RISK CHARACTERIZATION FOR *SALMONELLA* SPP. IN EGG PRODUCTS

Modeling Illnesses per Serving

The Exposure Assessment introduced the idea of illness per serving being calculated using a dose-response function with the number of SE per serving as its argument.

$$I_S = DR(S_2) \quad (5\text{-}4)$$

Where: I_S = the probability of illness resulting from consuming a serving of an egg meal. This probability can range over the [0,1] interval; S_2 = The number of SE in a contaminated serving.

Estimation of the dose, S_2, is discussed in the Exposure Assessment. The function relating the dose to the probability of illness (*DR*) is discussed at length in the Hazard Characterization and reproduced as equation 5-2.. Given a particular dose resulting from using a contaminated egg, Equation 5-4 calculates the probability that the dose would cause illness.

Calculating probability of illness per serving in the model

As with the shell egg model, the same model encompasses both the Exposure Assessment and the Risk Characterization. The model is written in Visual Basic for Applications. Inputs and outputs are stored in Excel worksheets. A more complete description of the model can be found in the Exposure Assessment chapter.

Each iteration of the exposure model describes a serving from the processing plant through consumption. At consumption, the model determines the number of bacteria per serving (S_2) and the servings per egg (V) are determined. These values are used in equation 5-4 above to determine the probability of illness per serving for that iteration. These values are averaged to give the probability of illness per serving for a given simulation.

Generating Baseline Estimates

Monte Carlo modeling

As with the shell egg model, the baseline model for egg products is run using Monte Carlo methods.

Seed values

All draws from distributions are governed by a two-dimension array that holds a specific set of random numbers generated by Visual Basic. This array is generated each time the model is run but can be replicated each time by ensuring that the seed value in the Inputs worksheet is the same. Many more iterations are run with the egg products model to ensure the same stability as with the shell egg model. Additionally, these iterations are run for each of seven different types of egg products. Consequently, the baseline model requires 3.5 million iterations (7 x 500,000).

Anchoring the Egg Products Model

Need for anchoring

Initial runs of the egg products model resulted in very large estimates of human illness, which could not be supported by epidemiologic information. These large estimates were generally due to large numbers of illnesses attributed to egg white product. Because the estimates were not supported by epidemiologic data, the model was anchored to a data source that was independent of data used for model development.

Using FSIS pasteurized egg product sampling to inform log reductions due to pasteurization

FSIS routinely collects and cultures 100 ml samples of pasteurized egg products. Positive samples are not enumerated. Table 5-20 summarizes pasteurized egg product testing results for calendar year 2002.

TABLE 5-20 RESULTS OF FSIS TESTING OF PASTEURIZED EGG PRODUCTS CY2002.

Code	Name	Samples	+	%
CAEW	Egg Whites, Raw	1	0	0.00%
CAWE	Whole Eggs, Raw	2	0	0.00%
CHEW	Egg Whites (with or without added ingredients)	352	3	0.85%
CHSWE	Whole Eggs (w/>2% salt or sugar added)	64	0	0.00%
CHSY	Yolks (w/>2% salt or sugar added)	282	1	0.35%
CHWE	Whole Eggs (w/<2% added ingred .besides salt/sugar)	432	0	0.00%
CHWEB	Whole Eggs w/Added Yolks (>2% added ingred.)	156	0	0.00%
CHWEY	Whole Eggs w/Added Yolks	32	0	0.00%
CHY	Yolks (w/<2% added ingred. besides salt/sugar)	29	0	0.00%
CIDEW	Spray Dried Egg Whites (w/wo added ingred.)	125	0	0.00%
CIDY	Dried Yellow Egg Products	159	3	1.89%
CIPDEW	Pan Dried Egg Whites	13	0	0.00%
Total		1647	7	

There were 352 samples taken of pasteurized egg white. Of these, 3 were positive for *Salmonella*. Figure 5-20 shows the relationship of this end product testing to the flow of egg products in the risk assessment.

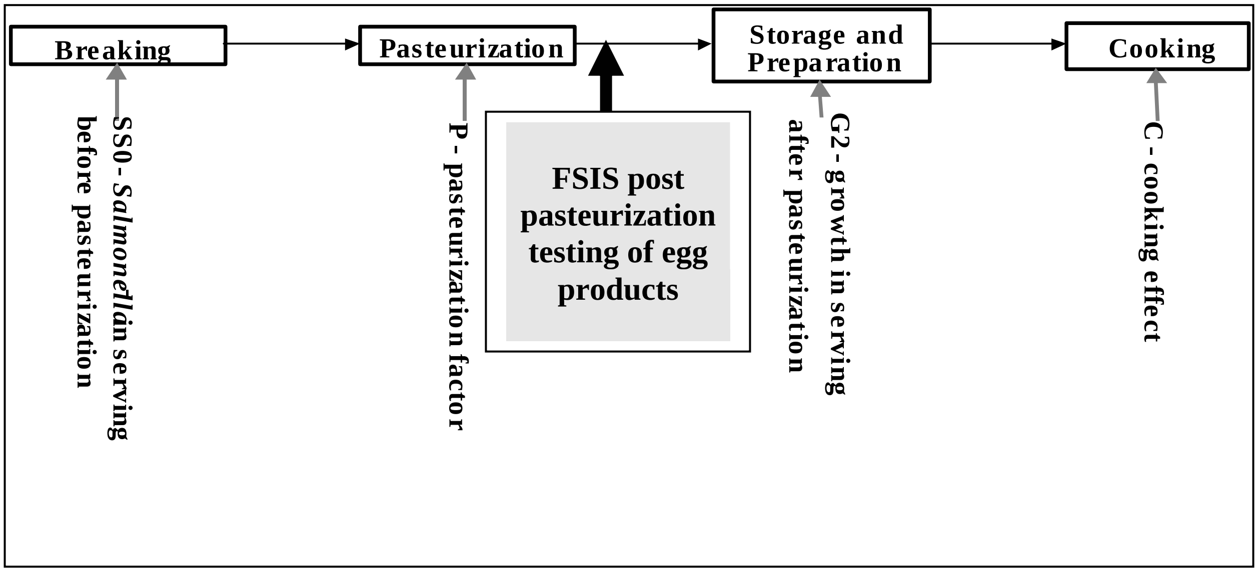

FIGURE 5-20 RELATIONSHIP OF FSIS END PRODUCT TESTING TO THE FLOW OF EGG PRODUCTS IN THE RISK ASSESSMENT.

An analysis was conducted in which it was assumed that the incoming concentration of *Salmonella* in unpasteurized egg white followed the distribution given in the exposure assessment and that within a vat of egg product bacteria were Poisson distributed. The probability of a 100 ml sample before and after a given pasteurization scenario can then be calculated. Table 5-21, Table 5-22, and Table 5-23 show the predicted percent positive samples for different test sensitivities and different $\log_{10}$ reductions due to pasteurization for egg white product, whole egg product, and egg yolk product respectively.

TABLE 5-21 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF EGG WHITE PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING DIFFERENT SENSITIVITIES OF CULTURE METHOD.

	Predicted percent positive samples				
Log_{10} reduction	**Sensitivity of Testing Method**				
	0.1	**0.25**	**0.5**	**0.75**	**0.9**
0	78.9%	83.5%	86.4%	87.8%	88.4%
1	62.7%	70.0%	74.8%	77.3%	78.4%
2	40.3%	49.7%	56.5%	60.2%	61.8%
3	17.9%	26.2%	33.1%	37.3%	39.2%
4	4.6%	8.5%	12.7%	15.6%	17.1%
5	0.7%	1.5%	2.7%	3.7%	4.3%
6	0.1%	0.2%	0.4%	0.5%	0.6%
7	0.0%	0.0%	0.0%	0.1%	0.1%
8	0.0%	0.0%	0.0%	0.0%	0.0%
9	0.0%	0.0%	0.0%	0.0%	0.0%

10	0.0%	0.0%	0.0%	0.0%	0.0%

TABLE 5-22 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF WHOLE EGG PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING DIFFERENT SENSITIVITIES OF CULTURE METHOD.

Log_{10} reduction	Predicted percent positive samples Sensitivity of Testing Method 0.1	0.25	0.5	0.75	0.9
0	80.1%	84.2%	86.9%	88.2%	88.8%
1	65.3%	71.9%	76.3%	78.6%	79.5%
2	44.6%	53.4%	59.6%	63.0%	64.5%
3	22.3%	30.8%	37.7%	41.7%	43.5%
4	6.9%	11.8%	16.6%	19.8%	21.4%
5	1.2%	2.6%	4.3%	5.7%	6.4%
6	0.1%	0.3%	0.6%	0.9%	1.1%
7	0.0%	0.0%	0.1%	0.1%	0.1%
8	0.0%	0.0%	0.0%	0.0%	0.0%
9	0.0%	0.0%	0.0%	0.0%	0.0%
10	0.0%	0.0%	0.0%	0.0%	0.0%

TABLE 5-23 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF EGG YOLK PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING 100% SENSITIVITY OF CULTURE METHOD.

Log_{10} reduction	Predicted percent positive samples Sensitivity of Testing Method 0.1	0.25	0.5	0.75	0.9
0	72.3%	77.0%	80.0%	81.7%	82.4%
1	57.5%	63.9%	68.3%	70.7%	71.7%
2	39.1%	46.7%	52.2%	55.3%	56.7%
3	20.7%	27.7%	33.3%	36.7%	38.2%
4	7.5%	11.9%	16.0%	18.7%	20.0%
5	1.7%	3.3%	5.1%	6.4%	7.1%
6	0.2%	0.5%	1.0%	1.3%	1.6%
7	0.0%	0.1%	0.1%	0.2%	0.2%
8	0.0%	0.0%	0.0%	0.0%	0.0%
9	0.0%	0.0%	0.0%	0.0%	0.0%
10	0.0%	0.0%	0.0%	0.0%	0.0%

The results of post-pasteurization testing by FSIS are inconsistent with modeled $\log_{10}$ reductions due to pasteurization of less than 5. Furthermore, FSIS requires the sensitivity of testing procedures for *Salmonella* in egg products to be at least 97% (USDA 1998) which would make $\log_{10}$ reductions less than 6 to be unlikely given the results in Table 5-20.

Table 5-24 summarizes the expected $\log_{10}$ reductions for current time and temperature requirements that were given in the exposure assessment.

TABLE 5-24 EXPECTED LOG10 REDUCTIONS FOR DIFFERENT EGG PRODUCTS.

Product	Expected Log_{10} Reduction	Log_{10} Reduction Modeled for Baseline
White	–3.3	–5.0
Whole	–5.9	–5.9
Yolk	–5.5	–5.5
Whole 10% salt	–6.0	–6.0
Whole 10% sugar	–42.0	–42.0
Yolk 10% salt	–7.2	–7.2
Yolk 10% sugar	–12.4	–12.4

The only product for which the expected $\log_{10}$ reduction is below five is egg white. Therefore, the baseline model estimates are simulated using an expected $\log_{10}$ reduction due to pasteurization of 5 for egg white only.

Answers to Risk Management Questions

What is the number of illnesses per serving and annual number of illnesses from *Salmonella* spp. in *pasteurized egg products* (*e.g.*, liquid whole eggs, yolks, and egg whites)?

Illnesses per serving for egg products (baseline)

The baseline model provides estimates for seven different types of egg products: white, whole, yolk, whole with 10% added salt, whole with 10% added sugar, yolk with 10% added salt, and yolk with 10% added sugar. These seven products are used to represent all possible types of egg products. Table 5-25 shows the baseline model results for the seven different types of egg products. White has the highest probability of illness per serving at 2.9 x 10^{-6}. Whole egg product has probability of illness per serving of 8.4 x 10^{-7}. Yolk product has a probability of illness of 2.8 x 10^{-6}. Products with added ingredients tended to have lower estimates. Whole egg product with salt had a probability of illness per serving of 6.2 x 10^{-7} and yolk product with salt had a probability of 8.6 x 10^{-8}. Sugar added product had even lower probabilities of illness. Yolk with sugar added had a probability of illness per serving of 4.8 x 10^{-13}. Whole egg product with added sugar had no predicted illnesses. This is represented as $<10^{-16}$. The reciprocals of these values give the servings per illness. Thus, there are about than 350,000 servings of white per illness, about than 1.2 million servings of whole egg product per illness and about 360,000 servings of yolk product. Whole egg product with added salt takes more than 1.6 million servings per illness while yolk product with salt takes more than 11 million. Yolk with added sugar has more than 2 trillion servings per illness, and no illnesses are predicted for whole product with added sugar.

TABLE 5-25 BASELINE MODEL RESULTS FOR SEVEN EGG PRODUCT TYPES.

Baseline Model Results							
Product	White	Whole	Yolk	Whole 10% salt	Whole 10% sugar	Yolk 10% salt	Yolk 10% sugar
Probability of illness	2.9×10^{-6}	8.4×10^{-7}	2.8×10^{-6}	6.2×10^{-7}	$<10^{-16}$	8.6×10^{-8}	4.8×10^{-13}

<u>Illnesses per serving for pasteurized egg products (3-12 $\log_{10}$ reductions due to pasteurization)</u>

The model was run with a series of scenarios for each type of egg product. The amount of pasteurization was set at values ranging from 3 to 12 $\log_{10}$ reductions at 1 $\log_{10}$ increments. In addition, a set of baseline scenarios was run for each product type. Thus, 77 (11 x 7) separate simulations were run. The number of iterations was set at 100,000 so the baseline results do not match those of the baseline with 500,000 iterations. Nevertheless, the relative effect of pasteurization will be consistent.

Table 5-26 shows the probabilities of illness per serving for each of the egg product types for each of the $\log_{10}$ reductions. Note that the probabilities of illness for whole egg product are identical to those for whole egg product with ingredients added and that the probabilities of illness for yolk product are identical to those for yolk product with ingredients added. This is because these products are modeled with the same beginning level of contamination.

If pasteurization effecting 3 $\log_{10}$ reduction were applied to egg products the probability of illness is expected to range from 1.0×10^{-4} for whites to 1.5×10^{-4} for egg yolk product. This corresponds with servings per illness from about 6700 to about 10,000. If all egg products had 10 $\log_{10}$ of pasteurization applied, then the probability of illness would range from 2.3×10^{-11} to 7.7×10^{-11} or one illness per 13 to 43 billion servings.

TABLE 5-26 MODEL RESULTS FOR SEVEN PRODUCT TYPES ASSUMING 3 TO 12 LOG10 OF PASTEURIZATION.

Model Results for 3-12 $\log_{10}$ Pasteurization								
	Product	White	Whole	Yolk	Whole 10% salt	Whole 10% sugar	Yolk 10% salt	Yolk 10% sugar
Probability of illness	Base	2.3×10^{-6}	6.3×10^{-7}	2.1×10^{-6}	4.8×10^{-7}	$<10^{-16}$	5.4×10^{-8}	3.1×10^{-13}
	-3	1.0×10^{-4}	1.4×10^{-4}	1.5×10^{-4}	1.4×10^{-4}	1.4×10^{-4}	1.5×10^{-4}	1.5×10^{-4}
	-4	1.8×10^{-5}	3.0×10^{-5}	3.7×10^{-5}	3.0×10^{-5}	3.0×10^{-5}	3.7×10^{-5}	3.7×10^{-5}
	-5	2.3×10^{-6}	4.4×10^{-6}	6.4×10^{-6}	4.4×10^{-6}	4.4×10^{-6}	6.4×10^{-6}	6.4×10^{-6}
	-6	2.4×10^{-7}	4.8×10^{-7}	7.6×10^{-7}	4.8×10^{-7}	4.8×10^{-7}	7.6×10^{-7}	7.6×10^{-7}
	-7	2.3×10^{-8}	4.9×10^{-8}	7.8×10^{-8}	4.9×10^{-8}	4.9×10^{-8}	7.8×10^{-8}	7.8×10^{-8}
	-8	2.3×10^{-9}	4.7×10^{-9}	7.7×10^{-9}	4.7×10^{-9}	4.7×10^{-9}	7.7×10^{-9}	7.7×10^{-9}
	-9	2.3×10^{-10}	4.7×10^{-10}	7.7×10^{-10}	4.7×10^{-10}	4.7×10^{-10}	7.7×10^{-10}	7.7×10^{-10}
	-10	2.3×10^{-11}	4.7×10^{-11}	7.7×10^{-11}	4.7×10^{-11}	4.7×10^{-11}	7.7×10^{-11}	7.7×10^{-11}
	-11	2.3×10^{-12}	4.7×10^{-12}	7.7×10^{-12}	4.7×10^{-12}	4.7×10^{-12}	7.7×10^{-12}	7.7×10^{-12}
	-12	2.3×10^{-13}	4.7×10^{-13}	7.7×10^{-13}	4.7×10^{-13}	4.7×10^{-13}	7.7×10^{-13}	7.7×10^{-13}

Calculating baseline annual number of illnesses

Calculating the total illnesses for a given year in the U.S. is accomplished by multiplying the probability of illness per serving by the total number of servings consumed. The consumption table in the exposure assessment chapter gives the number of eating occasions for two days from the 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals (CSFII). Table 5-27 reproduces the first part of the table and shows the total number of eating occasions observed for two days.

TABLE 5-27 TOTAL NUMBER OF SERVINGS FOR EGG PRODUCTS FOR TWO DAYS FROM CSFII 1994-1996, 1998.

	All Egg Products		
Meal type	Main meal	Beverage	Ingredient
Consumption average (g/p/d)	77.8	182.5	36.0
Std Dev (g)	49.0	75.1	71.0
Eating occasions	32,345,212	286,428	226,268,156

The total number of eating occasions is multiplied by 182.5 (365/2) to give the number of eating occasions for a year. This is estimated to be about 47 billion per year. The fraction of production represented by each egg product type is also shown in a chart in the exposure assessment chapter. These fractions are shown in TABLE 5-28 and FIGURE 5-21.

TABLE 5-28 FRACTION OF SERVINGS REPRESENTED BY EACH EGG PRODUCT TYPE. ESTIMATES WERE BASED ON USDA-NASS[4] DATA AND ASSUMED FRACTIONS OF DIFFERENT BLENDS.[5]

Egg Product	**Fraction**
White	0.169
Whole	0.456
Yolk	0.043
Whole 10% salt	0.127
Whole 10% sugar	0.127
Yolk 10% salt	0.031
Yolk 10% sugar	0.047

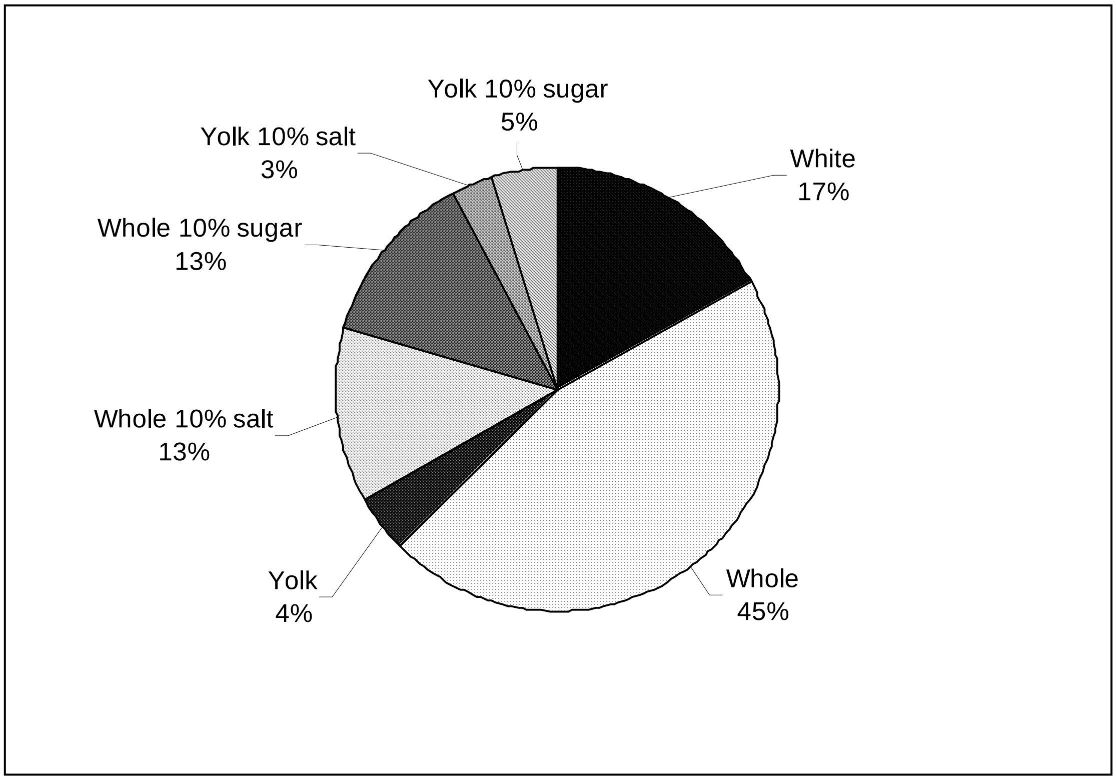

FIGURE 5-21 FRACTION OF SERVINGS REPRESENTED BY EACH EGG PRODUCT TYPE. ESTIMATES WERE BASED ON USDA-NASS[4] DATA AND ASSUMED FRACTIONS OF DIFFERENT BLENDS.[5]

Illnesses for each product type are calculated by multiplying the probability of illness by the number of servings per year for that product type.

$$Illnesses_{product} = I_s \text{ x } Servings \text{ X } F(\text{product}) \quad (5\text{-}5)$$

Where: $Illnesses_{product}$ = the illnesses resulting from consuming servings made with a particular egg product; I_S = the probability of illness resulting from consuming a serving of an egg meal. *Servings* = the total servings of egg products *F*(product) = the fraction of servings for a particular egg product.

Precision of Answers for Egg Products Model

Numbers of human illnesses in the egg products model are generally reported with more significant digits than in the shell egg model. This is because the differences between scenarios are often small. The appearance of more significant digits should not be taken as a more accurate portrayal of risk.

Table 5-29 shows the number of illnesses associated with each of the egg product types.

TABLE 5-29 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES.

Egg Type	Number ill
White	22,917
Whole	18,019
Yolk	5,672
Whole 10% salt	3,707
Whole 10% sugar	0
Yolk 10% salt	127
Yolk 10% sugar	0
Total	50,443

<u>Annual number of illnesses for different pasteurization scenarios</u>
Equation 5-4 can also be applied to each of the probabilities in Table 5-26. These can be used to estimate predicted illnesses when all egg products are pasteurized at the same level. The total for all of the egg products can be used to compare one the effect of different pasteurization standards. Table 5-30 shows the number of illnesses predicted for all egg products when they are pasteurized at various fixed levels.

TABLE 5-30 PREDICTED ILLNESSES FOR FIXED LOG10 REDUCTIONS AT THE PASTEURIZATION STEP FOR ALL EGG PRODUCTS.

	Predicted Illnesses for Egg Product Type							
Log_{10} Reduction	White	Whole	Yolk	Whole 10% salt	Whole 10% sugar	Yolk 10% salt	Yolk 10% sugar	Total Illnesses
Baseline	18,416	13,590	4,287	2,886	0	80	0	39,260
3	810,903	3,104,296	311,928	863,264	863,264	226,620	339,930	6,520,206
4	146,286	649,708	76,458	180,675	180,675	55,547	83,321	1,372,671
5	18,416	94,598	12,977	26,306	26,306	9,428	14,141	202,173
6	1,813	10,423	1,559	2,899	2,899	1,133	1,699	22,425
7	191	1,057	160	294	294	116	174	2,285
8	18	101	16	28	28	11	17	219
9	2	10	2	3	3	1	2	22
10	0	1	0	0	0	0	0	2
11	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0

Note, that the baseline number of illnesses using the probabilities from Table 5-26 is different because it is based on 100,000 iterations rather than 500,000.

What is the number of *Salmonella* spp. in a liter of egg product (whole, yolk, albumen) *before* and *after* a specified pasteurization scenario?

Pasteurization of egg products is meant to reduce the number of *Salmonella* by a specified amount. As with shell eggs, the amount of pasteurization is given in $\log_{10}$ reduction. A 1-$\log_{10}$ reduction means that the amount of contamination is reduced by 90%; a 2-$\log_{10}$ reduction corresponds to a 99% reduction in contamination, and a 3-$\log_{10}$ reduction to 99.9%.

Graphically, these $\log_{10}$ reductions due to pasteurization can be represented by shifting the distribution of the incoming concentration to the left. The following figures show the effect of pasteurization for egg whites, whole egg product, and egg yolk under the baseline scenario. For these figures, the effect of pasteurization is rounded to the nearest whole number. Thus, pasteurization of egg whites is shown as a 5-$\log_{10}$ reduction, pasteurization of whole egg product as a 6-$\log_{10}$ reduction, and pasteurization of egg yolk as a 5-$\log_{10}$ reduction.

Figure 5-22 compares the pre- and post-pasteurization levels of *Salmonella* in a liter of liquid egg white product given a 3-$\log_{10}$ reduction due to pasteurization. Three $\log_{10}$ is slightly less than the 3.3-$\log_{10}$ reduction actually modeled.

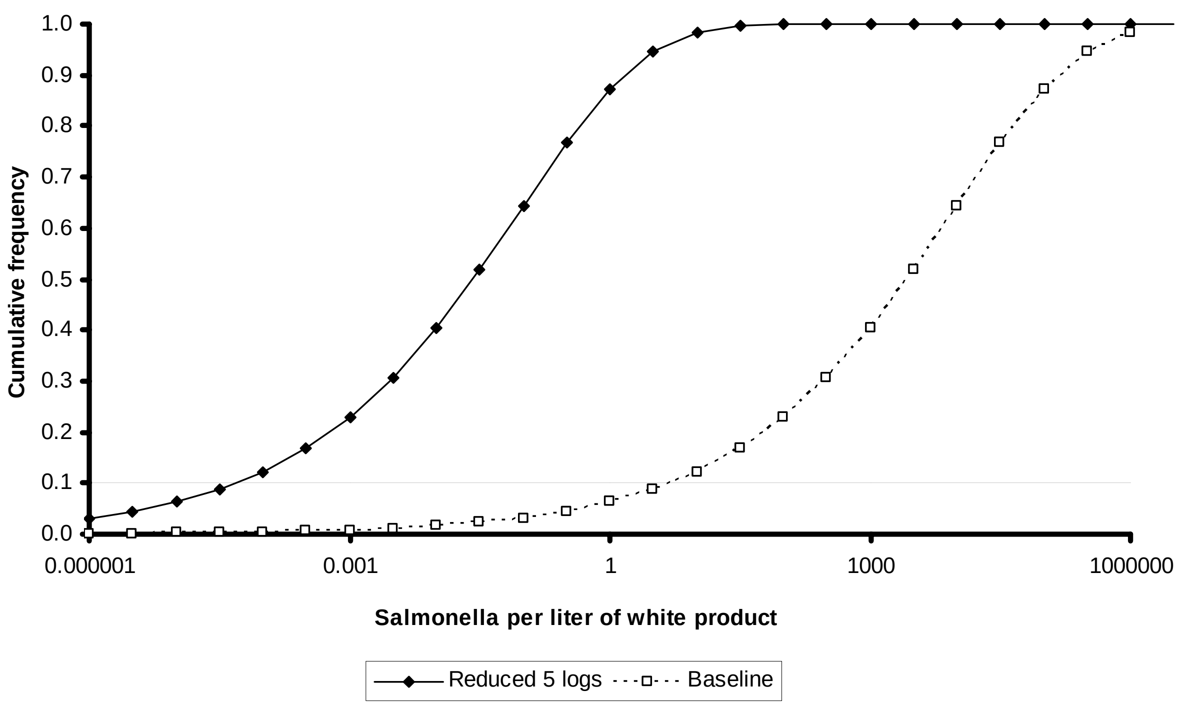

FIGURE 5-22 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID EGG WHITE PRODUCT GIVEN 5-LOG10 REDUCTION DUE TO PASTEURIZATION.

The x-axis shows the number of *Salmonella* per liter. Given a 5-$\log_{10}$ reduction due to pasteurization,

Figure 5-22 shows that about 90% of liters of egg white product would have 1 or less *Salmonella*. Thus, about 10% of liters would have one or more *Salmonella*. Figure 5-23 shows the effect of a 6-$\log_{10}$ reduction on the number of *Salmonella* in a liter of whole egg product. Given a 6-$\log_{10}$ reduction, nearly 100% of liters would have an expected number of *Salmonella* of 1 or less. Figure 5-24 shows the effect of a 5-$\log_{10}$ reduction in egg yolk product

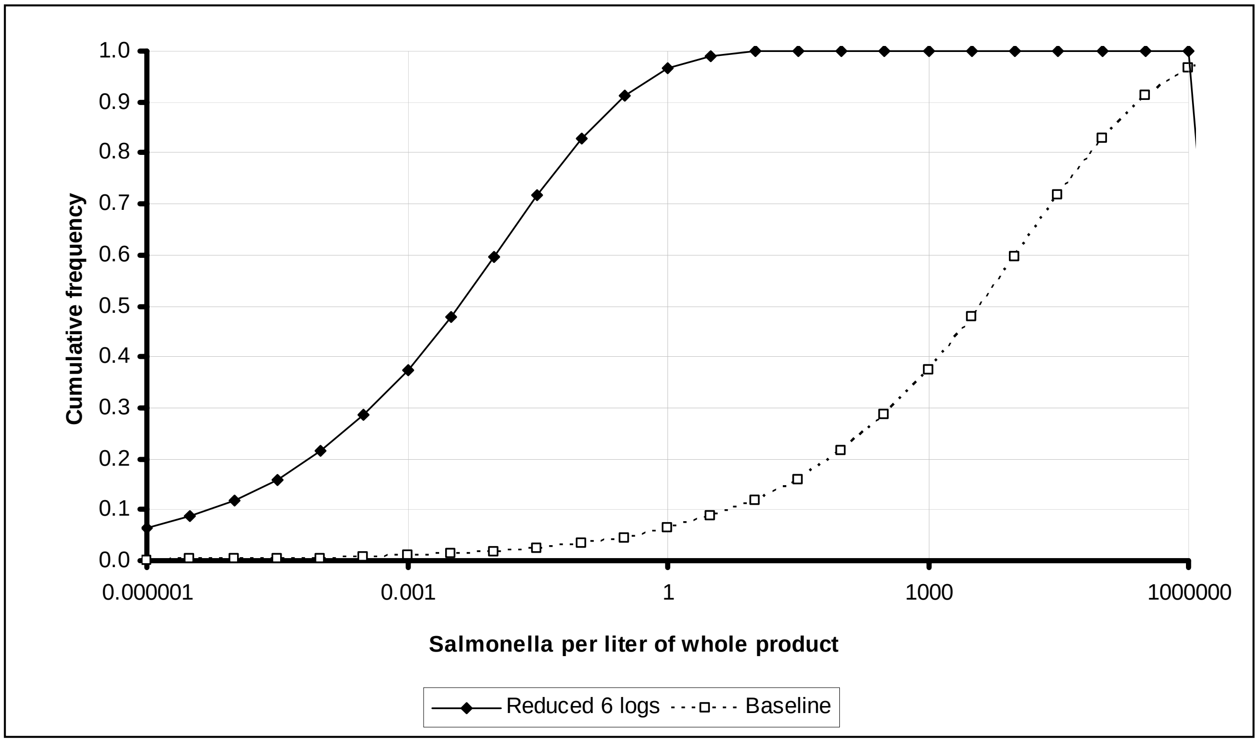

FIGURE 5-23 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID WHOLE EGG PRODUCT GIVEN 6-LOG_{10} REDUCTION DUE TO PASTEURIZATION.

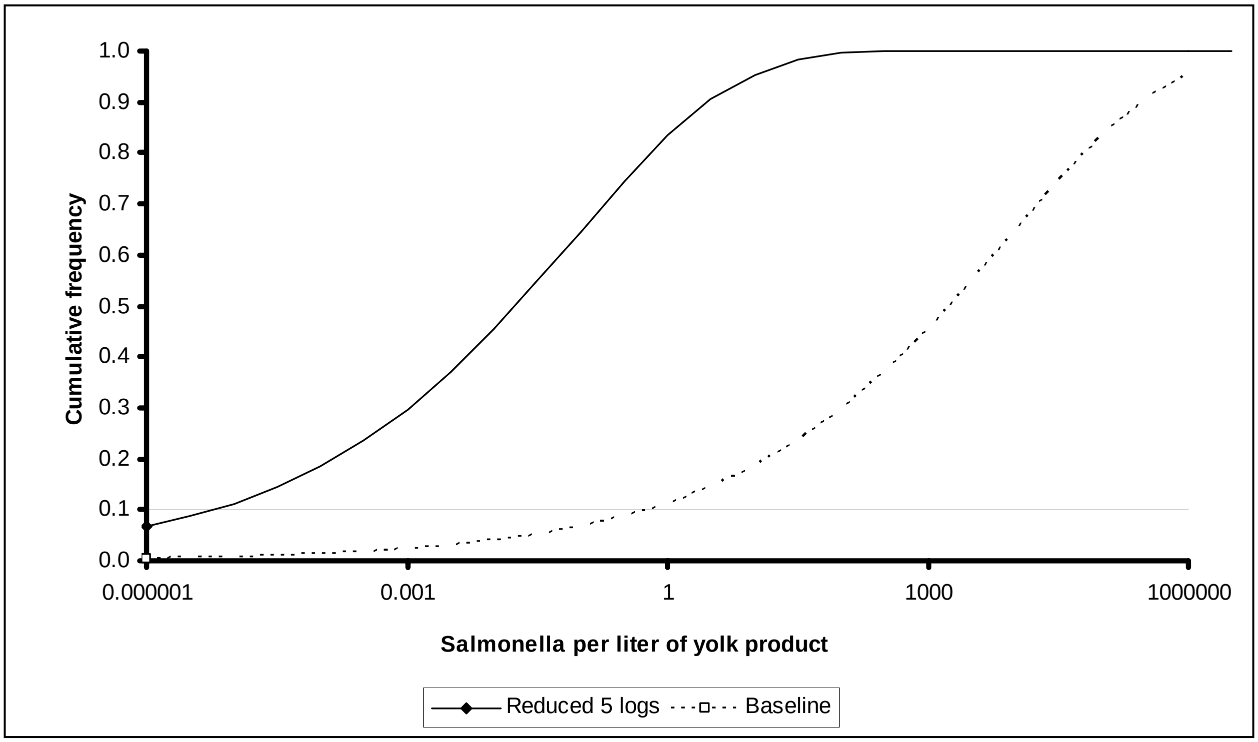

FIGURE 5-24 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID EGG YOLK PRODUCT GIVEN 5-LOG$_{10}$ REDUCTION DUE TO PASTEURIZATION.

Stability of the Baseline Model

Results from the baseline model are generated from 500,000 iterations using a particular seed value. The number of iterations was set at 500,000 because this number of iterations gives about the same stability as 50,000 iterations of the shell egg baseline model. The standard error is about 6% of the mean value. Unfortunately, inputs and outputs for each iteration are not readily captured in the Excel format when 500,000 iterations are run. The baseline output of 500,000 iterations is captured by setting the model to output only the probability of human illness for each of the seven egg product types.

As with the shell egg model, the baseline model run is based on a specific seed value. Thus, even with model runs of 100,000 comparisons can be made with other runs that had the same seed value. This ensures identical draws from distributions and that the only change is in the specific mitigation modeled.

Sensitivity Analysis

Types of sensitivity analysis

Three types of sensitivity analysis are conducted for the model. First, a correlation analysis of the baseline model identifies those variables that are most influential in the probability of human illness. Second, a nominal range sensitivity analysis identifies those parameters that are most influential. Third, a set of outputs is generated that identifies sensitivity of the model to different modeling choices. Sensitivity analysis is based on the unanchored baseline model.

Correlation analysis of the baseline scenario

Unlike the shell egg model, Spearman rank order correlations were not conducted due to the difficulty of ordering the large data sets in Excel. Rather, standard correlation coefficients using the Excel function Correl(input array, output array) were calculated for different inputs and intermediate outputs with the probability of negative servings (servings with no *Salmonella*) or of human illness for servings made with white, whole egg, or yolk. Table 5-31 shows the correlation of the probability of a negative serving before pasteurization with various intermediate outputs. The table shows that the probability of a negative serving is negatively correlated with the concentration of bacteria in the raw product. In other words, lower concentrations in raw product are more likely to be associated with negative servings. At first glance, it might be expected that the correlation should be more pronounced. Because most raw product have generally low concentrations of bacteria and servings sizes are relatively small, a less pronounced correlation makes sense.

TABLE 5-31. CORRELATION OF THE PROBABILITY OF A NEGATIVE SERVING BEFORE PASTEURIZATION WITH VARIOUS INTERMEDIATE OUTPUTS.

Parameter	**White**	**Whole**	**Yolk**
BegBacConc	-0.289	-0.517	-0.410
ServSize	-0.258	-0.228	-0.196
BacServMean	-0.178	-0.516	-0.313

Table 5-32 shows the correlation of the probability of a negative serving just at the point of consumption with various intermediate outputs.

TABLE 5-32 CORRELATION OF THE PROBABILITY OF A NEGATIVE SERVING AT CONSUMPTION WITH VARIOUS INTERMEDIATE OUTPUTS.

Parameter	White	Whole	Yolk
BegBacConc	-0.017	-0.031	-0.021
ServSize	-0.034	-0.021	-0.020
BacServMean	-0.018	-0.038	-0.023
NegServ	0.082	0.089	0.087
InitBac	-0.018	-0.040	-0.022
RefTemp	-0.001	0.003	0.003
RefDays	0.006	0.008	0.009
RefBac	-0.018	-0.015	-0.014
RoomTempFlag	-0.002	0.002	0.002
RoomTemp	-0.003	0.001	0.003
RoomDays	-0.008	-0.005	-0.007
RoomBac	-0.018	-0.040	-0.022
AttFac	0.150	0.068	0.073
BacServFinal	-0.362	-0.358	-0.573

Although there was some moderate correlation between the beginning bacterial concentration (*BegBacConc*) and the probability of a negative serving at pasteurization, there is no correlation between *BegBacConc* and the probability of a negative serving at consumption. Table 5-33 shows the correlations between the listed intermediate outputs and the probability of human illness from the baseline model with 100,000 iterations.

TABLE 5-33 CORRELATION OF HUMAN ILLNESS WITH VARIOUS INTERMEDIATE OUTPUTS.

Parameter	White	Whole	Yolk
BegBacConc	0.035	0.035	0.028
ServSize	0.010	0.010	0.008
BacServMean	0.035	0.035	0.029
NegServ	-0.070	-0.070	-0.061
InitBac	0.048	0.048	0.034
RefTemp	-0.003	-0.003	-0.004
RefDays	-0.007	-0.007	-0.007
RefBac	0.021	0.021	0.022
RoomTempFlag	-0.002	-0.002	-0.002
RoomTemp	-0.003	-0.003	-0.003
RoomDays	0.006	0.006	0.004
RoomBac	0.052	0.052	0.032
AttFac	-0.045	-0.045	-0.038
BacServFinal	0.458	0.458	0.762
TProbNeg	-0.848	-0.848	-0.769

Nominal range sensitivity analysis

Nominal range sensitivity analysis was conducted in manner similar to that used for the shell egg model. All inputs were set to their most likely values (baseline scenario) and the model was run for 100,000 iterations. Because the baseline model used 500,000 iterations, this baseline was slightly different. In addition, the sensitivity analysis was based on the unanchored baseline model. Upper and lower bounds were then selected for each of the inputs. For fixed inputs, bounds were generally selected by multiplying the input by a set factor. For distributional inputs, the distribution parameters such as the mean or standard deviation were adjusted. Some inputs were thought to be correlated with other inputs. For those inputs, if the correlation was below -0.5 or above 0.5 then the inputs were changed and evaluated separately. If the correlation was between -0.5 and 0.5 then the inputs were changed and evaluated separately.

After selecting lower and upper bounds for each input or set of inputs, the model was run for 100,000 iterations for each lower and upper bound modeled. After each input was evaluated at its lower and upper bound, the input was changed to its most likely value and the next input was evaluated.

Setting upper and lower bounds

Twenty-seven sets of inputs were changed and evaluated at the upper and lower bound. Two sets were specific to growth of *Salmonella* only in whites while two sets were specific to growth in other products. The number of scenarios simulated was (25 (sets of inputs when whites and other egg products are combined) x 2 (upper and lower) x 7 (egg product types)) + 7 (baseline) = 357. Table 5-34 shows bounds for parameters for the distributions that determine the initial levels of *Salmonella* in white, whole, or yolk egg products. Bounds are based on the uncertainty of the parameters estimated in annex F. Upper and lower bounds are two standard deviations away from the most likely estimates presented.

TABLE 5-34 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR WEIBULL DISTRIBUTION FOR EGG PRODUCT CONTAMINATION.

Parameter	LB	ML	UB
Initial levels µ - white	-0.14	0.44	1.02
Initial levels s - white	1.30	1.42	1.54
Initial levels µ - whole	1.73	2.27	2.81
Initial levels s - whole	1.30	1.40	1.50
Initial levels µ - yolk	0.41	1.13	1.85
Initial levels s - yolk	1.48	1.60	1.72

Table 5-35 shows bounds for growth parameters. Upper bound parameters and lower bound parameter, *f*, to estimate growth of bacteria in yolk or whole egg product are based on uncertainty estimates presented in Annex E. Lower bounds are set arbitrarily for parameters *e* and *b*. Other parameters are set arbitrarily.

TABLE 5-35 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR GROWTH PARAMETERS.

Parameter	LB	ML	UB	Corr
Yolk growth e	-1.3000	-1.0063	-0.4263	1
Yolk growth f	0.1954	0.2219	0.2484	1
Yolk growth b	0.0100	0.4007	0.8761	
Albumen growth SD	0.1925	0.3850	0.7700	
Albumen growth lag/growth	2	5	10	

Table 5-36 shows bounds for parameters for the Pert distributions that are used to model storage times and temperatures. The lower bound parameters are developed by changing the most likely mid to the lower bound max and the most likely min to the lower bound mid. Either the lower bound min is set at 0 for days of storage or refrigerator temperature in C or it is set at 10 for room storage temperature in C.

TABLE 5-36 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS FOR PERT DISTRIBUTIONS FOR EGG PRODUCT STORAGE TIMES AND TEMPERATURES.

		LB			ML			UB		
	Pert Parameter	min	mid	max	min	mid	max	min	mid	max
Parameter										
White	*Time and Temp RefriDays*	0.00	2.00	10.00	2.00	10.00	22.00	10.00	22.00	44.00
White	*Time and Temp RefriTemp*	0.00	0.00	3.33	0.00	3.33	4.44	3.33	4.44	8.89
White	*Time and Temp RSDays*	0.00	0.02	0.04	0.02	0.04	0.17	0.04	0.17	0.33
White	*Time and Temp RSTemp*	10.00	15.56	21.11	15.56	21.11	26.67	21.11	26.67	35.00
White	*Time and Temp FractRS*	0.00	0.02	0.05	0.02	0.05	0.10	0.05	0.10	0.20
Whole	*Time and Temp RefriDays*	0.00	2.00	5.50	2.00	5.50	13.00	5.50	13.00	26.00
Whole	*Time and Temp RefriTemp*	0.00	0.00	3.33	0.00	3.33	4.44	3.33	4.44	8.89
Whole	*Time and Temp RSDays*	0.00	0.02	0.04	0.02	0.04	0.17	0.04	0.17	0.33
Whole	*Time and Temp RSTemp*	10.00	15.56	21.11	15.56	21.11	26.67	21.11	26.67	35.00
Whole	*Time and Temp FractRS*	0.00	0.02	0.05	0.02	0.05	0.10	0.05	0.10	0.20
Yolk	*Time and Temp RefriDays*	0.00	2.00	5.50	2.00	5.50	11.00	5.50	11.00	22.00
Yolk	*Time and Temp RefriTemp*	0.00	0.00	2.22	0.00	2.22	4.44	2.22	4.44	8.89
Yolk	*Time and Temp RSDays*	0.00	0.02	0.04	0.02	0.04	0.17	0.04	0.17	0.33
Yolk	*Time and Temp RSTemp*	10.00	15.56	21.11	15.56	21.11	26.67	21.11	26.67	35.00
Yolk	*Time and Temp FractRS*	0.00	0.02	0.05	0.02	0.05	0.10	0.05	0.10	0.20

Upper and lower bounds for fractions of different types of servings made from egg products are developed using the number of eating occasions from CSFII. The bounds are set by either doubling or halving the eating occasions for the type of serving.

Upper and lower bounds for serving sizes are developed from summaries of serving size from the CSFII. All of the inputs for a cumulative distribution for a particular serving type are either doubled (upper bound) or halved (lower bound).

Table 5-37 shows the bounds for discrete distributions for the $\log_{10}$ reductions due to cooking for the different types of egg servings. As with the Pert distributions for time and temperature, these boundary distributions are developed by shifting the most likely distribution up or down.

TABLE 5-37 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS FOR DISCRETE DISTRIBUTIONS REPRESENTING LOG10 REDUCTIONS DUE TO COOKING.

	LB				**ML**				**UB**			
Log_{10} Reductions	0	4.9	6.1	12	0	4.9	6.1	12	0	4.9	6.1	12
Parameter												
Cooking EggUC	0.51	1	1	1	0.02	0.51	1	1	0	0.02	0.51	1
Cooking BevUC	1	1	1	1	1	1	1	1	0	1	1	1
Cooking IngUC	0.51	1	1	1	0.02	0.51	1	1	0	0.02	0.51	1
Cooking EggWC	0.51	1	1	1	0.02	0.51	1	1	0	0.02	0.51	1
Cooking BevWC	0	0	1	1	0	0	0	1	0	0	0	0
Cooking IngWC	0	0	1	1	0	0	0	1	0	0	0	0

Table 5-38 shows the bounds for the parameters for the dose response function. These bounds are identical to those presented in the hazard characterization chapter and Table 5-17.

TABLE 5-38 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS TO THE BETA-POISSON DOSE RESPONSE FUNCTION.

Parameter		**LB**	**ML**	**UB**
Dose response	*Alpha*	0.0763	0.1324	0.2274
(parameters correlated)	*Beta*	38.49	51.45	57.96

<u>Results of nominal range sensitivity analysis</u>

Results of the model runs are shown in the following figures. Each input is identified along the x-axis. The probability of illness is given on the y-axis. Each input has a corresponding vertical line with a diamond in the center that gives the probability of illness when the input is set at its most likely value. The probabilities of illness for the upper and lower bounds of the input are given by the horizontal lines at the ends of each vertical line. The longest vertical lines represent those inputs that have the most influence on the probability of illness.

Each egg product type is presented in a separate figure. Results for whole egg product with 10% added sugar are not shown because after pasteurization the simulated probability of illness results in 0 cases regardless of other factors.

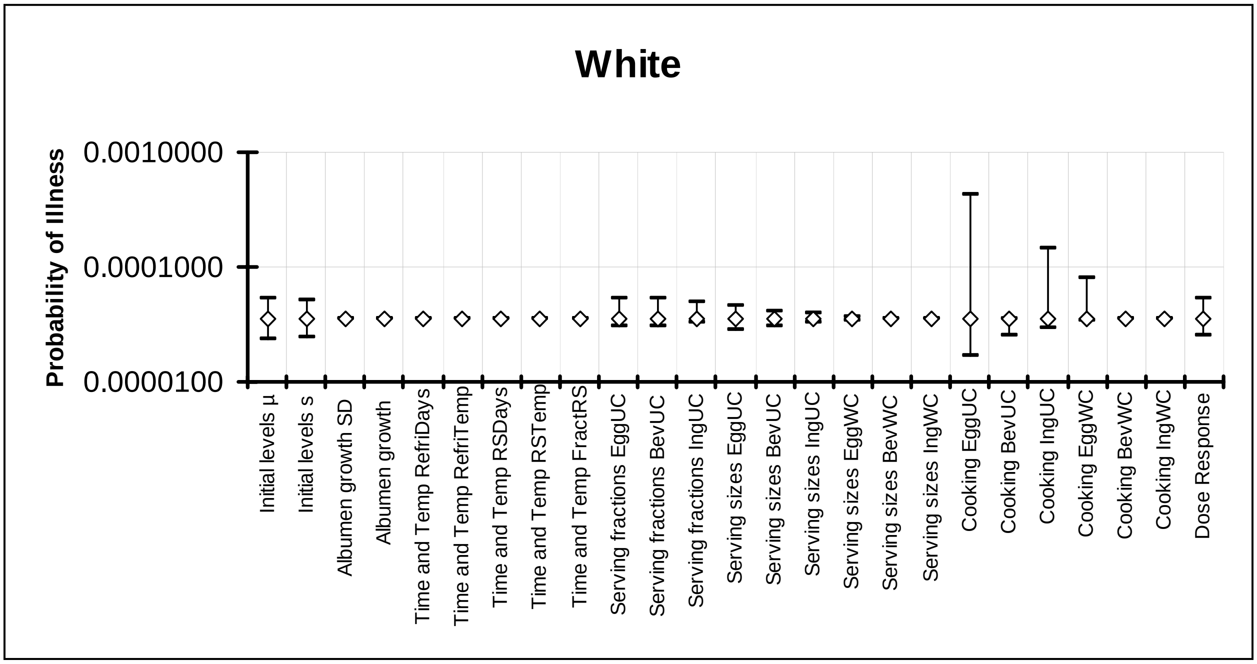

FIGURE 5-25 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG WHITE PRODUCT.

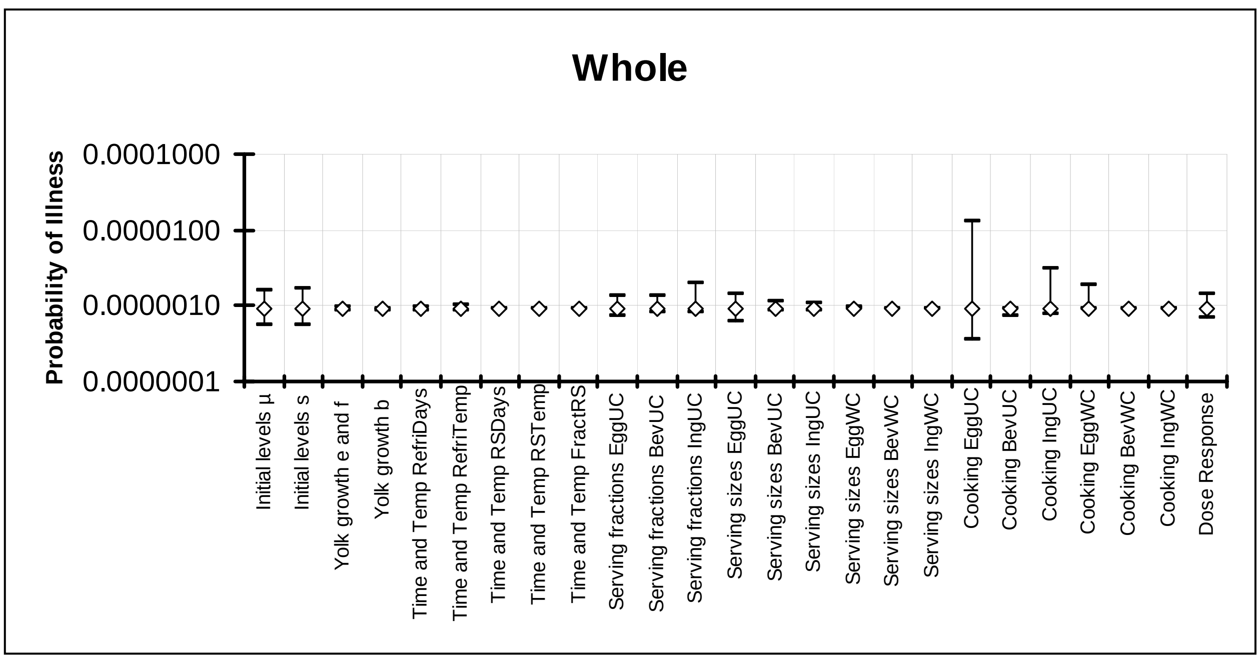

FIGURE 5-26 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR WHOLE EGG PRODUCT.

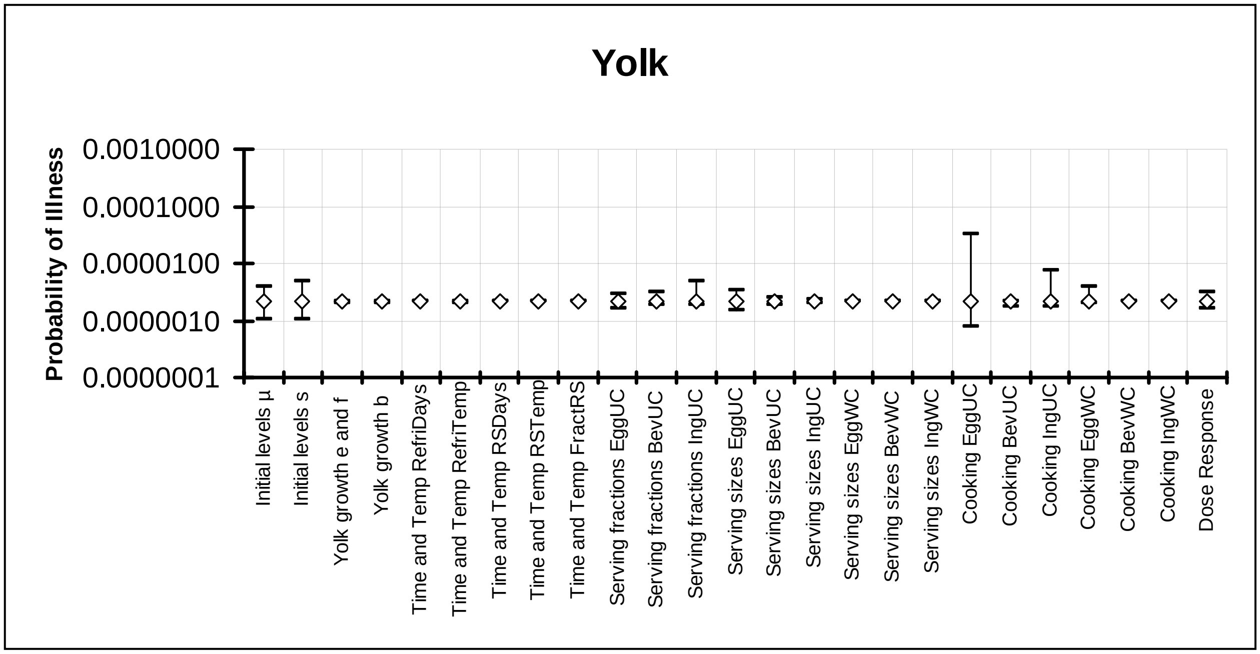

FIGURE 5-27 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR YOLK EGG PRODUCT.

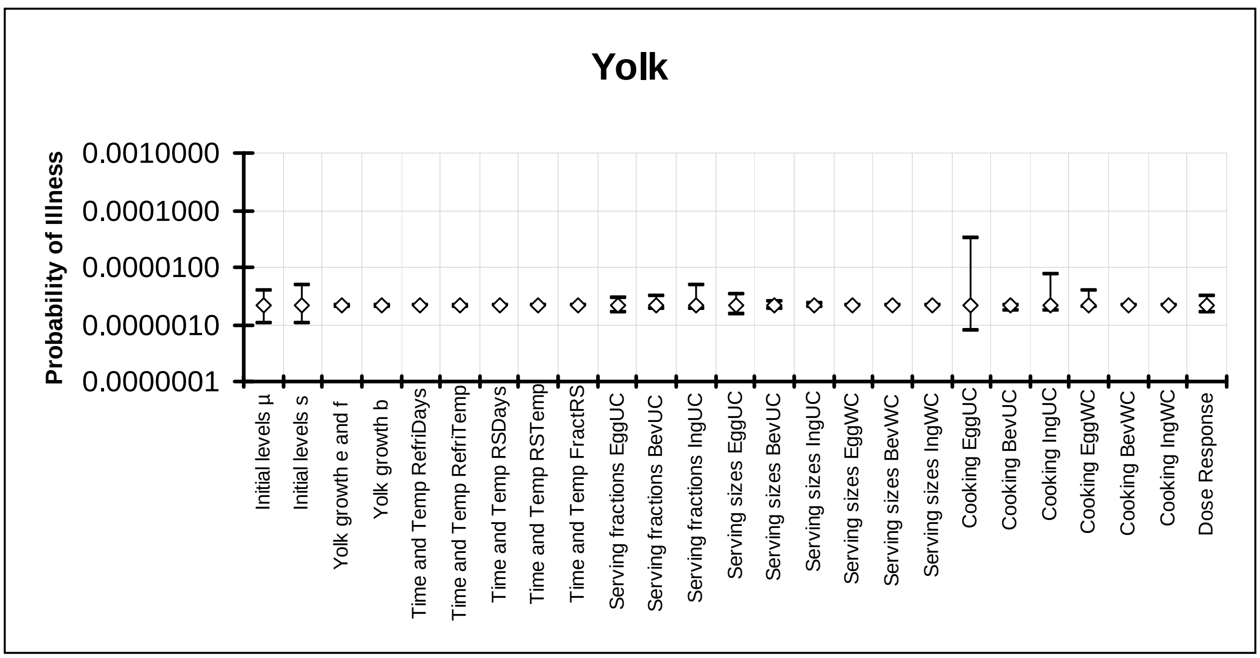

FIGURE 5-28 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR WHOLE EGG PRODUCT WITH 10% ADDED SALT.

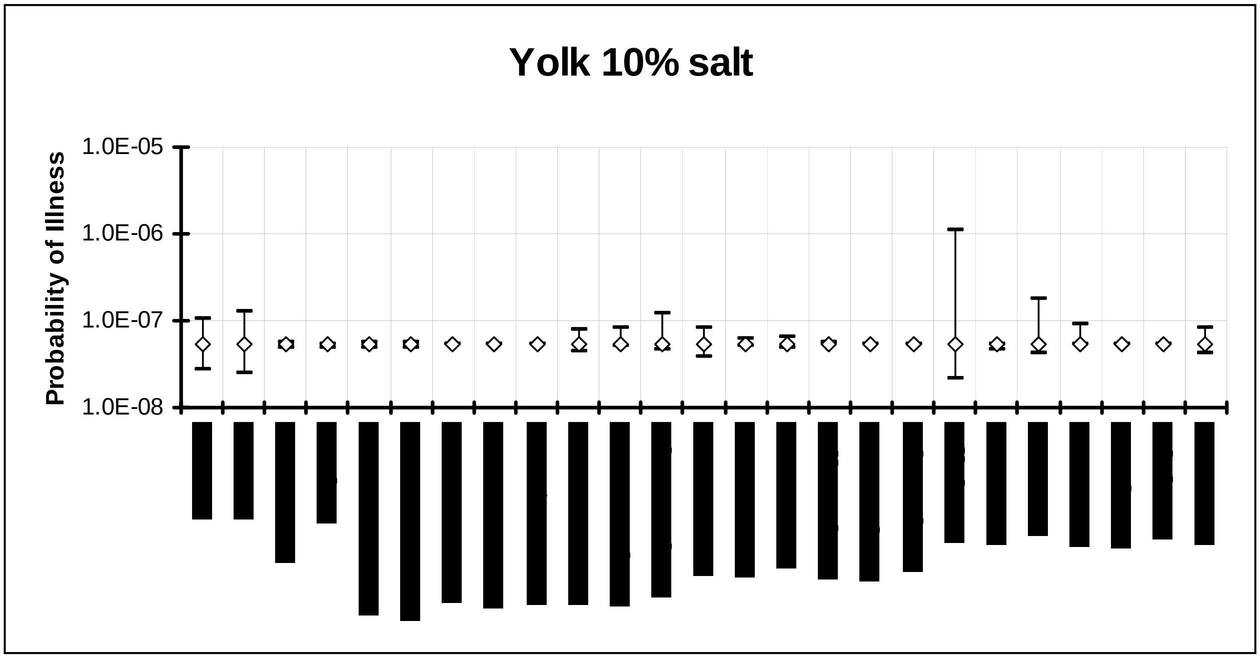

FIGURE 5-29 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG YOLK PRODUCT WITH 10% ADDED SALT.

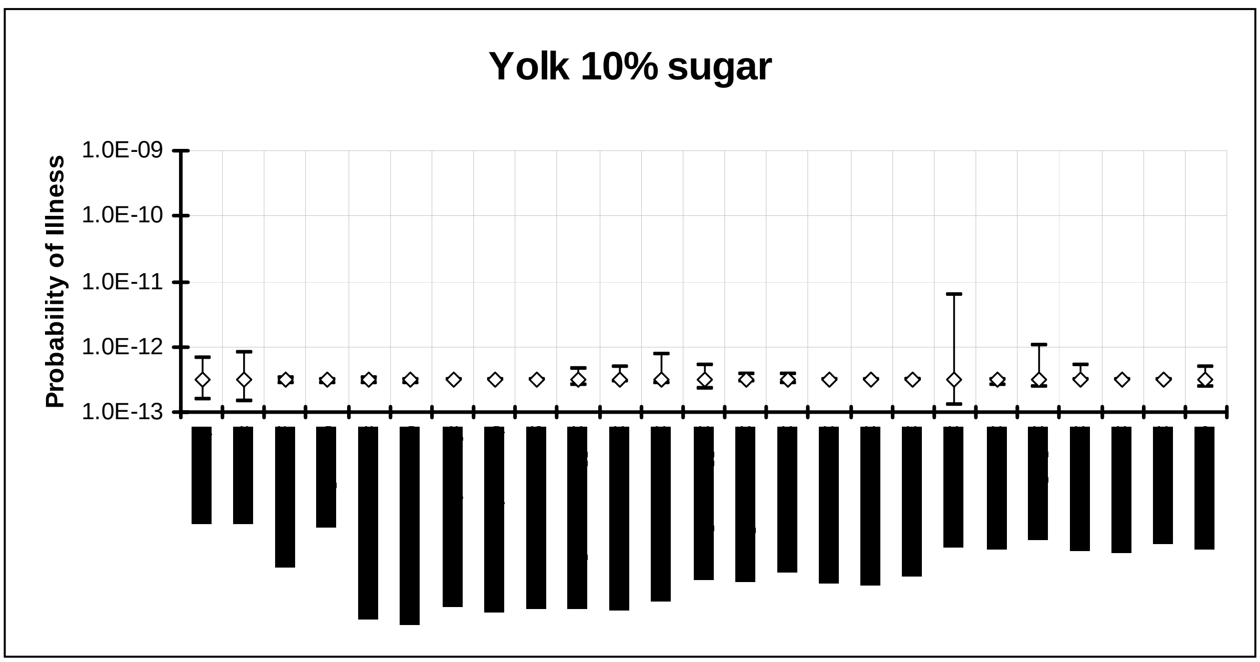

FIGURE 5-30 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG YOLK PRODUCT WITH 10% ADDED SUGAR.

Summary of nominal range sensitivity analysis

The effect of upper and lower bounds for the various inputs was similar across all egg product types. Cooking is noted to have a large potential effect. The uncertain parameters for the Weibull distribution that predicts the amount of contamination in egg products prior to pasteurization also had a relatively large effect. Little effect was noted from time and temperature of storage. This is due primarily to the relatively narrow range of times and temperatures which was informed by expert opinion. Furthermore, given the low temperatures modeled for egg product, storage time of storage would have a small effect.

Sensitivity to modeling assumptions

Stochastic growth modeling versus deterministic growth modeling

As with shell eggs, the difference between stochastic growth modeling and deterministic growth modeling was evaluated. There was much less difference between the two modeling assumptions than was noted for shell eggs in Table 5-18. This is likely due to the small amounts of growth modeled in the baseline model.

Post-pasteurization growth of thermally injured bacteria

Because all modeled egg products are subjected to pasteurization, the question of post-pasteurization growth of thermally injured bacteria is important. The effect of sub-lethal injury to bacteria that would affect the growth parameters was modeled similar to the method used to evaluate the same question for shell eggs. The baseline model was run with 100,000 iterations. These results were then compared with the results from running the model when the growth rate was set at one-half the expected growth rate after pasteurization. The modeled difference between these two assumptions was negligible. This was also likely due to the small amount of growth that takes place in the baseline model due to the time and temperature assumptions used.

Effect of pH on pasteurization of egg white

The lethality equation for egg white shown in **Error! Reference source not found.** is based on experimental studies of lethality in which the pH was 8.8. This value may be too low. Experimental studies have also been conducted for egg white with a pH of 9.3. The suggested model for lethality of Salmonella in eggwhite with pH = 9.3 is

$$\log_{10}\left(p\left(t\right)\right) = -\log_{10}\left(e\right)kt + \log_{10}\left(1 + \frac{k\left(e^{-wt}\right)}{w}\right) \quad (5.5)$$

Where: T is temperature ºC; $k = \exp(a + b(T\text{-}50))$; $w = \exp(c)$, for specified constants, a = -2.74273, b = 0.566244, and c = 0.229781.

At this pH the expected log reduction due to pasteurization in egg white is about 8.2. The expected number of illnesses due to egg white drops from about 23,000 (Table 5-29) to 5. The overall number of expected illnesses for all egg product types drops from about 50,000 to about 28,000. Thus, if egg white has a lower pH than modeled the estimated number of illnesses is lower than the anchored model would estimate.

Validation of the Egg Products Model

Lack of epidemiologic data

Historically, pasteurized egg products have been a very safe food. There have been no outbreaks linked to the consumption of egg products and consumption of pasteurized egg products does not appear as a risk factor in case control studies of foodborne illness. This is in contrast to shell eggs, which have been linked to about 80% of SE outbreaks in the U.S. The consumption of shell eggs, particularly lightly cooked shell eggs, appears as a risk factor in case control studies of SE. Thus, unlike shell eggs, there is no published estimate of human illness with which to validate the egg products model. Furthermore, an anchoring approach was used to adjust the log reduction due to pasteurization of egg white. Thus, the idea of validating the model is questionable. Nevertheless, it appears that a value of 50,000 for the number of human illnesses due to pasteurized egg product may be too high for the following reasons.

SE from eggs versus **Salmonella** *spp. from egg products*

Figure 5-19 shows the uncertainty around the estimate of human illness due to *Salmonella* Enteritidis from shell eggs based on epidemiologic data. The 95th percentile for the uncertainty is about 660,000. The hazard characterization chapter reports 794 outbreaks of SE in the 14 years from 1985 through 1998 inclusive, or about 57 (794/14) outbreaks per year. The hazard characterization chapter further reports an estimate that 80% of SE outbreaks are due to shell eggs, or about 45 outbreaks per year. Thus, there are about 15,000 (660,000 / 45) estimated cases at the 95th percentile for every reported outbreak due to shell eggs.

Based on the experience with shell eggs, one would less than 15,000 cases per year rather than the 50,000 cases modeled. On the other hand, outbreaks due to egg products may be more difficult to detect than outbreaks due to shell eggs. Contamination in a single lot of egg product can be distributed over many servings that are widely dispersed. There may be a higher index of suspicion associated with shell eggs related specifically to SE than with egg products related to *Salmonella spp*.

Potential sources for error

There are several potential sources for error in the egg products model that could result in estimates of illness that are too high. These include the incoming concentration, the effect of pasteurization, cooking, and consumption of foods containing egg products, and the dose response function.

<u>Incoming concentration</u>

The distribution for incoming concentration is based on analysis of the FSIS egg product baseline survey. If the sampling procedure did not adequately represent the concentration within the vats, the results could be biased.

<u>Log_{10} reductions due to pasteurization</u>
The effect of pasteurization was based on a single study. If the study was not representative, the results would not represent all egg products.

<u>Cooking and consumption of specific egg product types</u>
All seven egg product types were assumed to have been cooked in the same way and used in the same types of products. If the various products were used in distinctly different ways from that modeled, this would affect the results. For instance, if egg white is always cooked thoroughly, there would be fewer illnesses than predicted by the model.

<u>Dose-response function</u>
The dose-response function reported in the hazard characterization is based on a single set of dose response functions developed by the Joint Expert Meetings on Microbiological Risk Assessment organized by the WHO and FAO. This dose response function may not be applicable to all of the *Salmonella* serotypes recorded in the FSIS baseline survey. In addition, the dose response function may not be applicable to bacteria that have a sub-lethal injury because of pasteurization.

SUMMARY

Summary of Risk Estimates in Response to Management Questions Related to SE in Shell Eggs

What is the number of SE in shell eggs* before *and* after *a specified pasteurization scenario?
After pasteurization resulting in a 3-log_{10} reduction, the mean number of SE drops by 3 log_{10}. Similarly, a 5-log_{10} reduction results in a drop in the mean number of SE by 5 log_{10}. When eggs are finally consumed, however, the mean number of SE is not reflective of the 3- or 5-log_{10} reduction due to pasteurization.

***What is the number of illnesses per serving and annual number of illnesses from SE in* pasteurized *and* non-pasteurized shell eggs?**
The model predicts about 1 illness in every 150,000 eggs. Since eggs may contribute to more than one serving, the risk per serving is about 1 illness in every 470,000 servings. A 3-log_{10} reduction due to pasteurization reduces the risk of SE to about 1 illness in every 1.5 million servings. A 5-log_{10} reduction reduces the risk to about 1 illness in every 3.2 million servings. The baseline model predicts about 350,000 SE illnesses. A 3-log_{10} reduction due to pasteurization reduces the number of illnesses to 110,000 illnesses. A 5-log_{10} reduction results in a prediction of 52,000 illnesses. These predictions assume that all shell eggs would be pasteurized.

What is the effect of the temperature and length of time (in days) before eggs are collected after they are laid by the hen and then refrigerated and further processed on the estimated risk of illness?
Quick refrigeration of shell eggs has a significant effect on reducing the number of human illnesses. If eggs are stored and held at 45° F within 36 hours of lay, the estimated number of

human illnesses drops from 350,000 to 75,000. Storage time and temperature and pasteurization have a combined effect. Cooling eggs rapidly to 45° F makes pasteurization more effective. One surviving bacterium in an egg can rapidly multiply during the post-processing steps. Limiting growth of SE before pasteurization decreases the probability that there will be any surviving bacteria.

Summary of Risk Estimates in Response to Management Questions Related to *Salmonella* spp. in Egg Products

What is the number of illnesses per serving and annual number of illnesses from* Salmonella *spp. in* pasteurized egg products *(*e.g.*, liquid whole eggs, yolks, and egg whites)?

The baseline model provides estimates for seven different types of egg products: white, whole, yolk, whole with 10% added salt, whole with 10% added sugar, yolk with 10% added salt, and yolk with 10% added sugar. These seven products are used to represent all possible types of egg products. The probability of illness per serving ranged from 2.9×10^{-6} for egg white product to less than 10^{-16} for whole egg product with added sugar. The baseline model predicts about 50,000 illnesses. The seven egg products are pasteurized to varying amounts depending on current regulatory requirements. Pasteurization of all egg products to effect a 6-$\log_{10}$ reduction results in a prediction of about 22,000 annual illnesses. Pasteurization of all egg products to effect a 7-$\log_{10}$ reduction results in a prediction of about 2300 annual illnesses.

What is the number of* Salmonella *spp. in a liter of egg product (whole, yolk, albumen)* before *and* after *a specified pasteurization scenario?

Pasteurization of egg products is meant to reduce the number of *Salmonella* by a specified amount. As with shell eggs, the amount of pasteurization is given in $\log_{10}$ reduction. A 1-$\log_{10}$ reduction means that the amount of contamination is reduced by 90%; a 2-$\log_{10}$ reduction corresponds to a 99% reduction in contamination, and a 3-$\log_{10}$ reduction to 99.9%. Given a 5-$\log_{10}$ reduction due to pasteurization, about 90% of liters of egg white product would have 1 or less *Salmonella*. On the other hand, given the baseline $\log_{10}$ reductions, nearly 100% of liters of whole egg product would have an expected number of *Salmonella* of 1 or less.

REFERENCES

1. Vose D. Quantitative risk analysis: A guide to Monte Carlo simulation modeling. New York: John Wiley & Sons, Ltd., 1996.

2. Frey HC, Patil SR. Identification and review of sensitivity analysis methods. Risk Anal 2002 Jun;22(3):553-78.

3. Smelt JP, Otten GD, Bos AP. Modelling the effect of sublethal injury on the distribution of the lag times of individual cells of *Lactobacillus plantarum*. Int J Food Microbiol 2002;73(2-3):207-12.

4. National Agricultural Statistics Service. Egg products. Available at http://usda.mannlib.cornell.edu/. 1998.

5. Viator C, Kendall D. Pathogen reduction and other technological changes in the meat, poultry, and egg industries - Data report. RTI International. Research Triangle Park. 2002.