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

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

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

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

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

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

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

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

No data were available on the ratio of concentrations of *L. monocytogenes* to *Listeria* species. Data, however, were available on the prevalence of *L. monocytogenes* to *Listeria* species (i.e., data on when a food contact surface was found positive for *Listeria* species, whether or not the surface was also positive for *L. monocytogenes*). These prevalence data were available from the published literature (Tompkin 2002) and some unpublished industry data provided to FSIS (Cornell University, November 2002). Table 18 summarizes these values.

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

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

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

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

6) Probability of detecting 1cfu in a sample

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

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

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

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

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

where p is the probability of detecting 1 cfu in the sample, and n is the number of cfu's in the sample from the Poisson calculation. The p probability is based on the detection limit and microbiological test sensitivity, and is the input parameter to the risk assessment model.

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

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

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

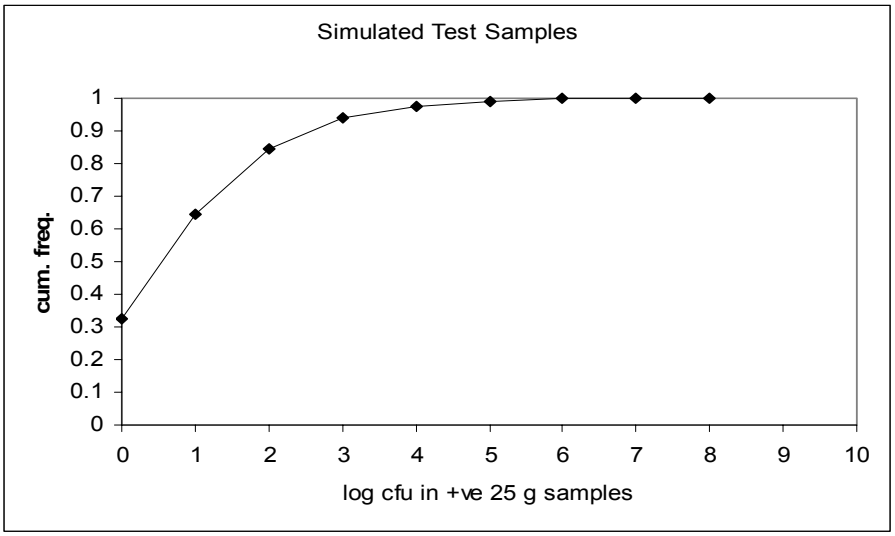



**Figure 7**. Levels of *L. monocytogenes* in 25-gram samples of RTE product.

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

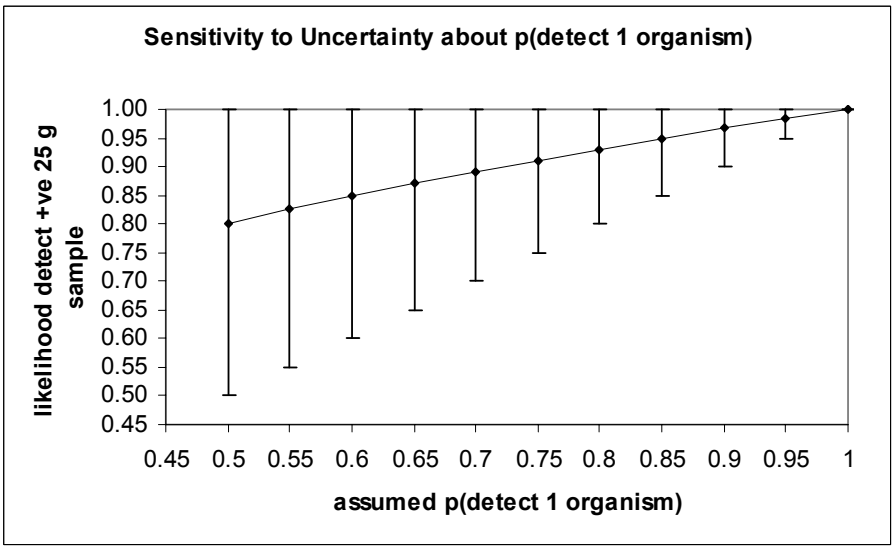



**Figure 8**. Likelihood of detecting *L. monocytogenes*-positive samples.

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

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

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

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

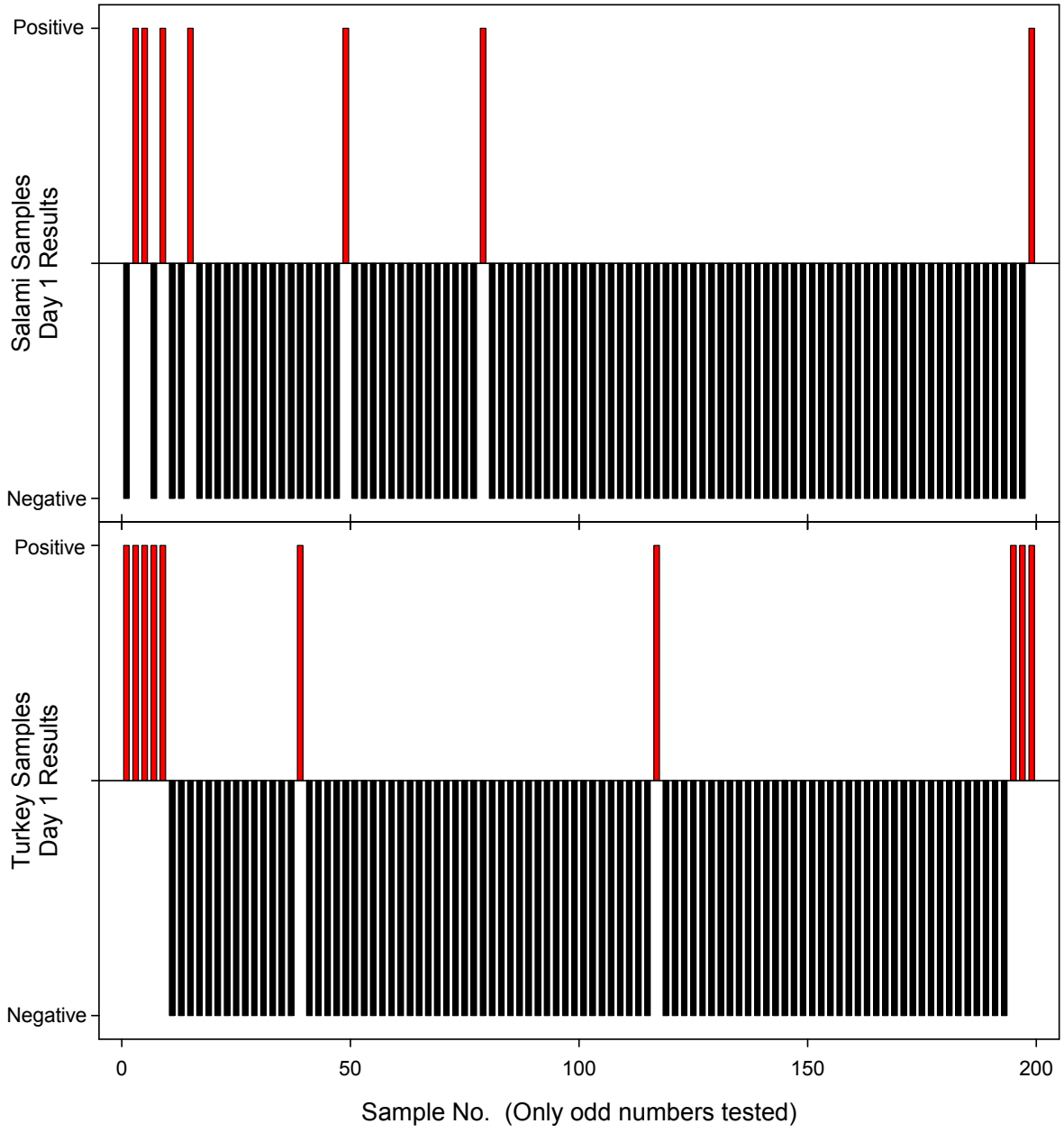



**Figure 9**. *L. monocytogenes* contamination on samples of RTE product to evaluate the effect assumption of clustering or homogeneity of contamination in a product lot.

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

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

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

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

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

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

9) Line production

FSIS (2003) reports a survey among RTE processors of deli meats (and hot dogs) to evaluate the fraction of the deli meat food supply produced by large, small and very small plants. Additionally, the pounds per shift per line for each plant size were also estimated. The survey found that for deli meats, about 48% of the food supply is produced by large plants, 48% by small plants, and the remaining 4% by very small plants. The estimated average production volume in pounds of deli meats per line per shift is shown in Table 19.

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

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

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

| | | |
|---|---|---|
| Small | 7100 | 10600 |
| Very Small | 2800 | 9500 |

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

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

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

10) Post Processing and Growth Inhibition

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

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

**Model Implementation and User Interface**

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

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

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

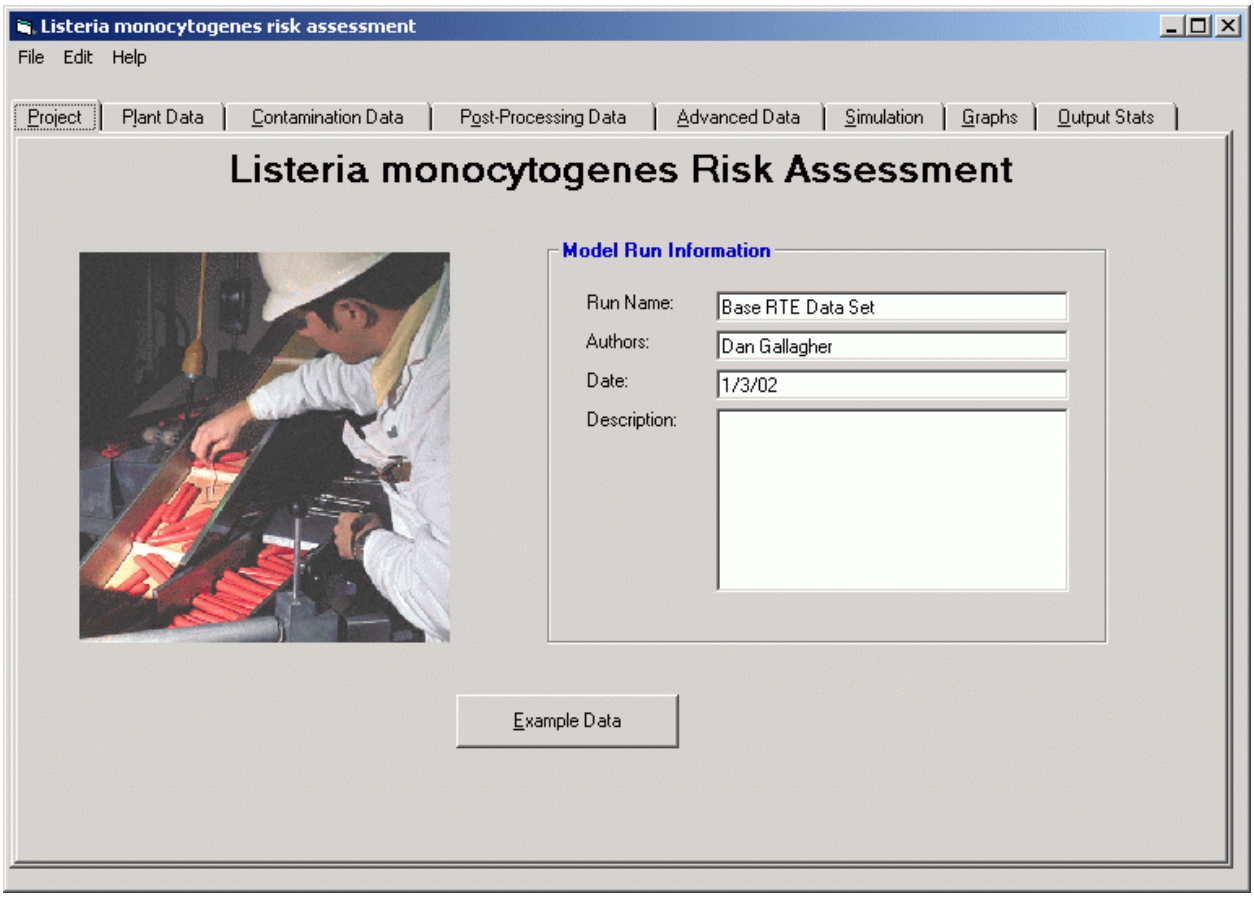



**Figure 10**. Project Data Entry Screen.

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

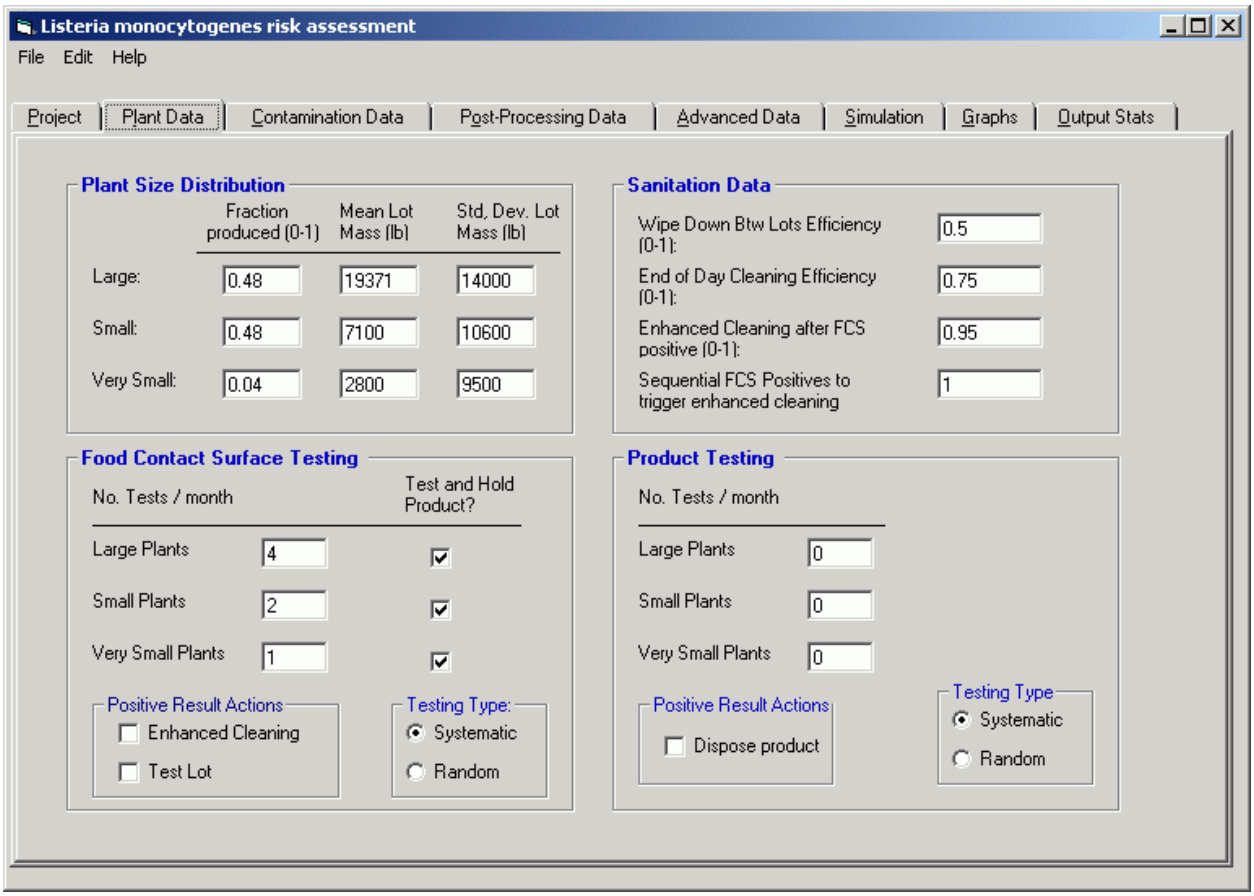



**Figure 11**. Plant Data Entry Screen

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

Finally, if a food contact surface was found positive for *Listeria* species, the base model assumes that the plant would conduct a more effective or enhanced cleaning to remove the bacterial contamination. This effectiveness was set at 95% for the base model. The enhanced cleaning was always lagged in time to allow for the time between the testing and when the results would be available.

The frequency of food contact surface testing for *Listeria* species varied depending on the scenario being analyzed. Different frequencies were allowed for different plant sizes (i.e., for large, small, and very small establishments). Two interventions based on testing results were allowed. First, if a food contact surface tests positive for *Listeria* species, then the RTE product lot would be tested for *L. monocytogenes*. If the RTE product lot was positive for *L.*

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

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

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

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

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

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

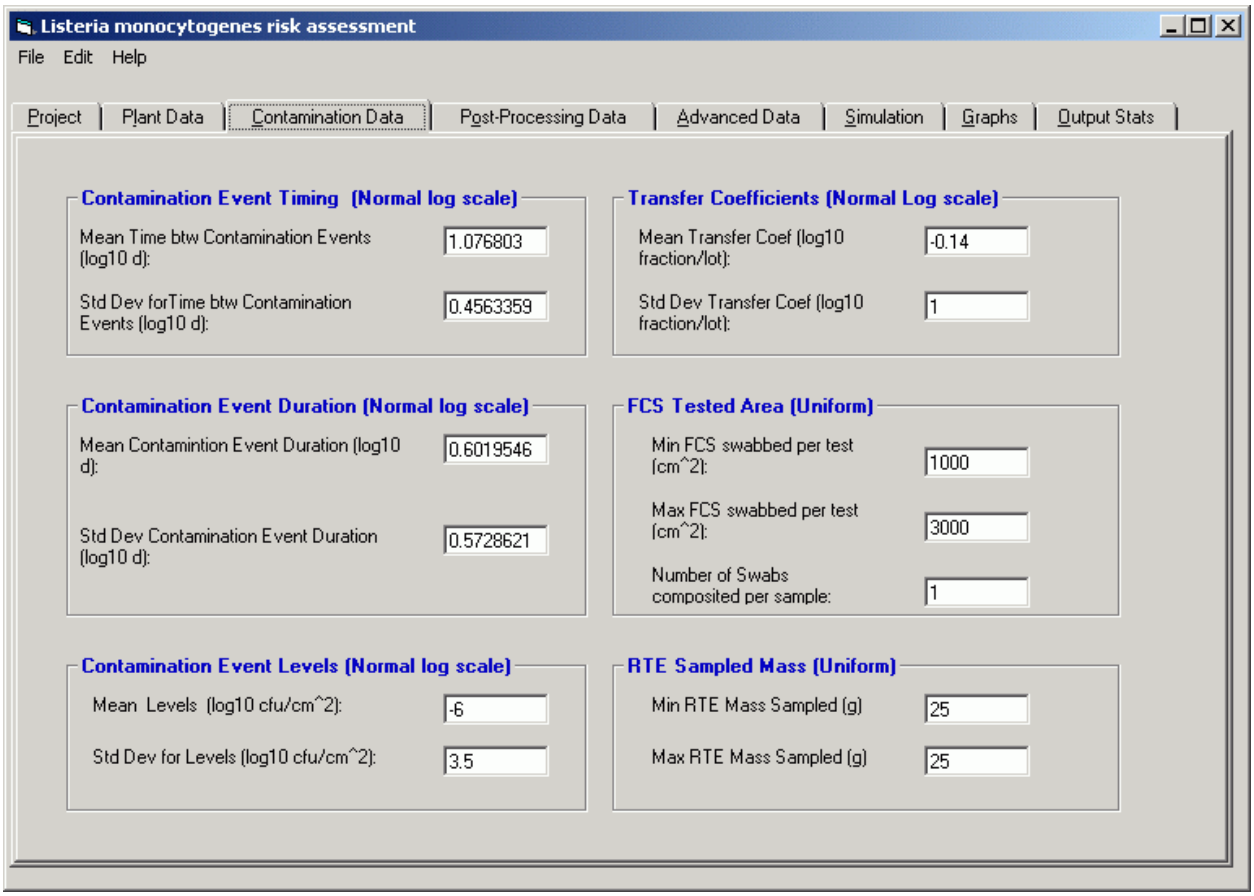



**Figure 12.** Contamination Data Entry Screen

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

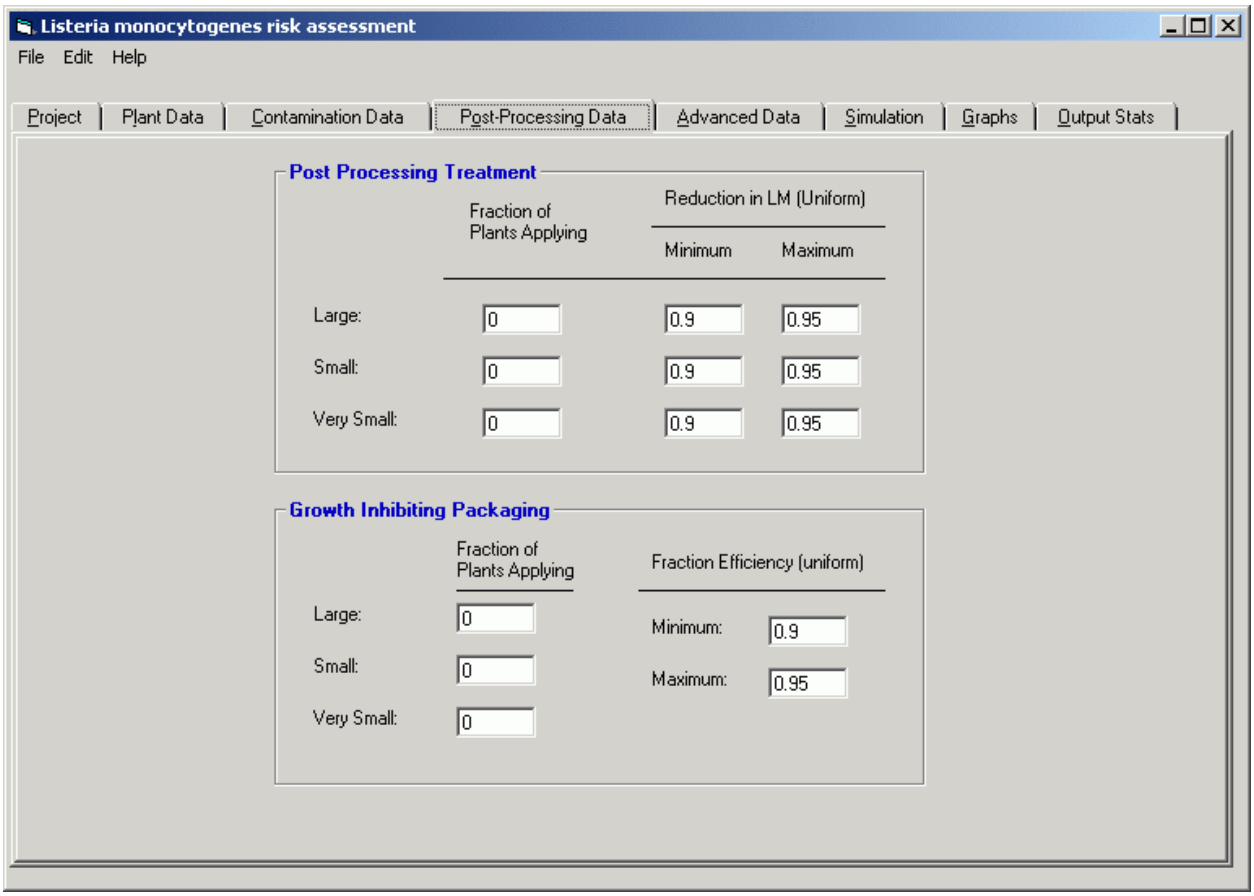



**Figure 13.** Post Processing Data Entry Screen

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

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

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

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

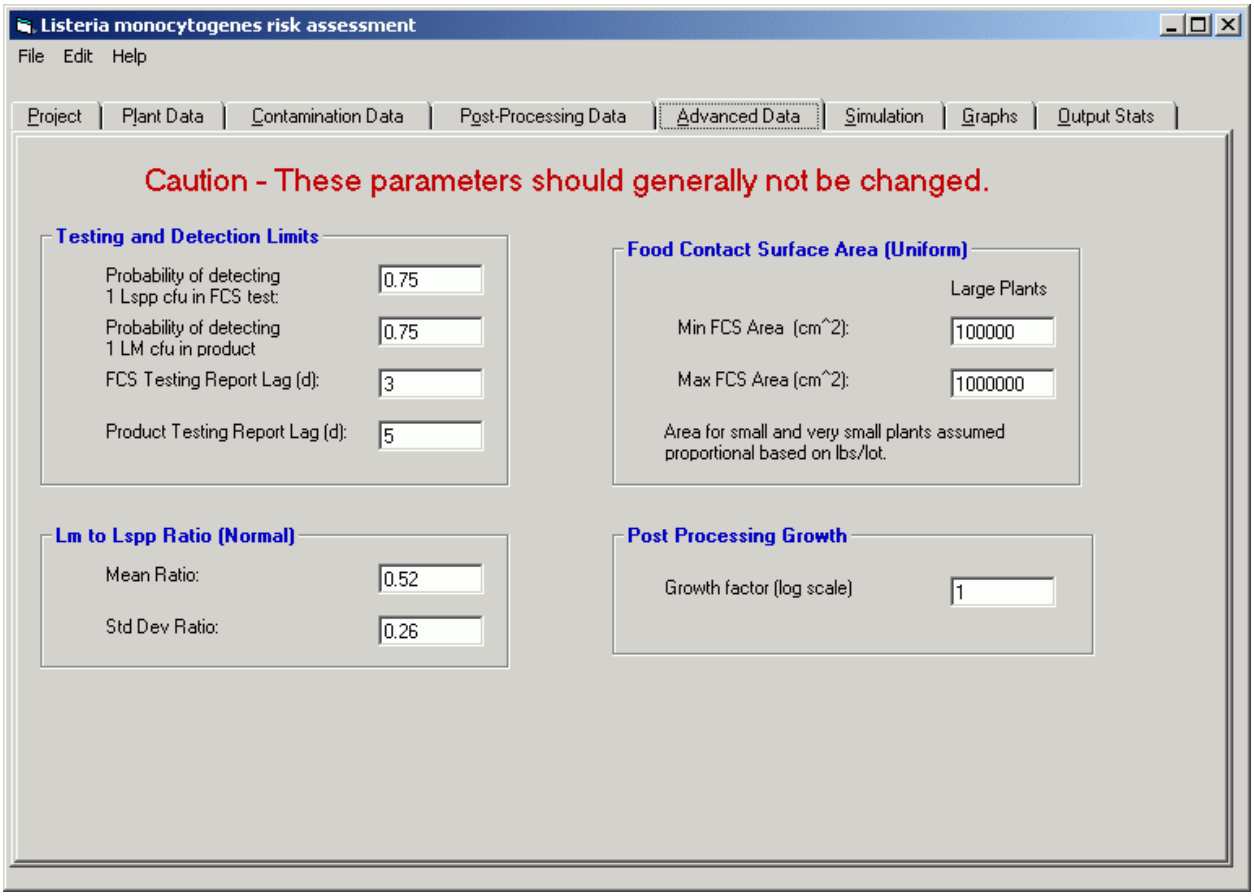



**Figure 14**. Advanced Data Entry Screen

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

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

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

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

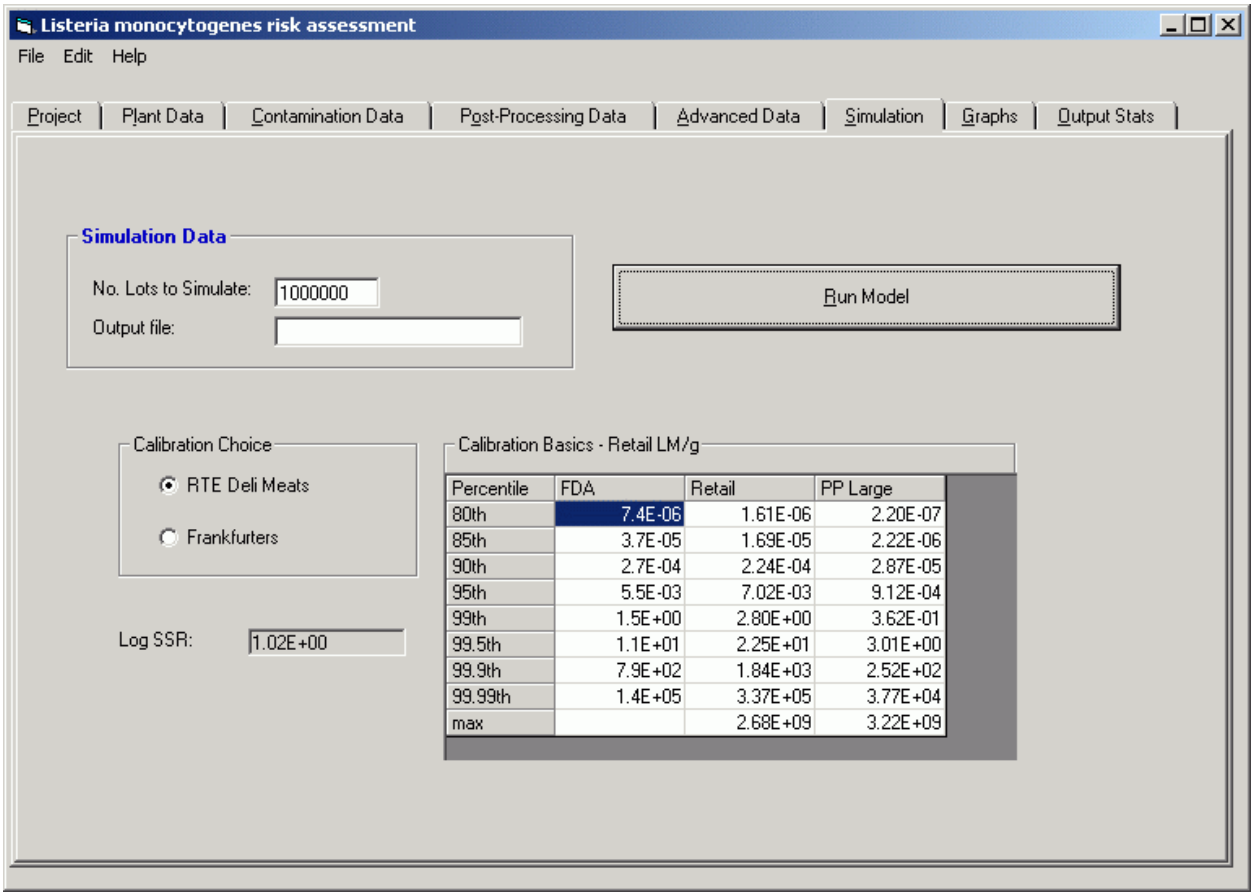



**Figure 15.** Simulation Screen

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

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

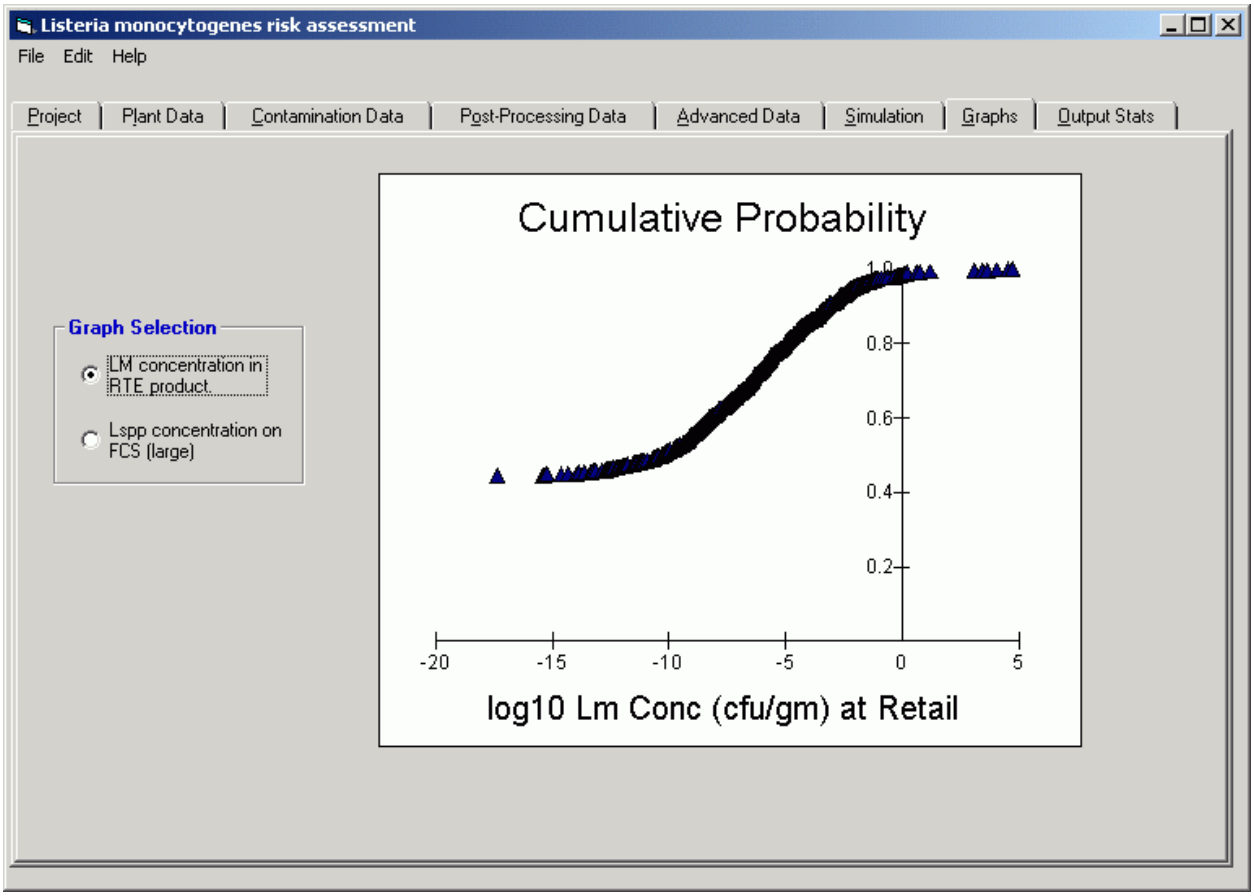
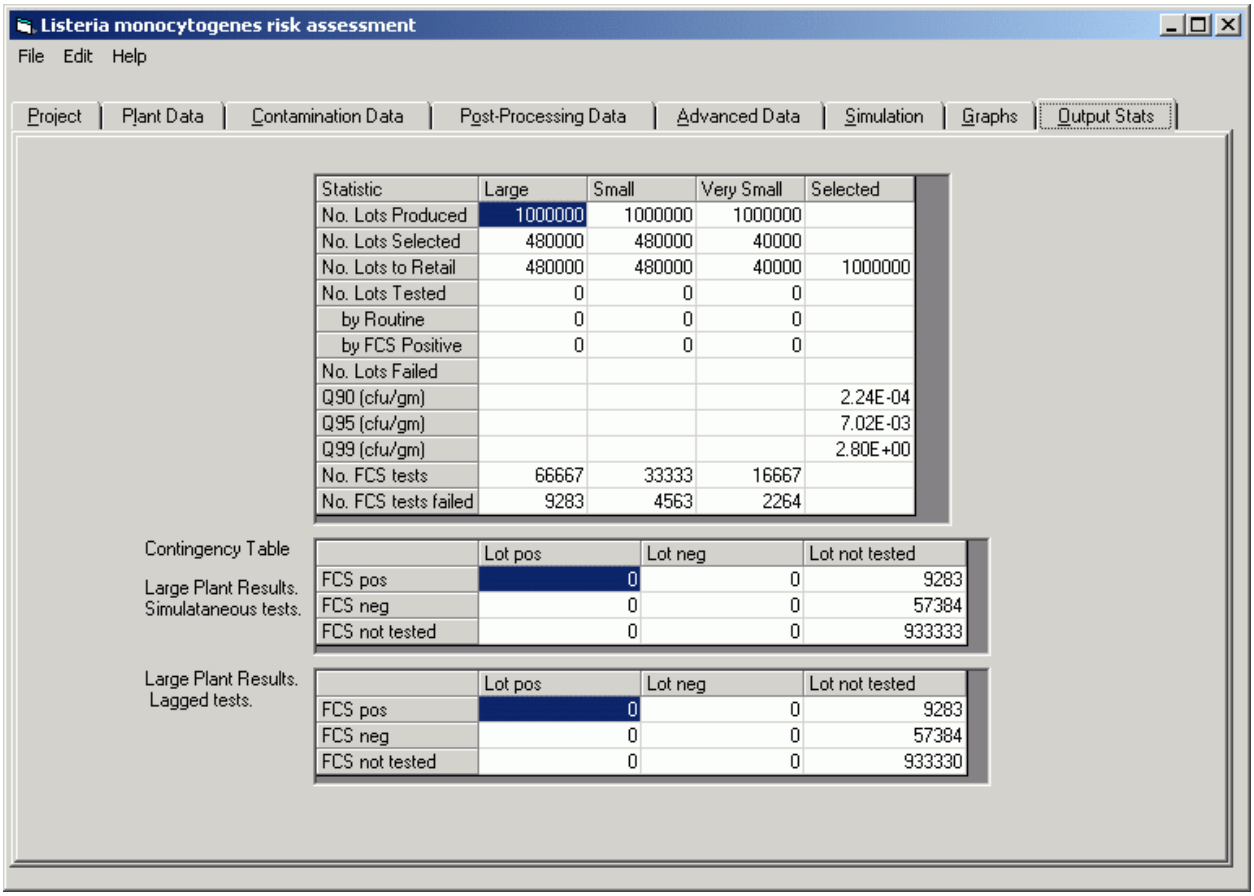



**Figure 16.** Graph Output Screen

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




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

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

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

**Figure 17**. Output Statistics Screen

### *Calibration of the In-plant Dynamic Model*

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

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

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

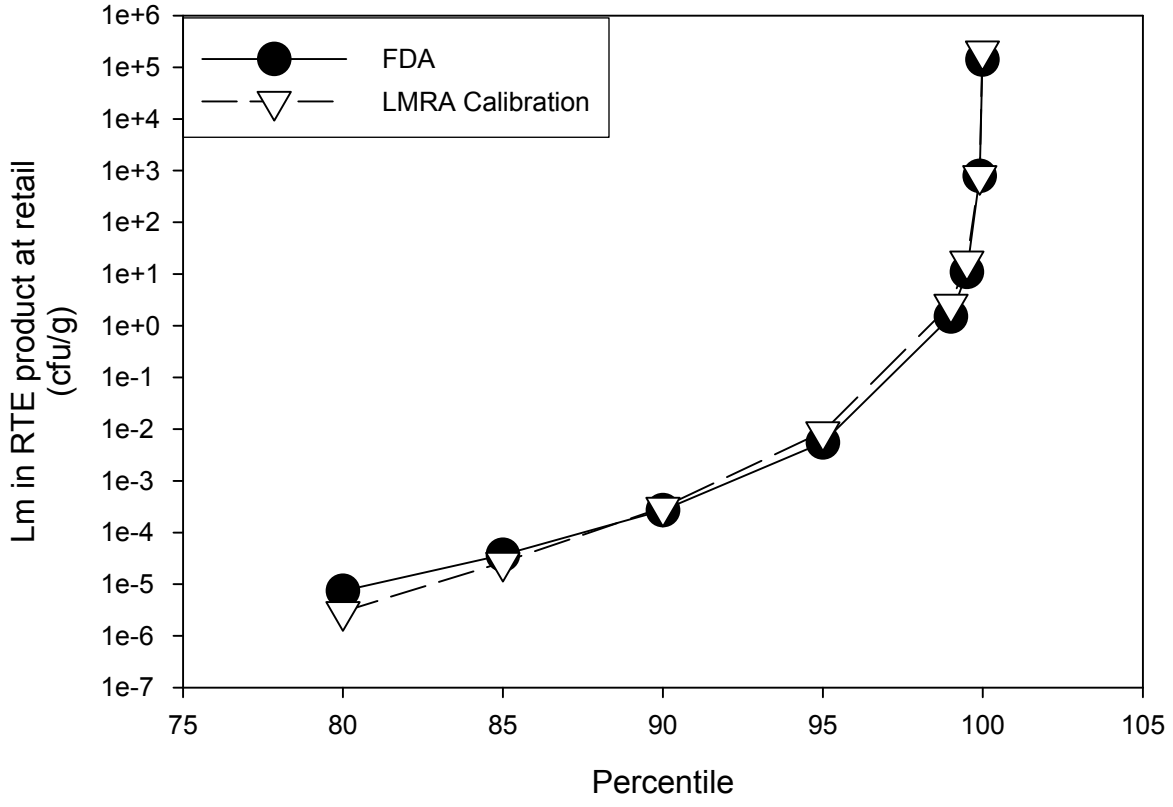



**Figure 18.** Final FSIS *Listeria* Risk Assessment In-plant Model Calibration to the Updated FDA/FSIS Exposure Assessment Concentrations of *L. monocytogenes* in Deli Meats at Retail. The mean and standard deviation of the log number of *Listeria* species transferred to the food contact surface at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

***Model Stability***

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

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

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

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

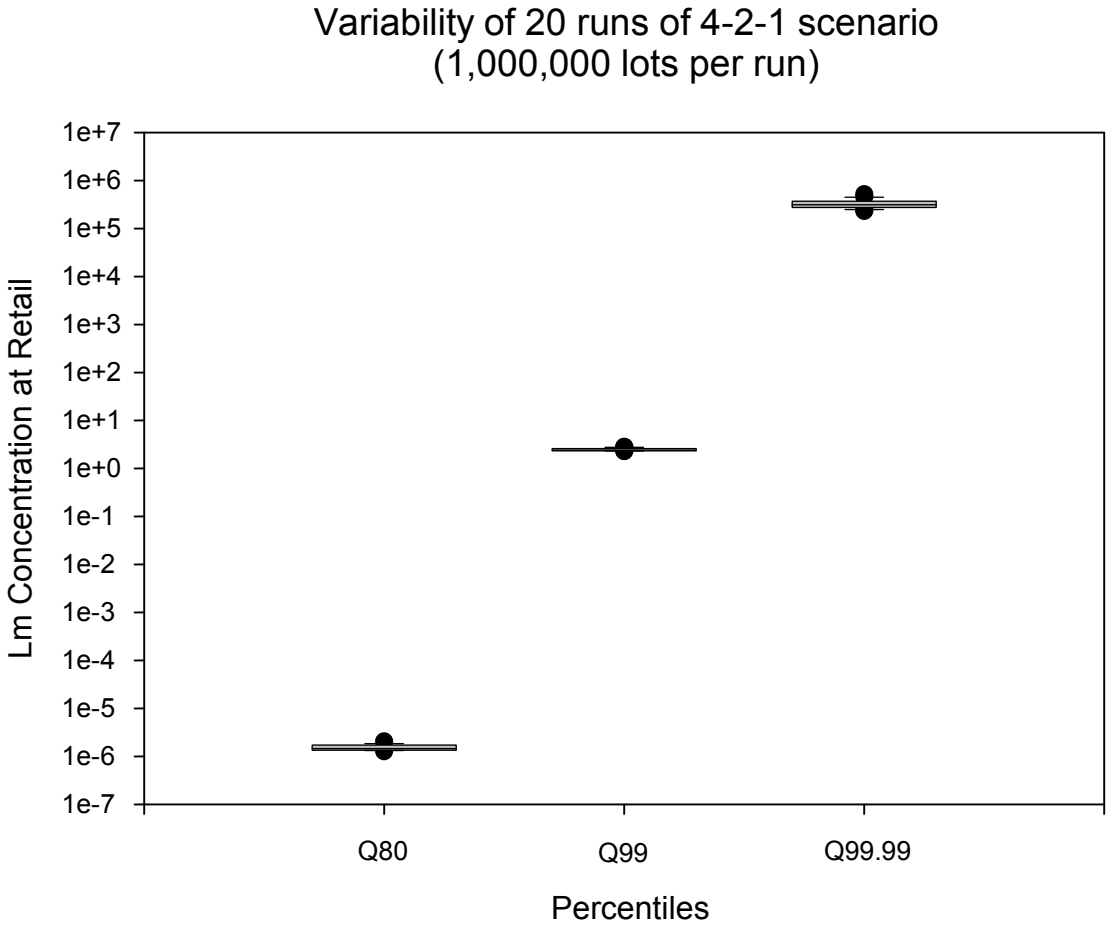



**Figure 19.** Stability of the FSIS *Listeria* risk assessment model simulated quantiles based on 20 runs of the 4-2-1 scenario.

## FSIS *LISTERIA* RISK ASSESSMENT OUTPUTS

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

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

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

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

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

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

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

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

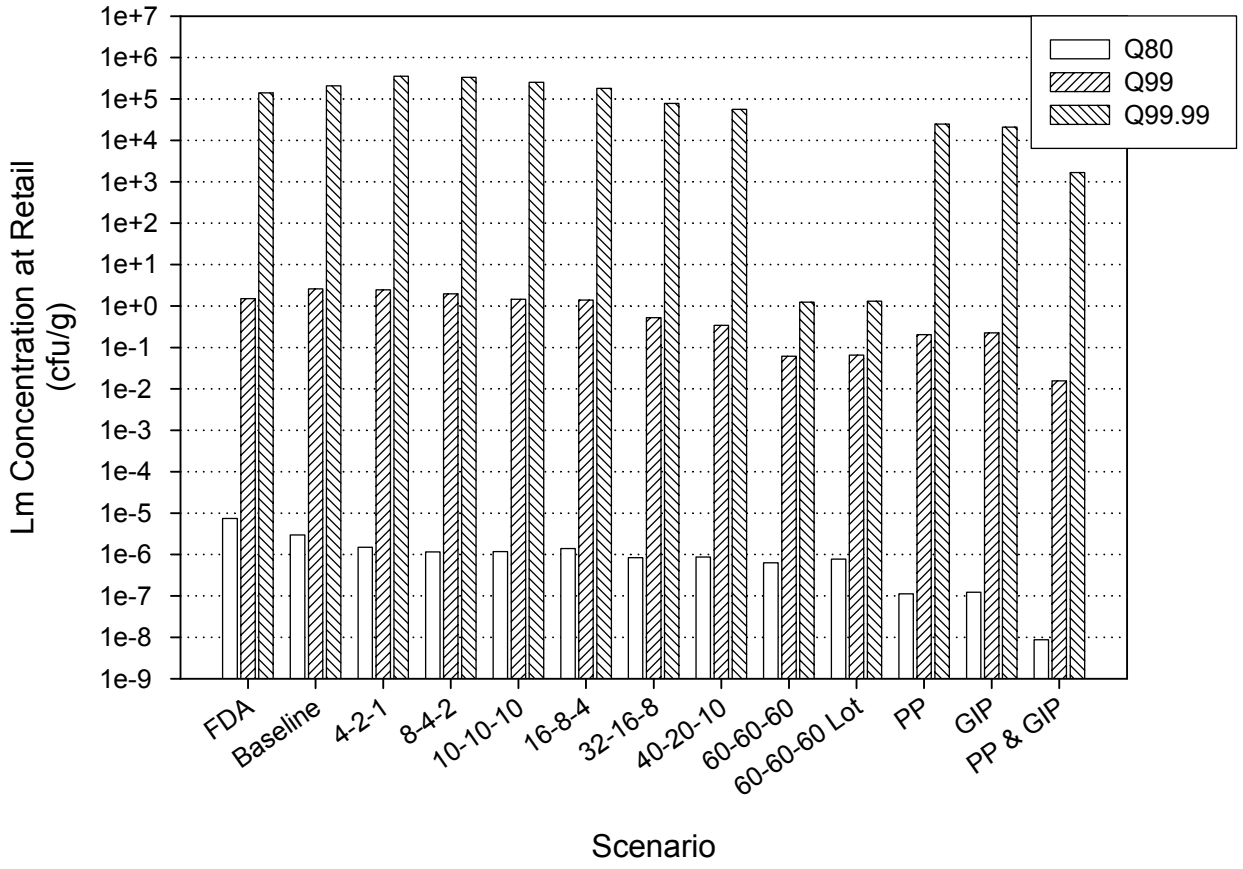



**Figure 20.** Quantiles of *L. monocytogenes* at Retail for Various Scenarios Tested.

The data generally show a decline in the *L. monocytogenes* concentration in RTE product at retail as the food contact surface testing and sanitation effort increases. The decline is more noticeable for the 80$^{th}$ and 99$^{th}$ percent quantiles. As previously described, the 99.99$^{th}$ percent quantile is more variable. Note the slight drop in the 80$^{th}$ 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 80$^{th}$ percent quantile. Post-processing interventions and growth inhibition (e.g., via the use of growth inhibitors/product reformulation) each have lower 80$^{th}$ 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 80$^{th}$ percent quantile when post-processing and growth inhibition are combined. Reminder: that these scenarios assume that 100% of the industry adopts such practices.

***Public Health Impacts***

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

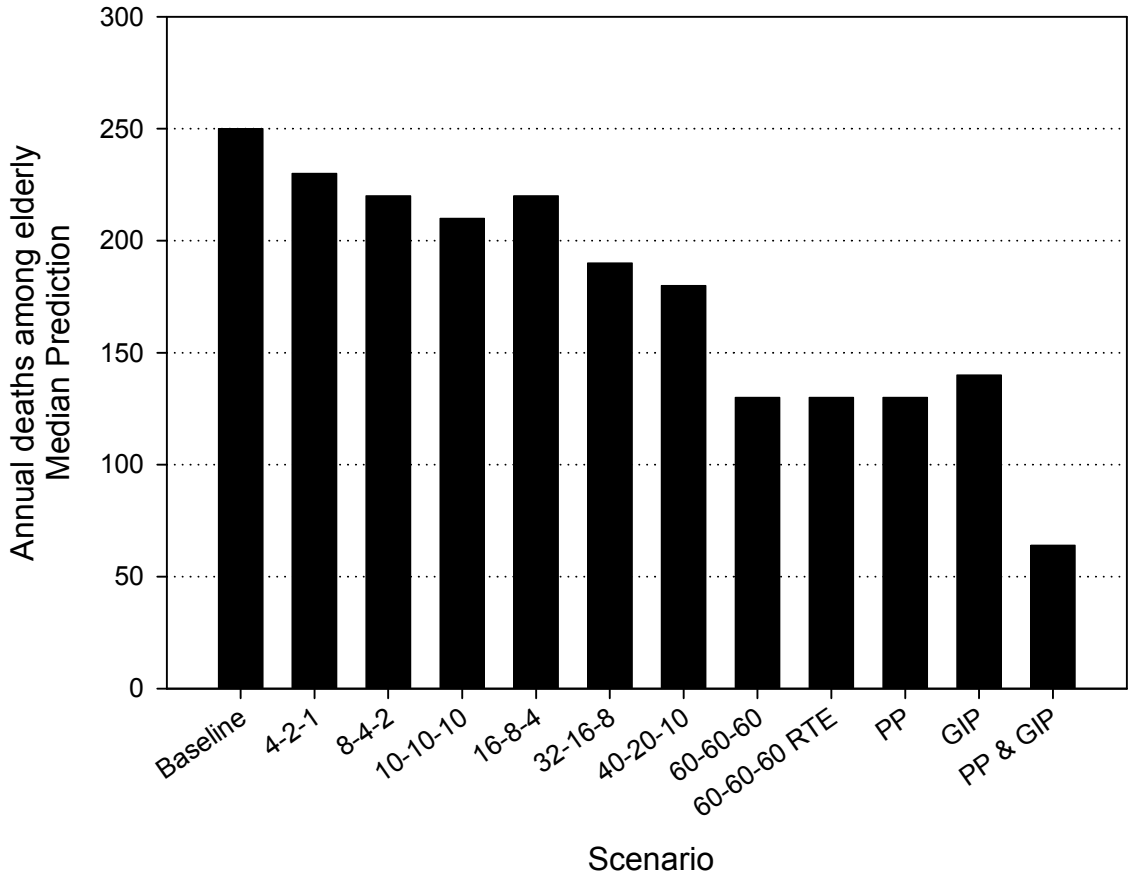



**Figure 21.** Estimated number of deaths among the elderly for the various scenarios tested.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NA – not available.

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

***Lot and Food Contact Surface Prevalence: Likelihood of Detection***

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

**Table 25. RTE** Product Lot and Food Contact Surface Prevalences

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

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

***Test and Hold Effectiveness***

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

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

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

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

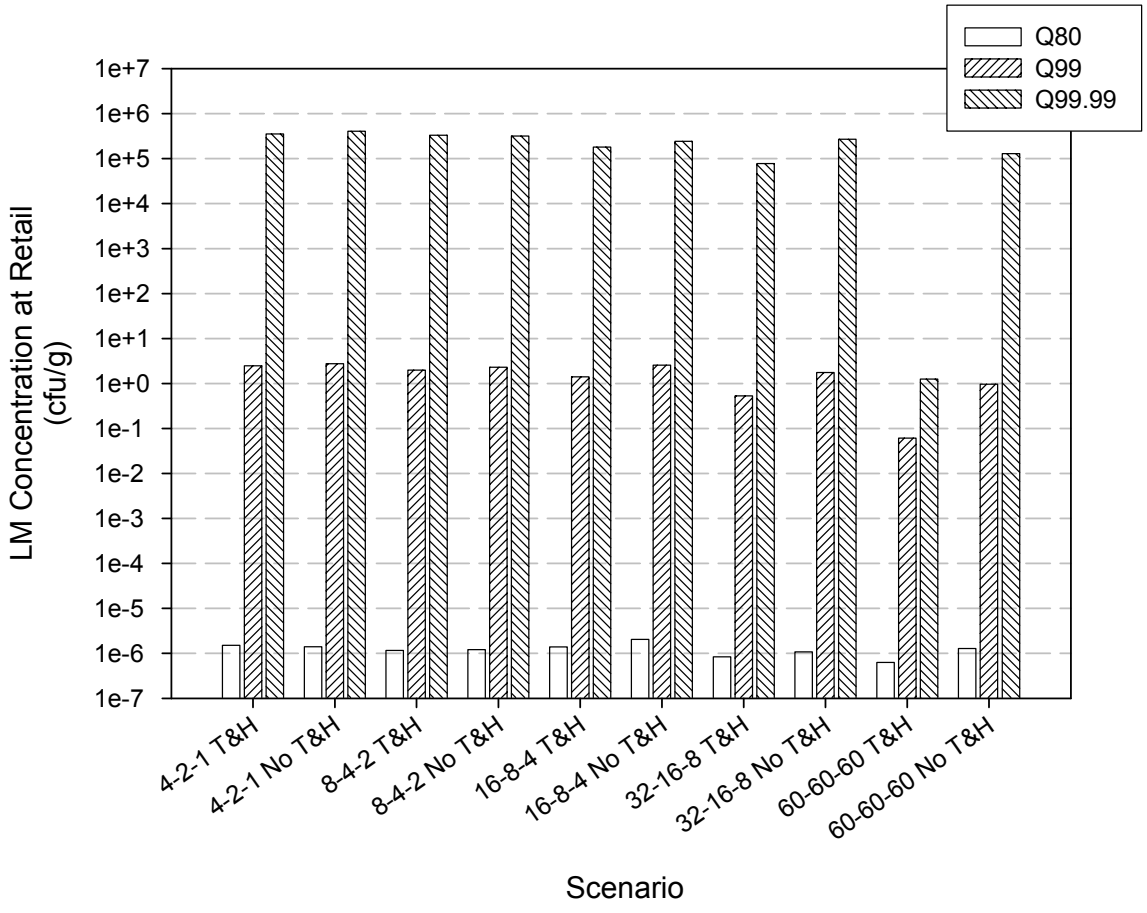



**Figure 22.** Comparison of Test and Hold Effectiveness for Difference Testing Frequencies.

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

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

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

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

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

## SENSITIVITY ANALYSIS

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

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

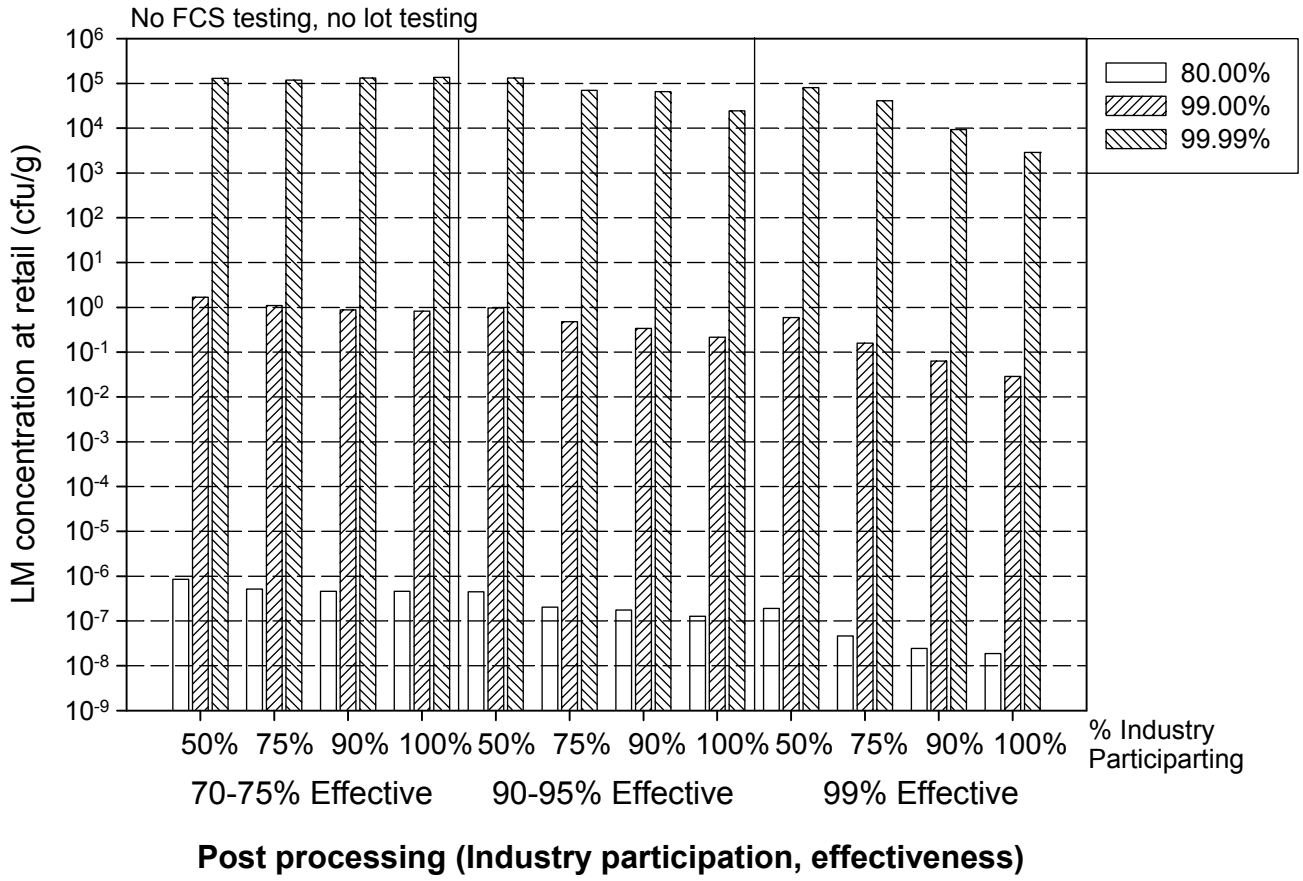



**Figure 23.** Sensitivity to Pre and Post Packaging Interventions**.**

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

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

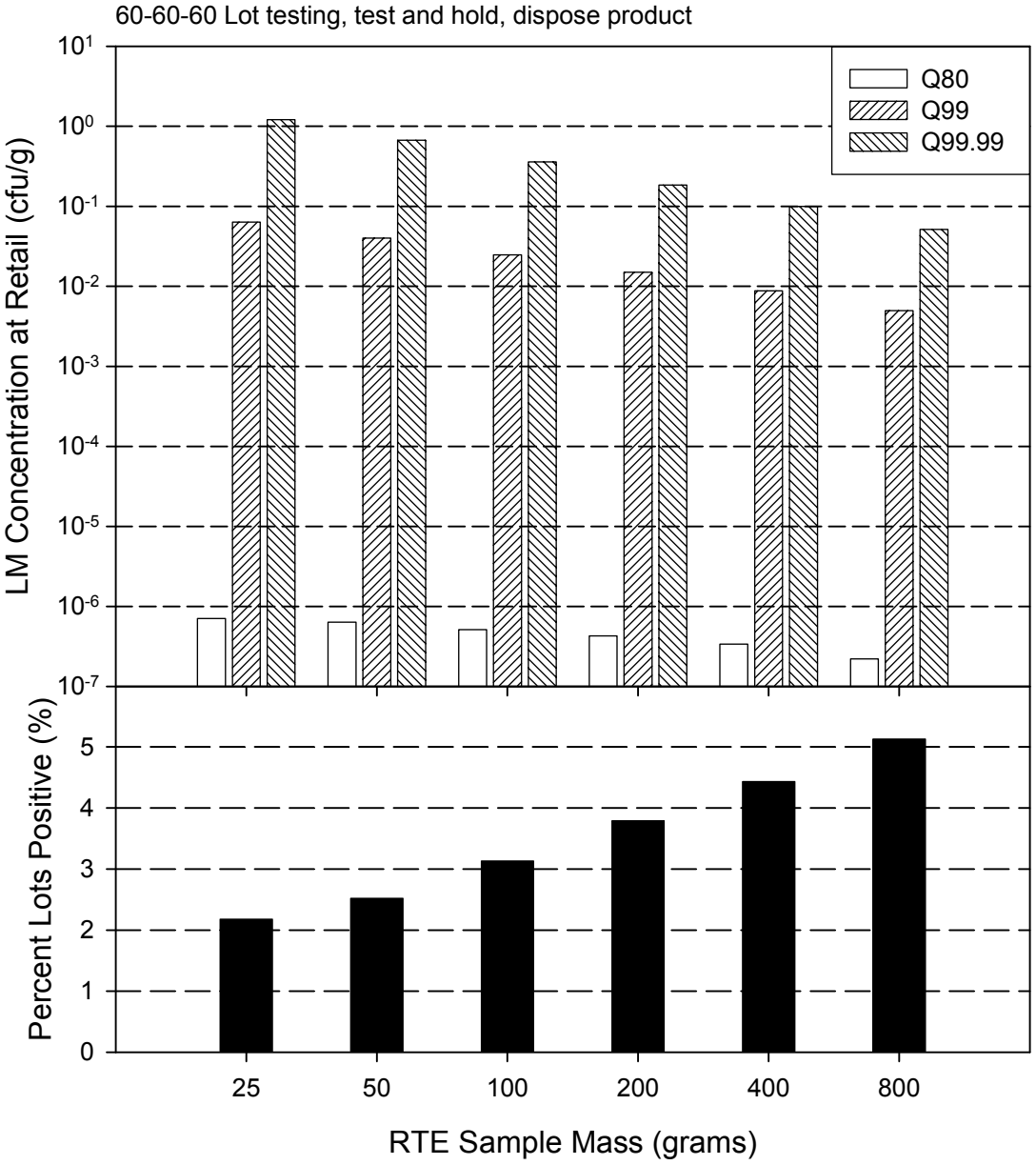



**Figure 24.** Sensitivity to RTE mass sampled.

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

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

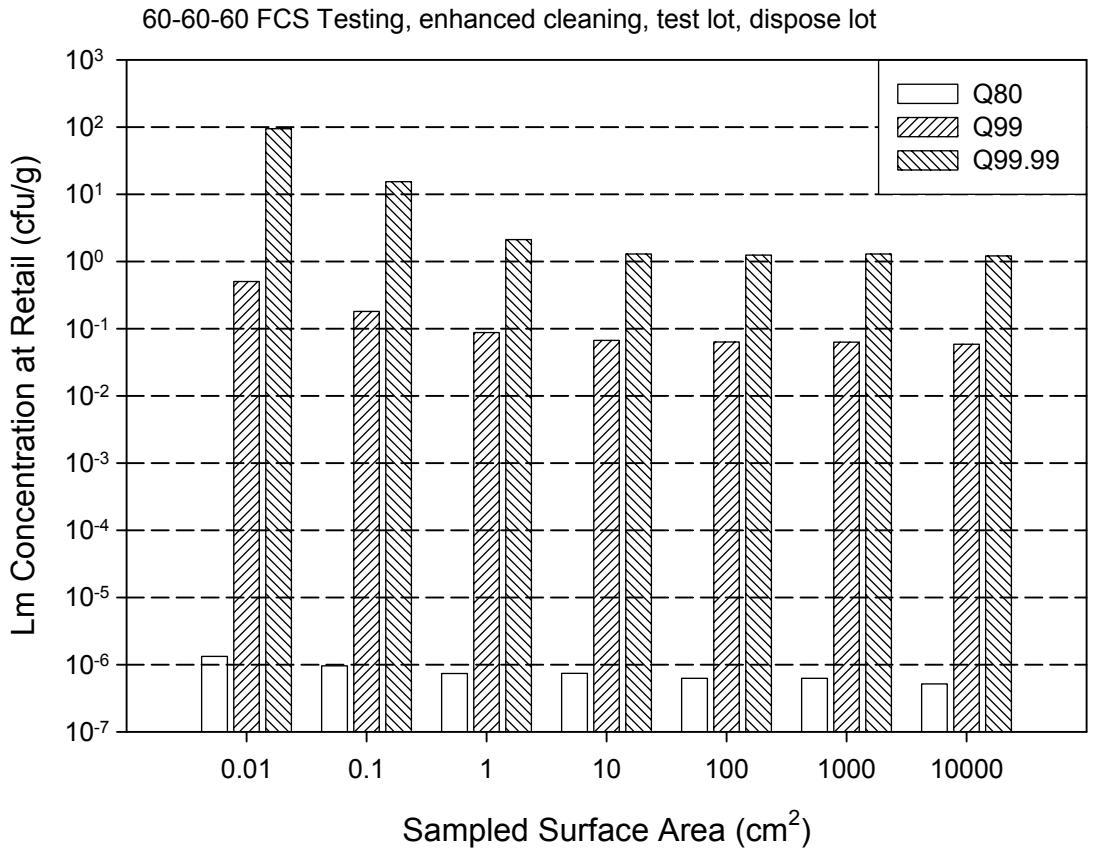



**Figure 25**. Retail *L. monocytogenes* concentrations in deli meats for different food contact surface area tested.

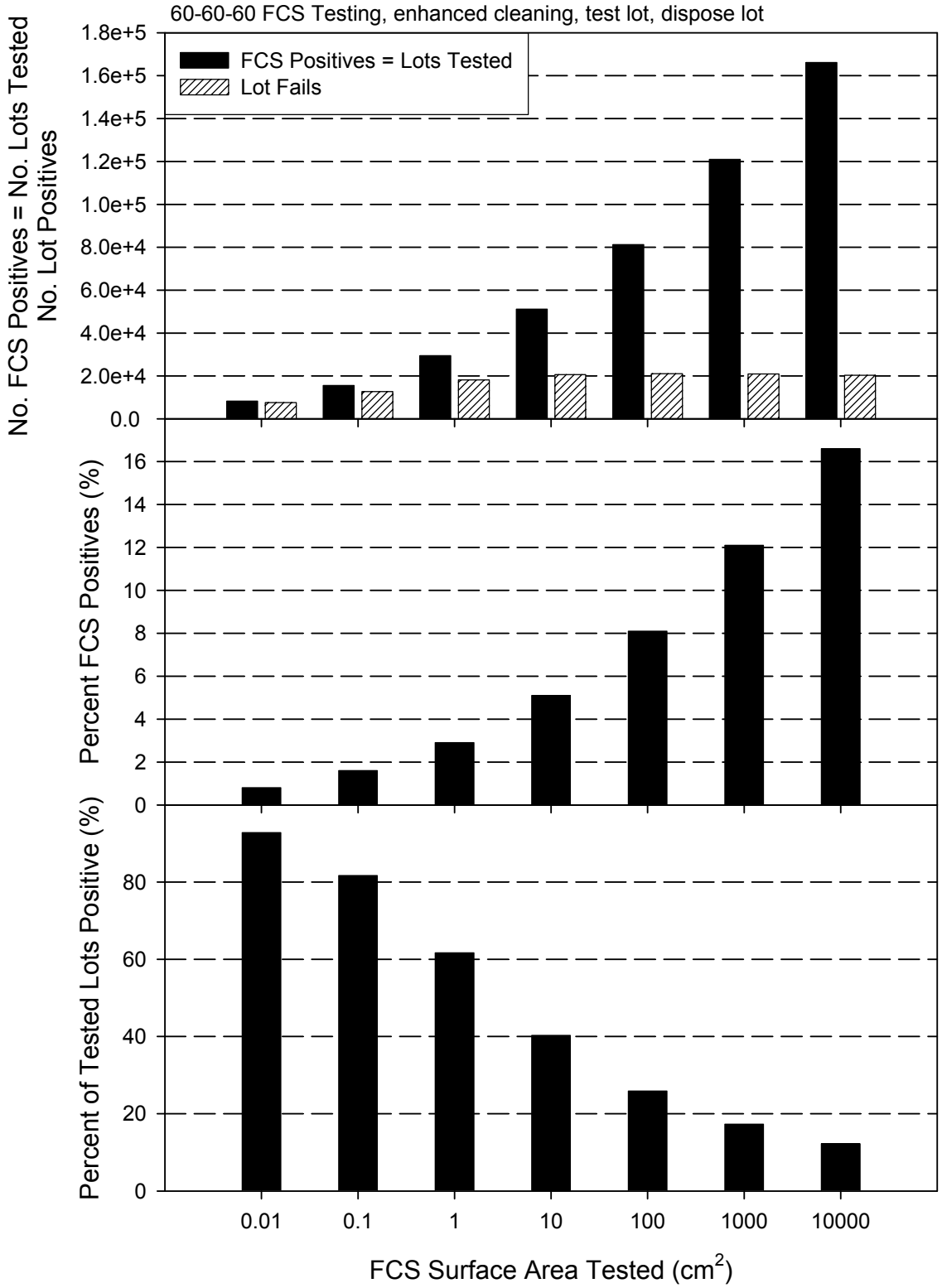



**Figure 26.** Sensitivity of positive RTE product lots and food contact surface area found to be positive based on the area of food contact surface tested.

### *L monocytogenes* to *Listeria* species ratio

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

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

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

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

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

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

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