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AMI

Review of FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats

Review of FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats

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Acronyms and Abbreviations

AMI	The American Meat Institute
FSIS	Food Safety and Inspection Services
LM	*Listeria monocytogenes*

1 Introduction

At the request of the American Meat Institute (AMI), Exponent conducted a review of the FSIS Risk Assessment for *Listeria monocytogenes* (LM) in Deli Meats. As described in the FSIS report,[1] the model is a dynamic in-plant Monte Carlo model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and LM in deli meats at retail.

The in-plant model incorporates several parameters, such as plant size, interval between contamination events, duration of contamination events, transfer coefficient, cleaning efficiency, contamination event levels, food contact surface testing, product testing, sanitation, pre- and post-packaging interventions, and the effect of growth inhibitors etc. and generates a distribution of concentrations of LM in deli meats at retail. Data from the literature or information provided by industry or expert opinion were used to estimate the parameters of the model, except for the number of LM transferred to food contact surface during each lot production. This parameter was estimated in the calibration of the base model. Specifically, the distribution used to represent the variable LM concentration (cfu/cm^2) added to the food contact surface (during a contamination event) was changed until the model provided a distribution of LM concentration that is similar to the distribution of LM at retail that was used in FDA's risk assessment. The following assumptions were made in the calibration of the FSIS in-plant model:

- All distributions for the model input variables (except for the LM added variable) were held constant, hence assumed as having been correctly parameterized.
- None of the plants have in place post-processing interventions, which can reduce the concentration of *L. monocytogenes* in the RTE lot or use growth inhibition product formulation and packaging.

[1] Gallagher, D.L., Ebel, E.D, and Kause, J.R. FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meats, May 2003.

In subsequent "what if" and "sensitive analyses," the distribution of LM concentration added that were derived from the calibration step was used. Conclusions based on these subsequent analyses could be misleading if any of the input variables were incorrectly parameterized. Thus, if some of the assumptions used in the base model were incorrect then the estimated distribution of LM concentration added to the food contact surface would be biased. The direction of bias would be dependent the direction of bias of the input variables. Further, if inaccurately calibrated, the LM concentration variable could have an impact on the results of subsequent assessments.

In the review of the FSIS in-plant model, Exponent conducted analyses aiming at:

1. Determining if the model works as described
2. Examining the impact of alternative model input assumptions on:
    a. Model calibration, and
    b. Intervention options and conclusions

2 Model/Algorithm Checks

Exponent checked the following model/algorithm:

1. Whether the model incorporates correlations between plant size, lot produced and FCS area, as stated in the report
2. Whether the mass balance approach indeed functions as described in the report
3. Whether the distribution of listeria contamination at retail used in the model is indeed similar to that summarized in FDA's assessment
4. What minimum number of runs is needed to stabilize estimates
5. Whether the distribution of added listeria contamination used by FSIS is the "best" distribution

Based on our examination, the following was found:

2.1 Correlations between plant size, lot produced and FCS area

The model assumes that 48% of all ready-to-eat deli meats and frankfurters are produced by "Large" plants, 48% by "Small" plants, and the remaining 4% by "Very small" plants. These three categories of plants are assumed to have different distributions of lot sizes (i.e., amounts produced per shift), and food contact surface area sizes. The model does not explicitly incorporate a correlation between plant size, lot produced and FCS area. However, the parameters of the uniform distribution used to represent the FCS area for "small" and medium" plants are proportionally smaller than those used for the large plants. The values used for the smaller plants are derived by multiplying the values used for large plants by the ratio of the mean values used for the distribution of lot sizes. Figure 1 illustrates the resulting distributions for the three size plants, while Figure 2 displays the distributions for very small plants. Figure 1 indicates that the parameters used to represent the distributions of lot size and FCS are correlated to the plant size, however, Figure 2 indicates that there is no correlation between lot size and FCS within plant size category, for instance the model assumes that it is possible to have plants with

FCS of about 23,000 cm^2 and 140,000 cm^2, respectively, produce lots of size 20,000 lbs and 2,000 lbs, respectively.

Figure 1: Distribution of food contact surface area and lot size for all plants

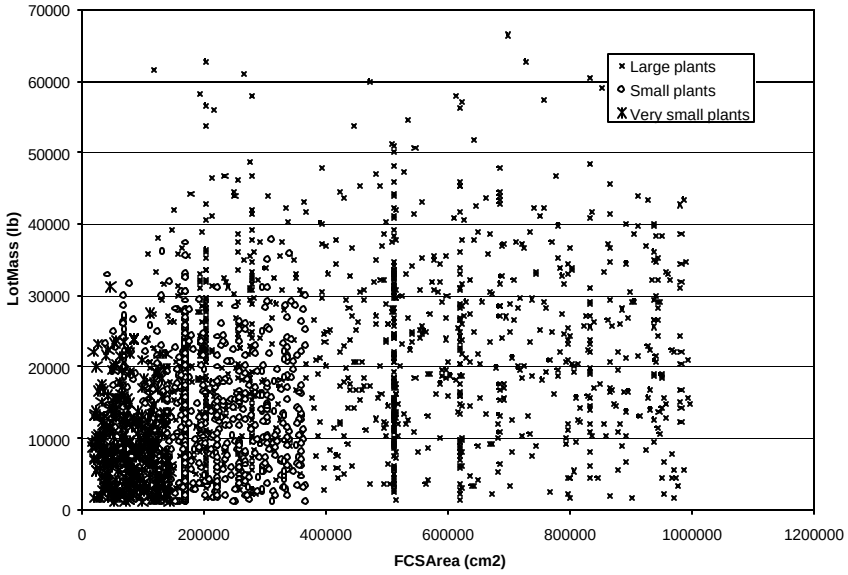
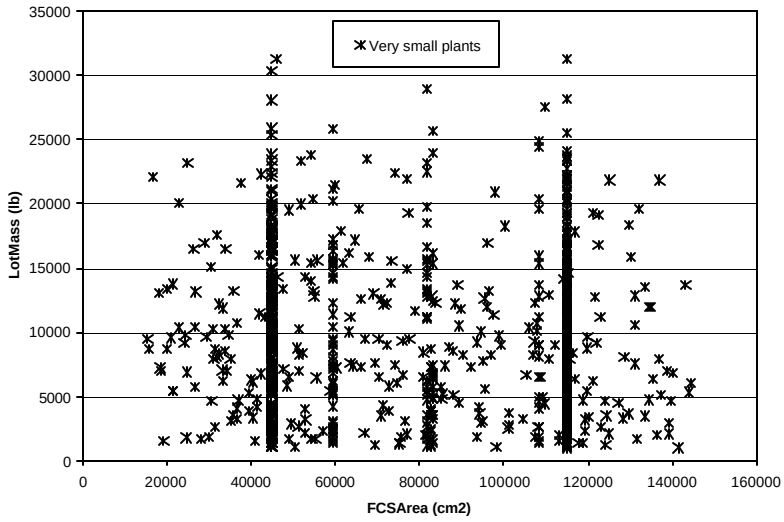


Figure 2: Distribution of food contact surface area and lot size for very small plants



2.2 The mass balance approach is correctly implemented in the model

Exponent ran the model and "dumped" the data from that run and independently verified that the total number of organisms can change due to growth of new organisms, die-off from sanitation, or transfer from external sources such as harborage sites. Specifically, the formulas presented for calculating the level of contamination at the end of a lot (page 18), for calculating the amount transferred to the product (page 19), and for adjusting for post processing interventions (page 20) and growth inhibition (page 21) appear to be correctly implemented in the program.

2.3 The distribution of *Listeria* contamination at retail used in the model is similar to that summarized in FDA's assessment

As mentioned above, the FSIS model generates a distribution of concentrations of LM in deli meats at retail. In the calibration of the base model, the updated FDA/FSIS exposure assessment for deli meats for LM in RTE products are used as calibration values for *Listeria* added during contamination event. Thus, it is important to confirm that the distribution used by the model accurately represents the data that were used in FDA's risk assessment.

In the case of deli meats, the FDA risk assessment used data from 61 studies conducted in the US as well as other countries. Data from the various studies were assigned different weights depending on when they were conducted and in which geographical region. Three hundred contamination curves were generated based on these data, each following a lognormal distribution.

In FSIS's model, a single set of parameters was estimated by calculating the average of the means and standard deviations of the 300 sets of parameters generated by FDA. Thus, a lognormal with mean: -8 and standard deviation of 3.5 was used by FSIS (page 75 of FSIS report).

Exponent used the data from the 61 studies and the same weighting scheme and estimation approach as that used by FDA/FSIS assessment to generate 300 contamination curves, and confirmed that these distributions were similar to those generated by FDA/FSIS. We then confirmed that the average mean and standard deviation for these 300 distributions were similar to the parameters assumed in FSIS model, and that the estimated percentiles used in the FSIS model do indeed come from a lognormal distribution using these parameters.

2.4 Minimum number of runs needed to stabilize estimates

The FSIS model uses Monte Carlo simulation to generate estimated distributions of listeria concentrations in deli meat products. The report states that results were based on runs of 1,000,000 lots, although early calibration runs were based on fewer lots.

The "log SSR" statistics, which is defined as:

$$\sum [\text{Log}_{10}\text{FDA}(i) - \text{Log}_{10}\ \text{Generated}(i)]^2 ,$$

where (i) indexes 8 upper percentiles (80^{th}, 85^{th}, 90^{th}, 95^{th}, 99^{th}, 99.5^{th}, 99.9^{th} and 99.99^{th}) is used by the FSIS model to compare the "fit" of FSIS simulated distribution of LM in deli meat at retail relative to the updated FDA/FSIS distribution of LM in deli meat at retail. Hence the Log SSR was used to confirm the number of iterations needed for the model to stabilize.

Exponent ran multiple sets of simulations of sizes 50000, 100000, 500000 and 1000000 iterations to assess the minimum number of runs needed to stabilize estimates and to confirm that the 1000000 iterations used by FSIS are sufficient. The results of these runs showed little changes in estimates derived from multiple simulations of size 500,000 each, indicating that the 1,000,000 iterations used by FSIS are indeed sufficient.

2.5 The distribution of added listeria contamination used by FSIS is not necessarily the "best" distribution

The Log SSR (as described above) was used to describe how well the distribution of LM concentration on deli meat at retail characterizes that based on the FDA/FSIS revised exposure assessment as the result of a given combination of mean and standard deviation for the LM added variable.

The FSIS calibration run resulted in final estimates of the LM species added to FCS with a mean on $\log_{10}$ scale of –6cfu/cm^2 and a standard deviation on the log scale of 3.5 cfu/cm^2, as having the best "fit." We conducted similar calibrations by holding all other model input variables at their base values and changing the mean and standard deviation of the added LM variable. We used the Log SSR to assess how well the fitted distribution of LM concentration compare to that based on the FDA/FSIS revised exposure assessment. The following log SSR's were obtained for runs using various combinations of mean and standard deviation values for the added LM parameter based on 500,000 iterations runs:

Table 1. Log SSR for various combinations of mean and standard deviation (on $\log_{10}$ scale) for the add LM variable, FSIS Base Values

Log SSR	CEAddStdDev								
CEAddMean	**2.5**	**2.7**	**2.9**	**3.1**	**3.3**	**3.5**	**3.7**	**3.9**	**4.1**
-8	118	93.4	75.4	59.7	41.7	31.4	22.3	15.9	11.8
-7.5	91.1	69.9	53.4	39.9	27	17.9	12.2	8.45	9.15
-7	64.7	47.8	34.6	24.2	16	9.03	4.46	4.48	8.05
-6.5	45.7	29.3	18.4	11.5	5.11	3.13	2.76	5.23	11.4
-6	29.5	17.7	8.81	4.08	1.26	**1.16**	5.21	11.3	20.3
-5.5	16	9.85	3.65	0.495	0.854	3.29	9.88	20.5	30.3
-5	8.74	3.05	0.621	0.79	4.45	9.02	20.6	27.5	44.3
-4.5	4.27	1.86	1.99	5.83	11.5	21	34.5	42.1	67.6

The FSIS final estimates of the LM species added to FCS is a lognormal distribution with a mean and standard deviation on $\log_{10}$ scale of –6 and 3.5 cfu/cm^2, has a log SSR of 1.16 in our runs (in FSIS's report, the log SSR value is 1.02). However, other combinations of mean and standard deviation (e.g., mean = -5.5 and SD = 3.1; mean = -5.5 and SD =

3.3; mean = -5.0 and SD = 2.9; and mean = -5.0 and SD=3.1) resulted in a smaller log SSR, and a better fit. As such, the FSIS calibrated values for the LM added to FCS are not necessarily the best estimates.

3 Alternative Model Input Assumptions

3.1 Impact on Model Calibration

The values for the mean and standard deviation of the number of LM species added to food contact surfaces (FCS) at the beginning of lot production are unknown. The FSIS model assumed that the distribution of this input variable is lognormal. In the calibration of the model, the mean and standard deviation of this input variable were changed until the resulting simulated distribution of LM in deli meat at retail were deemed sufficiently close to the updated FDA/FSIS exposure assessment values for the concentration of LM in deli meat at retail. All other model input variables were kept at their base values during the calibration. The FSIS final distribution estimate of the LM species added to FCS had a mean on $\log_{10}$ scale of –6cfu/cm^2 and a standard deviation on the log scale of 3.5 cfu/cm2.

The purpose of this assessment is to determine whether distribution of LM concentration added to the food contact surface developed based on the FSIS base is the "best" distribution. Based on limited "what if" assessments by changing the sanitation effectiveness parameter, and increase/decrease the number of iteration runs, the distribution of added *Listeria* contamination based on the FSIS base run does not appear to be the "best" baseline distribution. Further, in the calibration, no pre- or post-packaging processing is assumed. Thus, estimates of number of *Listeria* organisms added in the calibration model could be underestimated, if some of the plants use these practices.

To examine the validity of the distribution of added LM in the FSIS model, the reasonableness of various model input assumptions were evaluated and what-if assessments were carried out. Specifically, we re-calibrated the base model by replacing several FSIS model input assumptions with alternative distribution assumptions to examine the impact on the calibrated distribution of the added LM concentration. The

following sections describe the variables examined in these analyses and associated results.

3.1.1 Variables Examined

3.1.1.1 Distribution of Food Contact Surface (FCS) Area

The FSIS in-plant model assumes that 48% of all ready-to-eat deli meats and frankfurters are produced by "Large" plants, 48% by "Small" plants, and the remaining 4% by "Very small" plants. These three categories of plants are assumed to have different distributions of lot sizes (i.e., amounts produced per shift), and food contact surface area sizes. The food contact surface area is modeled as a uniform distribution ranging from 100,000 to 1,000,000 cm^2 (15,500 to 155,000 square inches) for large plants. For the other size plants, that range was modified proportionately to reflect the lower average amount produced per lot. Table 2 summarizes the distribution used for FCS area.

Table 2: Food contact surface area distribution (cm^2)

Plant size	Large plants	Small plants	Very small plants
Distribution	Uniform	Uniform	Uniform
Minimum	100,000	36,653	14,455
Maximum	1,000,000	366,527	144,546
Percentiles			
25	325,000	119,121	46,977
50	550,000	201,590	79,500
75	775,000	284,059	112,023
90	910,000	333,540	131,537
95	955,000	350,034	138,041
99	991,000	363,229	143,245

Discussion with AMI company members indicated that food contact surface areas can be much larger than the upper limit of the uniform distribution for a large plant that is used in the FSIS model. Industry information on type of surface and food contact areas for a typical large plant is summarized in Table 3.

Table 3. Industry Data on Food Contact Surface Areas for a Large Plant

Type of Surface	Contact Surface Area	Total FCS (cm^2)
Line 10 Fully Cooked Belts	**cm^2**	**3,250,200**
1-FUJI COOKER	1,210,836	
2-TRANSFER BETWEEN FUJI AND SPIRAL	4,168	
3-SPIRAL BELT	1,288,255	
4-INCLINE TO URSCHEL	49,548	
5-URSCHEL BELT	5,574	
6-FLIGHTED INFEED BELT	46,452	
7-FLIGHTED FREEZER BELTS	441,289	
8-FLIGHTED EXIT BELT	33,445	
9-BELT FEEDING BUCKETS	33,445	
10-BELT FEEDING TRIANGLE	61,935	
11-BELT FEEDING HOPPER	5,574	
12-HOPPER BELT	27,871	
13-BULK METAL DETECTOR BELT	41,806	
Line 20 Fully Cooked Belts		**1,383,017**
1-JSO EXIT CONVEYOR	29,729	
2-PRECHILL FREEZER	147,096	
3-URCSHEL INCLINE BELT	23,226	
4-URSCHEL BELT	66,890	
5-FLIGHTED FREEZER BELTS	441,289	
6-FLIGHTED EXIT BELT	16,723	
7- BUCKET ELEVATOR	23,226	
8-BELT FEEDING # 25 TRIANGLE	46,452	
9-BELT FEEDING REV. CONVEYOR	55,742	
10-REV. CONVEYOR TO #20 TRIANGLE	501,676	
11- HOPPER BELT	30,968	
Line 30 Fully Cooked Belts		**2,338,679**
1- JSO EXIT CONVEYOR	19,819	
2- SPIRAL FREEZER BELT	1,189,159	
3-SHUTTLE CONVEYOR EXIT OF SPIRAL	16,723	
4-BRIDGE CHOPPER BELT	18,581	
5-BRIDGE SLICER BELT	37,161	
6-BRIDGE SLICER EXIT BELT TO FLIGHTED	29,729	
7-URSCHEL INFEED CONVEYOR	5,574	
8-URSCHEL BELT	5,574	
9-FLIGHTED FREEZER BELTS	441,289	
10-FLIGHTED EXIT BELT	16,723	
11-LONG WIRE BELT INCLINE	74,322	
12-LONG INTRALOX INCLINE BELT	74,322	
13-CROSS CONVEYOR TO BULK DECLINE	200,671	
14-BULK DECLINE BELT	74,322	
15-BULK METAL DETECTOR	11,148	
16-REV. CONVEYOR FOR TRIANGLES	33,445	
17-INFEED CONVEYOR TO #30 TRIANGLE	33,445	
18-INFEED CONVEYOR TO # 35 TRIANGLE	33,445	
19- BUCKET ELEVATOR	23,226	

Data provided by industry for the surface contact area in 2 smaller plants ranged from about 39,000 to 322,500 cm^2 per line, and thus are similar to those assumed in the FSIS model for the smaller plants.

Based on the surface contact area data provided by industry for large plants, a more reasonable assumption for the food contact surface area than what is currently used in the FSIS model would be a uniform distribution ranging from 100,000 to 3,500,000 cm^2 for large plants. As described above (section 2), the FSIS model assumes that the parameters defining the FCS area distribution for small and very small plants, are proportionately smaller than those used to define the distribution for large plants. Using the modified food contact surface area for large plants results in a uniform distribution ranging from 36,653 to 1,282,845 cm^2 for small plants and 14,455 to 505,911 cm^2 for very small plants. Table 4 compares the FCS area distributions used by FSIS to those derived based on industry data.

Table 4: FCS area distributions used by FSIS v. derived from industry data

	Large plants		Small plants		Very small plants	
Plant size	**FSIS**	**Industry Data**	**FSIS**	**Industry Data**	**FSIS**	**Industry Data**
Distribution	Uniform	Uniform	Uniform	Uniform	Uniform	Uniform
Minimum	100,000	100,000	36,653	36,653	14,455	14,455
Maximum	1,000,000	3,500,000	366,527	1,282,845	144,546	505,911
Resulting Distribution						
Mean	550,000	1,800,000	201,590	659,749	79,500	260,183
25th	325,000	950,000	119,121	348,201	46,977	137,319
50th	550,000	1,800,000	201,590	659,749	79,500	260,183
75th	775,000	2,650,000	284,059	971,297	112,023	383,047
80th	820,000	2,820,000	300,552	1,033,607	118,528	407,620
90th	910,000	3,160,000	333,540	1,158,226	131,537	456,765
95th	955,000	3,330,000	350,034	1,220,536	138,041	481,338
99th	991,000	3,466,000	363,229	1,270,384	143,245	500,996

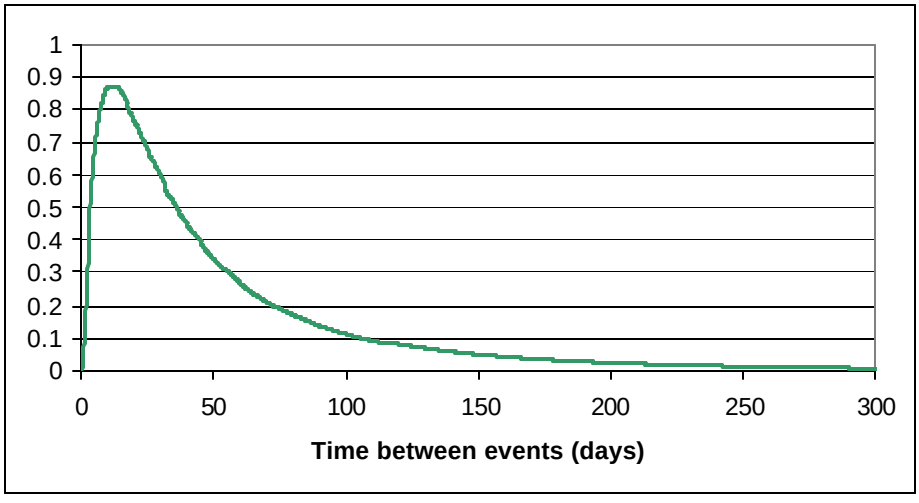
3.1.1.2 Distributions of interval between contamination events

Data on the interval between contaminations events used in the FSIS model come from a plant associated with an outbreak and not representative of other plants (p23-24). Thus, intervals between events may be underestimated. A potential impact of this bias is that number of *Listeria* organisms added during a contamination event may be underestimated in the calibration model. The current FSIS assumption for this variable is summarized in Table 5 and Figure 3

Table 5: Time between events (days)

Log_{10} Normal Distribution	
Mean	1.08
Standard deviation	0.46
Percentiles	days
25	6
50	12
75	24
90	46
95	67
99	138

Figure 3: Time between events (days)



Industry data of surface contamination event reported for the period of 7/7/2004 and 6/3/2005 were made available to Exponent (see Appendix A). In analyzing this dataset,

a plant/line was assumed to be contamination free during the sampling period if it had no reporting event. Similarly, it is assumed that no contamination occurred the latest reported event and 6/3/2005. It is also assumed that no contamination occurred between the beginning of the reporting period (7/7/2004) and the earliest reported date. The following three options were considered in estimating the distribution of time between contamination events:

1. Use all intervals that ended up with a contamination (i.e. intervals that correspond to a failure)
2. Use all the "data" (i.e., assume that the censored intervals were actually not censored), or
3. Use all non-censored (left or right) data (i.e., do not make any assumptions about starting and ended dates, and only use the intervals between reported events).

The FSIS model requires a $\log_{10}$ normal distribution be used for this variable, however, for all 3 options, the $\log_{10}$ normal distribution did not provide a good fit, and tended to underestimate the time between events (i.e., the modeled percentiles tended to be lower than the ones derived from the data). The resulting parameter estimates for all three options, assuming the $\log_{10}$ normal distribution are summarized below:

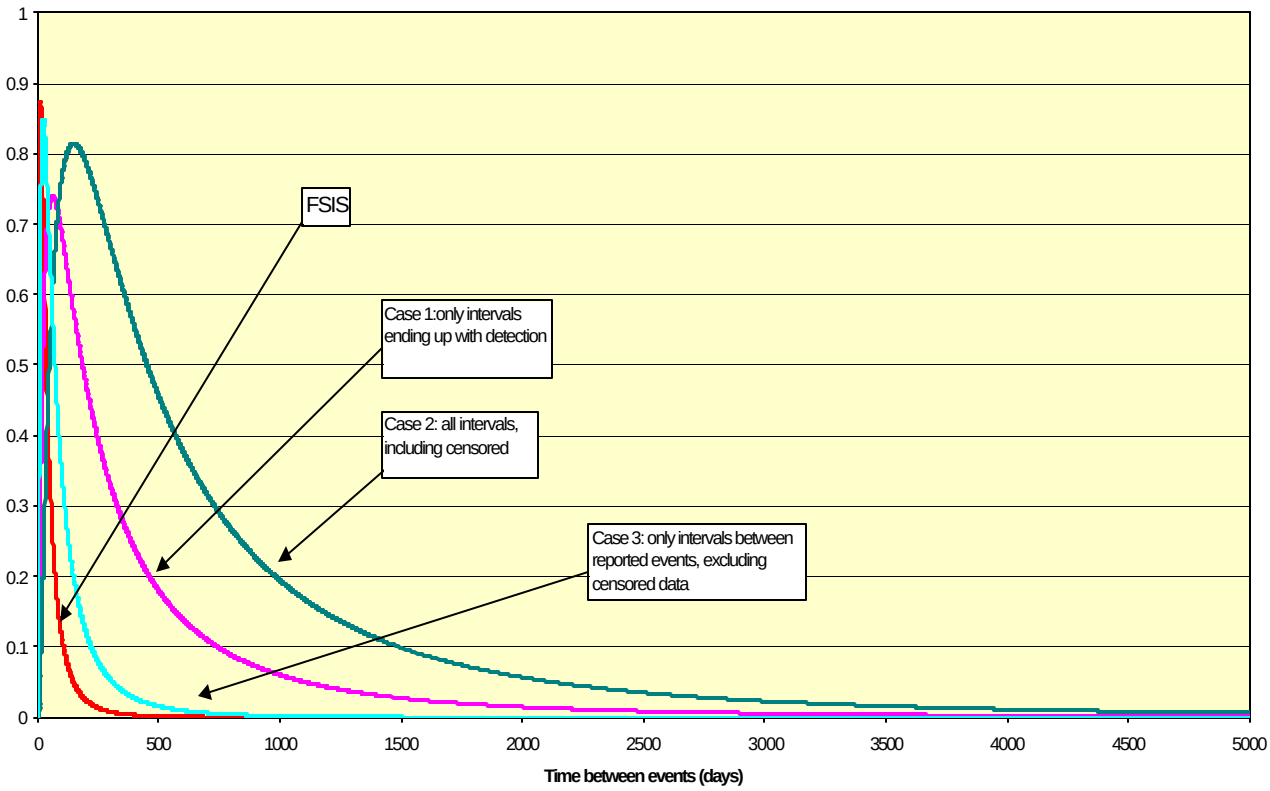
- Option 1 -- only intervals ending up with detection: mean = 1.79, sd = 0.54.
- Option 2 -- all intervals, including censored: mean = 2.17, sd = 0.49.
- Option 3 -- only intervals between reported events, so no left or right censored data: mean = 1.37, sd = 0.47

The percentile estimates of the number of days between contamination events based on FSIS assumption were consistently below the estimates based on the three distributions that were derived from industry reported data, with Option 3 distribution being the closest to FSIS estimates. These comparisons are provided in Table 6 and Figure 4.

Table 6: Days between contamination events – a comparison of FSIS assumption and industry reported data

Percentile	FSIS mean=1.08, sd=0.46	Case 1 mean=1.79, sd=0.54	Case 2 mean=2.17, sd =0.49	Case 3 mean=1.37, sd=0.47
0.1	3	13	35	6
0.2	5	22	57	9
0.3	7	32	82	13
0.4	9	45	111	18
0.5	12	62	148	23
0.6	16	84	197	31
0.7	21	118	267	41
0.8	29	176	382	58
0.9	46	303	628	94
0.95	67	477	946	139
0.99	138	1112	2041	291

Figure 4: Days between contamination events – a comparison of FSIS assumption and industry reported data



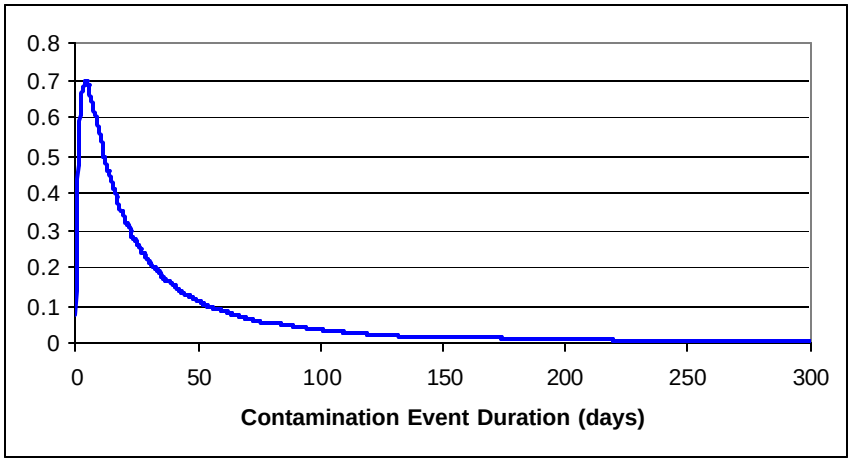
3.1.1.3 Distribution of Duration of a Contamination Event

The distribution for the duration of a contamination event variable in the FSIS base model was based on Tompkin's 2002 data. The current FSIS assumption for this variable is summarized in Table 7 and Figure 5.

Table 7: Duration of a contamination event (days)

Log_{10} normal Distribution	
Mean	0.60
Standard deviation	0.57
Percentiles	days
25	2
50	4
75	10
90	22
95	35
99	86

Figure 5: Duration of a contamination event (days)



According to industry information, data from Tompkin (2002) were based on small plants and possibly not applicable to conditions at large plants. Also, there have been many operational changes since the study was conducted such that the duration of a contamination event would not be allowed to last over 10-15 days (above the 90th

percentile estimate, see table 7). To reflect a more realistic duration of a contamination event, and for purpose of "what if" analyses, the standard deviation was reduced by 20% (Log10 normal, Mean = 0.602 and Standard Deviation = 0.458.)

3.1.1.4 Distribution of transfer coefficients

The transfer of *Listeria* species from food contact surface to RTE product is described as transfer coefficients. FSIS used a "truncated" lognormal distribution for transfer coefficient. The model assumes a lognormal distribution (-0.14, 1) with the mean value based on Midelet and Carpentier (2002) data but the standard deviation based on two other articles (Montville et al, 2001 and Chen et al, 2001) that examined the transfer of *Listeria spp.* from hands and spigots to chicken and lettuce. Table 8 summarizes the distribution used by FSIS.

Table 8: FSIS Transfer Coefficients

Distribution	Lognormal values >1, set at 1
Mean	-0.14
Standard deviation	1
Percentiles	
25	15%
50	72%
75	100%
90	100%
95	100%
99	100%

However, Chen et al (2001) found that mean transfer rates differ from one pair of surfaces to another and the standard deviation associated with the means also differ considerably between different surfaces. The differences between the surfaces involved in the studies and those assumed in the FSIS in-plant model thus suggest that alternative and more appropriate values/distribution should be considered. A technical presentation at the IAFP 2003 conference by Vorst, Todd, and Ryser of Michigan State University provided additional data on the contamination of commercial slicers by *Listeria.*[2] In this

[2] Silliker's Summary of the IAFP 2003 technical presentation by Vorst, Todd, and Ryser of Michigan State University

study retail blocks of Cheddar cheese (36.1% moisture, 25.5% fat) and smoked turkey breast (99% fat free) were inoculated (~10^6 CFU/cm^2) with L. monocytogenes Scott A and a 6-strain cocktail containing weak, medium, and strong biofilm formers. The inoculated product (3 replicates) was sliced (5 slices/replicate) at 4-7C on a modified commercial delicatessen slicer while applying 2 and 10 lbs of force. Five product contact areas on the slicer were identified based on Glo-Germ ®: the table, back plate, metal guard, blade, and product collection area. Using an application force of 2 lbs on turkey breast, greatest transfer was found on the metal guard (~10^3 CFU/cm^2) and blade (~10^2 CFU/cm^2) with *Listeria* transfer 10-fold higher using an application force of 10 lbs. Unlike turkey breast, Cheddar cheese transfer levels were highest on the collection area (10^2 CFU/cm^2 and blade (~10^3 CFU/cm^2) with the table yielding little or no transfer. A summary of the Transfer Coefficients that can be derived from this study is summarized in Table 9. Given the type of surfaces tested in this study and the Midlet and Carpenter (2002) study, pooled TC data from these two studies would be appropriate for use in characterizing the lognormal distribution of Transfer Coefficient. The parameter estimates for the $\log_{10}$ normal distribution of TC based on these two studies as compared with FSIS estimates are provided in Table 10.

Table 9: Transfer Coefficient by types of Food and Surface Areas

Study	Food	Surface	%TC
Vorst et al (2005)	Cheese	Table*	0.000001
	Smoked Turkey Breast	Table*	0.000001
	Cheese	Blade	0.001
	Smoked Turkey Breast	Metal guard	0.001
	Cheese	Collect area	0.0001
	Smoked Turkey Breast	Blade	0.0001
Midelet & Carpentier (2002)	Meat exudates	Stainless steel	1
		PU	0.45
		PVC	0.71

* No transfer was observed to table,. We used 0.00001 for modeling purposes.

Table 10: Comparison of revised distribution of TC and FSIS assumption

	Pooled Data From Vorst et al (2003) & Midelet & Carpentier (2002)	FSIS Assumption
Log_{10} Normal Distribution	Mean = -2.94, sd = 2.35	Mean = -0,14, sd = 1
Percentiles		
5%	0	0.02
10%	0.000001	0.04
15%	0.000004	0.07
20%	0.000012	0.11
25%	0.000029	0.17
30%	0.000072	0.23
35%	0.000138	0.32
40%	0.000297	0.43
45%	0.000698	0.57
50%	0.001252	0.73
55%	0.002146	0.95
60%	0.004073	1.00
65%	0.009598	1.00
70%	0.019223	1.00
75%	0.051072	1.00
80%	0.124854	1.00
85%	0.303350	1.00
90%	1.00	1.00
95%	1.00	1.00
100%	1.00	1.00

3.1.2 Findings

3.1.2.1 Calibration with Alternative Time Between Contamination Events

The model was run with the three alternative distributions for the interval between events parameters described above (Section 3.1.1.2) and a series of alternative listeria added distributions, while keeping all other parameters as in FSIS bases model. However, irrespective of what listeria added distribution used, distributions derived under Options 1 and 2 did not result in a distribution of listeria levels in retail deli meats that was similar to that based on the data summarized in FDA/FSIS report. Thus, if the lognormal distributions that were used for time between contamination events are good

representations of the distribution of actual time between events, one or more of the other assumptions and distributions used by the model are not adequate representations of what really occurs in processing plants.

The distribution derived under Option 3 yielded estimates of days between contamination events that were the closest to those estimated by FSIS, and thus was used in the re-calibration. All other model input variables were similar to those used in FSIS base runs. Table 11 is a summary of the log SSR given a combination of mean and standard deviation for the LM added variable. When using estimates of time between contamination events based on industry reported data rather than the FSIS base value for this variable, the FSIS final estimates of the mean and standard deviation for the LM added variable (in its calibration run) do not result in simulated distribution of LM in deli meat at retail that are "close" to those estimated in the revised FDA/FSIS exposure assessment (the log SSR = 30.9 when mean = -6.0 and SD = 3.5, see Table 11).

Table 11: Log SSR for various combinations of mean and standard deviation (on $\log_{10}$ scale) for the add LM variable, alternative time between contamination events

Mean	Standard Deviation								
	2.5	***2.7***	***2.9***	***3.1***	***3.3***	***3.5***	***3.7***	***3.9***	***4.1***
-6	82.6	58.9	50.1	35	38.7	30.9	42.1	35.9	32.9
-5.5	49.7	34.2	26.9	43.1	23.4	22.2	24.5	34.5	45.9
-5	27.4	30.3	15	15.3	16.9	32.6	23.3	38.1	37.1
-4.5	28.2	15.6	6.33	10.4	17	16.3	18.1	44.4	46.9
-4	9.67	6.77	6.98	12	10.6	18.4	27.1	43.4	56.8
-3.5	5.61	4.1	6.22	9.7	16.8	25.7	46.9	51.1	63.3
-3	4.57	4.45	9.23	15.6	24.2	34.9	50.2	74.2	82.8

Note: 300K runs

In fact, with the revised time between contamination events, the combination of the mean value at -3.5 (on log 10 scale) and standard deviation at 2.7 (on log 10 scale) for the LM added variable had the lowest log SSR of 4.1 (See Table 11). However, none of the mean and standard deviation combinations resulted in log SSR $\leq$ 1, i.e. none would yield distribution of LM in deli meat at retail that are close to estimates in the FDA/FSIS revised exposure assessment. As discussed above, if the lognormal distribution that was

used for time between contamination events is a good representation of the distribution of actual time between events, one or more of the other assumptions and distributions used by the model are not adequate representations of what really occurs in processing plants.

3.1.2.2 Calibration with alternative values for food contact surface areas, transfer coefficients, and duration of contamination events

Alternative values for food contact surface areas, transfer coefficients, and duration of contamination event, as previously described were used to recalibrate the values of mean and standard deviation for the LM added to FCS variable. The recalibration was done by changing each variable one at a time and by changing all three variables together. The re-calibrated values of the mean and standard deviation (on $\log_{10}$ scale) of the LM added to FCS variable that results in a distribution of LM concentration in deli meat at retail close to the revised FDA/FSIS LM concentration in deli meat at retail (based on logSSR $\leq$ 1, approximately equal to the Goodness of Fit value that was deemed acceptable by FSIS in baseline calibration runs) are summarized below. None of these "best fit" combinations are the same as the FSIS final values of mean and SD for LM added variable (-6, 3.5). When all three variables are modified, a mean of –4.8 and a standard deviation of 3.2 for the LM added variable appear to provide the best fit. (See Table 12)

Table 12: Recalibrated mean and standard deviation of LM added to FCS variable

Revised model input variable	**LM Added to FCS (on log $_{10}$ scale)**		**LogSSR**
	Mean	Standard Deviation	
Transfer Coefficient Mean = -0.26, SD = -0.64	-5.4	3.5	0.722
	-5.2	3.3	0.726
	-5.2	3.4	0.962
	-5.2	3.5	0.868
Event Duration Mean = 0.601 SD = 0.58	-5.0	3.1	0.600
	-4.5	2.9	0.600
FCS area (cm2) Min = 100,000 Max = 3,250,000	-6	3.1	0.800
	-6	3.3	0.500
	-5.5	2.9	1
Revised TC, Event Duration and FCS area	-5.0	3.3	1.05
	-4.8	3.1	1.15
	-4.8	3.2	1.01

Note: 300K iterations run

3.2 Impact on FSIS Conclusions

The FSIS model assumes that intervention does not affect the duration of a contamination event, the interval between contamination events, or the number of *Listeria* organisms transferred to the FCS. Food contact surface areas can act as long-term harborage sites over a long period of time (as indicated on page 14 of the FSIS report). According to industry sources, findings of contamination would typically trigger intense sampling to find niches and rigorous cleanup conducted to rid of niches. So implementation of sanitation interventions should affect the duration and interval between contamination events as well as the amount transferred from these areas. Since the FSIS in-plant model does not allow for this relationship (correlations) between these model input variables, it is not surprising that improved sanitation is found to have a limited effect based on analysis using this FSIS in-plant model (see conclusions on page 66 of the FSIS report). To appropriately address this fundamental model flaw, the FSIS in-plant model would need to be revised. This is beyond the scope of Exponent's review of the FSIS model.

The purpose of this evaluation is thus limited to determining if FSIS conclusions about the relative effectiveness of various intervention options based on the current model construct remain valid when different values for several model input variables were used, including the re-calibrated mean and standard deviation for the LM added variable. Based on available information and as discussed in previous sections, the following model inputs were changed in this evaluation:

Variable	***FSIS Values***	***Revised Values***
Transfer Coefficient	Mean = -0.14; SD = 1	Mean = -2.94; SD = 2.35
Event Duration	Mean = 0.602; SD = 0.573	Mean = 0.602; SD = 0.458
Food Contact Surface Area for large plants[3]	Min = 100,000 cm^2 Max = 1,000,000 cm^2	Min = 100,000 cm^2 Max = 3,250,000 cm^2
LM Added	Mean = -6.0; SD = 3.5	Mean = 4.8; SD = 3.2

In the FSIS report, LM concentrations on deli meat at retail were predicted for various scenarios of FCS and/or product testing using the FSIS Risk Assessment in-plant model.

The scenarios were given as triplet numbers, e.g. 4-2-1, and represent the number of monthly FCS samples per line for large, small, and very small plants. FSIS assumed test and hold for all FCS testing scenarios and if a lot tested positive for LM it was assumed not to be sold for retail. In addition to FCS testing scenarios, FSIS also provided scenarios of lot testing rather than FCS testing (i.e. 60-60-60 lot scenario), post-processing intervention/control (PP), growth inhibiting packaging (GIP), and combined PP and GIP scenarios. For the PP and GIP scenarios, FSIS assumed that 100% of industry implements these practices. Outputs of LM concentration at retail at the 80^{th}, 99^{th} and 99.99^{th} percentiles were compared against the FDA estimates and FSIS baseline estimates in Figure 20 and Table 20 of the FSIS report.

Exponent conducted analyses for several intervention scenarios that are similar to those described in the FSIS report. However, based on the description in the FSIS report, it is unclear what intervention was incorporated in the FSIS baseline scenario (i.e. 0-0-0 or 4-2-1 FCS sampling schemes). We assumed that when the 4-2-1 scenario is implemented without enhanced cleaning (i.e. when the "enhance cleaning" check box is not checked), the output would be similar to when the 0-0-0 scenario is implemented. The outputs of LM concentration on deli meat based on our revised input parameters for various scenarios are summarized below in Table 13. Figure 6 below shows 3 quantiles (80^{th}, 99^{th}, and 99.99^{th} percentiles) concentrations of LM in deli meats at retail for the various tested scenarios. In general, similar to the FSIS result, the data generally showed modest decline in the LM concentration at RTE product at retail as the food contact surface testing and sanitation effort increases. However, this trend is better observed for the 80^{th} and 99^{th} percentiles and not for the 99.99^{th} percentile. While the FSIS output showed a decline at the 99.99^{th} percentile for the 60-60-60 FCS testing and enhanced sanitation scenario, our analysis showed minimal decline from both the base values and Exponent revised base values. Most noticeable are the drop in LM concentrations at retail that were observed for both the 60-60-60 lot, PP, GIP and PP&GIP scenarios for all three quantiles when compared with the base values. Based on the Log SSR (Log SSR > 2), the predicted LM concentrations at retail are different from the FDA estimates or baseline

[3] Distributions for FCS area for small and very small plants are assumed to proportionately smaller

values (prior to intervention) only for the 60-60-60, 60-60-60 lot, PP, GIP and PP&GIP tested scenarios. (See Table 14)

Figure 6: Quantiles of LM at retail for tested intervention scenarios

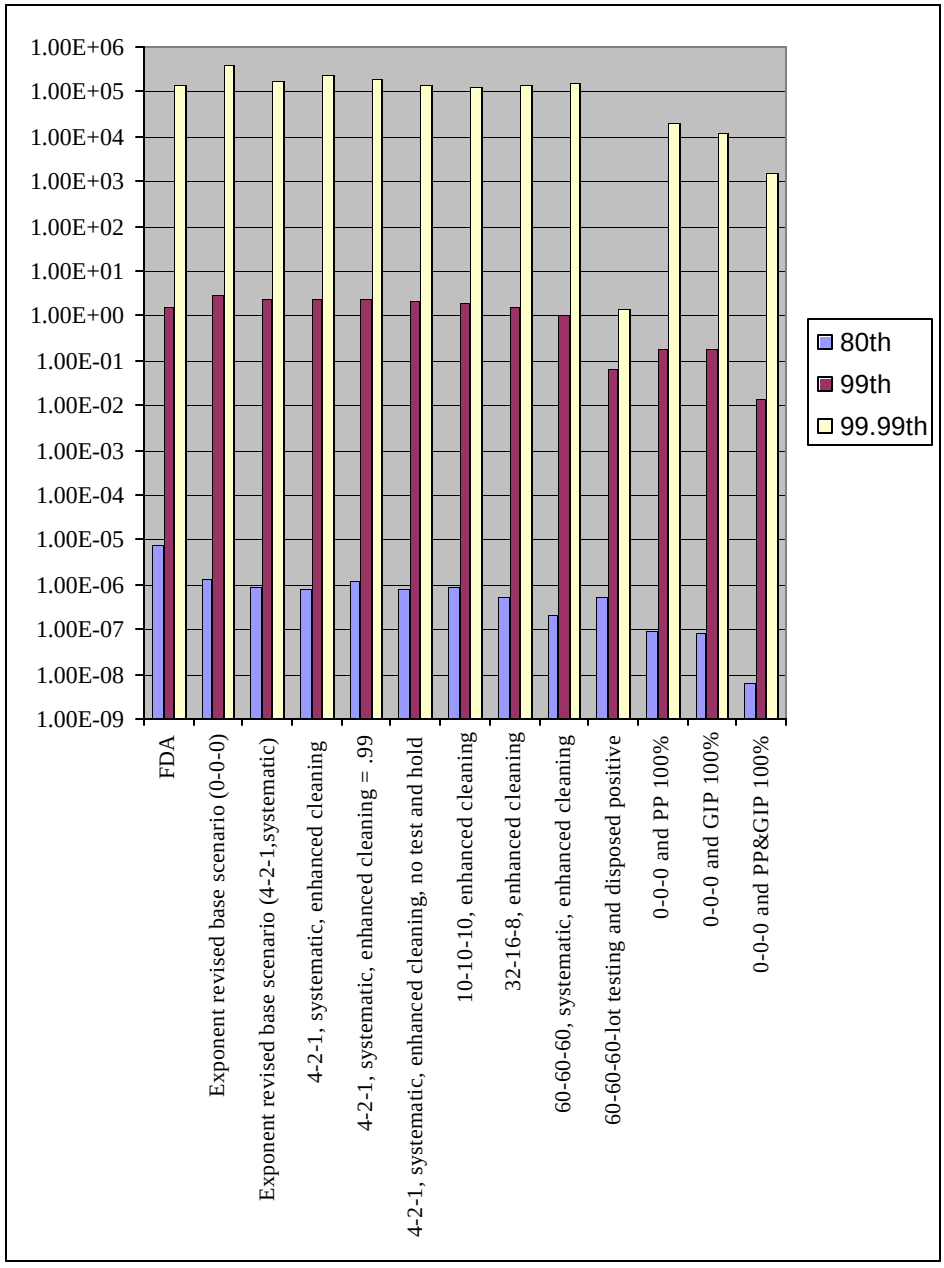


Table 13: Quantiles of *L. monocytogenes* concentrations in deli meat at retail for tested intervention scenarios and with revised model input parameters

	FDA	Exponent Revised base (0-0-0)	Exponent Revised Base parameters (4-2-1,systematic)	4-2-1 FCS, systematic, enhanced cleaning	4-2-1 FCS, systematic, enhanced cleaning = .99	4-2-1 FCS, systematic, enhanced cleaning, no test and hold	10-10-10, enhanced cleaning	32-16-8, enhanced cleaning	60-60-60 FCS, systematic, enhanced cleaning	60-60-60-lot testing and disposed positive	0-0-0 and PP 100%	0-0-0 and GIP 100%	0-0-0 and PP&GIP 100%
80th	7.40E-06	1.34E-06	8.76E-07	7.71E-07	1.17E-06	8.33E-07	9.02E-07	5.36E-07	2.04E-07	5.21E-07	8.93E-08	8.69E-08	6.57E-09
85th	3.70E-05	1.64E-05	1.13E-05	1.05E-05	1.43E-05	1.10E-05	1.10E-05	7.26E-06	3.16E-06	6.04E-06	1.11E-06	1.06E-06	8.37E-08
90th	2.70E-04	2.40E-04	1.82E-04	1.74E-04	2.24E-04	1.74E-04	1.69E-04	1.20E-04	5.65E-05	7.81E-05	1.70E-05	1.67E-05	1.27E-06
95th	5.50E-03	8.09E-03	6.34E-03	6.48E-03	7.35E-03	6.10E-03	5.72E-03	4.44E-03	2.32E-03	1.65E-03	5.79E-04	5.38E-04	4.24E-05
99th	1.50E+00	2.80E+00	2.38E+00	2.40E+00	2.44E+00	2.25E+00	1.84E+00	1.61E+00	1.05E+00	6.75E-02	1.90E-01	1.83E-01	1.45E-02
99.5th	1.10E+01	2.35E+01	1.83E+01	1.89E+01	1.90E+01	1.71E+01	1.37E+01	1.27E+01	8.49E+00	1.53E-01	1.54E+00	1.33E+00	1.12E-01
99.9th	7.90E+02	1.60E+03	1.31E+03	1.12E+03	1.34E+03	9.70E+02	8.61E+02	7.55E+02	5.58E+02	5.04E-01	1.06E+02	8.16E+01	7.35E+00
99.99th	1.40E+05	3.94E+05	1.82E+05	2.49E+05	2.01E+05	1.44E+05	1.26E+05	1.43E+05	1.53E+00	1.35E+00	2.10E+04	1.24E+04	1.61E+03

Notes: 500K Iterations

Table 14: Log SSR

Scenarios	*Log SSR vs. FDA*	*Log SSR vs. Exponent Revised Base*
FDA	NA	NA
Exponent revised base scenario (0-0-0)	1.18	NA
Exponent revised base scenario (4-2-1,systematic)	1.31	0.22
4-2-1, systematic, enhanced cleaning	1.49	0.20
4-2-1, systematic, enhanced cleaning = .99	1.01	0.11
4-2-1, systematic, enhanced cleaning, no test and hold	1.29	0.37
10-10-10, enhanced cleaning	1.18	0.51
32-16-8, enhanced cleaning	1.94	0.87
60-60-60, systematic, enhanced cleaning	4.24	2.62
60-60-60-lot testing and disposed positive	43.10	50.60
0-0-0 and PP 100%	11.40	11.16
0-0-0 and GIP 100%	12.30	12.44
0-0-0 and PP&GIP 100%	42.10	42.76

4 Conclusions

- In general, the FSIS model works as described in the FSIS report. The formulas used to model the mass balance approach are correctly implemented. The distribution used in the calibration to represent listeria concentrations in deli meats at retail correctly simulates the data in FDA/FSIS risk assessment. The number of iterations used in the risk assessment (1,000,000 iterations) is sufficient for the model output to stabilize. However, the distribution used by FSIS to represent the amount of listeria added during a contamination event is not necessarily the distribution that resulted in the best fit when compared to that based on the data in FDA/FSIS risk assessment.

- Estimates of several model input variables, i.e. transfer coefficient, interval between contamination event, event duration, food contact surface areas can be modified with industry data. These revised parameters can impact the calibrated values of mean and standard deviation for the LM added variable. In particular, when industry reported data are used to parameterize the interval between contamination events, the model cannot be calibrated to the FDA estimates of LM concentration at retail. This suggest that alternative parametric distribution for this specific variable may be needed, or there may be other model construct limitations, i.e. inability to correlate various input variables (see below)

- Assessment using the FSIS in-plant model with several revised input variables, generally showed modest decline in the LM concentration for RTE products at retail as the food contact surface testing and sanitation effort increases. This trend was observed for the 80^{th} and 99^{th} percentiles and not for the 99.99^{th} percentile. However, the decreases in LM concentrations at retail when compared with the base values were only significant for the 60-60-60, 60-60-60 lot, PP, GIP and PP&GIP tested scenarios.

- Correlation between the duration of a contamination event, the interval between contamination events, or the number of *Listeria* organisms transferred to the FCS is not allowed in the FSIS in-plant model. If such correlations are allowed, intervention such as enhanced cleaning once contamination is detected via FCS sampling to get rid of LM niches would reduce the level of LM added (now held constant in model) and the duration of a contamination event and would lengthen the duration between events (as shown with industry reported data). Thus, FSIS's conclusions about the relative effectiveness of various intervention scenarios remain questionable.

Appendix A: Time between event data

Plant #	Line	Number of samples	Date with Reported Positive Event			
			1st	2nd	3rd	4th
A	Precooked line A	727				
	Precooked line B	765	8/23/2004			
	Precooked line C	801	2/2/2005	5/26/2005		
	Precooked line Bits	652				
B	Prepared Saus. Pack	438				
	Prepared saus. Bulk	370				
	RTE Bacon line 1	134				
	RTE bacon Line 2	272				
	Bacon Bits	103				
C	Belt Grill Line 1	609				
	Belt Grill Line 2	502				
	CIB Line 1	484				
	CIB Line 2	501	20-Aug			
	CIB Line 3	537				
	CIB Line 4 & Dicer (add-ons)	534				
	Ham Pack Line 3	233				
	Ham Pack Line 4 (BNLS Spiral)	583	7/7/2004	7/27/2004	8/6/2004	
	Ham Pack Line 5(BI Spiral)	1736	8/25/2004	9/15/2004	9/23/2004	
	Ham Pack Line 6	523				
	Ham Pack Line 7	531	10/7/2004			
	Ham Pack Line 8	527				
	Ham Pack Line 9 Grd Ham	492				
D	Formax	569				
	Cocktails/Franks	479				
	Ham Pack Line	563				
	Bulk Sausage Pack	544				
	Slider Zipper Line	393				
	Toby Line	605				
	Ross Pack Chop line	570				
	Dicer	460	1/19/2005	6/3/2005		
	West Formax	590				
	Multivac Line	460				
	Crax Packaging	559				
E	Prepared Sausage Pack SLW	551				
	Canadian Bacon	572				

	West Ham RWO	637	10/13/2004			
	Belt Grill Bacon	320				
	Zipper Pack DS	666	9/1/2004	9/14/2004	9/14/2004	
	DS Pillow pack	562				
	DS Deli Line	598	11/8/2004			
	DS Chubb Line	430	5/19/2005			
	Prepared Saus. North (Bulk)	441				
	VSP	572				
	East Ham Line	562				
	DS Cry-O-Vac	585				
	DS Tote	315				
	DS Bulk	386	3/16/2005			
	F&E Bacon West	563				
	F&E Bacon East	576				
	F&E Bacon North	854	1/19/2005			
	F&E Bacon South	752				
	DS Ishida Zipper Line	690	10/20/2004	10/26/2004	11/17/2004	
	Bacon Bits	551				
	Ham Dice/Grind Pack	572				
	SM- 8610 Ham Pack	595				
F	Pillow Pack 1	579				
	A&B Bulk Line	567				
	C&D Bulk Line	622				
	Flex Vac 1	540				
	Flex Vac 2	593	4/6/2005			
	Pillow Pack 2	553				
	Dice	333	3/2/2005	3/9/2005		
G	Cryovac	532				
	Slice area	772	12/21/2004	3/29/2005	5/9/2005	
	Multivac Line	568	1/31/2005			
	Bulk Tote	553	11/1/2004			
	Pillow Pack	585	3/30/2005			
H	Room A LP	781	10/18/2004	11/30/2004		
	Room B LP	709				
	Room C LP	810	3/22/2005	3/29/2005		
	Room D LP	756				
	Browerville	554				
	Ends & Pieces	484				
	Slicing	626	3/3/2005	3/9/2005		
I	Belt Grill	1768	8/13/2004	9/7/2004	2/11/2005	3/9/2005
	Boneless Hams	209				
	Bone-In Hams	326				