FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats

Prepared by:

Daniel L. Gallagher
Dept. of Civil and Environmental Engineering
Virginia Polytechnic Institute and State University

Eric D. Ebel and Janell R. Kause
Risk Assessment Division
Food Safety and Inspection Service, USDA

May 2003

FSIS

FSIS *LISTERIA* RISK ASSESSMENT REPORT

SCOPE AND MANDATE

This risk assessment was initiated in February 2002 in response to public comments on the Food Safety and Inspection Service (FSIS) proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* [66 FR 12589, February 27, 2001]. Several comments indicated a need for a stronger scientific basis for the proposal to require testing and sanitation of food contact surfaces for *Listeria* species.[1] In general, the scientific literature indicated that the relationship between the prevalence and level of *Listeria* species in the plant environment (e.g., food contact and non-food contact surfaces) to the prevalence and level of *Listeria monocytogenes* (*L. monocytogenes*) in ready-to-eat (RTE) meat and poultry products is not well understood. To better understand this relationship, FSIS requested public input as part of the proposed rule for RTE meat and poultry products (66 FR 12609). In addition to the public request for data, FSIS initiated the planning and development of this risk assessment to: 1) provide insight into the relationship between *Listeria* species on food contact surface(s) and *L. monocytogenes* in RTE meat and poultry products; and 2) to evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, use of growth inhibitors, and combinations of these interventions to mitigate contamination on RTE meat and poultry products and reduce the subsequent risk of illness or death from *L. monocytogenes*.

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

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

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

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

PUBLIC HEALTH REGULATORY CONTEXT

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

Public Health Background

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

Definition: Ready-to-Eat (RTE)

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

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

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

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

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

Policy Context

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

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

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

---

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

RISK MANAGEMENT QUESTIONS

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

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

---

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

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

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

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

3) What guidance can be provided on testing and sanitization of food contact surfaces for *Listeria* species (e.g., the confidence of detecting a positive lot of RTE product given a positive food contact surface test result)?[15]

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

FSIS *LISTERIA* RISK ASSESSMENT

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

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

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

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

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

Model Overview

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

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

---

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

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

In the FSIS Listeria risk assessment, model inputs are assumed to be independent of one another. Without empirical information, specifying dependencies of inputs would be purely hypothetical. It seems reasonable to assume that variable model inputs (e.g., frequency, duration, and level of contamination) are independently distributed.

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

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

The in-plant model incorporates food contact surface testing, product testing, sanitation, pre- and post-packaging interventions, and the effect of growth inhibitors (or product reformulation[18]). The output of the in-plant model is combined with the updated version of the 2001 FDA/FSIS exposure retail-to-table pathway for deli meats and *Listeria* dose-response relationship to estimate the risk of illness or death on a per serving and per annum basis from *L. monocytogenes* in RTE product. Risk estimates are provided as a function of: testing (*Listeria* species) and sanitation frequency (based on plant size) of food contact surfaces (FCSs), testing (*L. monocytogenes*) and disposition of RTE product, pre- and post-packaging interventions, and growth inhibitors. The conditional likelihood of detecting *L. monocytogenes* in products, given that the FCS tests positive for *Listeria* species, was also evaluated.

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

Model Parameters

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

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

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

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

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

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

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

Updated FDA/FSIS Risk Ranking Model

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

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

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

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

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

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

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

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

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

In-plant Dynamic Model

Conceptual Model

A schematic overview of the conceptual model is provided in Figure 1 below. The model assumes that a *Listeria* reservoir exists in the plant and is capable of contaminating the food contact surface. This reservoir can be harborage sites such as floor drains or air conditioning ducts, or other surfaces/equipment in the plant.

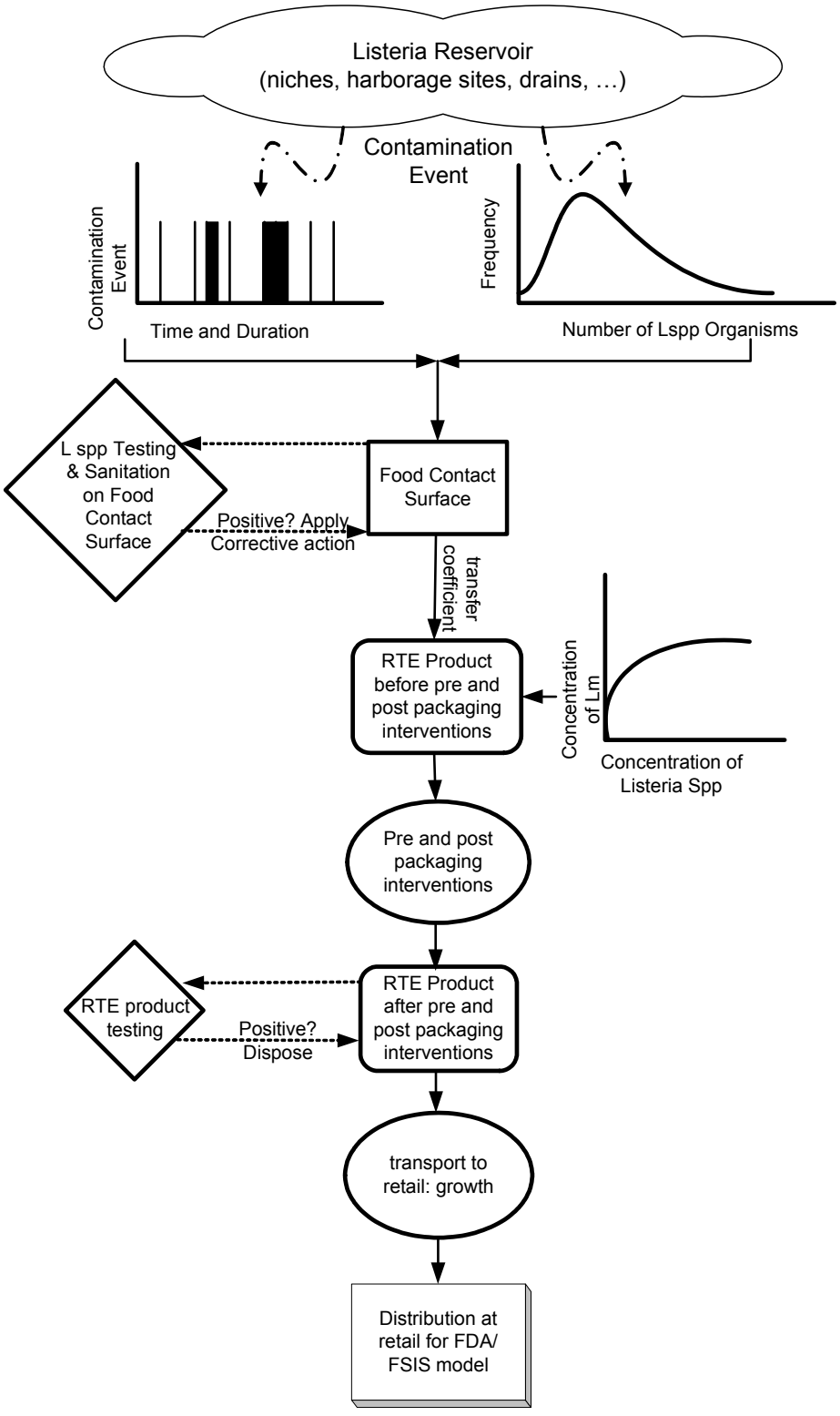

Figure 1. Conceptual Model for the "In-plant" Component of the FSIS *Listeria* Risk Assessment.

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

The FSIS *Listeria* risk assessment model supposes that *Listeria* species move from this reservoir onto the food contact surface during what is termed a contamination event. The key parameters defining a contamination event are: 1) the time between initialization of events (i.e., How often is a food contact surface contaminated?); 2) the duration of the event (i.e., How long does it last?); and 3) the amount of *Listeria* species transferred from the in-plant reservoir to the food contact surface.

Once on the food contact surface, *Listeria* species can be transferred to the lot of RTE product being processed, be removed from the food contact surface through sanitation at the end of each lot processing, or stay on the surface. Published studies support the concept that RTE product is primarily contaminated by food contact surface. In a study of *L. monocytogenes* in French delicatessen plants, Salvat *et al.* (1995) found that contact of cooked product with contaminated surfaces was a major route of product contamination, as was cross contamination between raw and cooked product.[20]

If the contamination event is continuing, the new *Listeria* species transferred from the reservoir will be added to the *Listeria* species already on the food contact surface. For each lot processed, the food contact surface can also be tested for *Listeria* species and various mitigation steps taken if the surface tests positive.

A positive food contact surface test can trigger a required lot of RTE product to be tested for *L. monocytogenes*. It can also trigger a more intensive sanitation (i.e., enhanced sanitation) of the food contact surface at the end of lot processing.

Some fraction of the *Listeria* species on the food contact surface is transferred to the lot. This fraction is the transfer coefficient, which can range from 0 to 1. A transfer coefficient of 0 indicates that none of the *Listeria* species are transferred. A transfer coefficient of 1 indicates that all the *Listeria* species is transferred to the product lot being processed.

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

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

At this point the product lot can undergo post-lethality treatment (i.e., pre- and post-packaging intervention(s)[21]**,** which will reduce the concentration of *L. monocytogenes*. After these interventions, the lot can then be tested for *L. monocytogenes*, either because of routine lot testing or because a food contact surface tested positive for *Listeria* species. If a test-and-hold procedure is in place, the lot tested for *L. monocytogenes*, based on a food contact surface positive for *Listeria* species, is the lot produced at the time the food contact surface sample was collected. If a test-and-hold procedure is not in place, the lot testing response is lagged by the time it takes to analyze a food contact surface sample for *Listeria* species and obtain results of this test, i.e., lot testing is applied to a lot lagging behind the tested food contact surface. The model assumes a lag time of about 3 days. The model also assumes that product lots of RTE product that test positive for *L. monocytogenes* are removed from the food supply. Operationally, this would be accomplished by re-processing the lot for human food, diversion of the lot into products not intended for human consumption, or disposal of the lot.

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

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

Sources of Data and Assumptions

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

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

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

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

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

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

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

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

Model Calculations and Base Values

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

The model starts by stochastically generating the start time and duration for each contamination event that will be needed for the simulation. These parameters are simply random variates drawn from distributions described below. The model also stochastically generates the timing for the requested testing of lots and FCS. These too are simply random variates.

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

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

where

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

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

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

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

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

where

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

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

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

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

where

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

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

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

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

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

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

where

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

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

Post processing interventions were not modeled for the base run. The different plant sizes were allowed to have different minimum and maximum values. Note: only a percentage of the lots produced by each different plant size were assumed to undergo post processing interventions.

The decision on which lots undergo post processing was a simple binomial test based on the fraction of lots appropriate for the given plant size.

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

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

where

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

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

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

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

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

where

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

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

	plant size		

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

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

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

FCS and RTE Lot Testing

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

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

The RTE lot sample is judged positive by

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

where

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

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

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

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

The FCS sample is judged positive by

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

where

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

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

Parameter Descriptions and Baseline Values

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

Time series *Listeria* species prevalence on various pieces of equipment were available from an FSIS in-depth verification conducted in a plant that was associated with an *L. monocytogenes* outbreak in humans (Hynes 2000). These data are shown in Table 10, and summarized in Table 11. The data were analyzed using survival analysis and distribution fitting using NCSS[23] statistical software (Hintz, 2001)**.** Several distributions were compared, and the $\log_{10}$ normal distribution had the greatest likelihood (Table 12). On a $\log_{10}$ scale, the mean time between contamination events was 1.08 with a standard deviation of 0.46. This is approximately 20 days ± 29 days. Figure 2 shows the resulting fit.

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

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

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

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

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

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

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

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

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

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

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

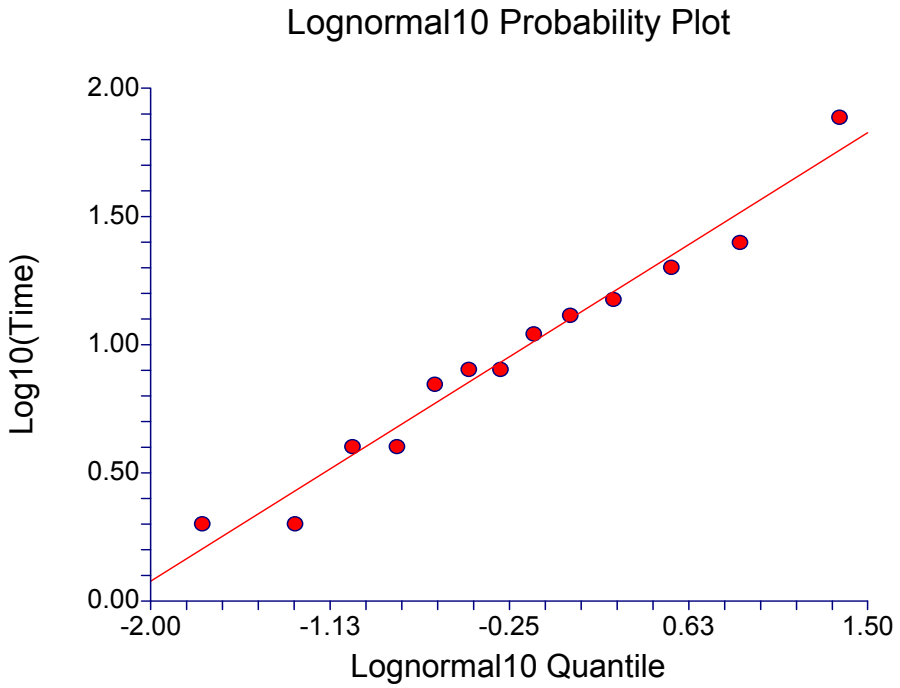

Figure 2. Fit of mean time between contamination events to log normal distribution.

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

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

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

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

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

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

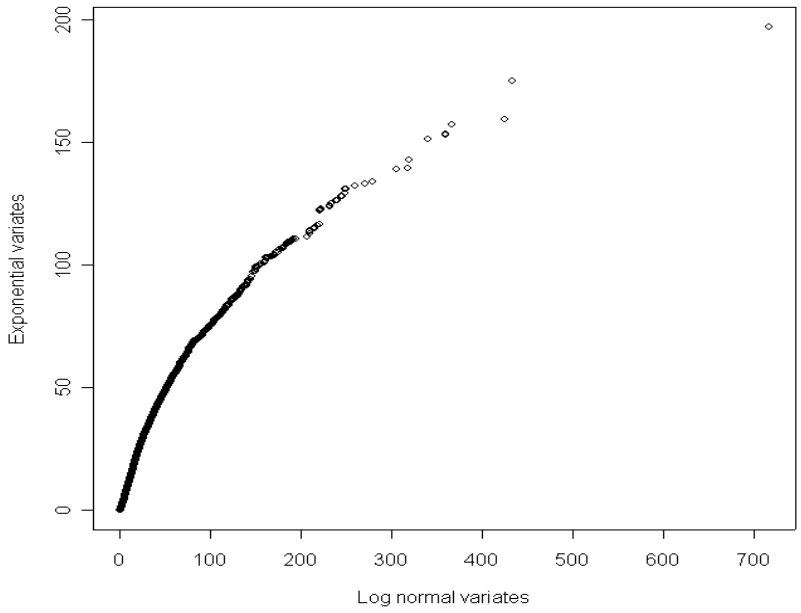

Figure 3. Quantile-Quantile Plot Comparison of the Lognormal and Exponental Distributions for the Time Between Contamination Events.

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

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

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

Tompkin (2002) provided a table of sequential weekly *Listeria* species testing results and the number of weeks that *Listeria* species positives persisted. While the data available to estimate this parameter was limited, the Tompkin (2002) data was peer-reviewed, represented industry data, and was likely more representative than targeted environmental sampling data. Therefore, FSIS concludes that its reliance on these data was appropriate. These data were analyzed using survival analysis and distribution fitting with NCSS (Hintz 2001). Table 14 shows the data and Table 15 summarizes it. Table 16 provides the maximum likelihoods estimates for a variety of parameters. The $\log_{10}$ normal distribution had the second greatest likelihood (behind the log logistic). On the basis of consistency, ease of interpretation and ease of implementation, the lognormal distribution was used during the simulation. On a $\log_{10}$ scale, the mean contamination event duration was 0.60 with a standard deviation of 0.57. This is approximately 9 days ± 20 days. Figure 4 illustrates the fit

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

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

Table 15. Summary of Duration of Contamination Event

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

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

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

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

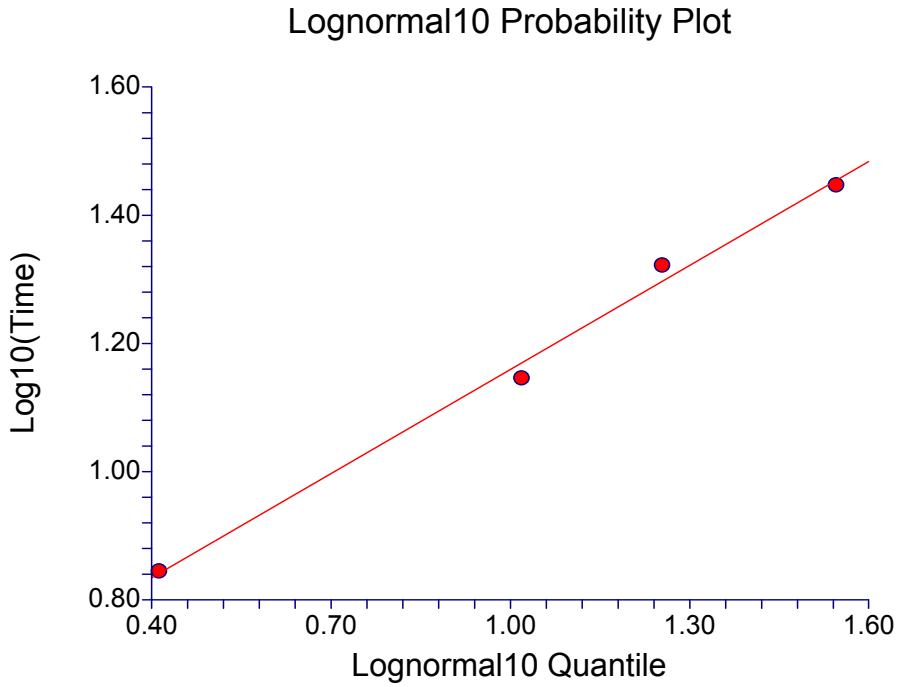

Figure 4. Log normal distribution fit for duration of contamination event.

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

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

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

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

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

4) Sanitation Effectiveness

Clean-up effectiveness measures the proportion of bacteria on the food contact surface that is removed through sanitation procedures. The model assumes the effectiveness of clean-up between lots is 50% and end of day clean-up is 75%. Therefore, total effectiveness of routine cleaning is actually 1-[(1-50%)*(1-75%)]=87.5%, or just less than a one log10 reduction in the amount of contamination remaining on food contact surfaces. A similar level of effectiveness was estimated for cleaning of stainless steel surfaces experimentally inoculated with a biofilm of *Pseudomonas aeruginosa* and *Staphylococcus aureus* by Gibson *et al.* (1999). While some plants may achieve greater log reductions from their cleaning practices, the effectiveness levels assumed in this risk assessment seem reasonable as averages across the entire industry.

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

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

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

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

Midelet and Carpentier (2002) prepared *L. monocytogenes* biofilms by contacting meat exudates with $5x10^7$ cfu/mL to stainless steel slides for 3 hours. The planktonic bacteria were then removed by washing. The resulting *L. monocytogenes* surface concentrations were estimated in the range $10^{6.1}$ cfu/cm2 for stainless steel to $10^{6.4}$ cfu/cm2 for PVC. Twelve sequential contacts with beef were then conducted. After 12 contacts, the study results suggested that approximately

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

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

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

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

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

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

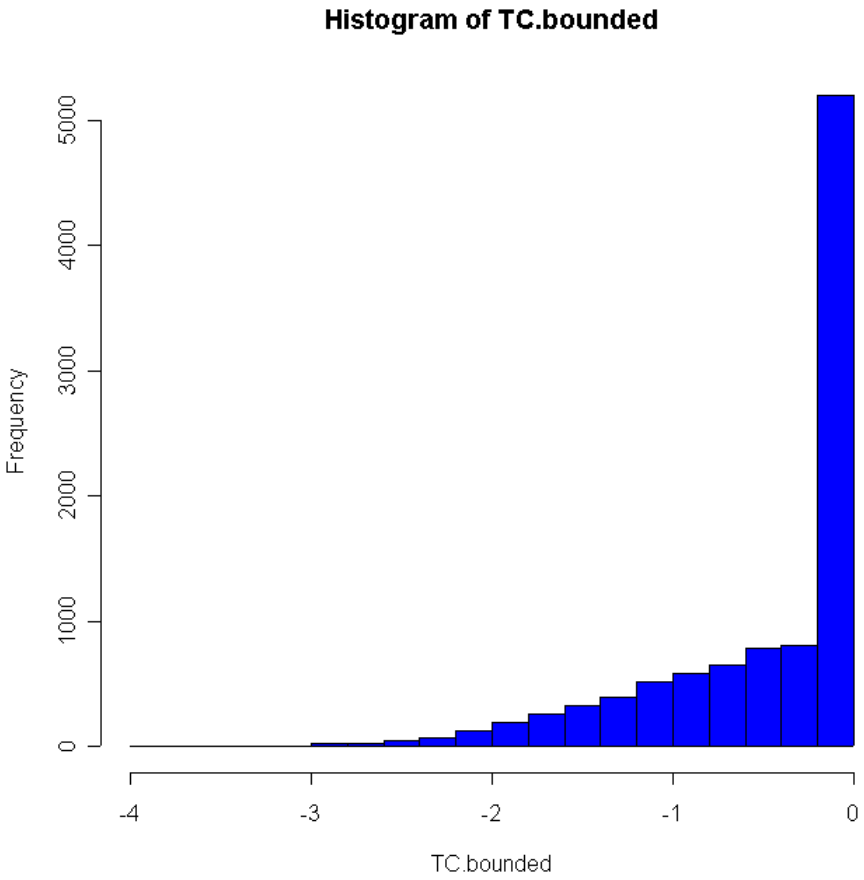

Figure 5. Histogram for the fit of the transfer coefficient data.

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

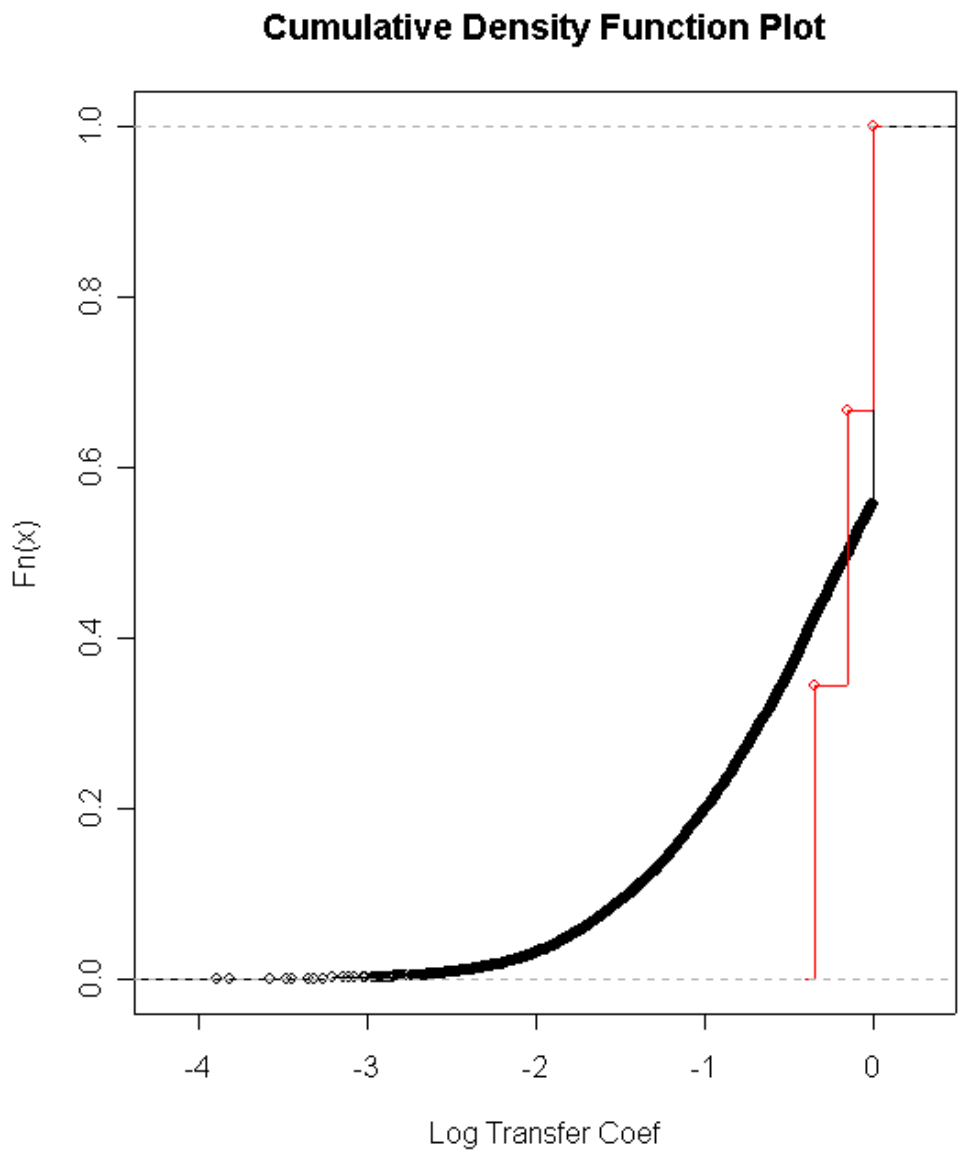

Figure 6. Empirical Cumulative Density Distribution for the Transfer Coefficient.

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

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