Uncertainty versus Variability

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

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

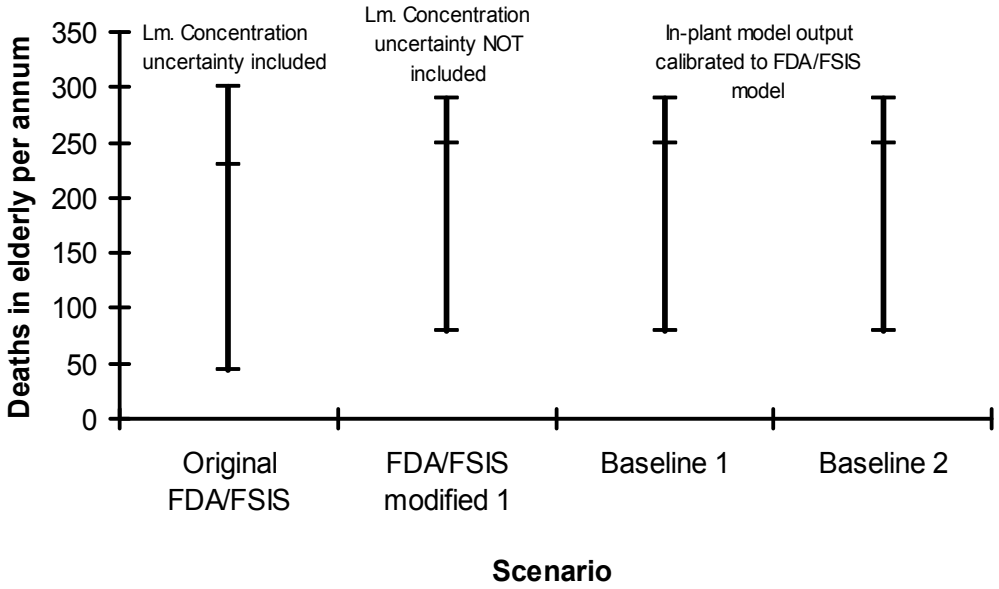

Figure 27. Per Annum Deaths Among the Elderly – A Comparison of FDA/FSIS Model Estimates with the FSIS *Listeria* Risk Assessment Baseline.

Model Validation

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

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

SUMMARY

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

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

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

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

Food Category Changes

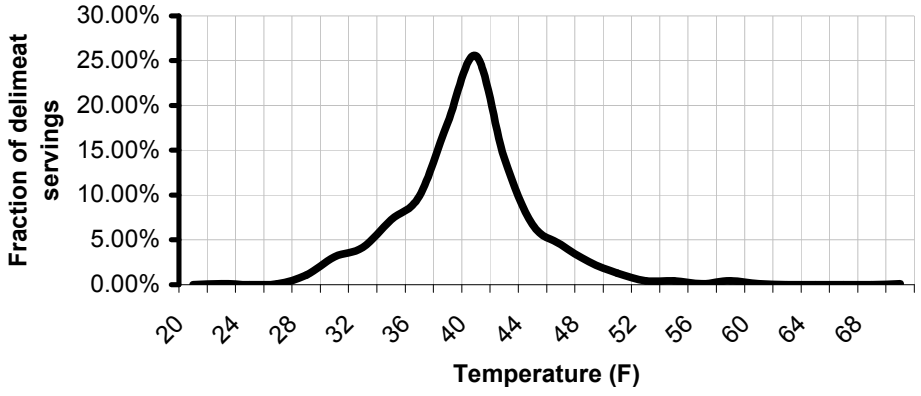
- Split frankfurters into two categories: not reheated and reheated.

Contamination Data Changes

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

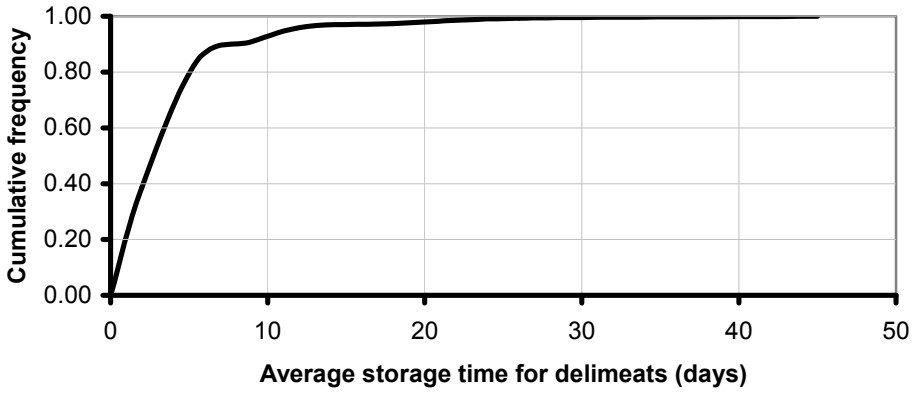
Growth Data Changes

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



Post-retail Storage Duration Changes

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



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

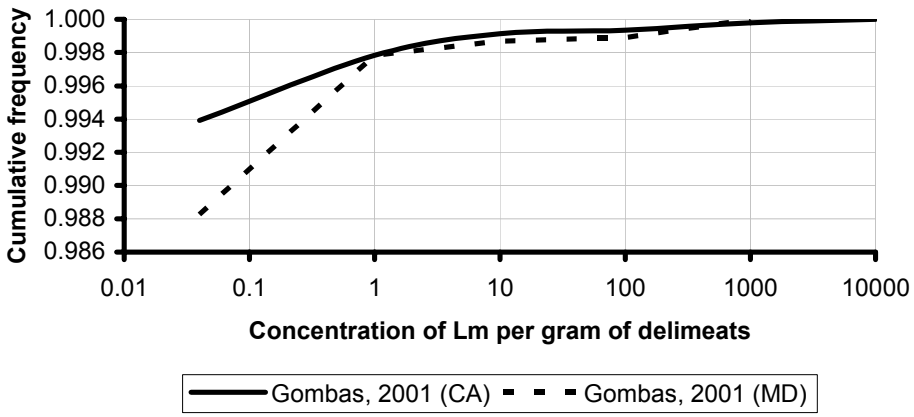
Changes to Modeling L. monocytogenes Levels in Food at Retail

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

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

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

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



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

  Prevalence data used for deli meats are summarized below.

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

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

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

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

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

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

Changes to Dose-response Modeling

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

General Model Change

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

Appendix B. Predicted growth between processing and retail

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

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

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

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

> The log concentration of *L. monocytogenes* at retail is the sum of the log concentration at processing and the log of growth.
>
> $$(1.1)\ \text{Retail}_{\text{Log(Lm per gram)}} = \text{Processing}_{\text{Log(Lm per gram)}} + \text{Growth}_{\text{Log(Growth multiplier)}}$$
>
> The retail concentration distribution is assumed in the FDA/FSIS risk ranking to be a lognormal. Therefore, the log of concentration is normally distributed. The logs of the processing and growth distributions are also assumed to be normal distributions for these examples. Consequently, the following equation results.
>
> $$(1.2)\ \text{Normal}_{\text{retail}}(\mu_1+\mu_2, \sqrt{\sigma^2{}_1+\sigma^2{}_2}) = \text{Normal}_{\text{process}}(\mu_1,\sigma_1) + \text{Normal}_{\text{growth}}(\mu_2,\sigma_2)$$
>
> The FDA/FSIS exposure assessment model for deli meats provides the parameters for the $\text{Normal}_{\text{retail}}$ distribution. The mean is approximately -8 and the standard deviation is about 3.5. Given these parameters, the parameters of the $\text{Normal}_{\text{process}}$ distribution are calculated for different cases of growth. These cases are defined by assuming different parameters for the $\text{Normal}_{\text{growth}}$ distribution.

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

Case 1

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

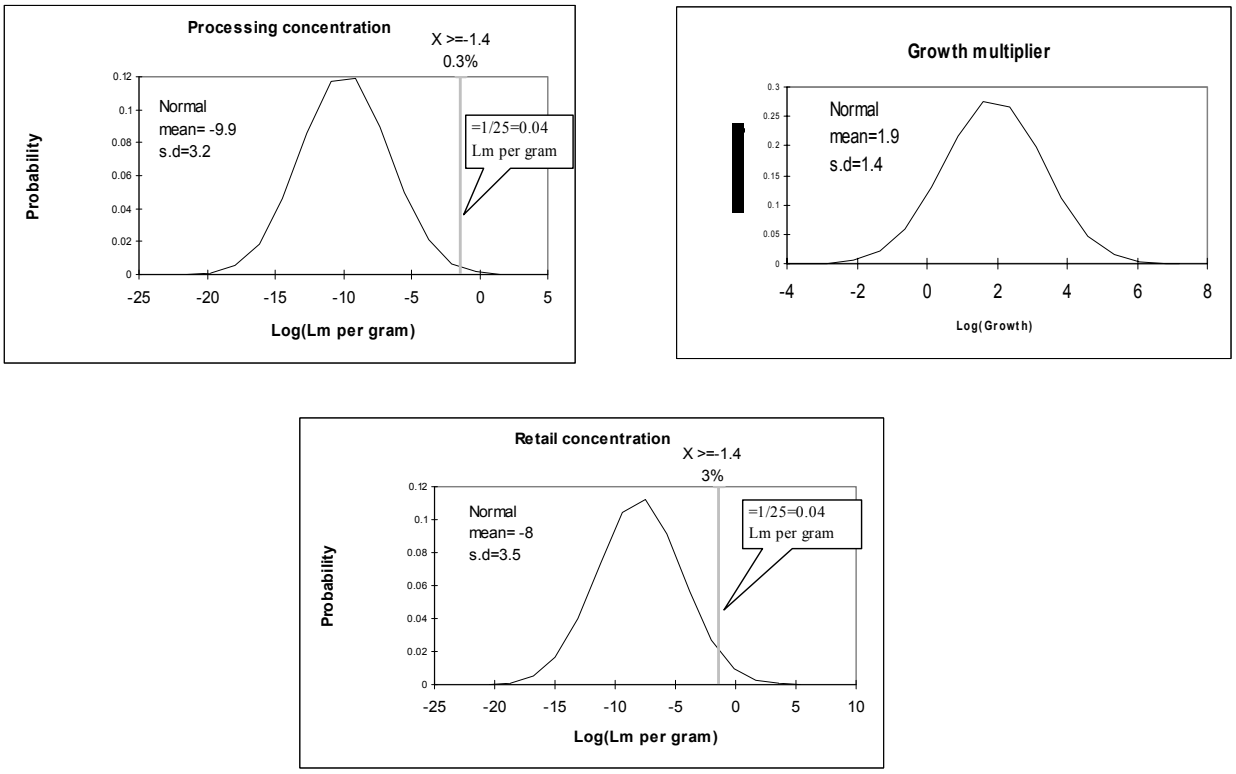


Figure A-1. Case 1 example where growth multiplier is assumed to be a normal distribution with a mean and standard deviation consistent with those predicted by the growth model in the 2001 FDA/FSIS exposure assessment model for deli meats.

Case 2

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

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

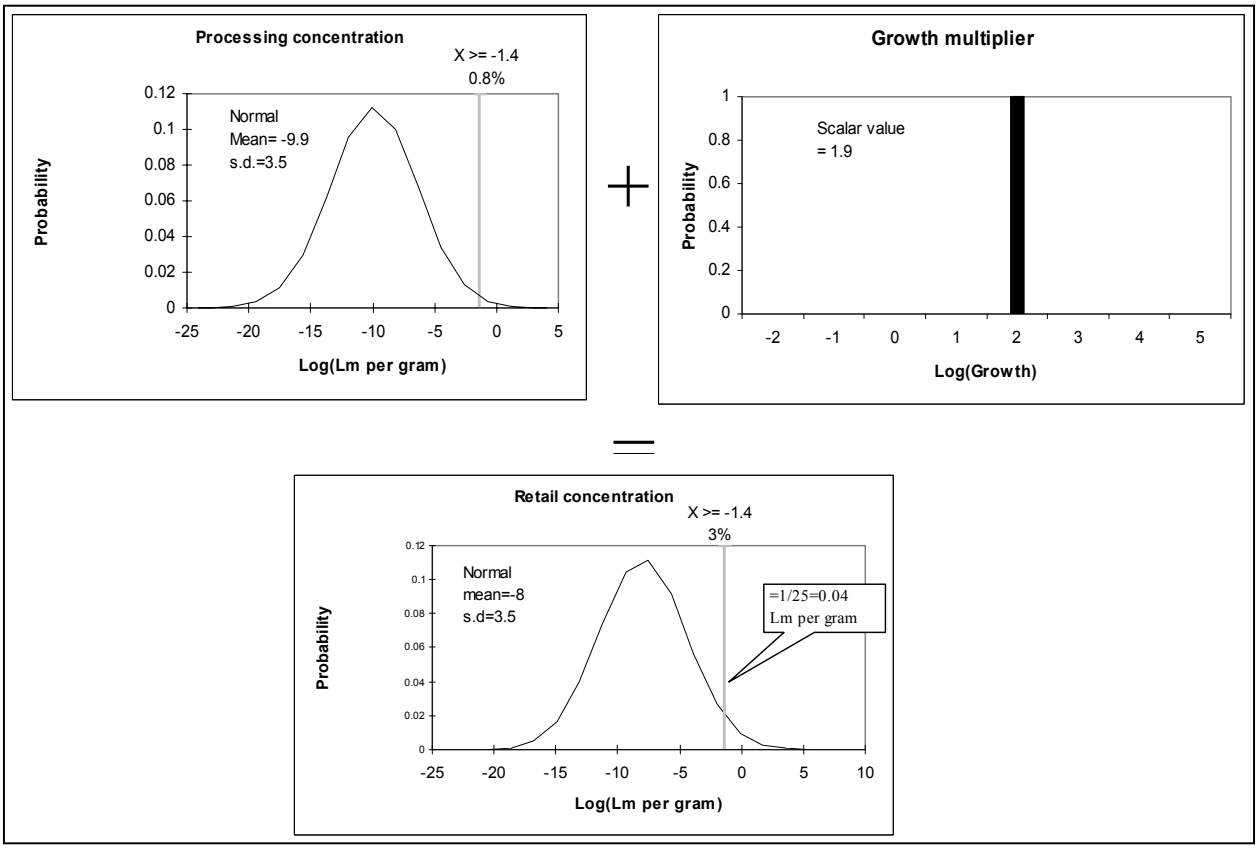


Figure A-2. Case 2 example where growth multiplier is a constant value of 1.9 logs. This is the assumption made when accounting for growth in the FDA/FSIS exposure assessment model for deli meats.

Case 3

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

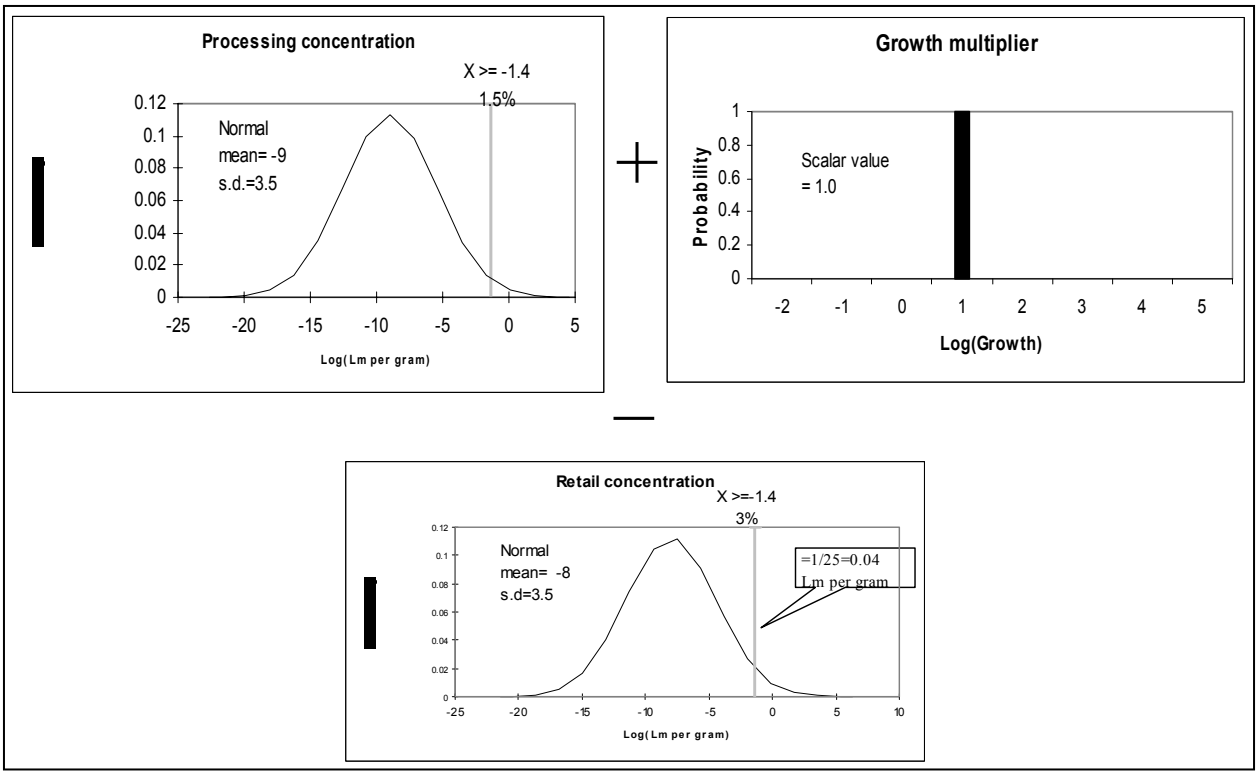


Figure A-3. Case 3 example where growth multiplier is a constant 1 log. This is the assumption used in the in-plant model.

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

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

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

Purpose

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

Data

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

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

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

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

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

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

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

PRODUCTION PER SHIFT

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

a. < or = 1,000 lbs

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

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

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

LINES PER SHIFT

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

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

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

SHIFTS PER WEEK

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

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

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

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

NUMBER OF WEEKS OF PRODUCTION

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

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

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

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

Methods

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

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

TOTAL ANNUAL PRODUCTION PER PROCESSING PLANT

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

Production per shift x Shifts per week x Weeks per year

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

CATEGORIZING LARGE, MEDIUM, AND SMALL VOLUME PROCESSING PLANTS

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

ESTIMATING PRODUCTION PER LINE PER SHIFT

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

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

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

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

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

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

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

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

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

Results

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

TOTAL ANNUAL PRODUCTION ACROSS ALL PLANTS

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

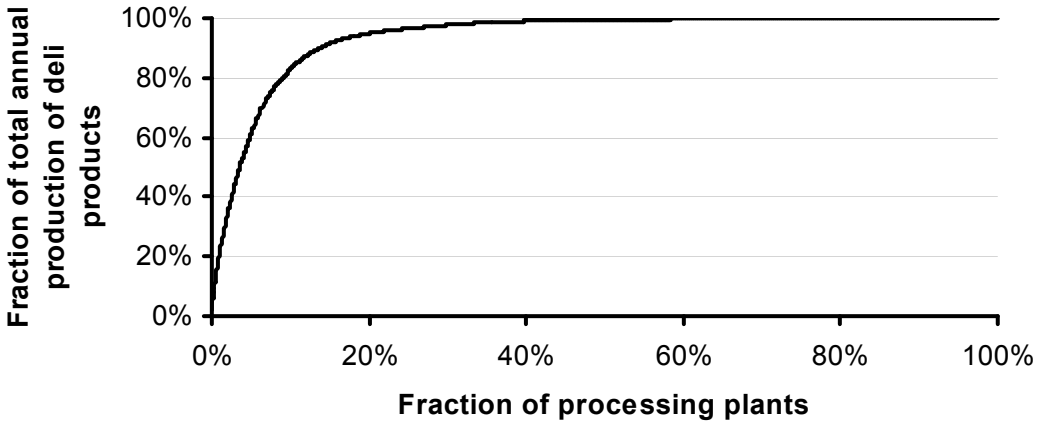


Figure C-1. Relationship between the fraction of processing plants and the cumulative total annual production of deli products by the processing plants.

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

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

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

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

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

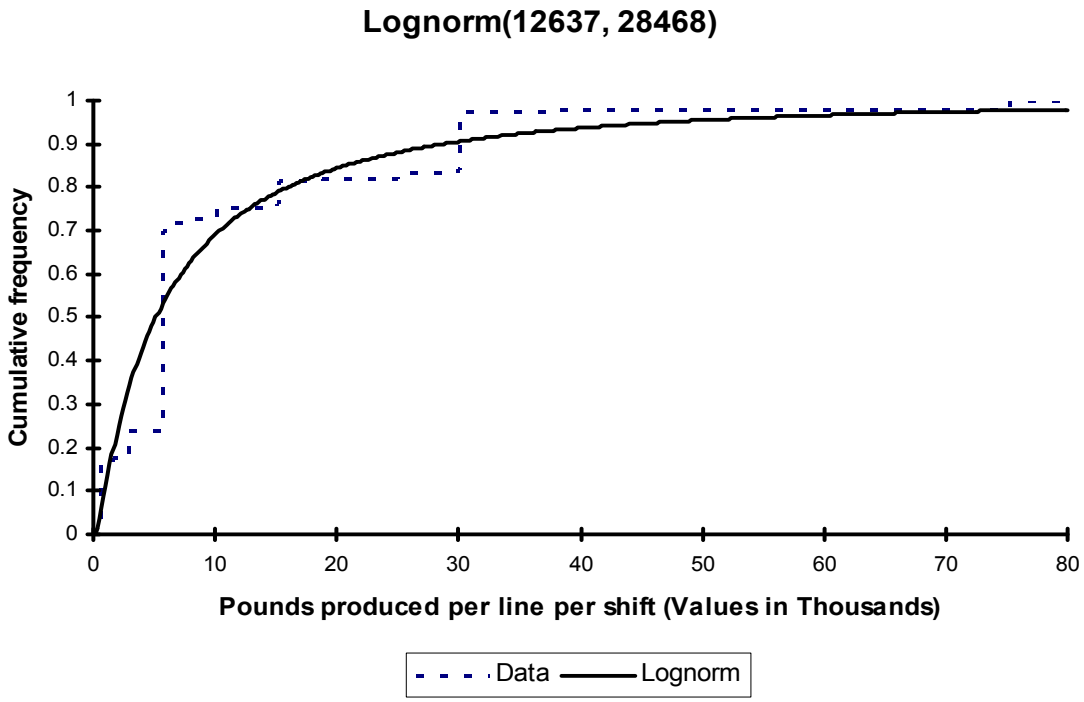


Figure C-2. Comparison of lognormal distribution to data on production per line per shift from large volume processing plants' production of deli product category 1.

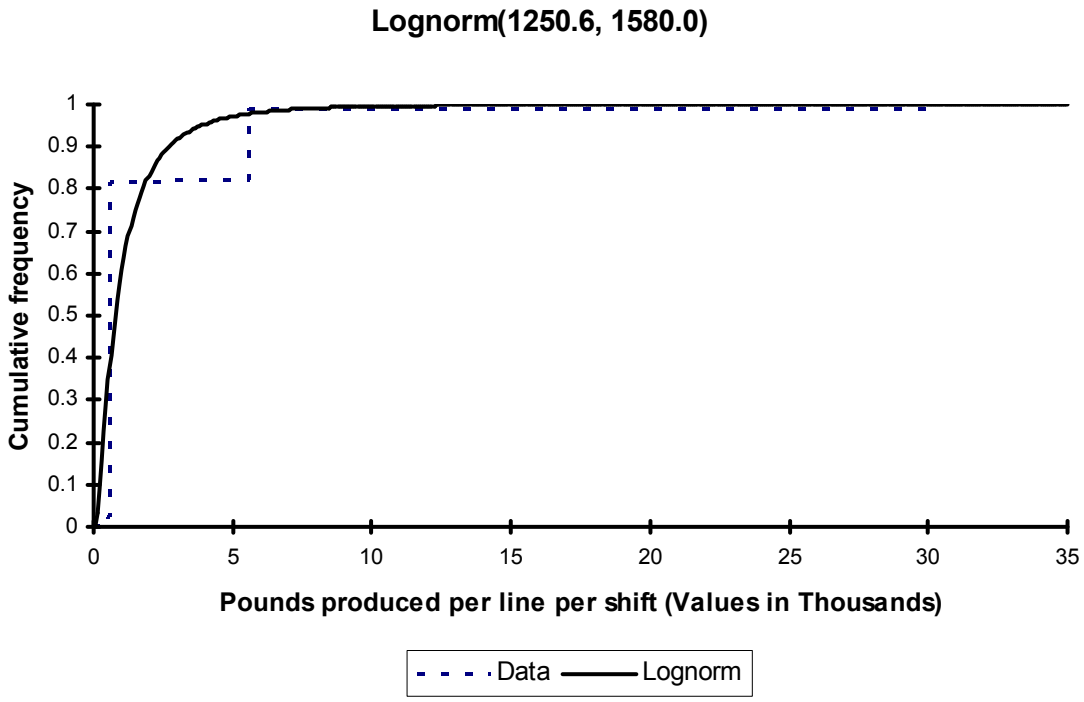


Figure C-3. Comparison of lognormal distribution to data on production per line per shift from medium volume processing plants' production of deli product category 1.

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

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

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

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

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

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

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

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

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

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

Conclusions

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

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

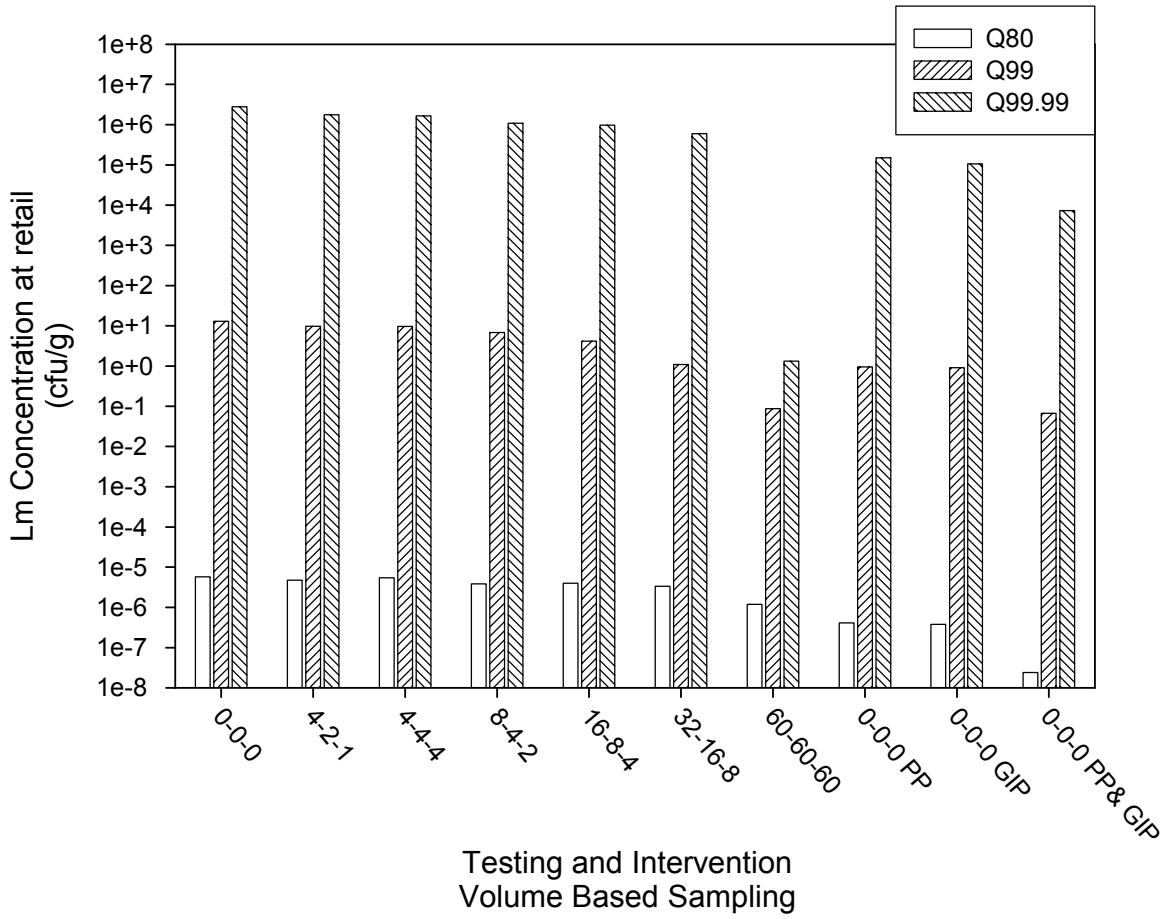
1) VOLUME BASED TESTING

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

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

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

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



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

Description of Lot Testing Based on Sequential Positive Food Contact Surface

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

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

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

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

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

Table D-1: Simple Consecutive Positive Example

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

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

Table D-2: Complex Consecutive Positive Example

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

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

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

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

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

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

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

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

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

CONCLUSIONS

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

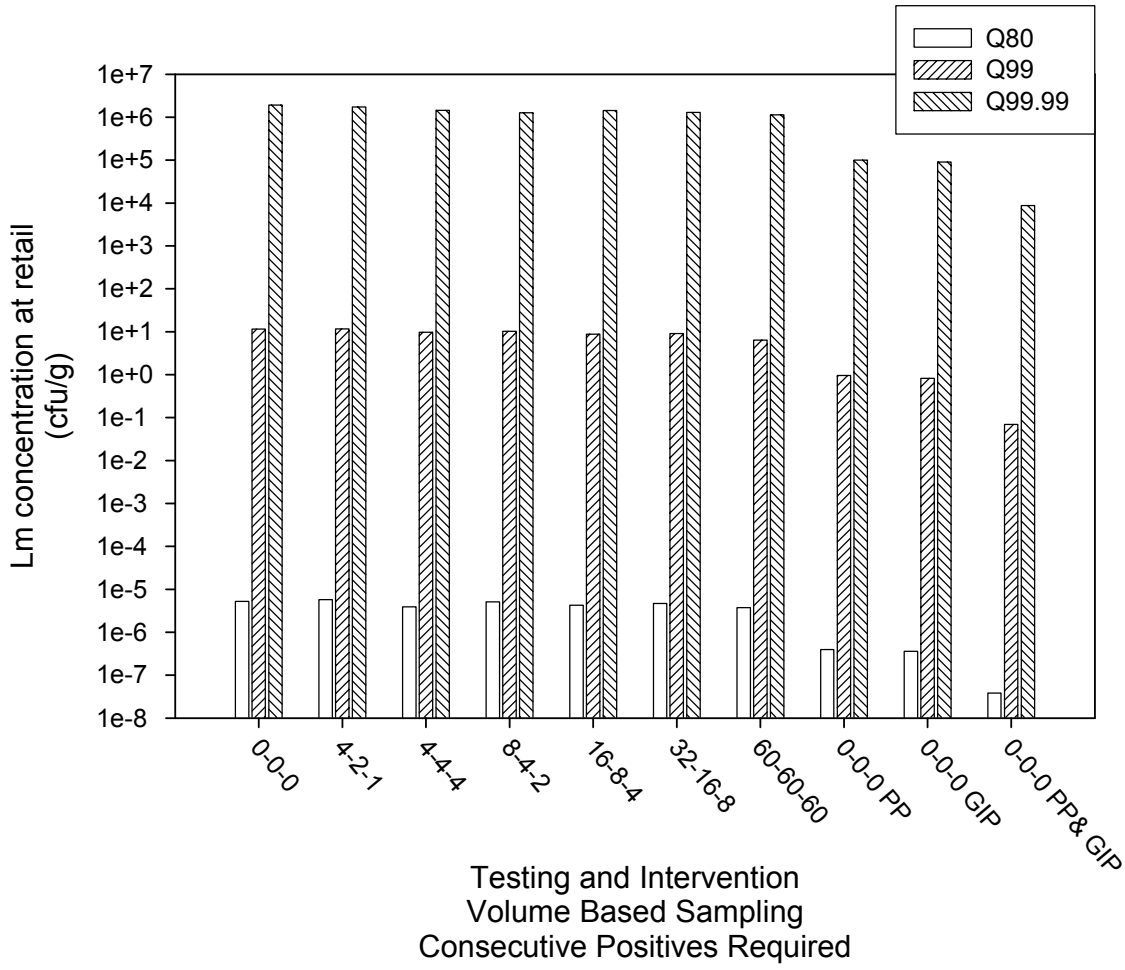


Figure D-2. Lm Concentrations at Retail Under Various FCS Sampling Frequencies When Consecutive FCS Samples are Required to Trigger a Product Test.

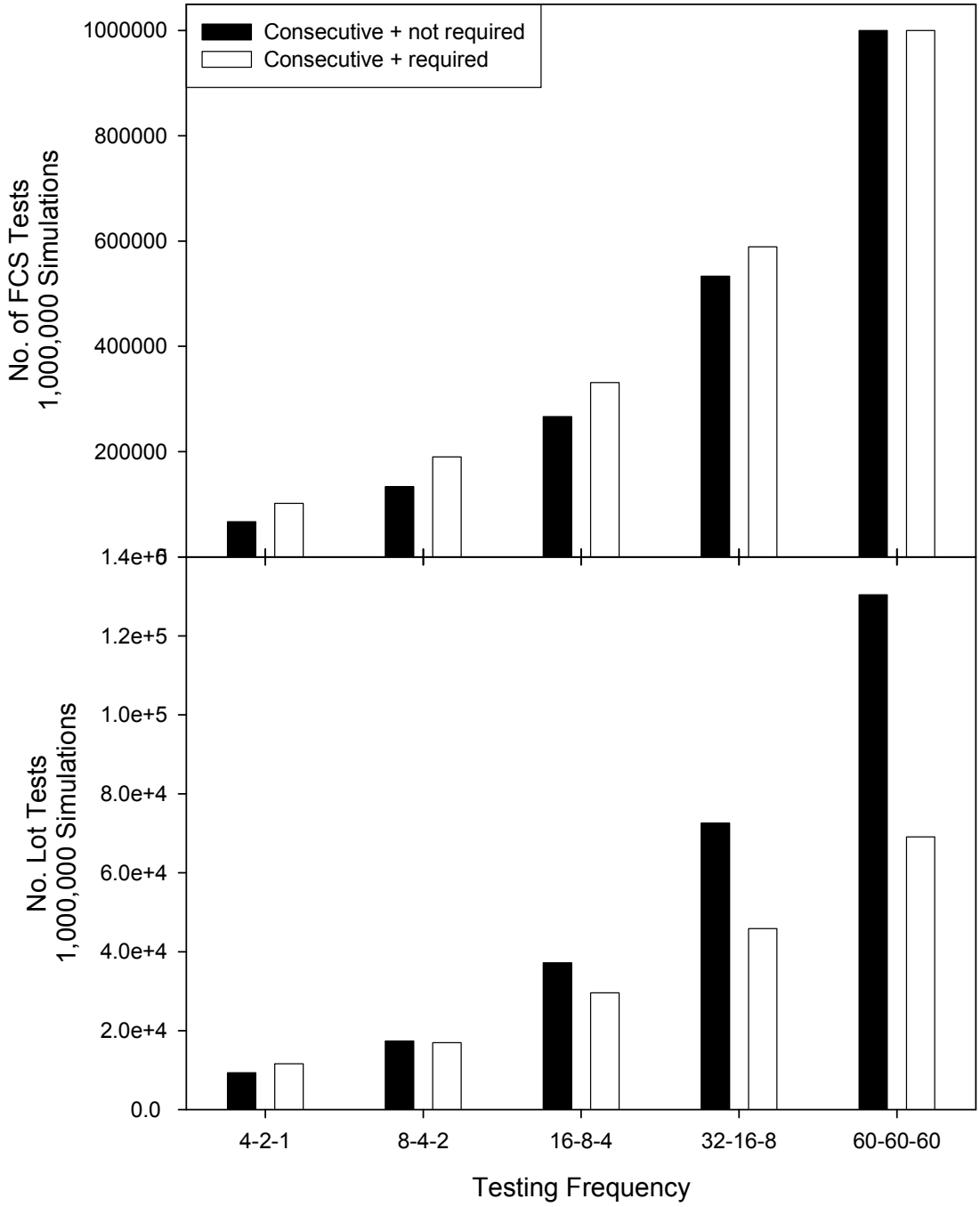


Figure D-3. Comparison of the number of FCS tests and product lot tests when consecutive positives are required and not required to trigger a product lot test.

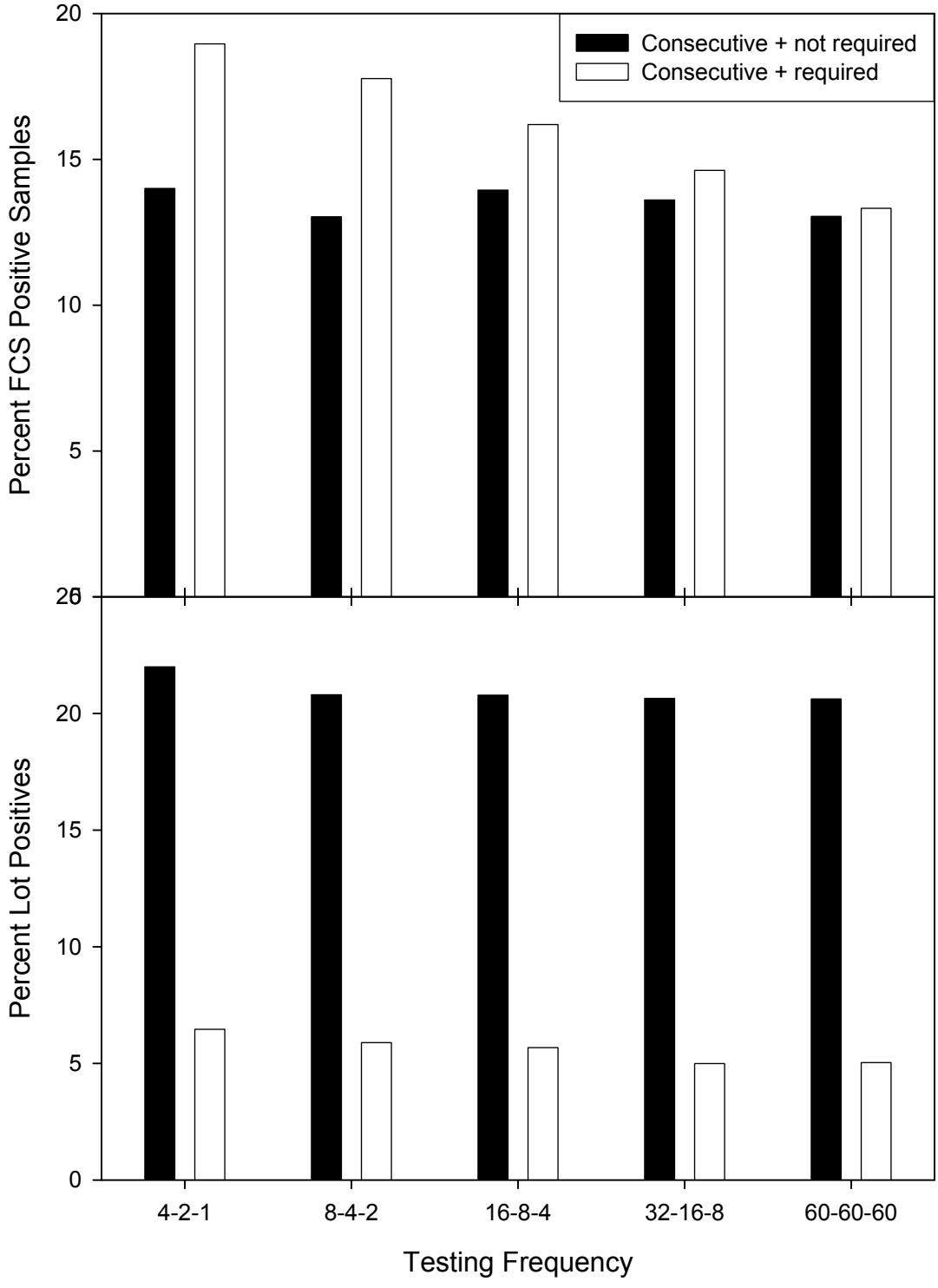


Figure D-4. Comparison of the efficiency of FCS and product lot sampling when consecutive positives are required and not required to trigger a product lot test.