Draft FSIS Risk Assessment for *Listeria* in Ready-to-eat Meat and Poultry Products

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DRAFT 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. 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, 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, and techniques applied, to provide risk assessment outputs in response to specific FSIS 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
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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).[1] 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 deli meats[2] and the dose-response relationship (see Appendix A).

Definition: Ready-to-Eat (RTE)

RTE meat and poultry products are products that have been processed so that they may be safely consumed without further preparation by the consumer (i.e., without cooking or application of some other lethality treatment to destroy pathogens). (66 FR 39:12590).

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 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).[3] Each year, *L. monocytogenes* causes an estimated 2,500 cases of foodborne listeriosis, including approximately 500 fatalities (Mead 1999a, b).

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[1] 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.

[2] 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.

[3] 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).

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[4] 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)).[5] 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*.[6]

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.

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.

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[4] 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.

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

[6] 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 mitigate illness from RTE meat and poultry products. See current RTE sampling directive: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.3.htm.

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.[7] 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).[8,9] 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).[10]

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.

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

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[7] 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.*

[8] 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.

[9] 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.

[10] 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).

efficacy of environmental testing for *Listeria* species.[11] 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.[12]

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 MANAGEMENT QUESTIONS

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

1) How effective are various food contact surface[13] 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)?

* Note: none of the questions relate to non-food contact surfaces.

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[11] 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 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.

[12] 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 either test product contact surfaces for *Listeria* species at prescribed frequencies based on plant size.

[13] 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.

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 RTE product 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 specific components of the updated FDA/FSIS risk ranking model. The outputs of the in-plant model were calibrated to the concentration of *L. monocytogenes* in RTE product at retail in the updated exposure assessment portion of the FDA/FSIS risk ranking model. The FDA/FSIS exposure assessment then tracks the level of *L. monocytogenes* in RTE product (i.e., 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.

By changing in-plant practices such as the frequency of testing and sanitation of food contact surfaces, the effectiveness of pre- and post-packaging interventions[14], the effectiveness of growth inhibitors, effectiveness of enhanced sanitation, etc., including combinations, this risk assessment can provide numerous outputs to address specific risk management questions. This 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.[15]

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.

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

[15] 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. The FDA/FSIS exposure assessment does incorporate some consideration for cross-contamination of RTE products at retail.

The primary output of the in-plant model was the concentration of *L. monocytogenes* in RTE meat and poultry products at retail. This output was then coupled with theFDA/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* 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[16]). The output of the in-plant model is combined with the updated version of the 2001 FDA/FSIS risk ranking model to estimate the risk of illness or death on a per serving and per annum basis from *L. monocytogenes* in RTE product 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 likelihood of detecting *L. monocytogenes* in product if a FCS tests positive for *Listeria* species was also be 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.

2) Only a generic food contact surface is modeled. A lot, for purposes of this analysis consists of production 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 evenly distributed across food contact surface, and *L. monocytogenes* evenly distributed within product. In other words, the variability across a food contact surface or across a lot is not accounted for in this model.

[16] Product reformulation is another process for achieving inhibition of growth and is treated the same as using other growth inhibitors 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. 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 exposure assessment retail to table 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.[17]

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 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,

[17] 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 60 years old or less; 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).

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. The creation of the half $\log_{10}$ increments for each distribution avoided the use of random numbers and greater precision the tails of the summed distribution. 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 were 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 anchored 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, fixed sets of random numbers were used for all portions of the exposure and dose-response simulations. This was accomplished by either using pre-generated sets of random numbers, or by seeding the random numbers with fixed values.

In-plant Dynamic Model

Conceptual Model

An 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, floor drains, air conditioning ducts, etc. The 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 through sanitation at the end of each lot processing, or stay on the surface. 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 on the product lot is calculated, the concentration of *Listeria* species 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.

At this point the lot can undergo post-lethality treatment (i.e., pre- and post-packaging intervention(s)[18]**,** 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 tested is lagged behind by the time it takes to analyze a food contact surface sample for *Listeria* species and obtain results of this test. Product lots of RTE product that test positive for *L. monocytogenes* are removed from the food supply.

After pre- and post-packaging interventions and possible additional RTE product testing, the lot proceeds to retail. 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. 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).

[18] 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. monocytogenese*, in RTE products.

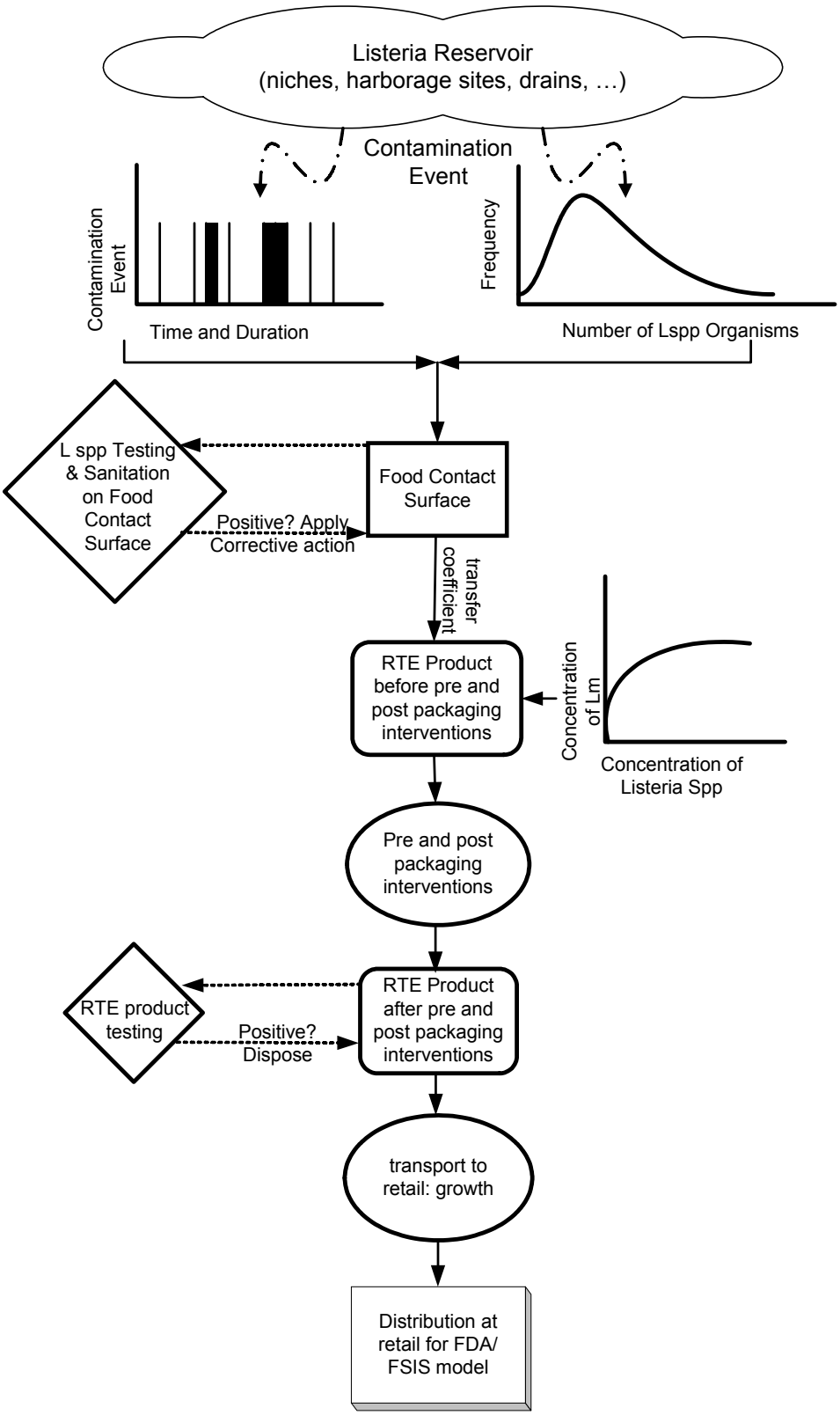


Figure 1. Conceptual Model for the "In-plant" Component of the FSIS *Listeria* Risk Assessment.

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 is provided below (Table 1).

Table 1. Available data and potential assumptions for the "plant to table" *L. monocytogenes* risk assessment.

Model Step	Data Required	Available Data	Assumptions
Occurrence of a "contamination event"[19]	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 detection 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.	

[19] A "contamination event" is defined as the *Listeria* spp. from workers hands, through environmental disruption, etc.)

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 (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	

Each step of the FSIS *Listeria* risk assessment model is described in more detail below.

Contamination of Food Contact Surfaces

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 2, and summarized in Table 3. The data were analyzed using survival analysis and distribution fitting using NCSS statistical software.** Several distributions were compared, and the $\log_{10}$ normal distribution had the greatest likelihood. On a $\log_{10}$ scale, the mean time between contamination events was 1.07 with a standard deviation of 0.456. This is approximately 23 days ± 38 days (truncated at zero). 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 tend to exhibit the duration seen in other data. 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 2. FSIS in-depth verification time series data for estimating time between contamination events (Hynes 2000).

Day	Sequential Number Positive	Line	Days Between Positives	Censor[1] 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	13	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

[1] 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 3. 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 4. Maximum Likelihood Fits to Mean Time Between Contamination Events for Various Distributions

Distribution	Likelihood	Shape	Scale	Threshold
Lognormal10	-50.57246	1.076803	0.4563359	0.0
Lognormal	-50.57246	2.479432	1.050752	0.0
Loglogistic	-50.84553	2.479641	0.6122292	0.0
Weibull	-51.51661	1.042931	19.51887	0.0
Exponential	-51.53823	1	19.38461	0.0
Logistic	-57.20407	14.44572	8.208793	0.0
Normal	-59.09212	18.84816	19.00071	0.0
Extreme Value	-63.8031	32.03982	25.80604	0.0

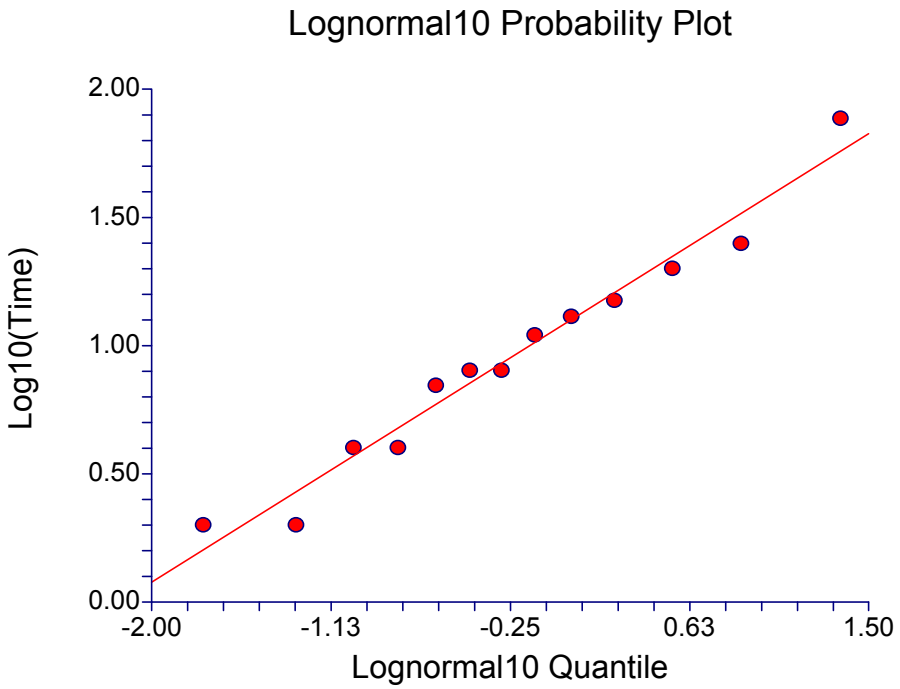


Figure 2. Fit of mean time between contamination events to log normal distribution.

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. These data were analyzed using survival analysis and distribution fitting with NCSS (Hintz 2001). Table 5 shows the data and Table 6 summarizes it. Table 7 provides the maximum likelihoods estimates for a variety of parameters. The $\log_{10}$ normal distribution had the second greatest likelihood (behind the log logistic) and 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 8.8 days ± 2.1 days. Figure 3 illustrates the fit

Table 5. 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 6. 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 7. 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

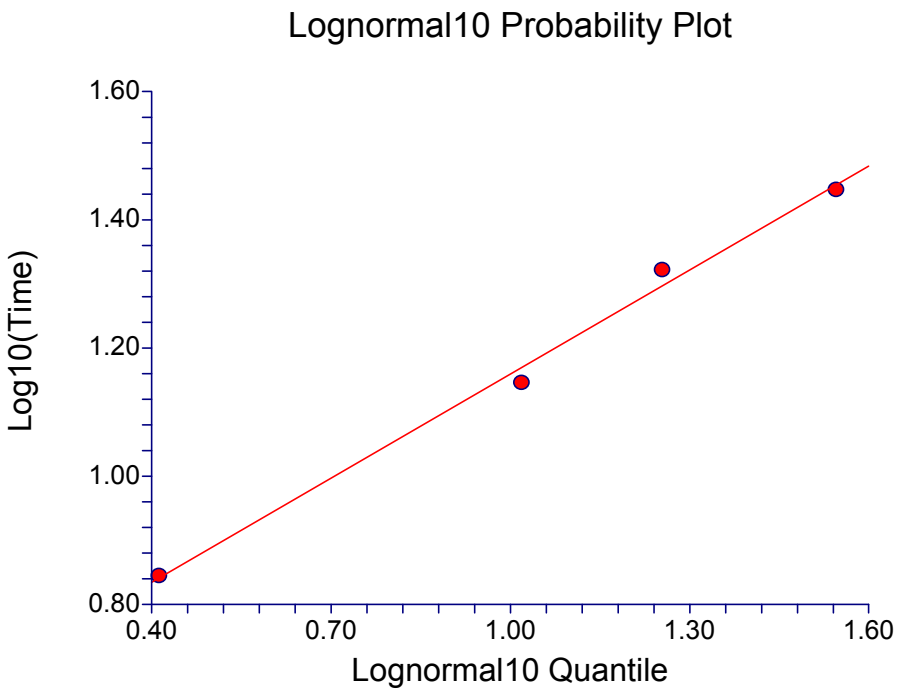


Figure 3. Log normal distribution fit for duration of contamination event.

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

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 log transfer coefficient used was thus -0.14. Transfer coefficients were 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.

4) 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 8 summarizes these values.

Table 8. 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

The ratios for *Listeria* species to *L. monocytogenes* were tested and found not to be significantly different from a normal 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. This assumption was judged to be the best approach available given current data.

5) 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.

The prevalence levels measured at the plant by FSIS varies by deli-meat product (Levine et al. 2001). The authors report a 1999 prevalence of *L. monocytogenes* in cooked, roast and corned beef of 2.71%, and in sliced ham and other pork luncheon meats of 4.58%. The National Food Processors Association (NFPA) survey of RTE products at retail found an *L. monocytogenes* prevalence of 0.9%. Although these *L. monocytogenese* levels and prevalences 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.

6) Line production

FSIS conducted 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 9.

Table 9. 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.

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 4 is used to store information about the specific model run. None of the data are used within the simulation itself.

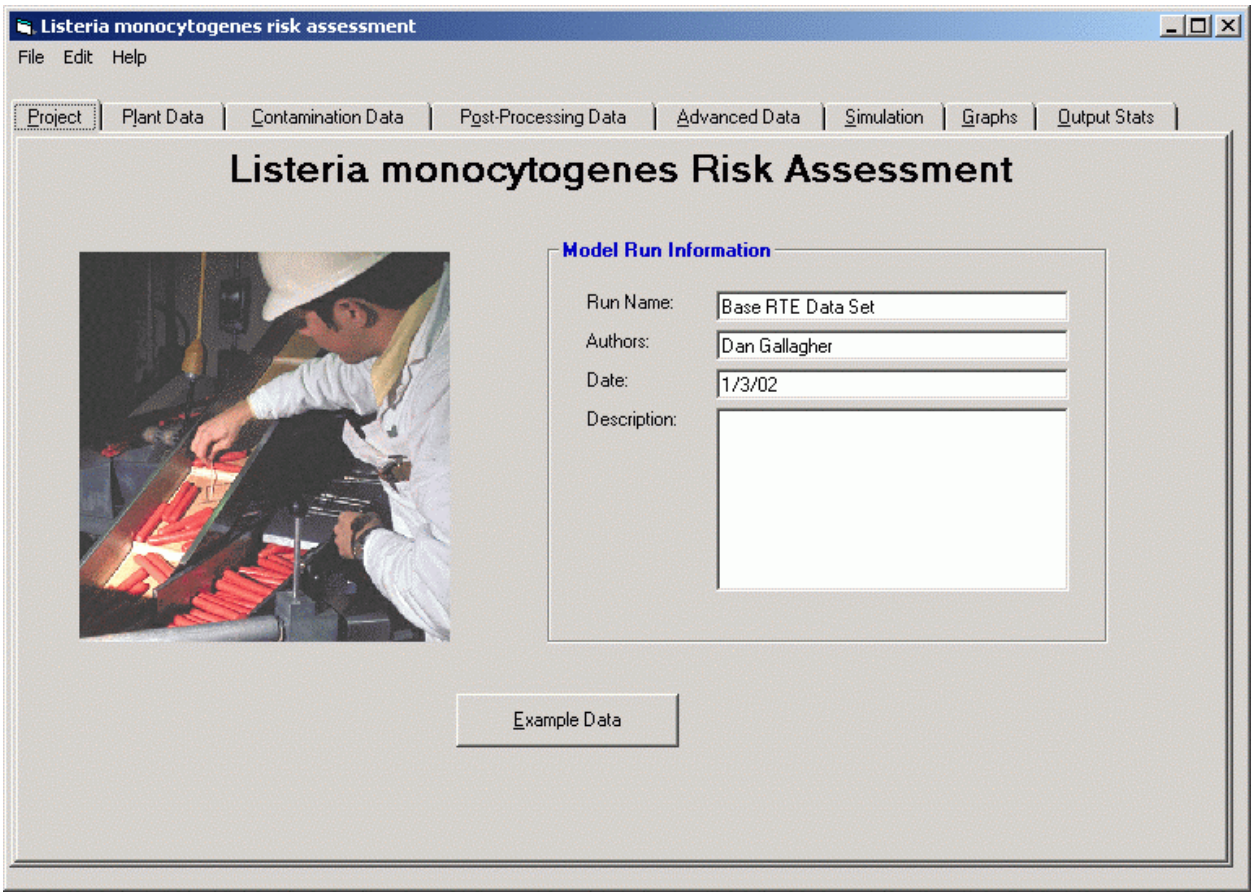


Figure 4. Project Data Entry Screen.

The Plant Data screen shown in Figure 5 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.

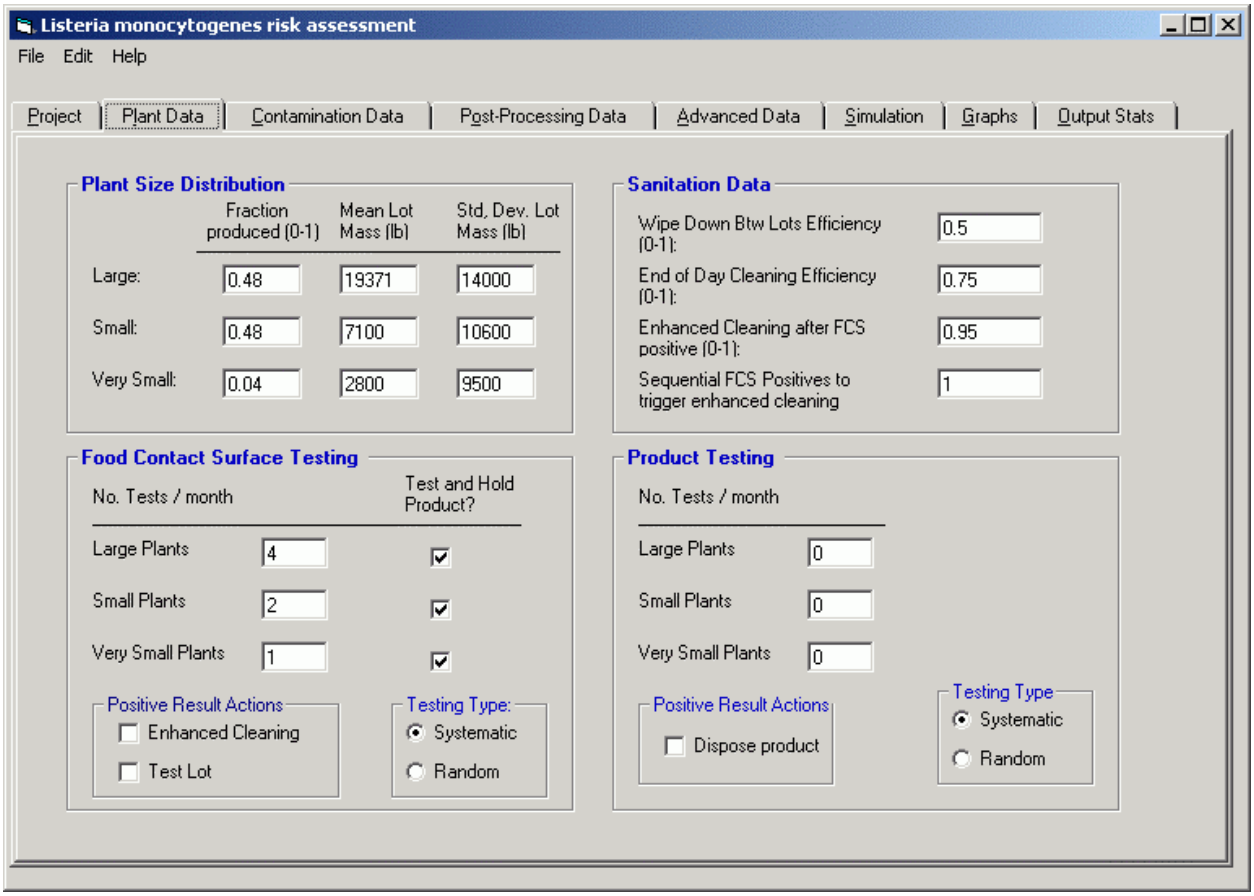


Figure 5. Plant Data Entry Screen

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.

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, and 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 6, 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.

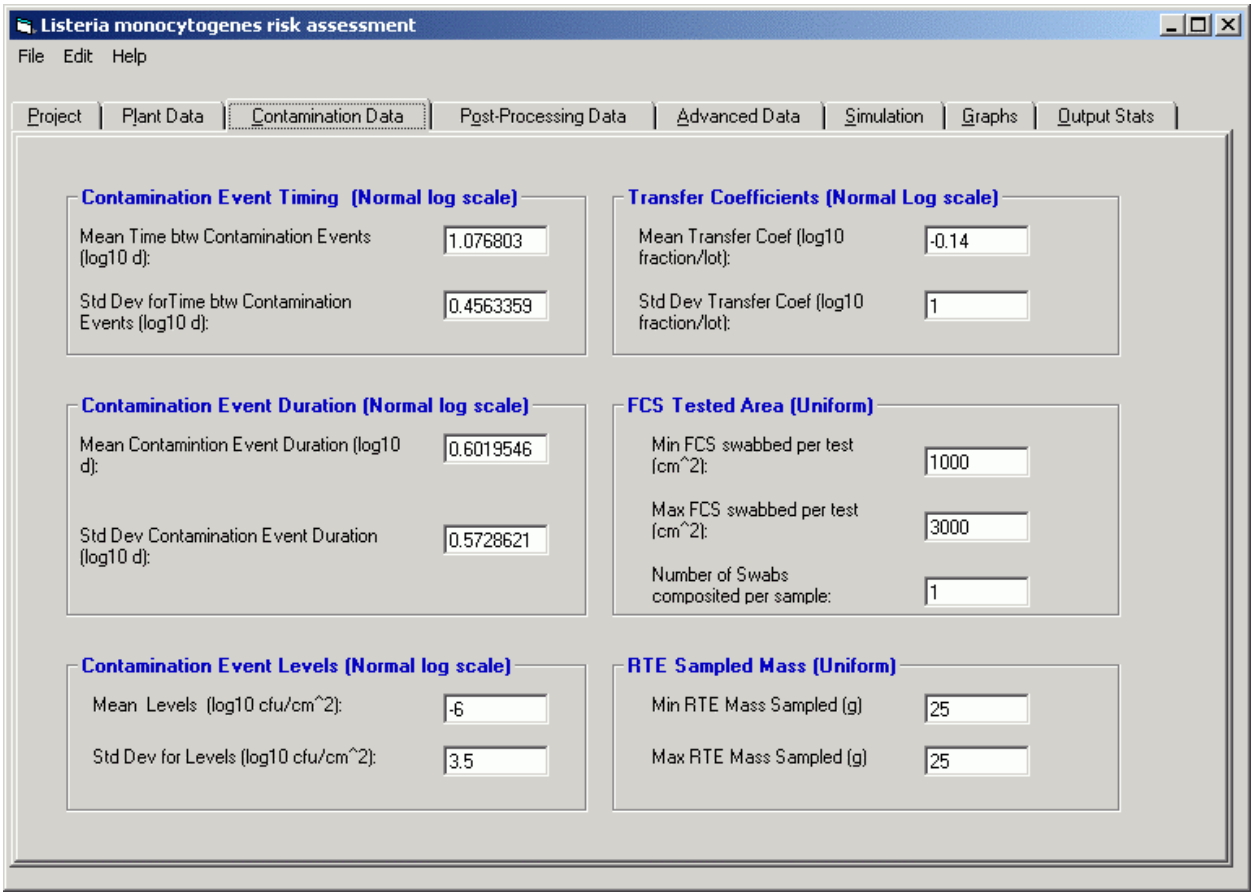


Figure 6. Contamination Data Entry Screen

The Post-Processing Data screen shown in Figure 7 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. These 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).

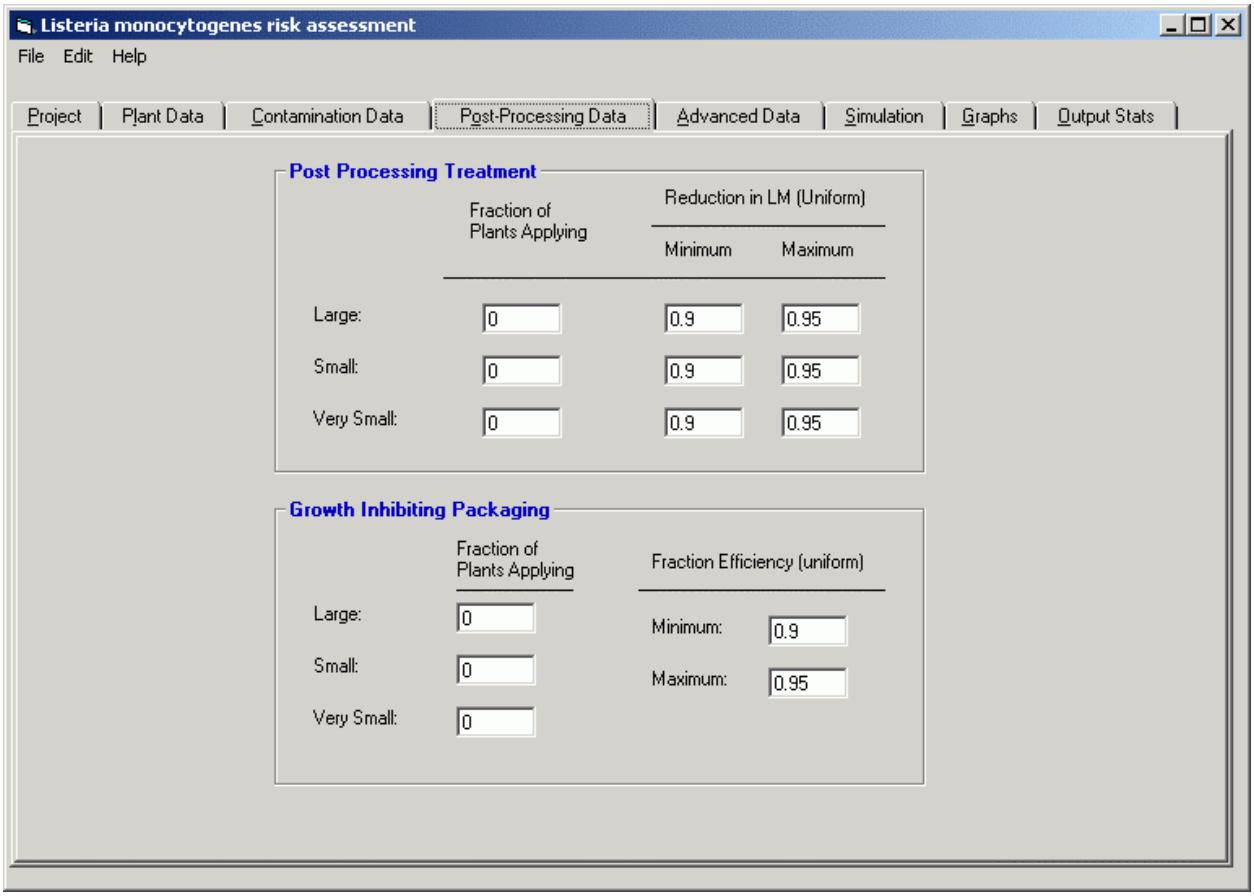


Figure 7. Post Processing Data Entry Screen

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 an 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 8 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%.

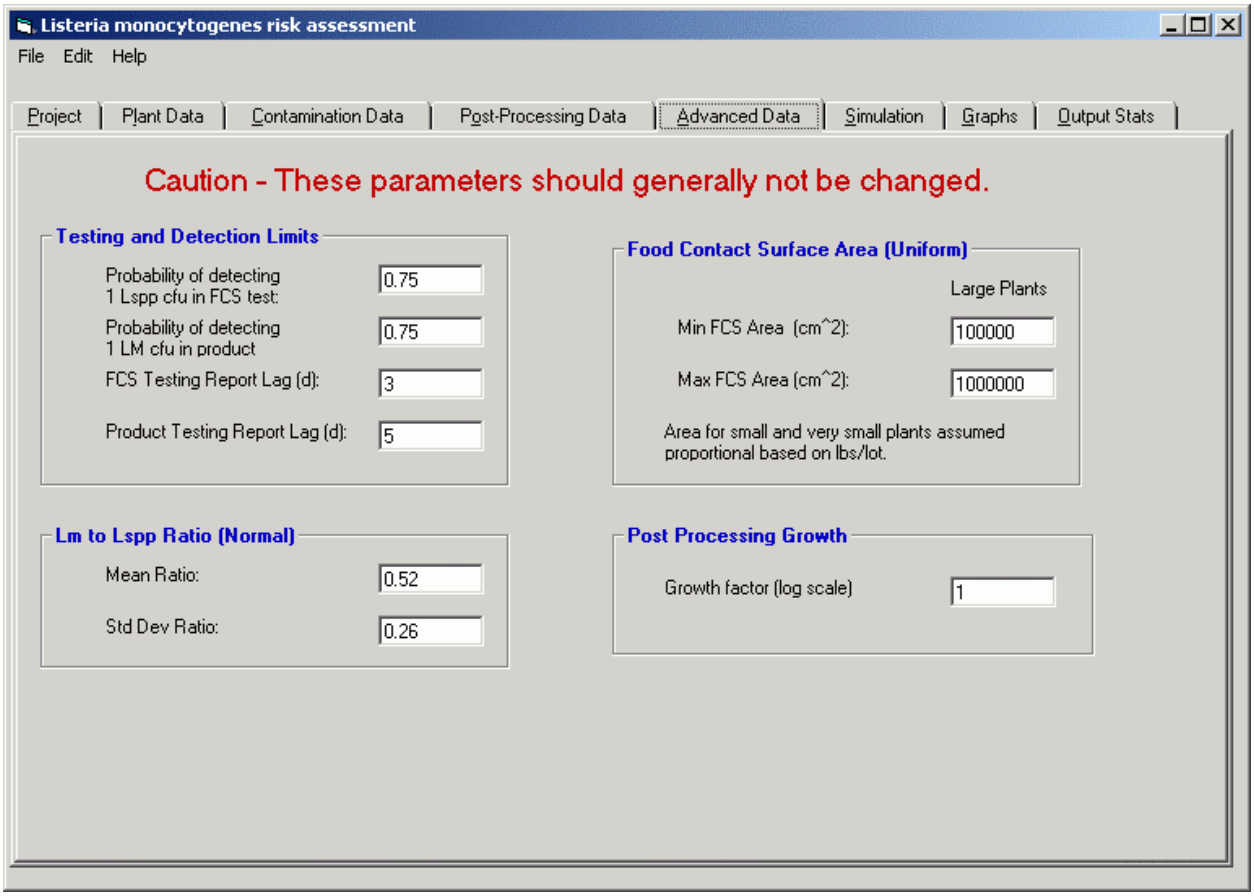


Figure 8. Advanced Data Entry Screen

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 9 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.

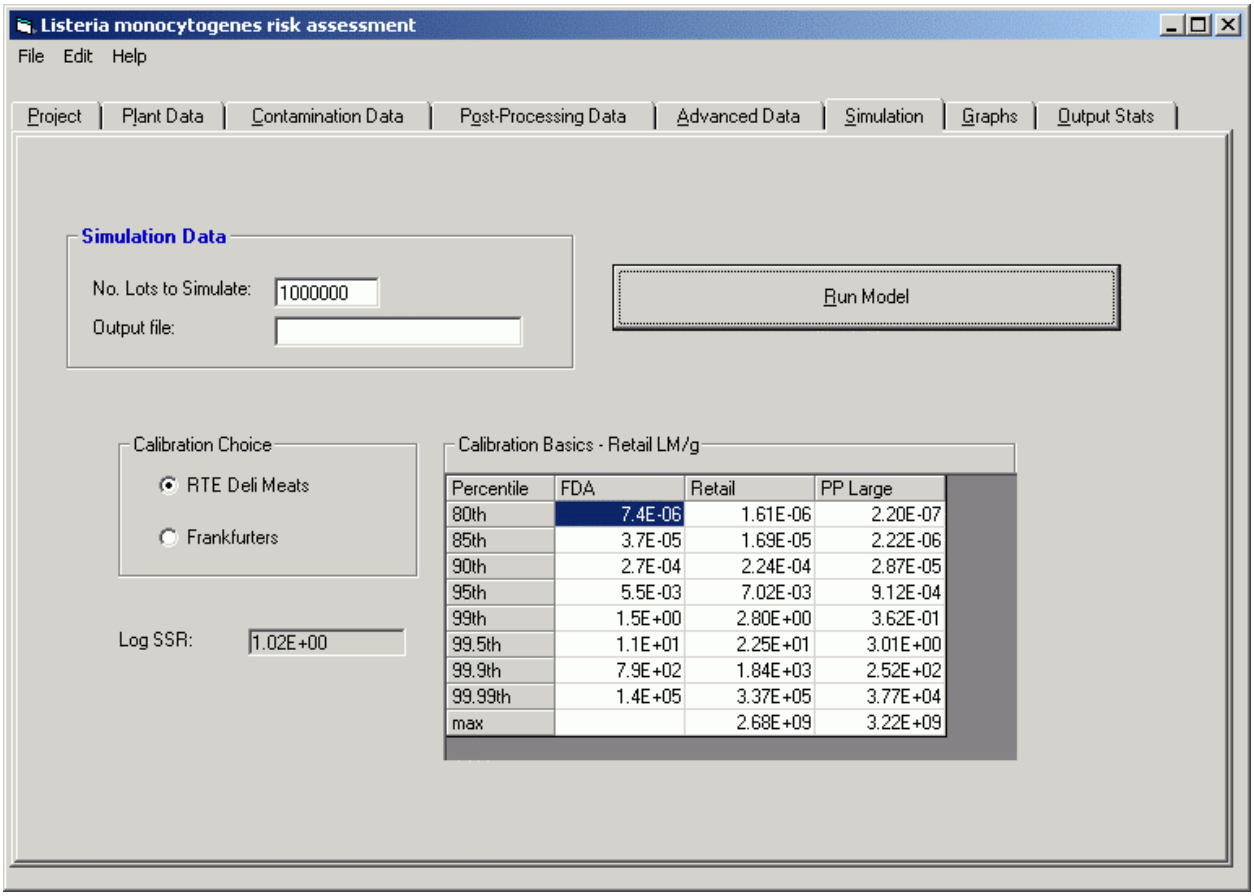


Figure 9. Simulation Screen

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 10 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.

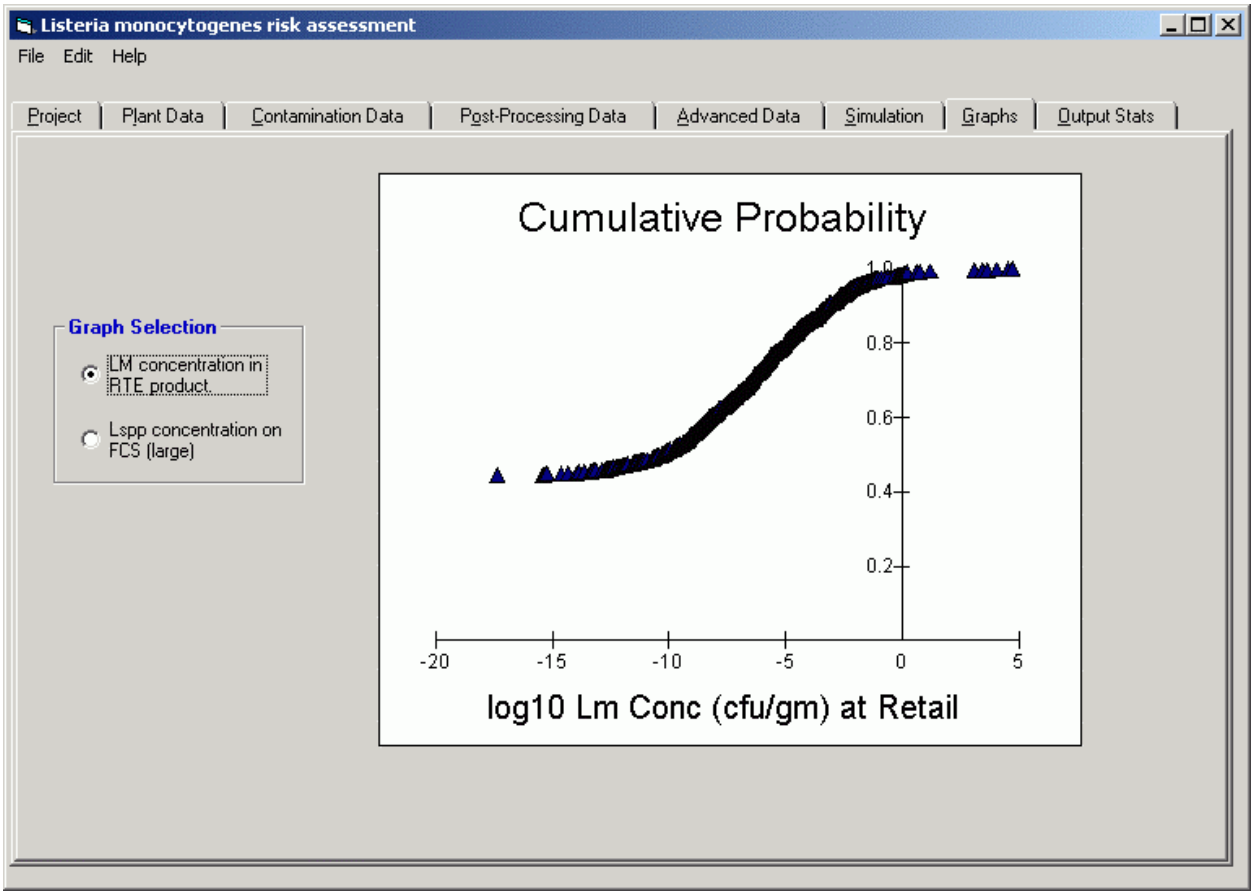
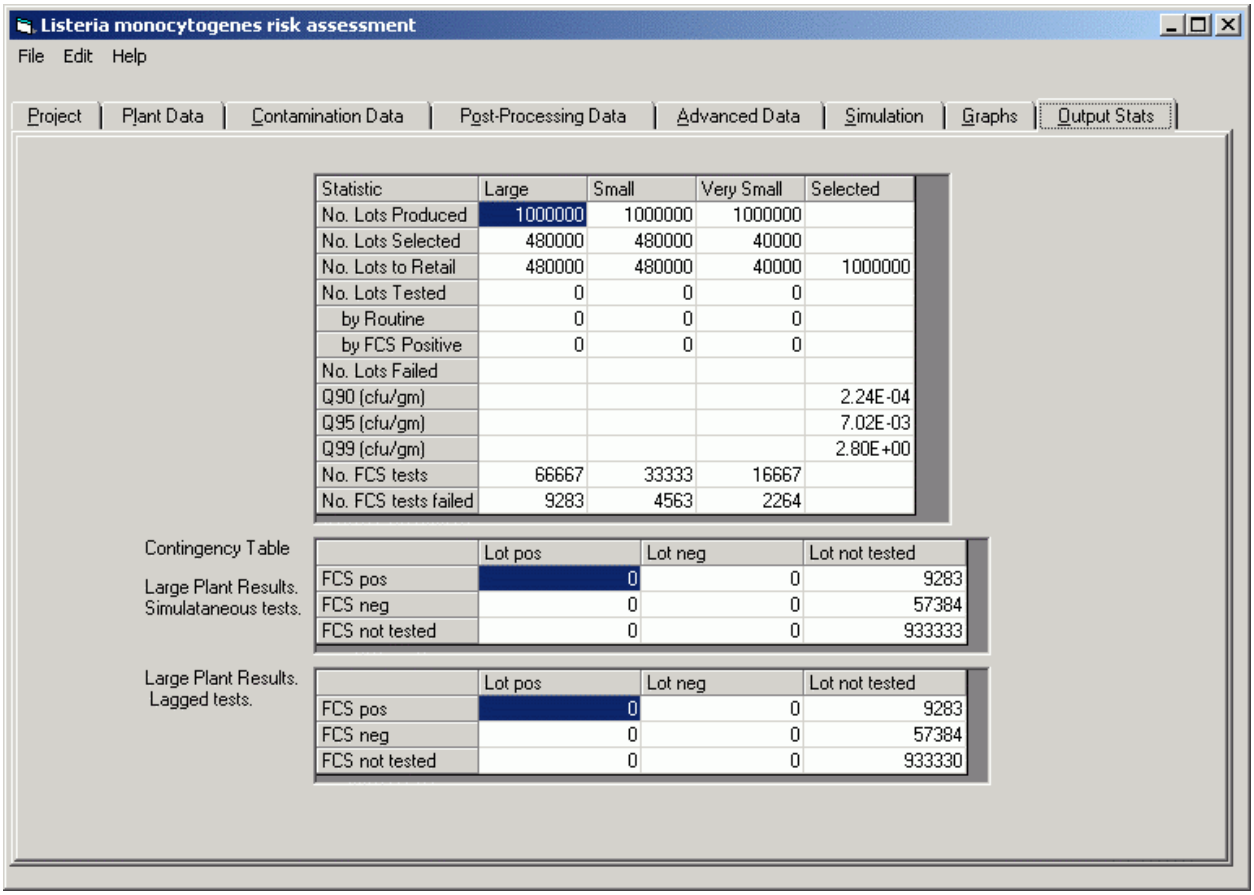


Figure 10. Graph Output Screen

The Output Stats screen shown in Figure 11 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 11 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 11. 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 12 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.

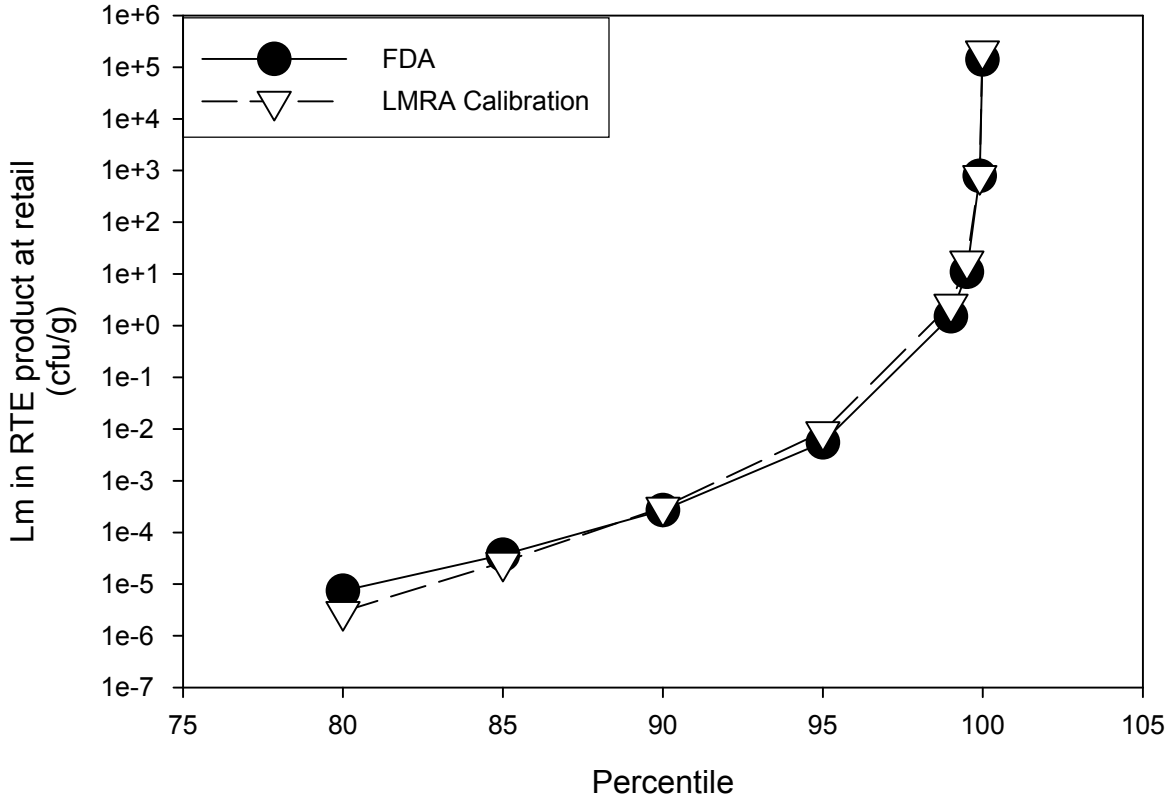


Figure 12. Final FSIS *Listeria* Risk Assessment In-plant Model Calibration to the Updated FDA/FSIS Exposure Assessment Concentrations of *L. monocytogenes* in Deli Meats at Retail. The mean and standard deviation of the log number of *Listeria* species transferred to the food contact surface at the 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 13 below. As expected, the 99.99th quantile exhibited more variability than the lower quantiles. Overall however, the variability appears small among replicate simulations.

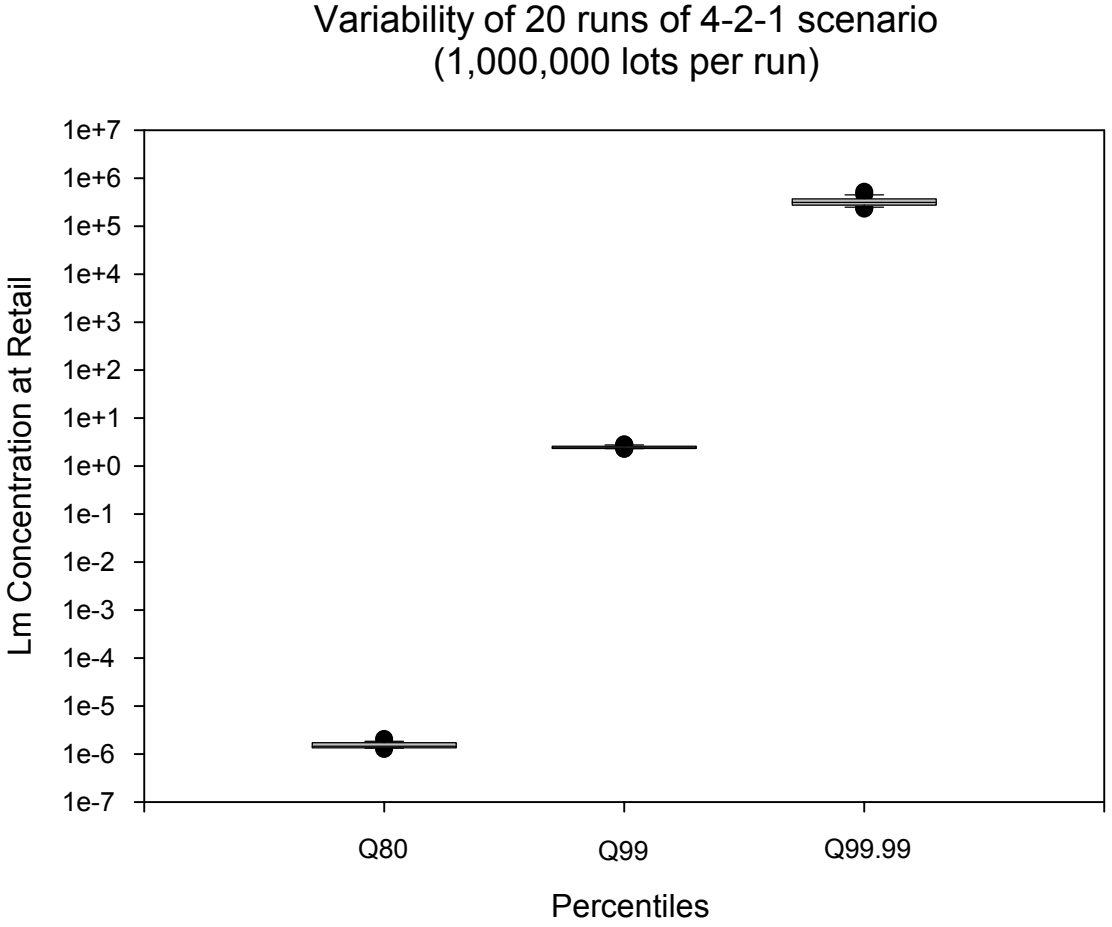


Figure 13. Stability of the FSIS *Listeria* risk assessment model simulated quantiles based on 20 runs of the 4-2-1 scenario.

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* (*L. monocytogenes*) concentrations at retail (outputs of the FSIS Risk Assessment in-plant model).'**

Figure 15 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 per shift 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.

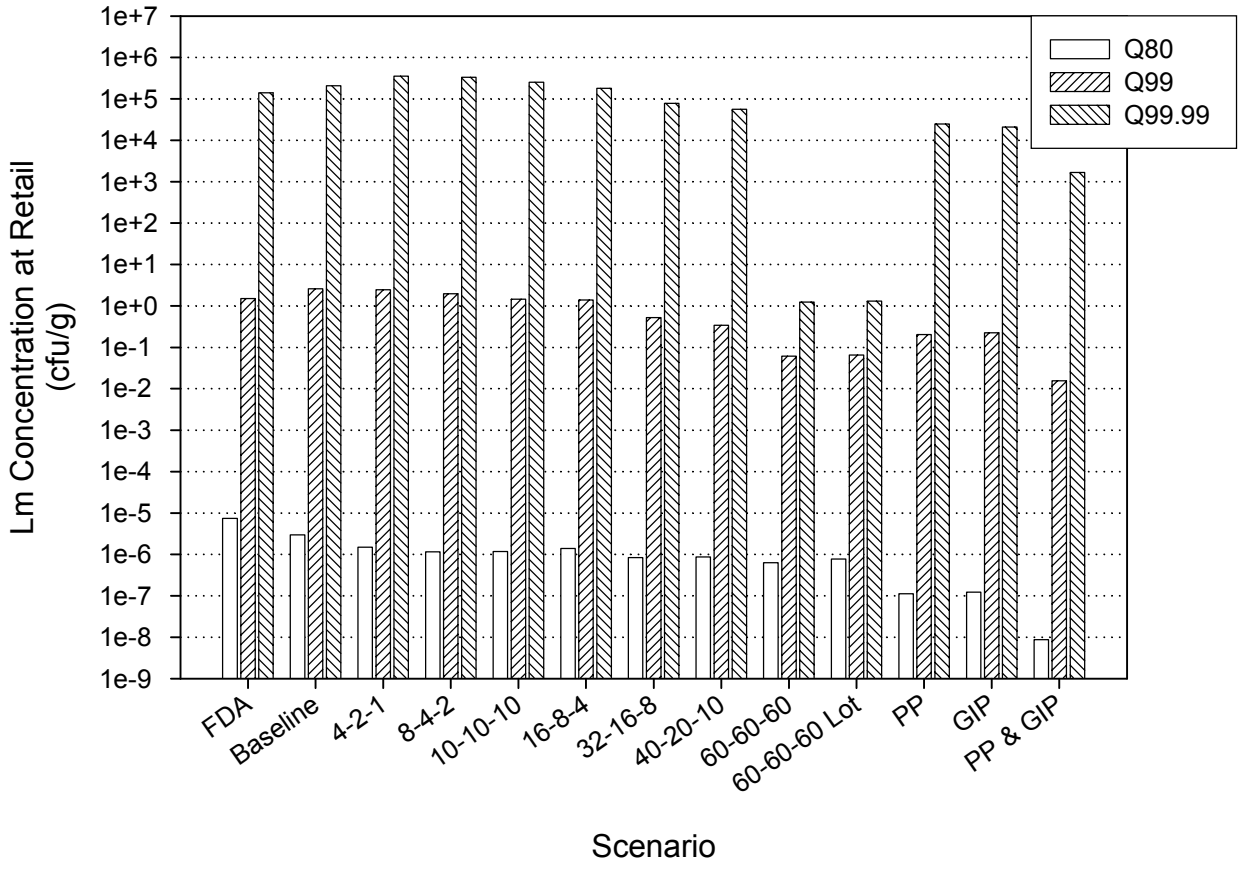


Figure 15. Quantiles of *L. monocytogenes* at Retail for Various Scenarios Tested.

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 16 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 number of deaths among the elderly drops only slightly (reduces the number of deaths among the elderly by about 20 per year).

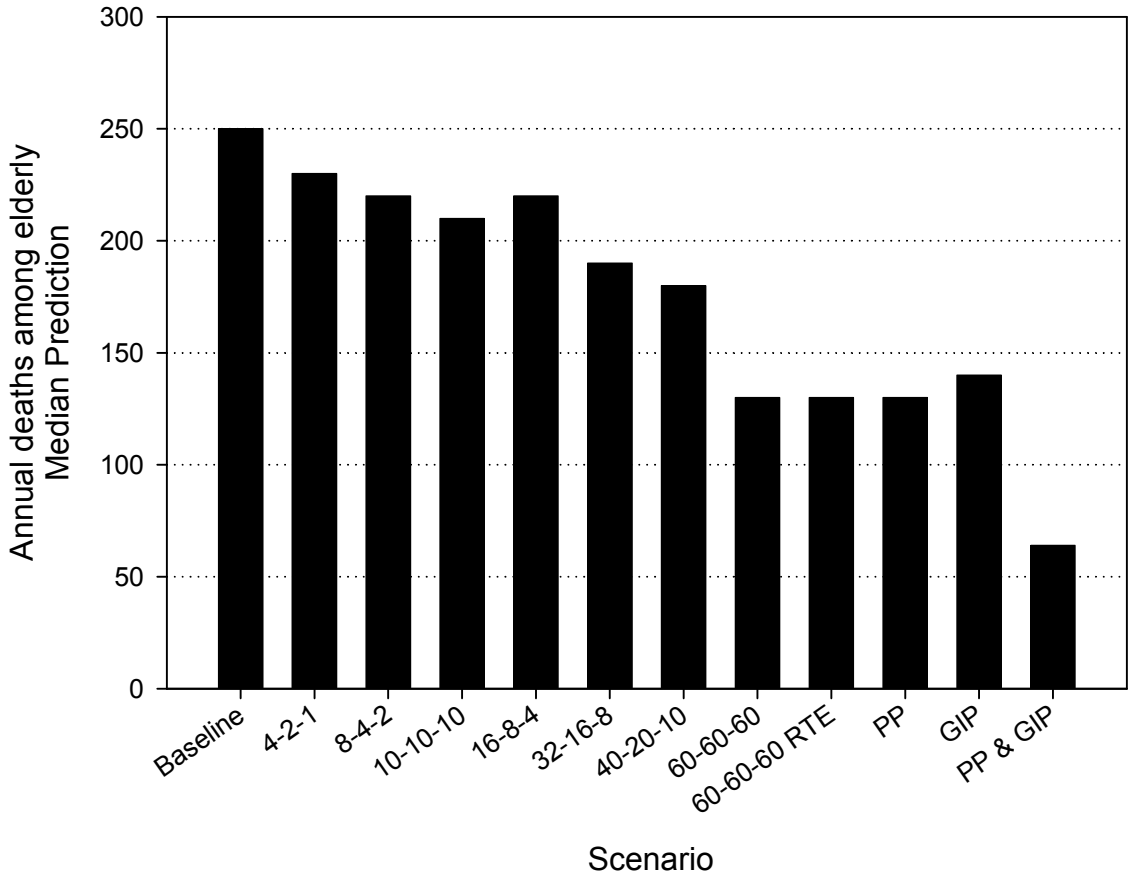


Figure 16. Estimated number of deaths among the elderly for the various scenarios tested.

Tables 10-13 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.

The updated FDA/FSIS exposure assessment results for the concentration of *L. monocytogenes* in deli meat at retail are shown in Tables 10-13. The FDA/FSIS results include additional 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 10. 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+00	1.47E+00	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+00	2.09E+00	1.67E+03

Table 11. Estimated 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 12. Estimated 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 13. Estimated 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	N/A	1.7
50%	13	14	13	N/A	N/A	N/A	10	7	7.3	N/A	N/A	3.5
95%	16	15	14	N/A	N/A	N/A	11	8	8.3	N/A	N/A	4
Average	12	13	12	N/A	N/A	N/A	9.3	6.6	6.8	N/A	N/A	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 14 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 14. 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. The particular scenario has not yet been run.

Lot and Food Contact Surface Prevalence: Likelihood of Detection

Table 15 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 15. 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 16 below provides data for evaluating the effectiveness of test and hold at various testing frequency. Figure 17 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 16. 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

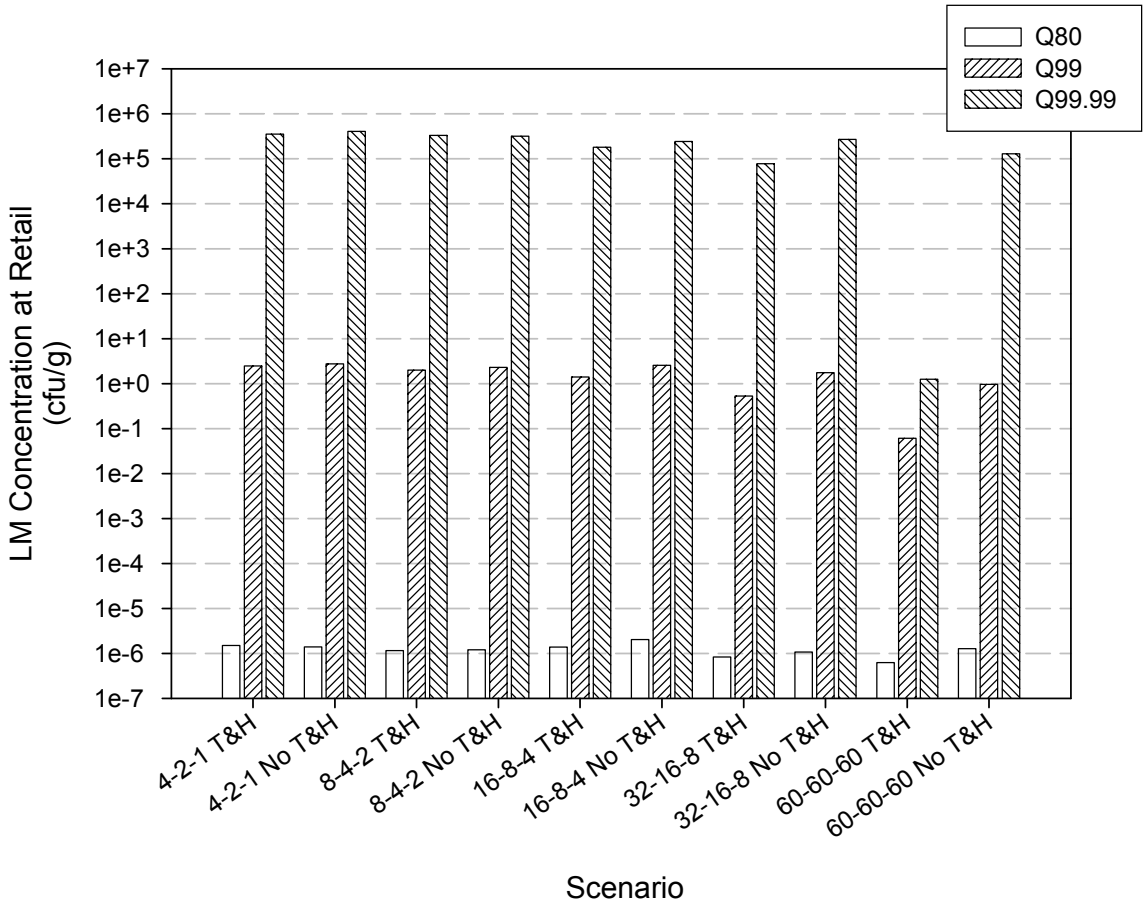


Figure 17. Comparison of Test and Hold Effectiveness for Difference Testing Frequencies.

This changing impact can be best illustrated in Table 17, 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 17: Example comparison of % food contact surface positives and lot positives under different test and hold scenarios

FCS Test and Sample Frequency	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 422/1000000 lots (0.04%) 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 18 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.

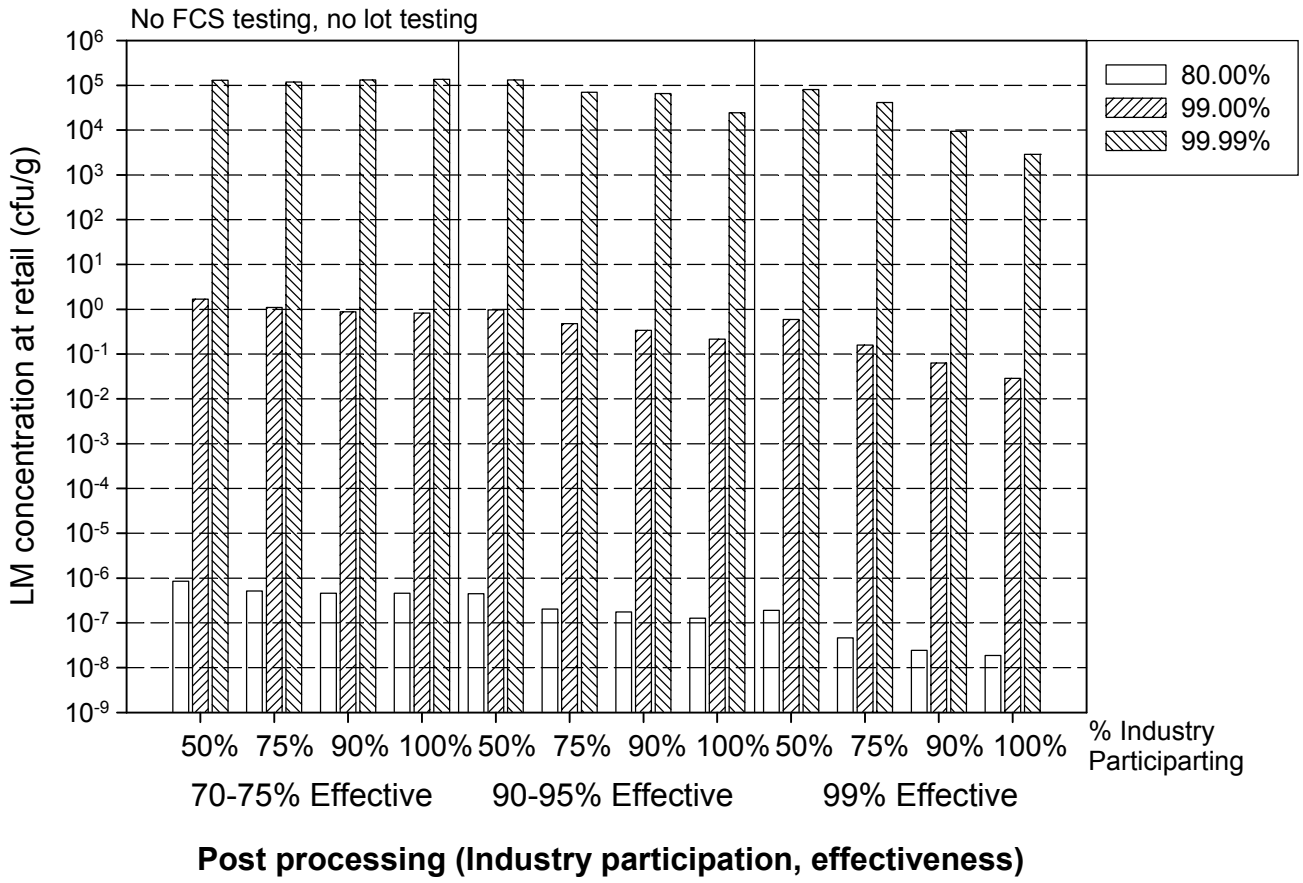


Figure 18. Sensitivity to Pre and Post Packaging Interventions**.**

Figure 19 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.

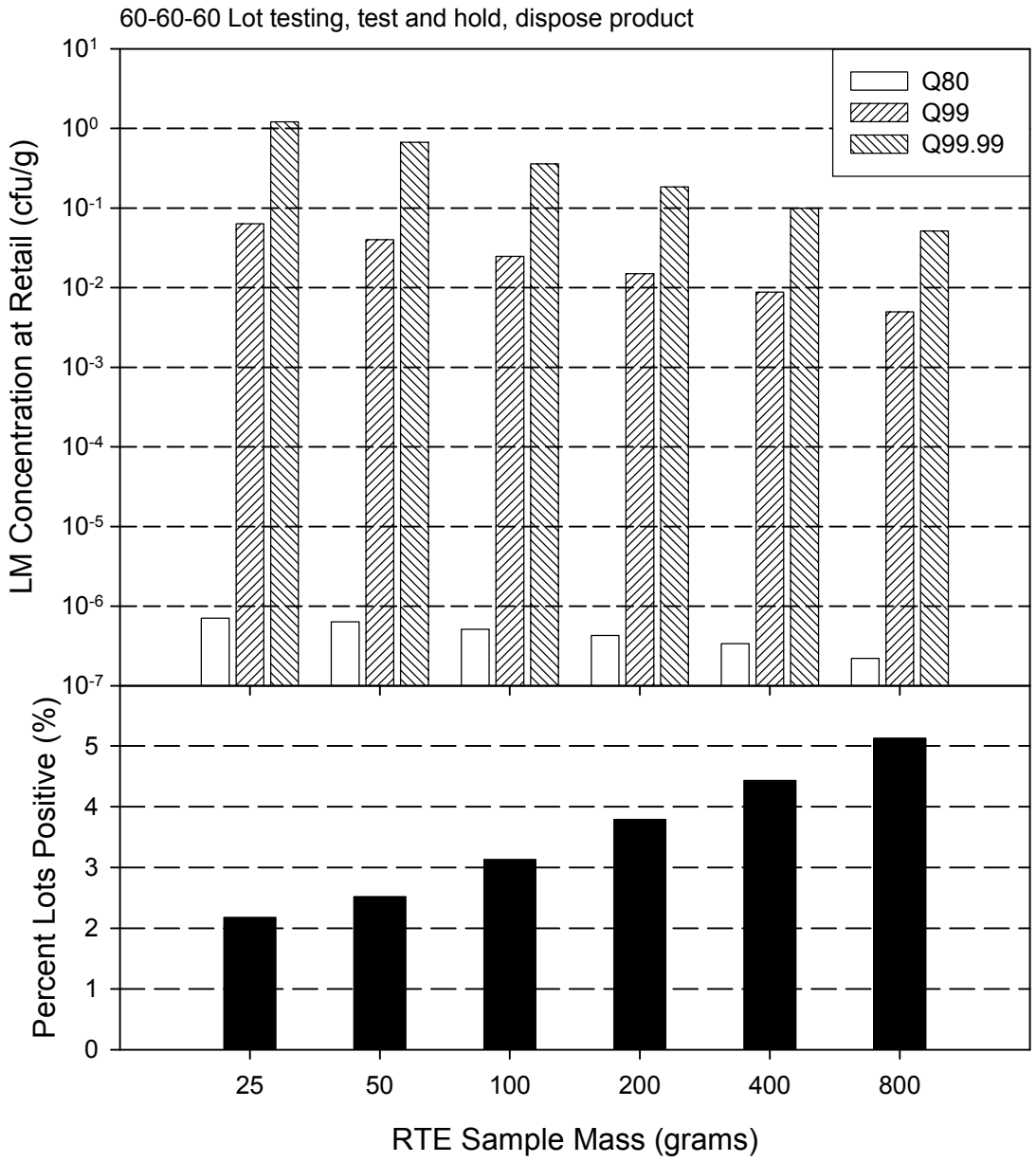


Figure 19. Sensitivity to RTE mass sampled.

Figure 21 and 22 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 cm2 are sampled. Larger areas do not provide additional benefits. This is confirmed in Figure 21. The total number of positive lots found reaches its maximum when about 100 cm2 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.

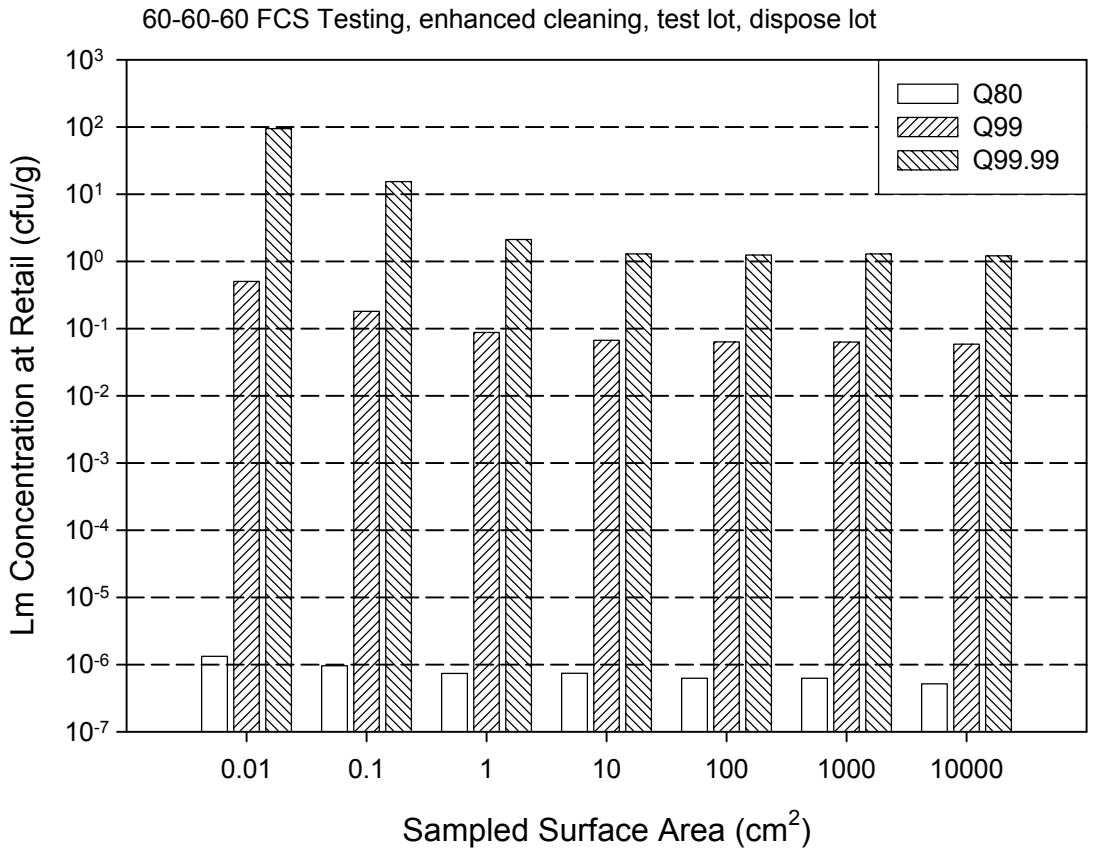


Figure 20. Retail *L. monocytogenes* concentrations in deli meats for different food contact surface area tested.

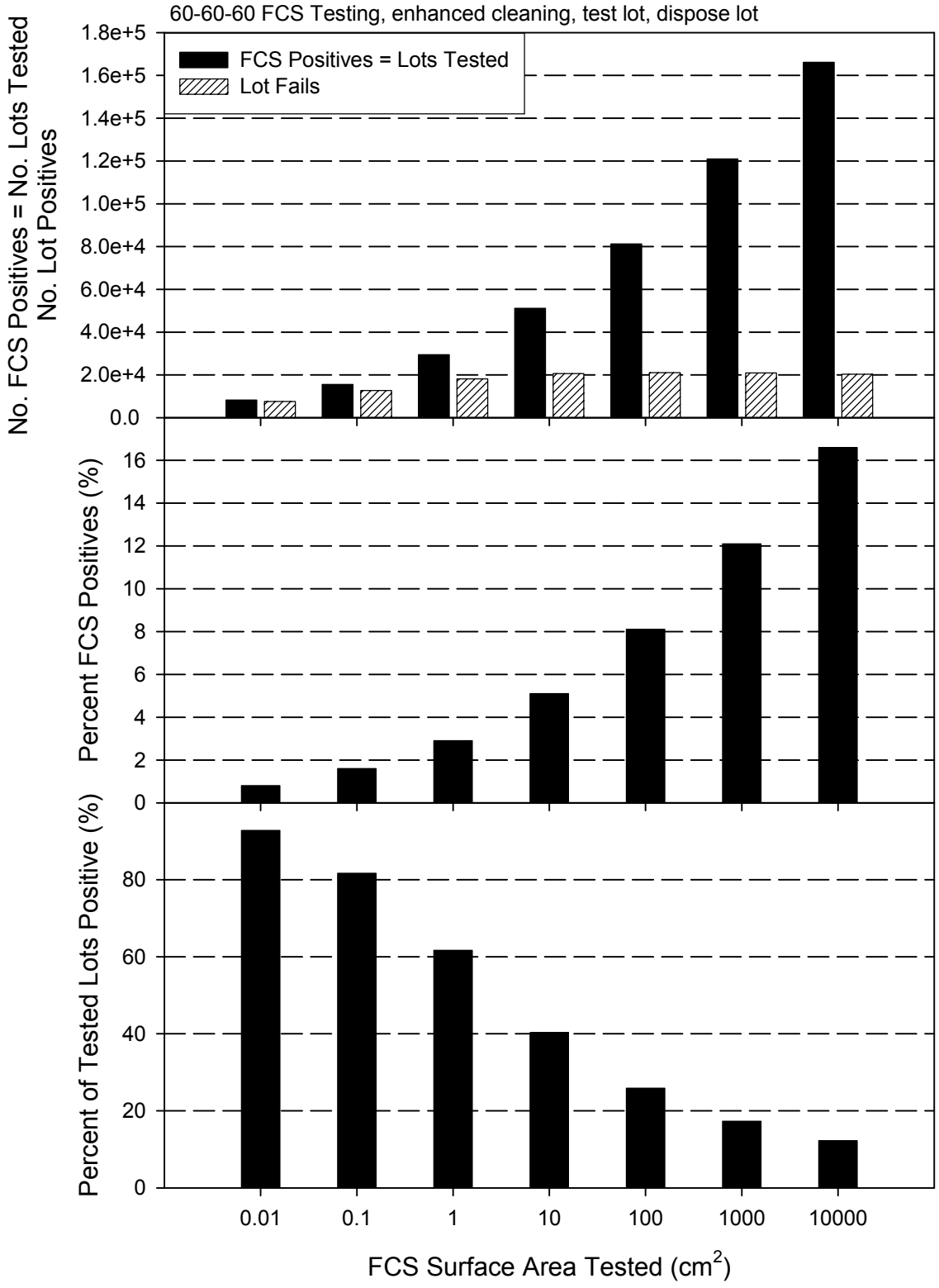


Figure 21. Sensitivity of positive RTE product lots and food contact surface area found to be positive based on the area of food contact surface tested.

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 18.

Table 18. 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.

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), results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail
- Increased frequency of food contact surface testing and sanitation leads 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.

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[1] 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 relationhip. 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

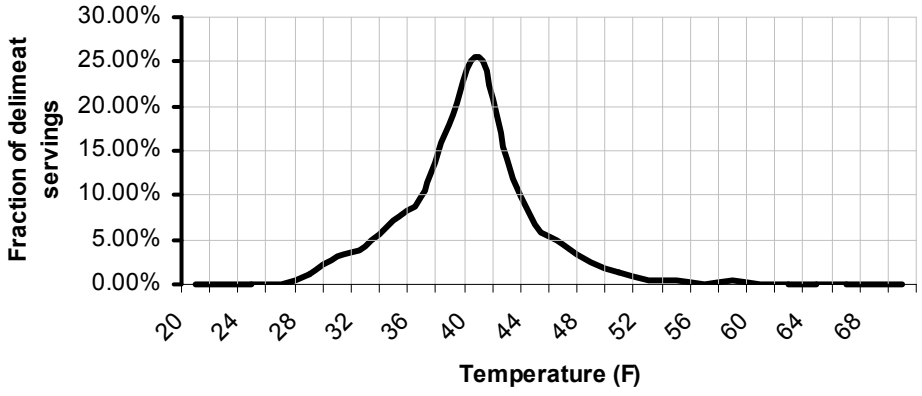
- Split frankfurters into two categories: not reheated and reheated.

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).

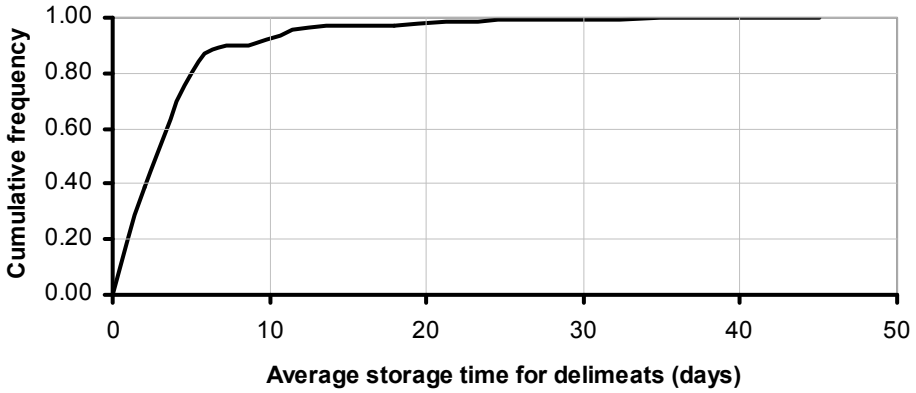
Growth Data Changes

- 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.

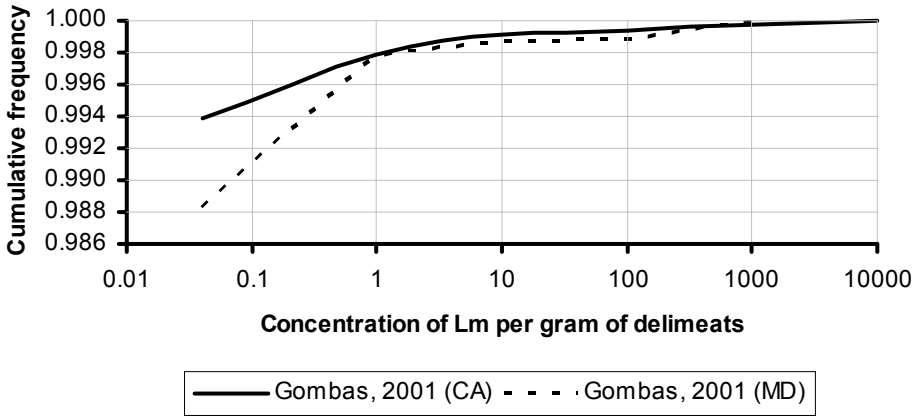
Changes to Modeling L. monocytogenes Levels in Food at Retail

- 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 import 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. 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.

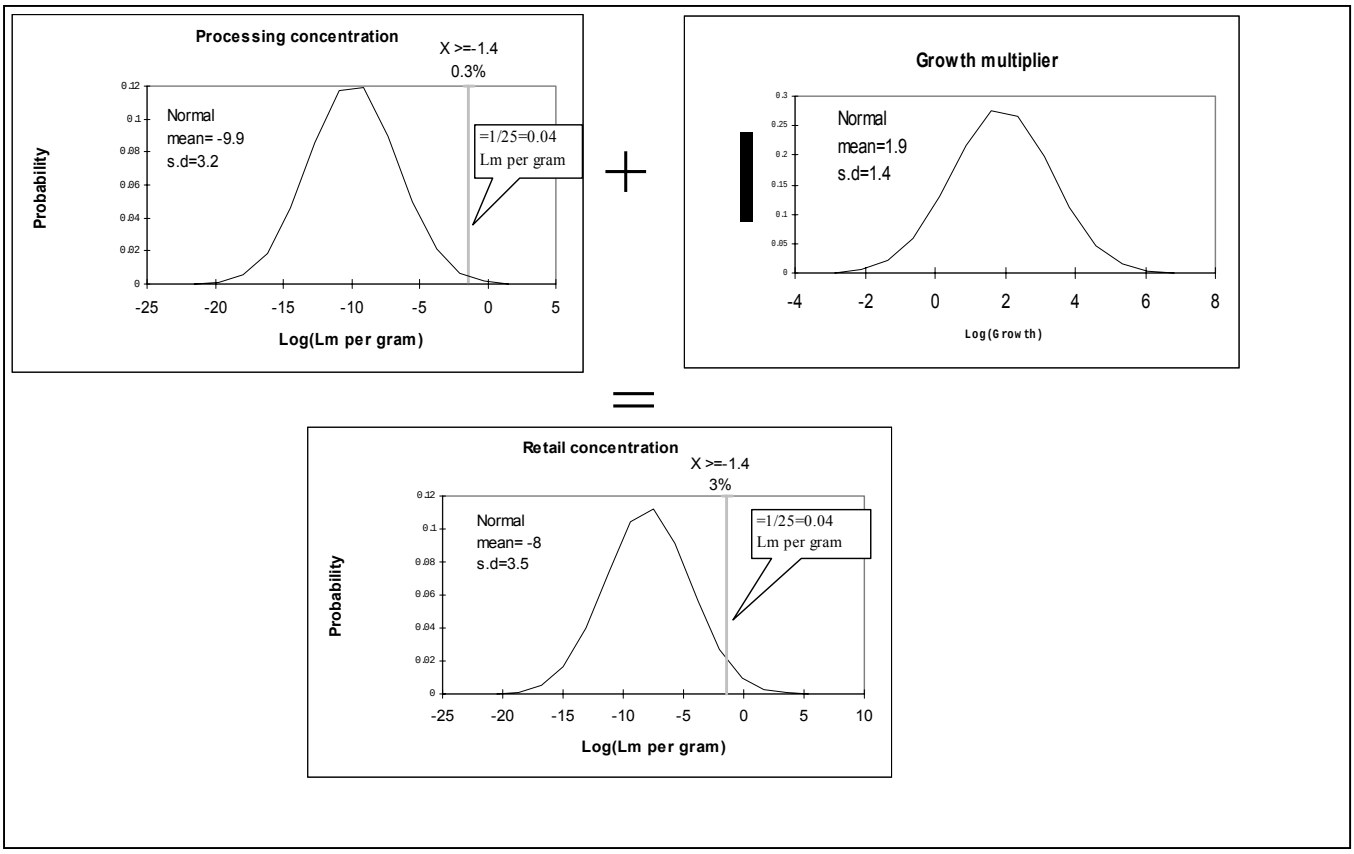

Processing concentration
X >=-1.4
0.3%
Normal
mean= -9.9
s.d=3.2
=1/25=0.04
Lm per gram
Probability
Log(Lm per gram)
Growth multiplier
Normal
mean=1.9
s.d=1.4
Log(Growth)
Retail concentration
X >=-1.4
3%
Normal
mean= -8
s.d=3.5
=1/25=0.04
Lm per gram
Probability
Log(Lm per gram)

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.

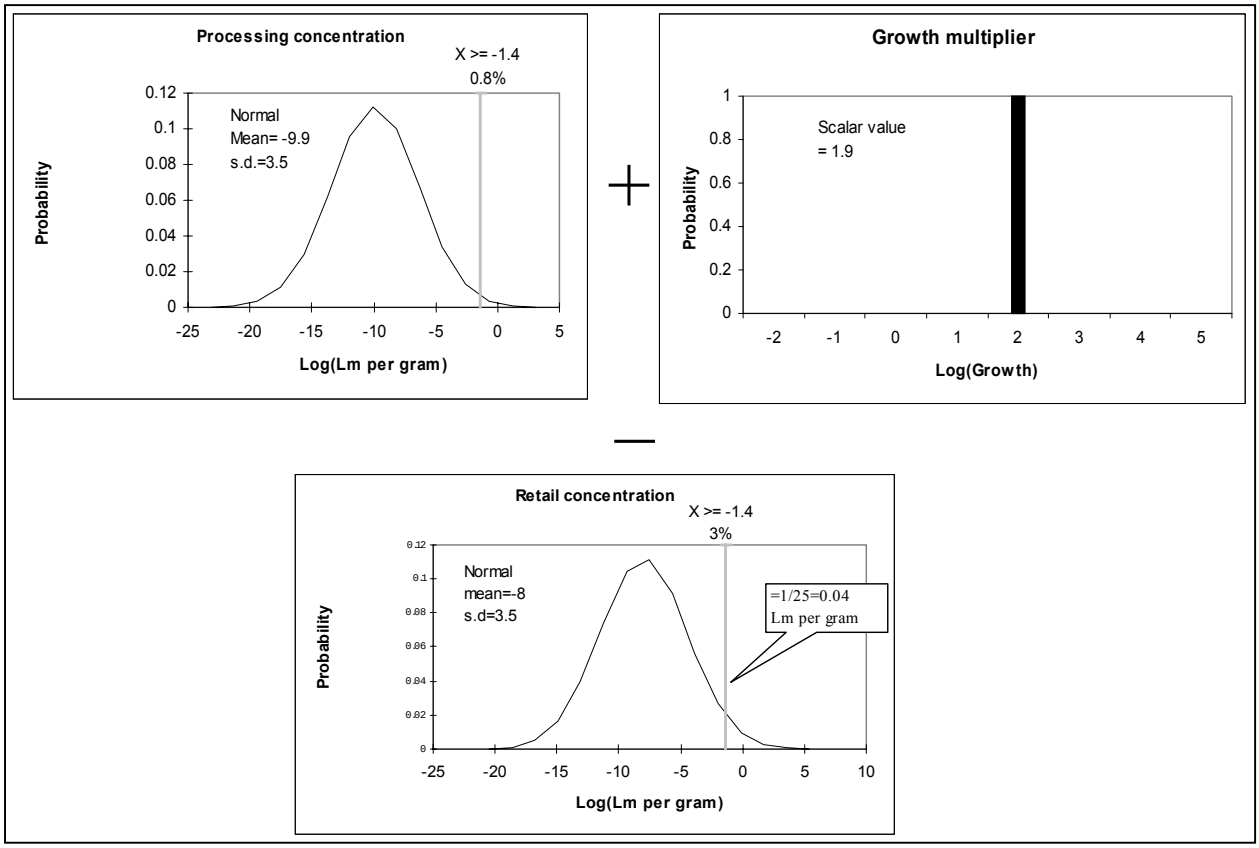


Figure A-2. Case 2 example where growth multiplier is a constant value of 1.9 logs. This is the assumption made when accounting for growth in the FDA/FSIS exposure assessment model for deli meats.

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.

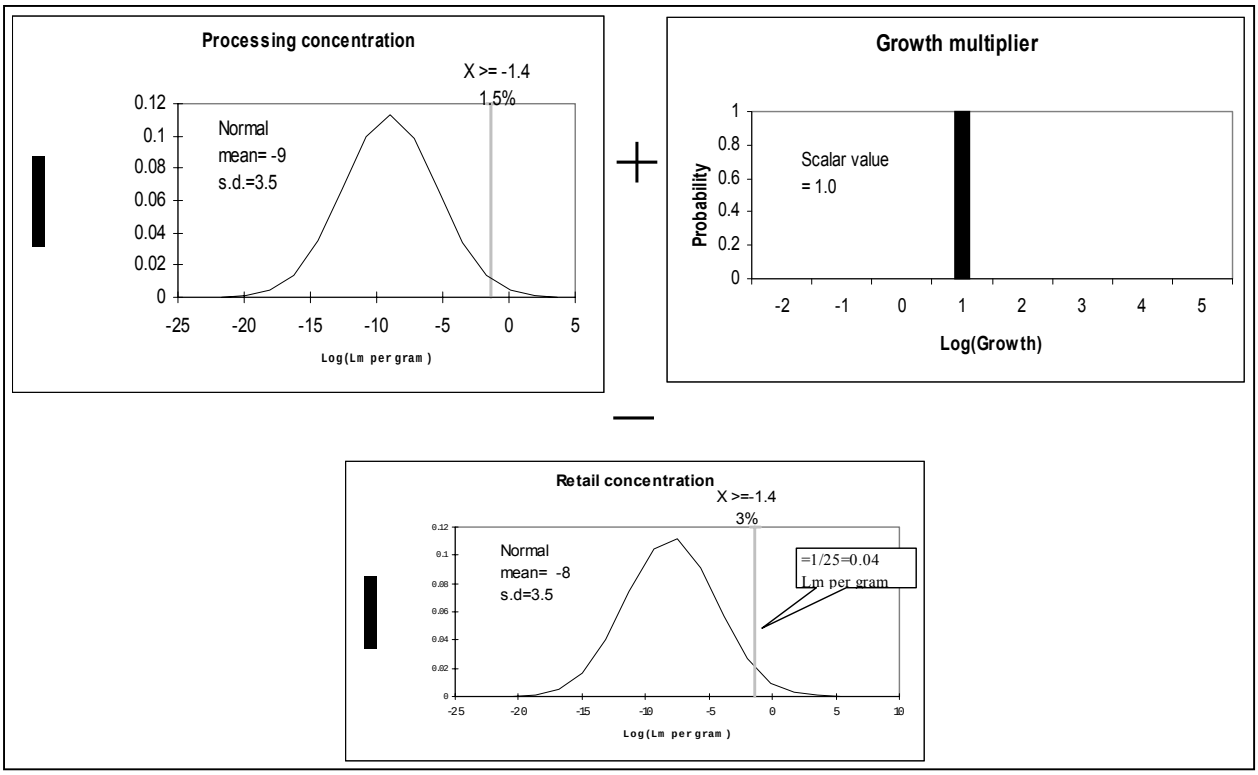


Figure A-3. Case 3 example where growth multiplier is a constant 1 log. This is the assumption used in the in-plant model.

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.