
929		neg	0		n
930		neg	0		n

Note in Table D-2 that upon the receipt of the 3rd positive FCS result, the number of product lots tested increases dramatically as the held lots are tested. The more important impact of requiring sequential FCS positives before a product lot sample is taken is that two Lspp reporting lags occur before a product sample is taken. For the Lm risk assessment, each reporting lag was taken as 3 days, so this approach does not take a lot sample 6 days after the first FCS positive occurred.

The duration of a contamination event in the model has a mean of about 9 days and a median of about 4 days. (Recall the parameter is log10 normally distributed.) Thus the majority of the contamination events are over before a lot sample is taken. Only long term contamination events are likely to be detected. The problem is compounded by the fact that even within a contamination event, not all FCS samples are positive. One negative FCS sample is enough to reset the number of consecutive positives.

The model results bear out these concerns. Figure D-2 illustrates the Lm concentrations at retail. Increased testing does not reduce the concentrations, even at the higher quantiles.

The nonconsecutive positive approach for Figures D-3 and D-4 used test-and-hold, so that the lot sampled corresponded to the FCS positive.

Figure D-3 compares the number of FCS and product lot tests between the two approaches. The consecutive positive approach often requires more FCS tests. In Table D-2 for example, 5 FCS tests were required while waiting for the result after the second FCS positive. Figure D-3 also shows, however, that in general fewer products lots are tested. The proposed approach, as defined, results in more FCS samples taken and fewer product lot samples than the alternative approach of not requiring consecutive positives.

Figure D-4 illustrates the likelihood of detecting a positive once a FCS or product lot sample has been taken. The consecutive positive approach consistently has higher probability of finding a positive FCS once a FCS sample is taken. The efficiency drops off with increasing testing frequencies. The original approach had lower, and more constant efficiency levels.

The lot testing level efficiencies are quite different. The consecutive positive approach always resulted in lower likelihood of finding a positive product lot by about a factor of 4. Lot samples appear to be taken too late compared to when the contamination even is ongoing.

CONCLUSIONS

The overall effect of requiring consecutive FCS positives before taking a product lot sample results in fewer lot samples being collected and a much lower likelihood of finding positives lots for those that are collected. Based on these findings, and the lack of any decrease in the Lm concentration at retail, the consecutive positive requirement appears to be ineffectual in protecting public health

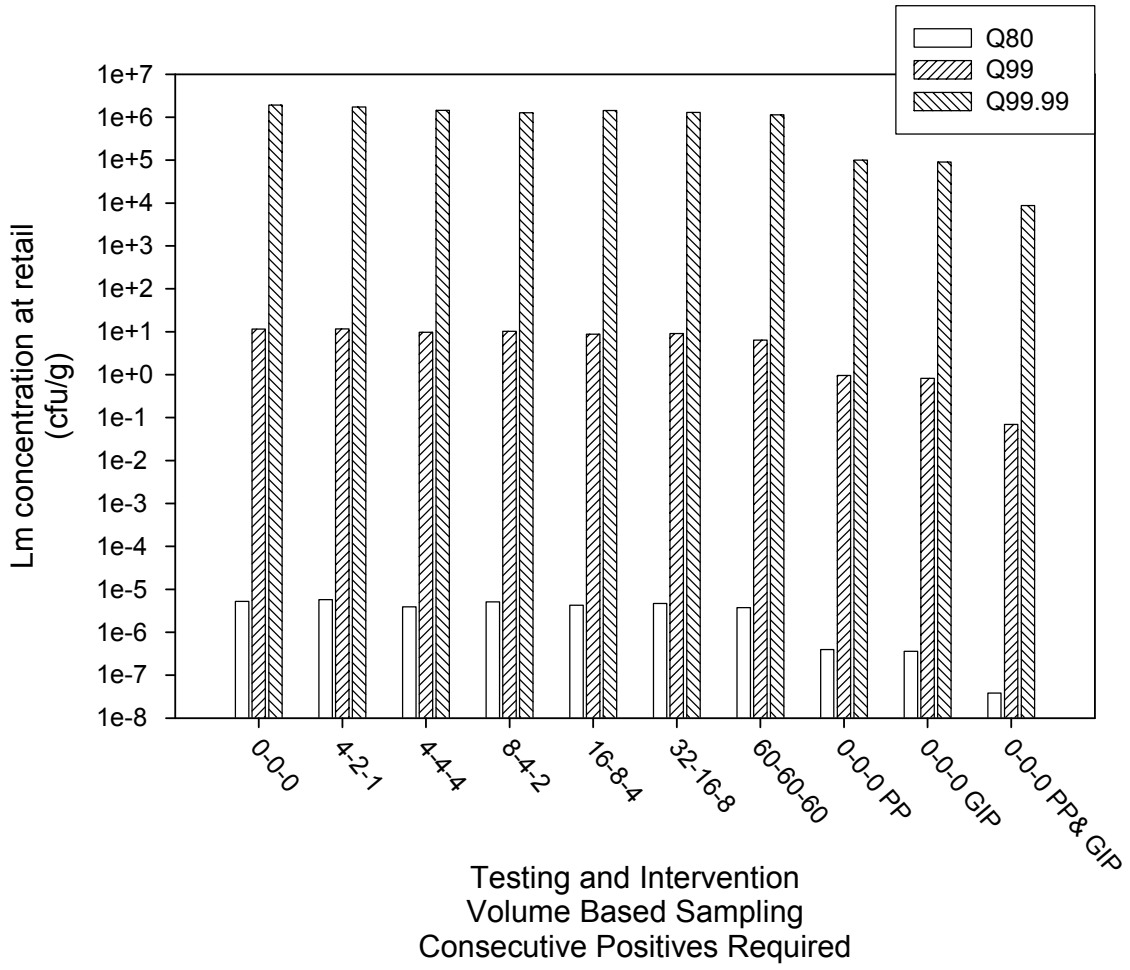


Figure D-2. Lm Concentrations at Retail Under Various FCS Sampling Frequencies When Consecutive FCS Samples are Required to Trigger a Product Test.

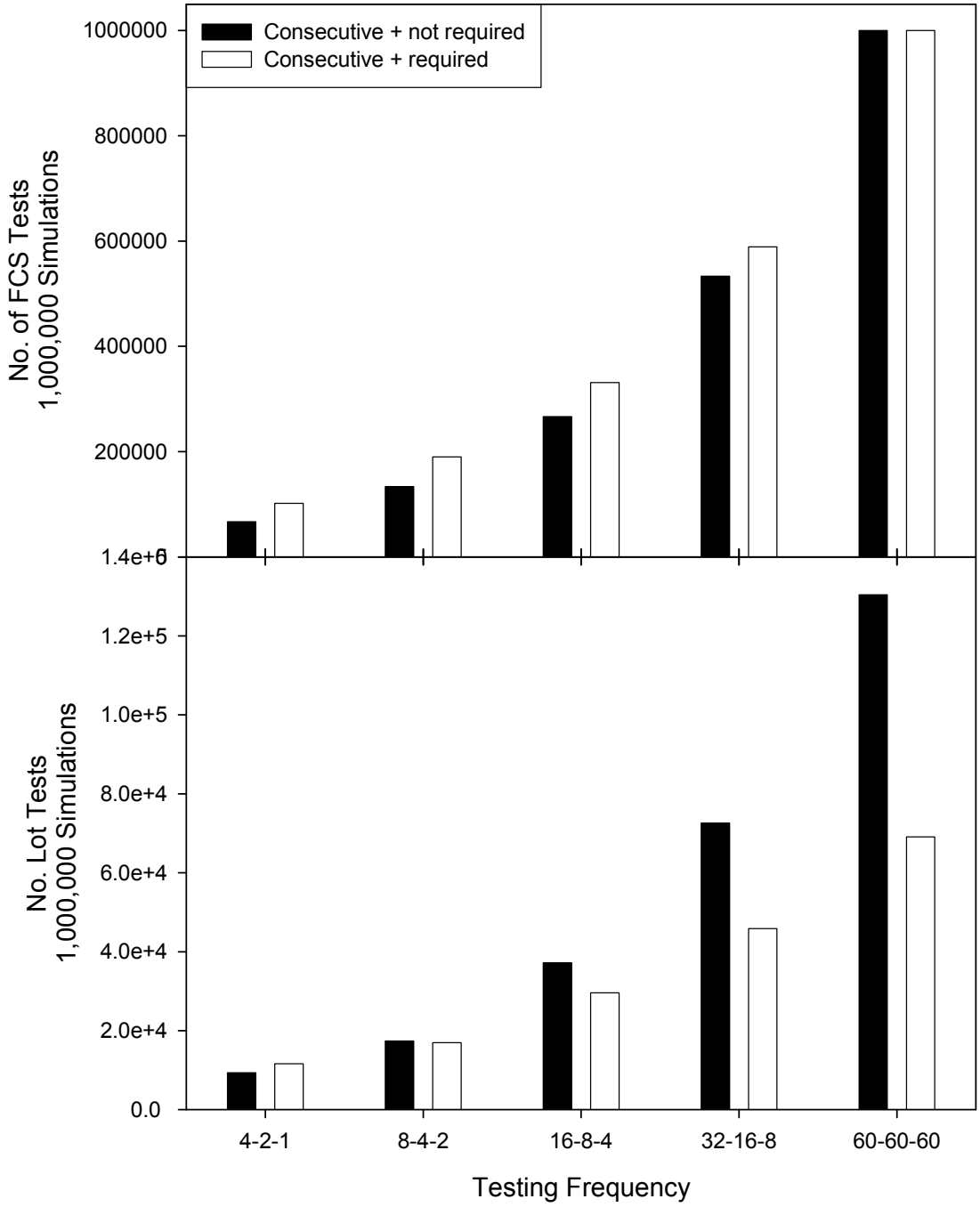


Figure D-3. Comparison of the number of FCS tests and product lot tests when consecutive positives are required and not required to trigger a product lot test.

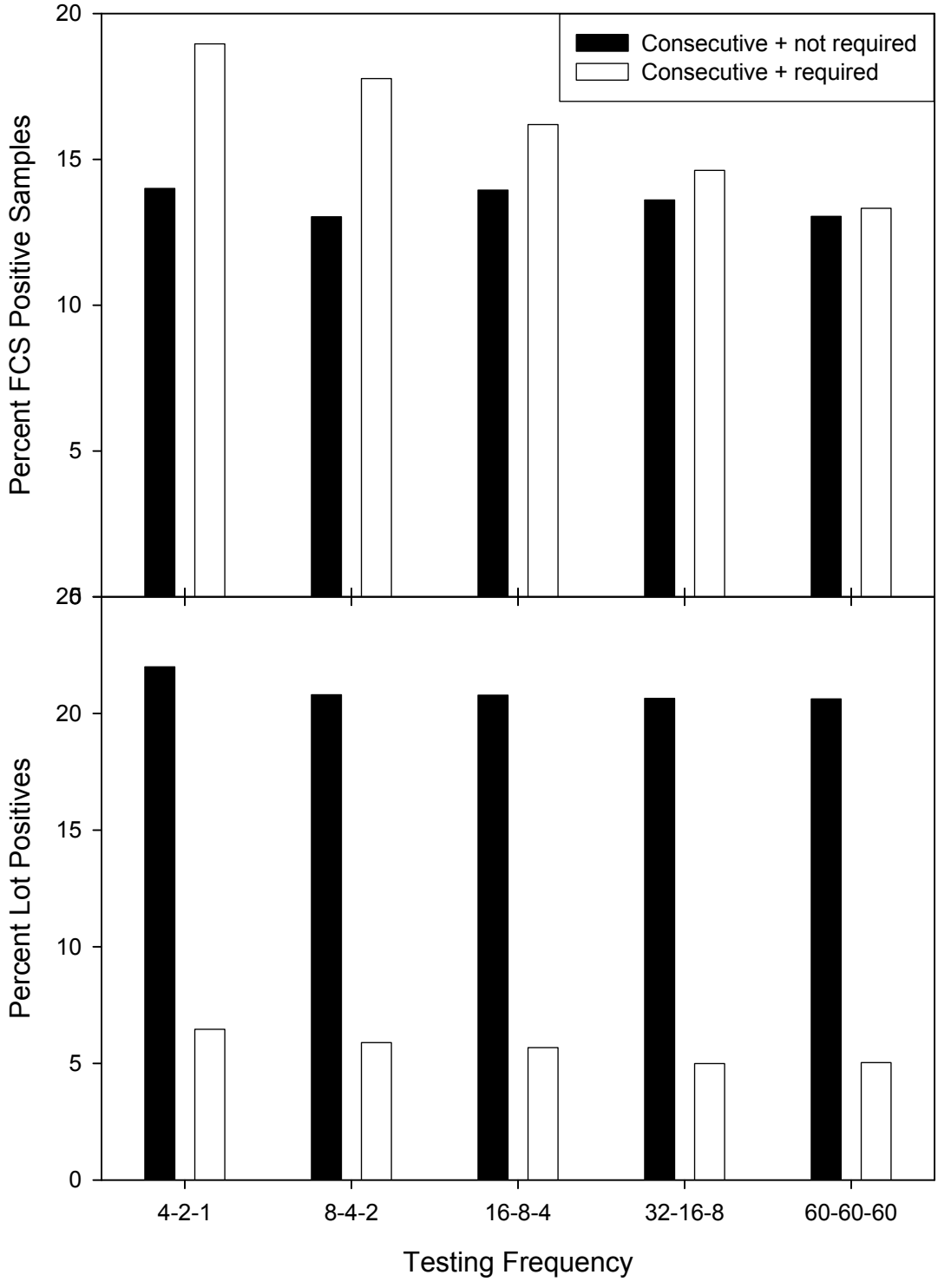


Figure D-4. Comparison of the efficiency of FCS and product lot sampling when consecutive positives are required and not required to trigger a product lot test.