5 Risk Characterization

INTRODUCTION

The World Health Organization defines risk characterization as the "integration of hazard identification, hazard characterization, and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties." (http://www.who.int/fsf/Micro/Definition_risk_analysis_terms_related_to_food_safety.pdf).

The Hazard Identification chapter of this report described qualitatively associations of human salmonellosis associated with *Salmonella* Enteritidis (SE) in shell eggs and with *Salmonella* spp. in egg products. In the Hazard Characterization chapter of the report, development of a dose response function, in which various levels of *Salmonella* contamination were associated with probabilities of illness, was presented. In the Exposure Assessment chapter of the report, derivation of estimates of human exposure to *Salmonella* contamination in shell eggs and egg products was described. This section, Risk Characterization, draws on the information in these previous sections to estimate human illness.

At its most basic level, risk characterization is simply incorporating the exposure distribution derived in the exposure assessment with the dose response function derived in the hazard characterization. Each point in the exposure distribution is multiplied by both its likelihood of occurrence and the likelihood of illness given that level of exposure. The resulting likelihoods are then summed to give the overall probability of illness. Thus, the final output of each model is a single estimate of the probability of illness from either SE in shell eggs or *Salmonella* spp. in egg products. In addition, risk characterization represents an evaluation of the risk of certain practices, procedures, or populations. Risk managers can use this feature of risk characterization to evaluate whether regulatory action may be helpful in a certain area and/or whether educational efforts should be targeted at certain subpopulations, for instance. The risk characterization also uses sensitivity analysis to identify the relative importance of specific model inputs.

Using the Risk Characterization to Answer Risk Management Questions

The introduction to this report identified five "risk management questions" to be answered by the risk assessment. These questions are related to the estimates of risk of illness and risk reduction at intermediate points in the exposure assessment.

Risk management questions related to SE in shell eggs

- What is the number of SE in shell eggs *before* and *after* a specified pasteurization scenario?
- What is the number of illnesses per serving and annual number of illnesses from SE in *pasteurized* and *non-pasteurized shell eggs*?
- 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?

Shell egg pasteurization scenarios

Currently, few shell eggs (less than 0.05%) processed in the U.S. are pasteurized. The goal of pasteurization is to achieve a very high likelihood of no SE in shell eggs, with a high level of confidence. Risk managers requested that the risk assessment consider the per annum risk of illness (number of illnesses per year) if 0.05%, 1%, 5%, 10%, 25%, 50%, 75%, or 100% of the industry pasteurizes shell eggs. As a result, this risk assessment has been developed with the flexibility to examine different shell egg pasteurization scenarios, and it can incorporate new information about industry practices as it becomes available. At this point, limited information on industry practices constrained the extent of the modeling of pasteurization practices.

Shell egg handling scenarios

The time at which shell eggs are pasteurized is critical. The amount of SE within a contaminated egg may increase over time, largely based on the temperature at which the egg is stored. As a result, FSIS risk managers requested that this risk assessment consider the age of shell eggs and the corresponding storage times and temperatures prior to reaching the processor (where they may be pasteurized). As a result, this risk assessment considers several egg handling and storage scenarios for eggs (e.g., the cooling of eggs commences at 24 and 36 hours for eggs that are 1 to 60 days old and stored at temperatures from 45 to 60^{o}F, followed by a refrigeration at 45ºF until the eggs are pasteurized). By considering these "egg handling" scenarios (i.e., when shell eggs should be refrigerated and the extent of refrigeration), the risk assessment provides insight to the effectiveness of various egg handling performance standards to limit the growth of SE in shell eggs, and mitigate the subsequent risk of illness.

Egg production risk factors for SE

Risk managers requested that this risk assessment evaluate the effects of season and the molting of flocks on the production of SE-contaminated eggs and the consequent risk of illness. Unfortunately, data were not available to estimate fully the effect of season on the production of SE-contaminated eggs and the subsequent risk of illness. This risk assessment does, however, include the effects of molting of flocks on the prevalence of SE-contaminated eggs.

Risk 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* (liquid whole eggs, yolks, and egg whites)?
- What is the number of *Salmonella* in a liter of egg product (whole, yolk, albumen) *before* and *after* a specified pasteurization scenario?

Egg product pasteurization scenarios

Current command-and-control regulations for the pasteurization of egg products are based on specific time and temperature requirements (9 CFR 590.570). These regulations do not cover all liquid egg products; nor do they differentiate the various types of liquid egg product (e.g., whole egg, yolk, or albumen), which may vary in prevalence and/or level of *Salmonella* spp. prior to pasteurization. Moreover, these prescriptive regulations do not allow industry the flexibility to implement hazard controls that are most effective for specific processes and products. Risk managers requested that this risk assessment consider egg product pasteurization scenarios in which the level of *Salmonella* spp. in egg products is reduced by 7 to 12 $\log_{10}$.

RISK CHARACTERIZATION FOR *SALMONELLA* ENTERITIDIS IN SHELL EGGS

Modeling Illnesses per Egg

Probability of illness per serving

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

$$IS = DR(S2) \tag{5.1}$$

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.

The dose response function was given as a beta-Poisson model in chapter 4. Thus the probability of illness (IS) becomes:

$$IS = 1 - \left(1 + \frac{S_2}{\beta}\right)^{-\alpha} \tag{5.2}$$

Where: α = 0.1324 and β = 51.45 in the baseline model.

Estimation of the dose per serving, 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. Given a particular dose resulting from a contaminated egg, Equation 5.1 calculates the probability that the dose would cause illness.

Illnesses per egg

Multiple Illnesses Per Egg
The probability of illness per serving will always be between 0 and 1. If multiple servings were generated from a contaminated egg, however, it is possible to have many illnesses that result from the consumption of that single egg. For example, consider one contaminated egg that is used to make a pitcher of eggnog. Assume the pitcher serves 10 persons and that the egg was contaminated with 10^9 SE. Each serving thus contained 10^8 bacteria. Conceivably, that single egg could account for 10 illnesses. This illustration represents one way many persons can become ill from a single egg.

As noted in the Exposure Assessment, a single egg may serve more than one person. Thus, Equation 5.1 would apply to each person that consumed a portion of the egg. Furthermore, the dose to which each person would be exposed would be effectively reduced. Consequently, the Exposure Assessment determined the contamination per serving by dividing the contamination in the egg by the number of servings. The Risk Characterization accounts for these eggs potentially serving multiple persons by multiplying the illnesses per serving by the number of servings. The number of illnesses per egg is thus the probability of illness per serving multiplied by the number of servings per egg.

$$I_E = I_S \text{ x } V \tag{5.3}$$

Where: I_E = the frequency of illnesses resulting from one or more persons consuming servings generated from a single egg. This value can exceed 1; I_S as defined in 5.1.; V = the number of servings generated from a single egg.

Calculating illnesses per egg in the model

The model represents exposure assessment and risk characterization. The model is written in Visual Basic for Applications (Microsoft Corp., Redmond, WA) and inputs and outputs are stored in Excel worksheets. A more complete description of the model structure can be found in the exposure assessment and hazard characterization chapters. Each iteration of the model follows an egg from the farm to consumption. At consumption, the model estimates the number of bacteria per serving (S_2), and the number of servings per egg (V) is determined. These values are used in 5.1 and 5.3 above to determine the total illnesses for the egg for that iteration. These values are averaged to give the expected illnesses per egg for a given simulation.

Generating Baseline Estimates

Monte Carlo modeling

The baseline model contains distributions that represent variability in storage times and temperatures, initial levels of bacteria, the effect of growth parameters, serving size, the effect of cooking, and other factors. The baseline model is run using Monte Carlo methods.[1]

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.

Answers to Risk Management Questions

What is the number of *Salmonella* Enteritidis in shell eggs *before* and *after* a specified pasteurization scenario?

In-shell pasteurization of eggs is meant to reduce the number of SE by a specified amount. 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%. In the model, $\log_{10}$ reductions are handled probabilistically. For example, if an egg has 1 SE and is exposed to a 3-$\log_{10}$ reduction there is a 99.9% probability that the organism will be killed and a 0.01% probability that it will survive.

Intuitively, 3 $\log_{10}$ pasteurization or a 3-$\log_{10}$ reduction would be expected to reduce the number of SE by 99.9%. Table 5-1 shows the mean number of bacteria per contaminated egg at each of the steps from lay through consumption. It should be noted that most eggs are not capable of supporting bacterial growth, either in the layer house or during on-farm storage; thus most of the eggs would have the same number of bacteria with which they were contaminated, generally no more than 1,000. If just a few bacteria grow to high levels, however, the mean number of bacteria will reflect those high levels. Table 5-1 shows that after pasteurization resulting in a 3-log reduction, the mean number of SE drops by 3 $\log_{10}$.

Precision of Answers

Answers to risk management questions are typically given with two or three significant digits. The model provides more precise answers, but reporting them does not portray risk more accurately. It is best to think of the answers as approximations. That said, in some cases, more that two or three significant digits will be given to show the effect of model parameters.

TABLE 5-1 MEAN NUMBER OF SE IN CONTAMINATED EGGS AFTER EACH MODEL STEP FOR BASELINE AND PASTEURIZATION.

Step	Baseline	3 $\log_{10}$	5 $\log_{10}$
Layer	9,100,000		
Farm	100,000,000		
Trans	110,000,000		
PreProcess	200,000,000		
Past	200,000,000	190,000	1,900
PostProcess	290,000,000	46,000,000	27,000,000
Trans	310,000,000	53,000,000	31,000,000
Retail	330,000,000	63,000,000	37,000,000
Trans	340,000,000	66,000,000	39,000,000
Home	360,000,000	72,000,000	42,000,000

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. This is graphically illustrated in Figure 5-1.

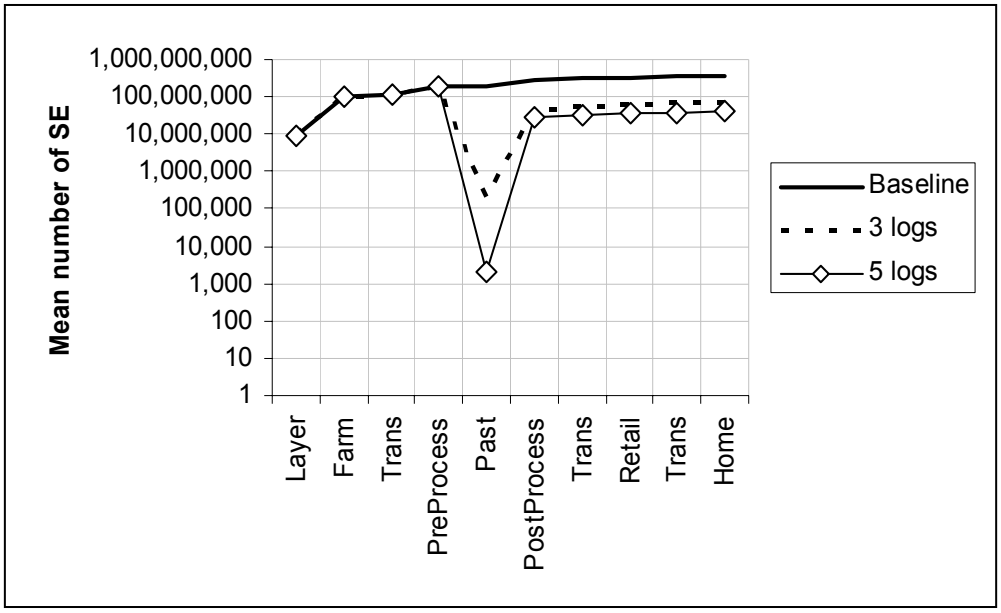

Figure 5-1 Mean number of SE per egg at different steps in model with and without pasteurization.

Table 5-1 and Figure 5-1 may both cause some confusion because as noted before they show the mean number of SE bacteria at each of the steps. It may be helpful instead to show the potential effect of the number of bacteria per contaminated egg on the number of human illnesses that would occur. This assumes that eggs were immediately consumed at the end of each model step. Figure 5-2 shows the number of estimated human illnesses after each step in model if eggs were immediately consumed.

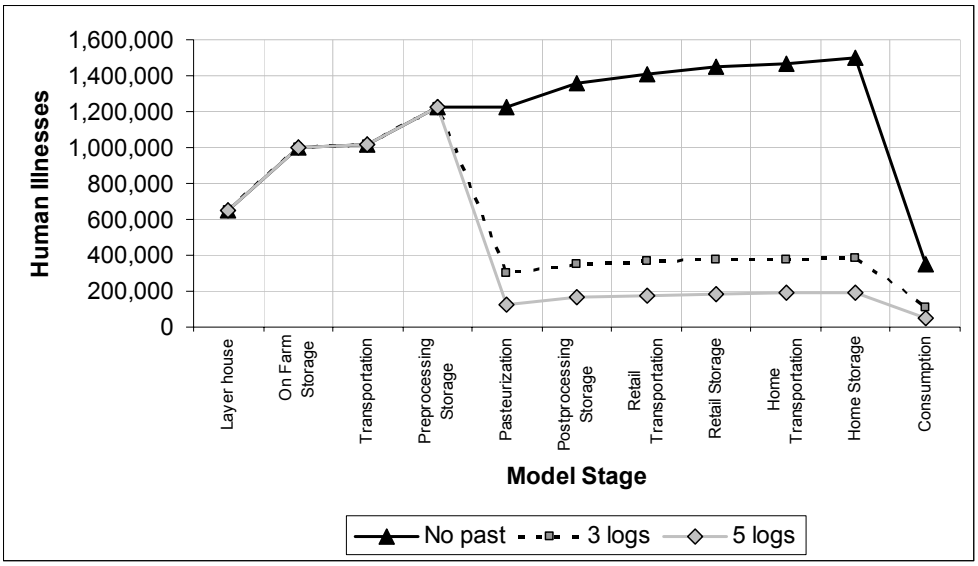

FIGURE 5-2 NUMBER OF ESTIMATED HUMAN ILLNESSES AFTER EACH STEP IN MODEL IF EGGS WERE IMMEDIATELY CONSUMED.

Figure 5-2 shows that if eggs were consumed immediately after pasteurization the numbers of illnesses would be substantially reduced. Pasteurization does not affect the way eggs are handled in subsequent steps. If eggs are handled in such a way to allow bacterial growth, then any bacteria left after pasteurization can theoretically rapidly grow to pre-pasteurization levels. Furthermore, the heat of pasteurization may have an effect on the yolk membrane, which could conceivably allow more rapid growth of bacteria following pasteurization. Figure 5-2 shows the percent of eggs estimated to have yolk membrane breakdown (YMB) at different model steps with and without pasteurization. The model estimates that, based on the temperatures necessary to achieve a 3-$\log_{10}$ reduction, YMB will always occur.

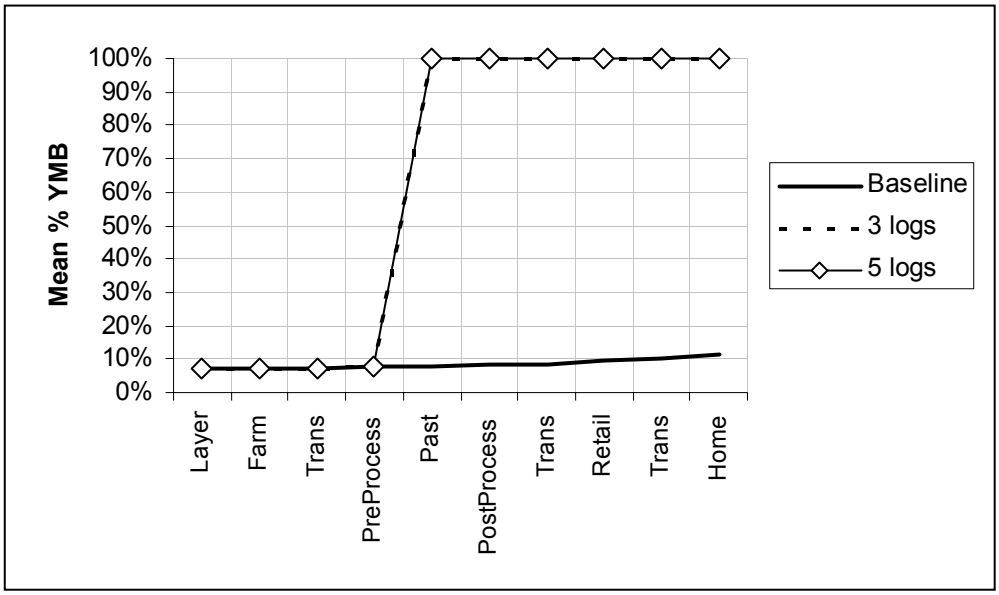

FIGURE 5-2 MEAN % YMB IN EGGS AT DIFFERENT STEPS IN THE MODEL WITH AND WITHOUT PASTEURIZATION.

Despite the opportunities for additional growth of bacteria after pasteurization as shown in Figure 5-3. Figure 5-2 shows that the increase in potential human illnesses is less following pasteurization than would normally occur in the no pasteurization scenario.

What is the number of illnesses per serving and annual number of illnesses from* Salmonella *Enteritidis in pasteurized and non-pasteurized shell eggs?

Estimated illnesses per serving for non-pasteurized shell eggs

The baseline model estimates approximately 0.023 illnesses per contaminated egg. It further estimates approximately 0.0003, or about 3 eggs in every 10,000, would be contaminated at lay. Thus, the number of illnesses per egg in the baseline model is approximately $0.023 \times 0.0003 \approx 0.000007$, or about 1 illness in every 150,000 eggs. As noted earlier, eggs may contribute to more than one serving. Thus, the risk per serving is equal to the illnesses per egg divided by the number of servings per egg. The mean number of servings per egg from the distribution shown in the exposure assessment is approximately 3.2. Therefore, the risk of illness per serving is $0.000007 / 3.2 \approx 0.000002$, or about 1 illness in every 470,000 servings.

Estimated illnesses per serving for pasteurized shell eggs

As noted earlier, a particular $\log_{10}$ reduction in bacteria at pasteurization does not necessarily correspond with a similar $\log_{10}$ reduction in bacteria at consumption. Likewise, given the number of steps following processing, pasteurization does not have as large an effect on illnesses as might be thought given the data and model assumptions. A 3-$\log_{10}$ reduction at pasteurization reduces the number of illnesses per egg from approximately 6.9×10^{-6} to approximately 2.2×10^{-6}. A 5-$\log_{10}$ reduction at pasteurization further reduces the number of illnesses to approximately 1.0×10^{-6}. Thus, the number of illnesses per serving is approximately 2.1×10^{-6} for the baseline

scenario, 0.69 x 10^{-6} for a 3-$\log_{10}$ reduction, and 0.31 x 10^{-6} for a 5-$\log_{10}$ reduction. Table 5-2 shows the illnesses per egg and illnesses per serving, as well as the reciprocals of these values (eggs per illness and servings per illness).

TABLE 5-2 ILLNESSES PER EGG AND SERVING FOR PASTEURIZED AND NON-PASTEURIZED EGGS.

Scenario	Illnesses per egg	Eggs per illness	Illnesses per serving	Servings per illness
Baseline	0.0000069	150,000	0.0000021	470,000
3 Log_{10}	0.0000022	450,000	0.0000007	1,500,000
5 Log_{10}	0.000001	1,000,000	0.0000003	3,200,000

Estimating the annual number of illnesses

Estimating the total illnesses for a given year in the U.S. is accomplished by multiplying the illnesses per egg by the total number of eggs consumed. Total egg consumption is given in Table 5-3.

TABLE 5-3 ANNUAL EGG CONSUMPTION IN THE U.S.

Year	Million dozens consumed	Eggs per capita
1997	5,358.6	235.8
1998	5,522.2	240.2
1999	5,816.6	250.1
2000	5,926.8	252.1
2001	6,010.6	252.6
2002	6,101.1	253.7
2003[a]	6,132.1	252.3
2004[b]	6,159.0	250.9

[a]Preliminary data.
[b]Forecasted data.
Source: http://www.ers.usda.gov/publications/Agoutlook/AOTables/

For the purposes of this risk assessment, egg consumption data for the year 2002 were used (http://www.ers.usda.gov/publications/Agoutlook/AOTables/). This was the most recent year for which a full year's observation was available.

Only a portion of the eggs shown in Table 5-3 is consumed as shell eggs. The rest are consumed as egg products. Use of egg products has continued to rise over the past decade. The Economic Research Service states:

> Through August 2002, 1.25 billion dozen eggs, approximately 31 percent of all eggs produced for table use, went to the breaking-egg market. This volume was up 4 percent from the same period in 2001. (http://www.ers.usda.gov/publications/agoutlook/Nov2002/ao296a.pdf).

and:

> Since 1996, the amount of eggs going to the breaking market has risen by about 25 percent and now uses about one-third of total table egg production. (http://www.ers.usda.gov/publications/ldp/may03/ldpm107f.pdf)

This risk assessment thus assumes that 31 percent of the total egg consumption for 2002 was in the form of egg products. Thus, shell egg consumption was estimated at 0.69 * 6.1 billion dozen ≈ 4.2 billion dozen, or about 50.5, billion eggs.

Estimated annual number of illnesses for non-pasteurized shell eggs

The annual number of illnesses from non-pasteurized shell eggs (this assumes that all eggs in the U.S. are non-pasteurized) is given by 0.0000069 illnesses per egg * 50.5 billion eggs ≈ 350,000 illnesses.

Estimated annual number of illnesses for pasteurized shell eggs

The annual number of illnesses for pasteurized shell eggs assumes that all eggs in the U.S. are pasteurized. Given a 3-$\log_{10}$ reduction, the annual estimate of illnesses is about 200,000. A 5-$\log_{10}$ reduction is predicted to result in about 170,000 illnesses annually.

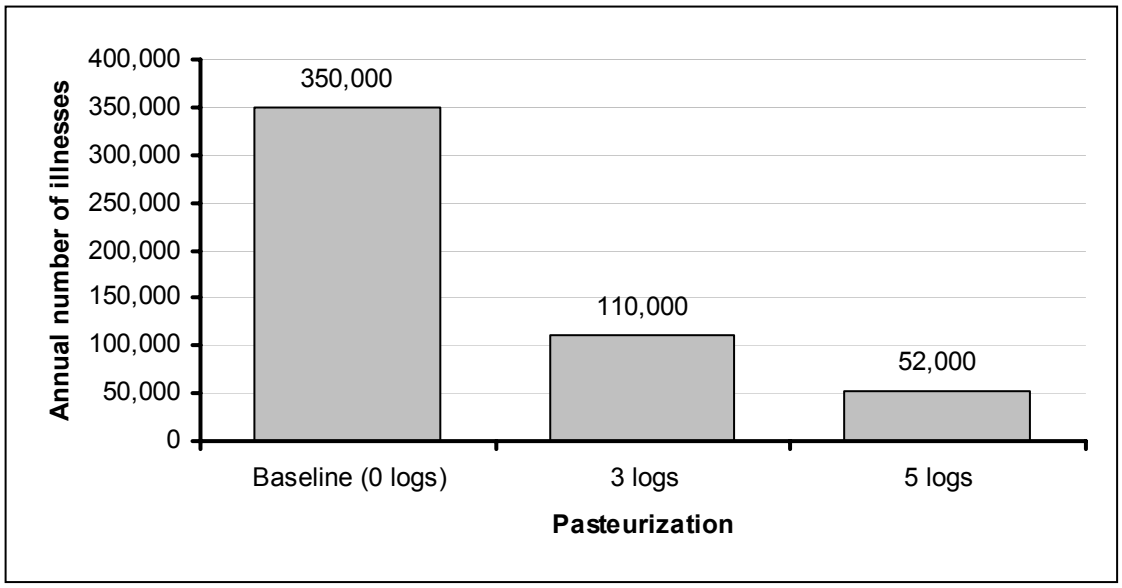

FIGURE 5-3 EFFECT OF PASTEURIZATION ON ANNUAL NUMBER OF ILLNESSES.

Estimated annual number of illnesses assuming varying proportions of pasteurized shell eggs

It is unlikely that all shell eggs in the U.S. would be pasteurized. The annual number of illnesses in such cases is directly proportional to the percent of eggs pasteurized. As an example, if no eggs were pasteurized the model estimates 350,000 annual illnesses. If all eggs were pasteurized to a 3-$\log_{10}$ reduction, the model predicts 110,000 illnesses. If 50% of the eggs were pasteurized then the number of illnesses would be halfway between 350,000 and 110,000 illnesses, or about 230,000 illnesses. (Each of these estimates assumes no differences in growth parameters for surviving SE). Table 5-4 and Figure 5-5 show this effect.

TABLE 5-4 EFFECT OF PERCENT EGGS PASTEURIZED ON ANNUAL NUMBER OF ILLNESSES.

	Pasteurization Level	
% Eggs Pasteurized	**3 log_{10}**	**5 log_{10}**
0.00	350,000	350,000
0.05	350,000	350,000
0.10	350,000	350,000
1.00	350,000	350,000
5.00	340,000	330,000
10.00	320,000	320,000
20.00	300,000	290,000
30.00	280,000	260,000
40.00	250,000	230,000
50.00	230,000	200,000
60.00	200,000	170,000
70.00	180,000	140,000
80.00	160,000	110,000
90.00	130,000	81,000
95.00	120,000	66,000
99.00	110,000	55,000
99.90	110,000	52,000
100.00	110,000	52,000

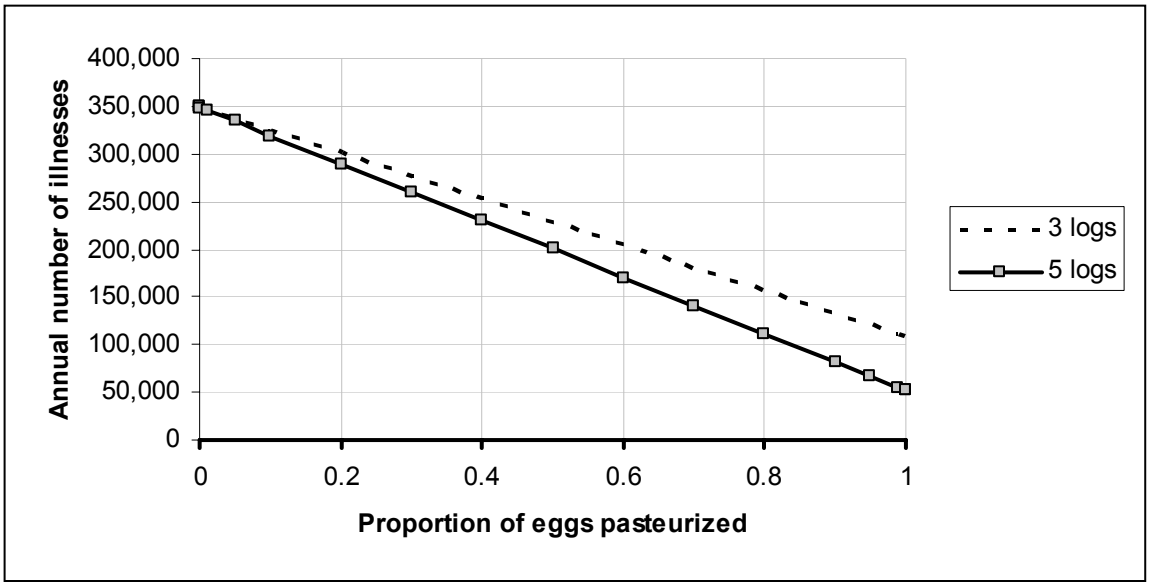

FIGURE 5-4 EFFECT OF PROPORTION OF EGGS PASTEURIZED ON ANNUAL NUMBER OF ILLNESSES.

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?

Eggs are collected at various intervals after lay. If eggs are collected twice a day, one would expect about twelve hours to elapse between collections. The average egg would thus be about six hours old at the time of collection. Of course, eggs are not always collected twice a day. Nor does twice a day collection necessarily correspond with collection every twelve hours. Nevertheless, after collection, eggs are stored at different temperatures for different periods until processing.

One possible way to limit the growth of SE in shell eggs is to require refrigeration of the eggs soon after lay. This is modeled by truncating the distribution for the time spent in the layer house at a set value and then subjecting all eggs to a particular temperature for the time of storage until processing. Eggs after processing are stored in the same manner as in the baseline.

Storage time in the layer house was truncated at 3 different values: 12 hours, 24 hours, and 36 hours. This does not mean that each egg was stored for 12, 24, or 36 hours, because eggs may be laid at different times throughout the day. Rather, each egg in the scenario was stored for no more than 12, 24, or 36 hours. Since very few eggs in the baseline were stored in the layer house for as long as 36 hours, truncating the distribution at 36 hours would be expected to have relatively little effect on subsequent human illness. On the other hand, many more eggs were stored for more than 12 hours. Thus, limiting the time in the layer house to no more than 12 hours would be expected to have a greater effect.

Storage temperature after processing was set at 3 different values: 45, 53, and 60° F. In these scenarios, eggs were stored only at those temperatures. For instance, if there is a requirement that eggs after collection must be stored at temperatures no greater than 60° F, it is reasonable to assume that producers currently storing eggs at 45° F would wish to save money on refrigeration costs while maintaining compliance with regulations.

Storage Temperature is Ambient Temperature
Throughout the model storage temperature is the ambient or air temperature at which eggs are stored.

Thus, there are three scenarios in which eggs are refrigerated within 12, 24, or 36 hours. For each of these scenarios, there are three other scenarios in which eggs are stored at 45° F, 53° F, or 60° F. In addition, there is the baseline scenario for ten scenarios. The total number of human illnesses is modeled for each of these scenarios with no pasteurization and with 3 and 5 $\log_{10}$ pasteurization. Results are shown in Table 5-5.

TABLE 5-5 COMPARING DIFFERENT PASTEURIZATION AND STORAGE PROTOCOLS ON ESTIMATED NUMBERS OF HUMAN ILLNESSES.

Time and Temperature	Pasteurization		
	None	3 $\log_{10}$	5 $\log_{10}$
Storage at 45F within 0.5 days	77,000	14,000	7,200
Storage at 45F within 1.0 days	130,000	33,000	17,000
Storage at 45F within 1.5 days	240,000	66,000	32,000
Baseline	350,000	110,000	52,000

The bottom row in Table 5-5 refers to the baseline values for the model simulated with and without pasteurization. These are identical to the values shown in Figure 5-3. Storage of eggs at collected within 1.5 days and stored at 53° F produces values similar to the baseline. In other words, a requirement to store eggs at 53° F within 36 hours of lay would likely have little effect on reducing the number of human illnesses. Storage at 60° F would increase the number of human illnesses, even if eggs were subsequently pasteurized with a 3-$\log_{10}$ reduction. Storage at 45° F after collection reduces human illness.

Combined effect of storage and pasteurization

Storage time and temperature and pasteurization have a combined effect. In the baseline row in Table 5-5 pasteurization at 5-$\log_{10}$ results in reduction of human illness from 350,000 to 52,000 or 15% of the no pasteurization value. If eggs are stored at 45° F within 12 hours of collection the model estimates 77,000 illnesses or 22% of the no pasteurization value. If eggs are stored at 45° F within 12 hours of collection and subjected to a 5-$\log_{10}$ reduction from pasteurization, the total illnesses expected would be 350,000 x 15% x 22% = 11,000. Instead, the model estimates only 7,200 illnesses.

Cooling eggs rapidly to 45° F after processing makes pasteurization more effective. One surviving bacterium in an egg could rapidly multiply during the post-processing steps. Limiting growth of SE before pasteurization decreases the probability that there will be any surviving bacteria.

Stability of the Baseline Model

Results from the baseline model are generated from 50,000 iterations using a particular seed value. The number of iterations was set at 50,000 because each of the inputs and outputs for each iteration can be easily saved to an Excel worksheet. This allows for both easier auditing of model results and subsequent analysis of correlations between inputs and outputs. When the seed value for the model changes, the number of human illnesses per egg and the annual number of human illnesses change.

The output from a set of 50,000 iterations can be thought of as a sample from a population of all possible output values. Thus, in addition to the mean number of illnesses per egg reported earlier (0.0000069), the standard deviation (0.0001) can also be determined. The standard error can then be calculated from the mean, standard deviation, and sample size, and the size of the standard error can be compared to the size of the mean. For the baseline model with 50,000 iterations, the standard error is about 6% of the mean. This gives an idea of how much the model output will vary given different seed values.

The model was simulated twenty separate times using a different randomly generated seed value (from the Excel Rand() function) for each simulation. Table 5-6 shows the results of the 20 simulations.

TABLE 5-6 ESTIMATES OF HUMAN SE ILLNESSES PER YEAR FROM 20 BASELINE SIMULATIONS USING DIFFERENT RANDOM SEED VALUES.

285,219	317,474	342,432	345,989
289,189	318,063	342,847	347,129
300,389	324,891	342,882	350,787
303,557	335,180	343,079	372,016
304,454	337,108	345,518	382,883

The model has an option that allows simulation in such a way that the only value captured is the probability of human illnesses. This allows a greater number of iterations to be conducted and results in greater stability. More iterations, however, result in greater model run times, and preclude correlation analysis of inputs and outputs. Furthermore, the model presently stores all distributions in memory. Depending on the computer, large models may require paging to virtual memory and thus, slow the simulation more than would be expected.

Because the baseline model run used a specific seed value, comparisons can easily be made with mitigation runs with the same seed value. This ensures identical draws from distributions and that the only change is in the specific mitigation modeled.

Sensitivity Analysis

Sensitivity analysis shows the effect of changing input values on the outcome of a model, given model structure, data, and assumptions. For instance, the effect of forced molting on the likelihood of human illness from SE in shell eggs can be examined by changing the input fraction of flocks that are molted. Sensitivity analysis can thus address directly some risk management questions.

Sensitivity analysis can also identify those inputs that have the biggest effect on the model output for the current model structure. The reason for the effect may be obvious. For instance, it is intuitive that reducing the number of contaminated eggs by one half would reduce the number of human illnesses by one-half. Often, however, the reason is not obvious. Changes in equation parameters may have non-intuitive effects that can only be understood through further study. Although inputs that have a great deal of uncertainty associated with them would be expected to have a greater effect on the model output than more certainly defined outputs, this is not always the case. Some inputs may be very uncertain but have little effect on the model output. Identifying those inputs that have significant effects on model outputs is an important step in prioritizing research needs. Little benefit is gained from additional research into unimportant variables or those variables that are already well characterized.

Second-order modeling
A first-order model accounts for variability in a system by iterating through specific values and distributions. A second-order model accounts for uncertainty by iteratively choosing from sets of values and distributions to use for the first-order model. A second-order model allows characterization of the uncertainty in the output distribution.

Sensitivity analysis as proxy for second-order model

In this report, sensitivity analysis serves as a proxy for conducting a second-order model in which all inputs have their uncertainties characterized probabilistically. A second-order model would then generate a series of exposure distributions and a series of dose response functions that would all be integrated to generate a distribution that would characterize our uncertainty about the likelihood of illness. This second-order approach was not conducted for the following reasons:

1) The uncertainty and variability about the likelihood of human illness from SE in shell eggs are characterized in the Hazard Characterization chapter of this report. The characterization is based on epidemiologic evidence regarding the occurrence of human illness.

2) Additional uncertainties within the model have not been adequately characterized for a second-order model. In particular, uncertainties regarding producer, processor, and consumer behavior in the storage, transportation, cooking, and consumption of eggs were not characterized probabilistically. Consequently, a second-order model would not adequately show the uncertainty within the system.

3) A second-order model is computationally impractical at present and requires considerably more time to run than a first-order model. A first-order model seeks only to characterize the variability in a system. Thus, a single simulation of the model is sufficient to generate a single exposure distribution. The shell egg model takes about 1½ hours to generate a single exposure distribution (50,000 iterations) and a single estimate of the probability of human illness due to SE from shell eggs. This long run time is due to extensive growth calculations throughout the model. A second-order model of 300 uncertainty simulations would thus take more than 420 hours. This is too long to be of practical use when evaluating multiple mitigations. On the other hand, a one-time evaluation of sensitivity for the first-order model was completed in about 40 hours.

Types of sensitivity analysis conducted

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 uncertainties deemed most influential. Third, a set of outputs is generated that identifies sensitivity of the model to different modeling choices.

Correlation analysis of the baseline scenario

Spearman rank order correlations were conducted for a number of inputs and intermediate outputs with the probability of human illness. Rank order correlation is useful "because it makes no assumption about the relationship between the input and the output."[1]

Correlation with storage variables

Time, temperature, and cooling constant inputs for specific stages do not appear to be correlated with human illness (Table 5-7). This is likely because it is only necessary for growth to occur at any step for illness to occur.

TABLE 5-7 CORRELATION OF HUMAN ILLNESS WITH INPUT FOR TIME, TEMPERATURE, AND COOLING CONSTANT AT EACH STEP.

	Correlation with:		
Model Step	**Time**	**Temp**	***k***
Layer	0.023	0.015	NA
On Farm	0.032	0.042	-0.005
Transportation to Processor	-0.002	0.004	-0.005
Pre-processing	0.034	0.038	-0.009
Post-processing	0.021	0.021	0.002
Retail Transportation	0.010	0.007	0.002
Retail Storage	-0.003	0.019	-0.004
Home Transportation	0.001	0.003	-0.002
Home Storage	0.003	0.010	-0.002

Correlation with intermediate outputs

Tornado Charts
Tornado charts are an easy way of visualizing the relative degree of correlation of an output to several variables. It consists of bars that either approach 1 (positive correlation or -1 (negative correlation).

The model can capture four intermediate outputs at the end of each step. These are (i) age of the egg, (ii) internal egg temperature, (iii) the amount of yolk membrane (YMB) that has occurred, and (iv) the number of bacteria in the egg. As with the storage time and temperature variables shown in Table 5-7, the age of the egg and the internal egg temperature at the end of a step are not correlated with human illness (Table 5-8). There is a slight correlation, however, for the amount of YMB that has occurred. The correlation also increases slightly through processing, but then levels off. There is a larger correlation between the number of bacteria at the end of each step and human illness. Again, this correlation increases through processing and then plateaus. This effect is visible in Table 5-8 and the tornado charts in Figure 5-6.

TABLE 5-8 CORRELATION OF HUMAN ILLNESS WITH OUTPUT AT END OF EACH STEP.

Model Step	Correlation with: Egg Age	Egg Temp	YMB	Bacteria
Layer	0.023	0.014	0.090	0.150
On Farm	0.034	0.048	0.120	0.326
Transportation to Processor	0.033	0.018	0.120	0.335
Pre-processing	0.054	0.041	0.147	0.402
Post-processing	0.060	0.041	0.154	0.426
Retail Transportation	0.061	0.028	0.156	0.432
Retail Storage	0.033	0.024	0.145	0.437
Home Transportation	0.033	0.007	0.145	0.438
Home Storage	0.031	0.015	0.144	0.441

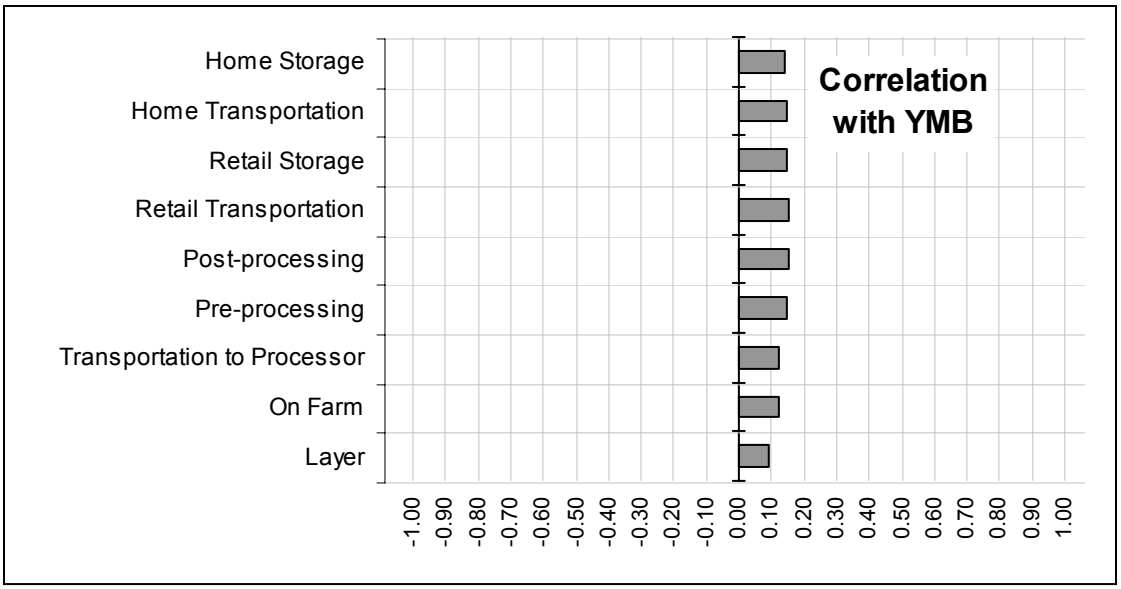

FIGURE 5-5 CORRELATION OF % YOLK MEMBRANE BREAKDOWN THAT HAS OCCURRED BY THE END OF EACH STEP WITH PROBABILITY OF HUMAN ILLNESS.

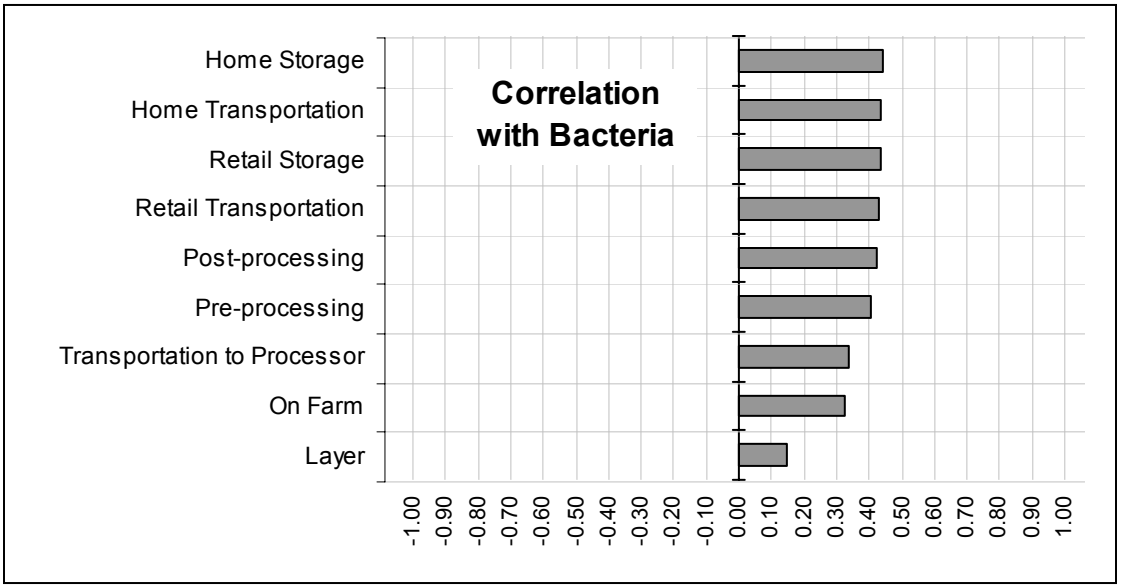

FIGURE 5-6 CORRELATION OF NUMBER OF BACTERIA AT END OF EACH STEP WITH PROBABILITY OF HUMAN ILLNESS.

Correlation with other variables

Also of interest in the model is the initial number of bacteria with which an egg is contaminated. As can be seen in Table 5-9 this is not correlated with human illness. The number of servings produced by an egg is also not correlated with human illness. The $\log_{10}$ reduction due to cooking, however, is strongly negatively correlated with the probability of human illness. Cooking directly affects the number of bacteria consumed.

Table 5-9 Correlation of human illness with other model variables.

Variable	Correlation
Initial Bact	0.064
Servings	0.001
Cooking	-0.863

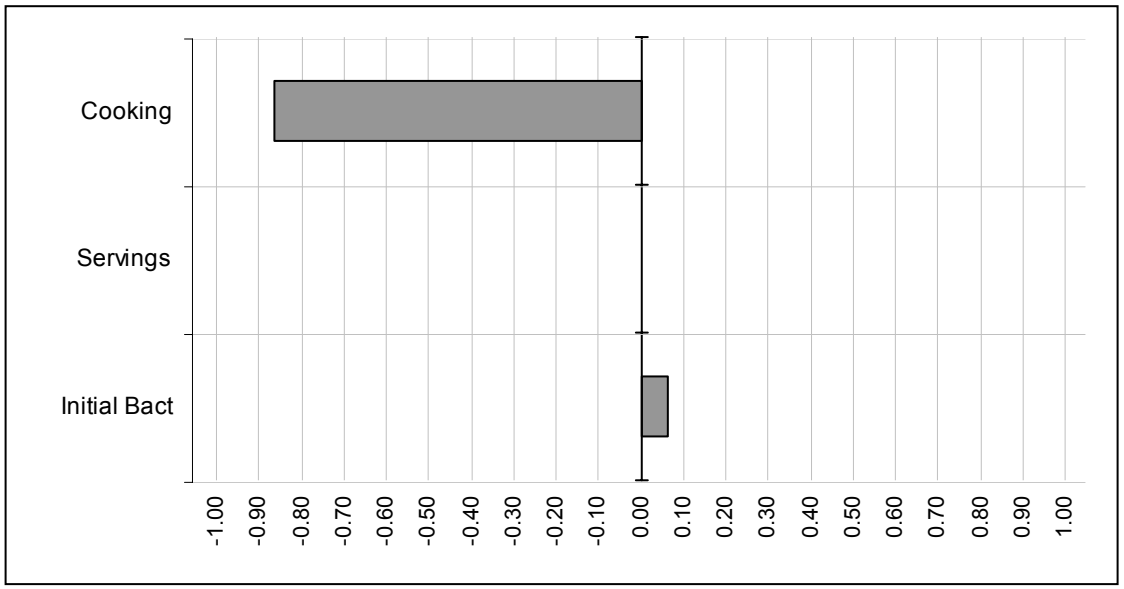

Figure 5-7 Correlation of log10 reductions due to cooking, number of servings per egg, and initial bacteria with probability of human illness.

Nominal range sensitivity analysis

Nominal range sensitivity analysis evaluates the effect of changing only one input at a time in the model while holding other inputs constant. It is a relatively simple method and is generally used with linear models rather than probabilistic models. It does not, however, capture the effect of interactions between inputs.[2]

The analysis was conducted by setting all inputs to their most likely values (baseline scenario) and running the model for 10,000 iterations. Because the baseline model used 50,000 iterations, this baseline was slightly different. Then upper and lower bounds were selected for each of the inputs. Generally, these bounds were set arbitrarily. 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 10,000 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.

Ninety-eight sets of inputs were changed and evaluated at the upper and lower bound. The following tables and charts show the results of the simulations. The inputs are displayed in categories. The bounds for each input are displayed in tables. Results of the analysis are shown in charts following each table.

Egg contamination

Inputs that affect the probability of contamination of an egg with SE and the number of SE contaminating the egg are shown in TABLE 5-10. For each of these inputs the lower bound was set to the most likely value x 0.5 and the upper bound was set to the most likely value x 2.

TABLE 5-10 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR EGG CONTAMINATION.

Parameter	LB	ML	UB
p(Flock infected)	0.099	0.198	0.396
p(Hen is infected | flock is infected)	0.007	0.015	0.030
p(Egg contaminated | hen infected, not molted)	0.043	0.086	0.172
p(Flock is molted)	0.047	0.094	0.188
molting multiplier	1.430	2.860	5.720
Albumen init cont (mean of lognormal)	1.301	2.602	5.204
Albumen init cont (st. dev. of lognormal)	0.648	1.295	2.591
Yolk and VM init cont (mean of Poisson)	0.695	1.390	2.780
Yolk and VM init cont (prob. of 0)	0.125	0.249	0.498

Some of the values in Table 5-10 were compared to values calculated for the uncertainty characterized in Annex C. Table 5-11 shows the bounds that would result from the uncertainty calculations. Since the bounds are reasonably close to those shown in Table 5-10, the bounds in Table 5-10 are used to help maintain a more consistent approach.

TABLE 5-11 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR EGG CONTAMINATION USING 5TH AND 95TH UNCERTAINTY LIMITS.

Parameter	LB	ML	UB
p(Flock infected)	0.018	0.198	0.454
p(Hen is infected | flock is infected)	0.005	0.015	0.218
p(Egg contaminated | hen infected, not molted)	0.069	0.086	0.123
molting multiplier	1.670	2.860	8.518

Results of the model runs are shown in Figure 5-9. For this chart and subsequent charts, 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.

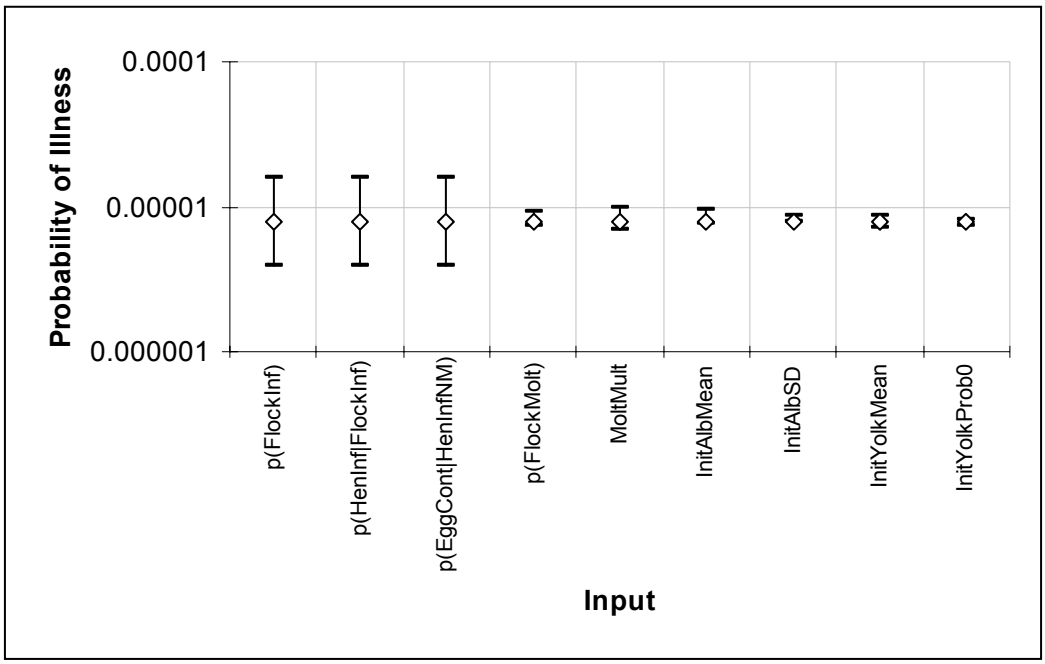

FIGURE 5-8 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG CONTAMINATION INPUTS.

Fraction of contaminated eggs

The model identifies nine different types of contaminated eggs depending on where contamination occurs, the amount of contamination, and when growth takes place. TABLE 5-12 identifies the nine types of contaminated eggs. The nine most likely values for each of these fractions sum to 1. When the bounds are modeled, the most likely fraction is replaced by the appropriate bound and the resultant fractions are normalized. Thus, the individual bounds represent weights for each of nine egg types rather than fractions.

TABLE 5-12 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR CONTAMINATED EGG FRACTIONS.

Parameter	LB	ML	UB
Shell	0.0926	0.1852	0.3704
Alb C G	0.0361	0.0723	0.1446
Alb C N	0.0097	0.0194	0.0387
Alb F G	0.1024	0.2048	0.4097
Alb F N	0.1573	0.3146	0.6292
VM Low	0.0852	0.1704	0.3407
VM High	0.0061	0.0123	0.0245
Yolk Low	0.0098	0.0197	0.0393
Yolk High	0.0007	0.0014	0.0028

Figure 5-9 shows the results of the nominal range sensitivity analysis for contaminated egg fractions.

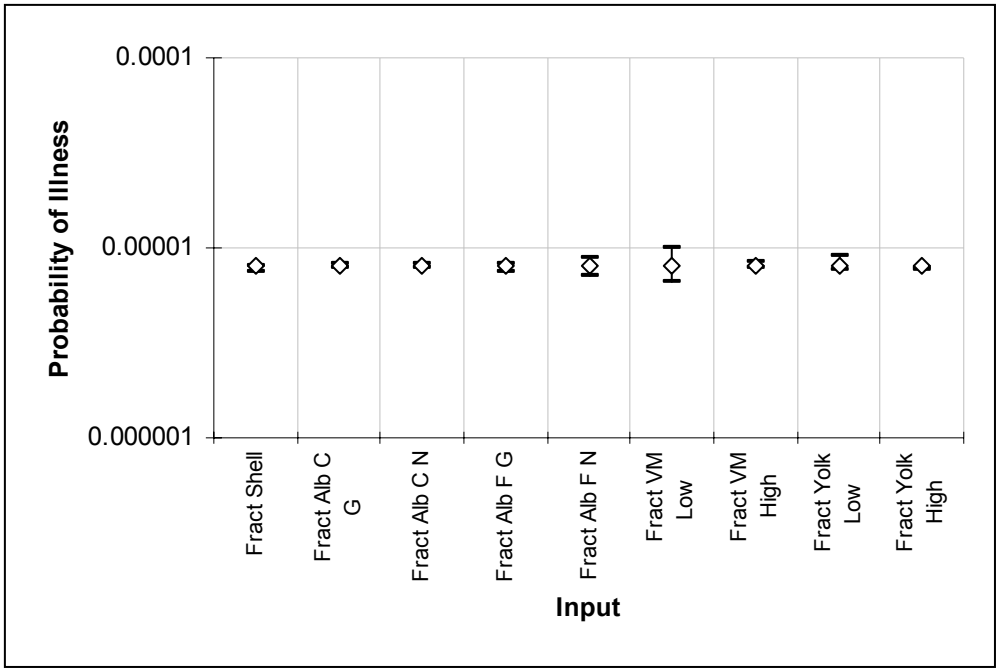

Figure 5-9 Results of nominal range sensitivity analysis for contaminated egg fractions.

Storage temperature

Egg storage temperatures were modeled using lognormal distributions with means and standard deviations coming from fits to the data. Some steps had no data available for storage temperatures, and thus were modeled using parameters from other steps. Uncertainty in storage temperatures was not characterized. Bounds for means were established at 45 and 90° F for each of the temperatures. For the standard deviations, the lower bounds were set at 0.01 and the upper bounds were set at Ln(*e*(most likely)x2). These values are shown in TABLE 5-13.

TABLE 5-13 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE TEMPERATURES (°F).

	LB		ML		UB	
Parameter	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
Layerhouse	3.81	0.01	4.32	0.15	4.50	0.84
OnFarm	3.81	0.01	4.01	0.14	4.50	0.83
TransportationFromFarm	3.81	0.01	3.92	0.14	4.50	0.83
PreProcessingOffLine	3.81	0.01	3.86	0.15	4.50	0.84
PreProcessingInLine	3.81	0.01	3.97	0.14	4.50	0.83
PostProcessing	3.81	0.01	3.87	0.15	4.50	0.84
RetailTransportation	3.81	0.01	3.94	0.15	4.50	0.84
RetailStorage	3.81	0.01	3.66	0.10	4.50	0.79
HomeTransportation	3.81	0.01	4.42	0.14	4.50	0.84
HomeStorage	3.81	0.01	3.66	0.11	4.50	0.80

Figure 5-11 shows the results for this analysis. Storage temperatures in the layer house, during on farm storage, before processing at off-line facilities, at retail establishments, and at end users have a significant effect on the probability of illness. Temperature during transportation has less effect, probably because the time available for bacterial growth is generally much less. The lower bound for retail and home storage temperatures show a higher probability of illness than the most likely values. This is because the most likely values for the lognormal means for the distributions of retail and home storage temperatures are below 45° F.

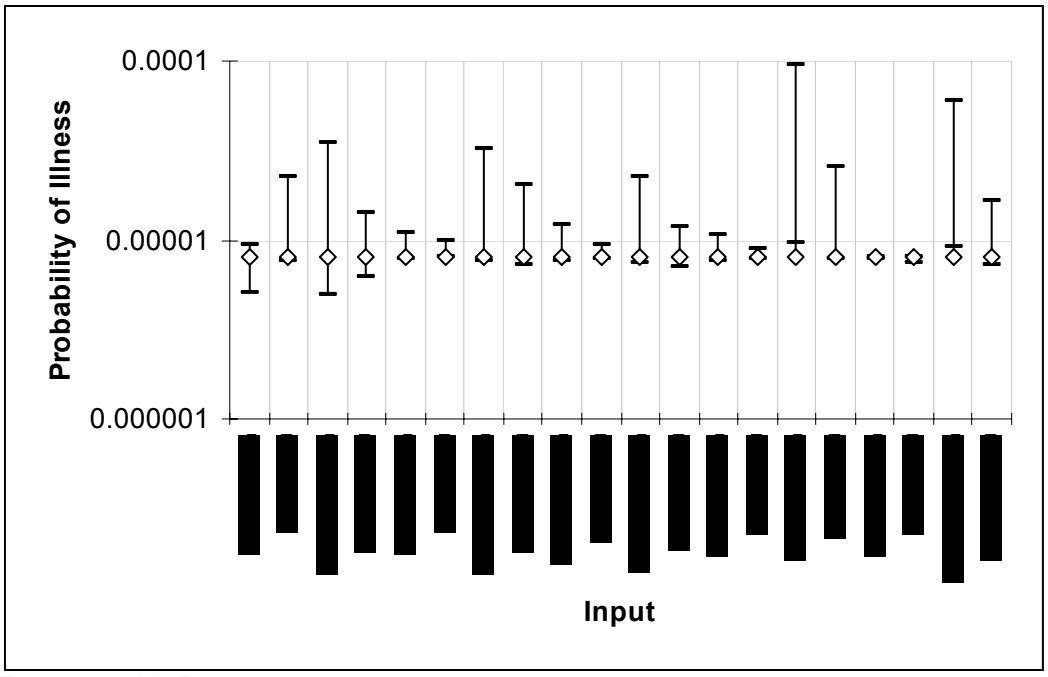

FIGURE 5-10 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR STORAGE TEMPERATURE INPUTS.

Growth parameters

Parameters for bacterial growth have their uncertainty characterized in annex E. Bounds are based on the 5th and 95th percentiles for the yolk growth parameters (*e*, *f*, and *b*) and yolk membrane breakdown (YMB) parameters (*d*, *f*, *g*, and *k*). Two sets of these inputs are correlated. Bounds and identification of correlations are shown in Table 5-14. Results are shown in Figure 5-11.

TABLE 5-14 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR GROWTH PARAMETERS.

Parameter		LB	ML	UB	Correlated
Yolk growth	*e*	-1.5863	-1.0063	-0.4263	1
	f	0.1954	0.2219	0.2484	1
	b	0.0100	0.4007	0.8761	
YMB	*d*	1.0869	1.3103	1.5337	
	f	-3.2745	-1.5087	-0.0100	2
	g	0.0299	0.0751	0.1203	2
	k	2.6227	3.4825	4.3423	2
	Omega	1	1	2.6	
Albumen growth	*SD*	0.1925	0.385	0.77	
	lag/growth	2	5	10	

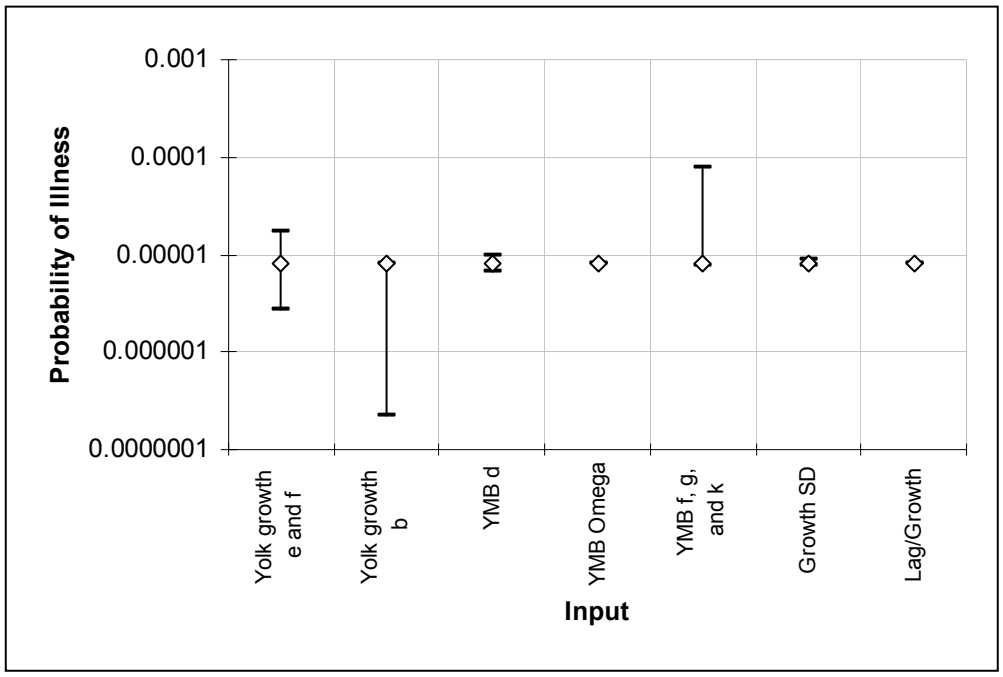

FIGURE 5-11 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR BACTERIAL GROWTH INPUTS.

Figure 5-11 shows a considerable effect on the probability of illness from the uncertainty related to both yolk growth and yolk membrane breakdown.

Storage time

Bounds for mean storage times are set at one-half [Ln($e^{(\text{most likely})}$x0.5)] and double [Ln($e^{(\text{most likely})}$x2)] those in the most likely scenario. Bounds for standard deviations are set in a similar way to those for storage temperatures.

TABLE 5-15 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE TIMES (DAYS).

Parameter	LB		ML		UB	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Layerhouse	(2.07)	0.01	(1.38)	0.59	(0.69)	1.29
OnFarm	0.03	0.01	0.72	0.59	1.41	1.29
TransportationFromFarm	(2.08)	0.01	(1.39)	0.59	(0.69)	1.28
PreProcessingOffLine	(0.74)	0.01	(0.04)	1.33	0.65	2.03
PreProcessingInLine	(0.03)	0.01	0.67	0.89	1.36	1.58
PostProcessing	(0.64)	0.01	0.05	1.33	0.75	2.03
RetailTransportation	(1.39)	0.01	(0.69)	0.59	0.00	1.28
RetailStorage	1.64	0.01	2.33	0.59	3.02	1.28
HomeTransportation	(3.81)	0.01	(3.12)	0.37	(2.43)	1.07
HomeStorage	1.08	0.01	1.78	0.59	2.47	1.28

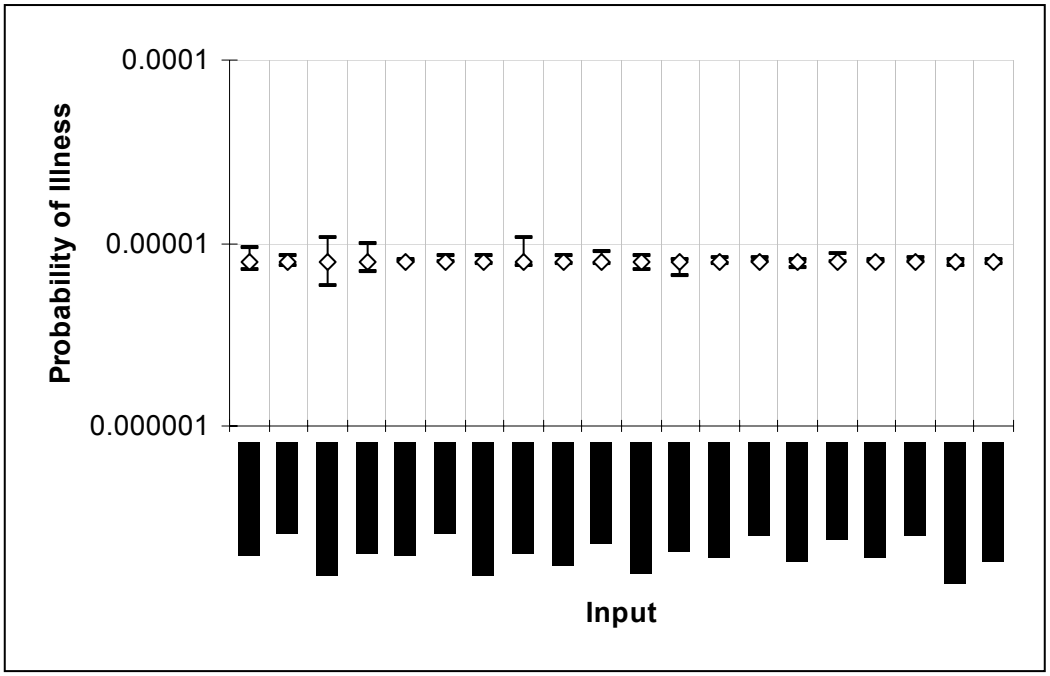

FIGURE 5-12 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR STORAGE TIME INPUTS.

Cooling constants

Bounds for cooling constants are established by setting the "central egg" cooling constant for a case or pallet to either the minimum modeled value (0.001) or the maximum modeled value (1) (Table 5-16).

TABLE 5-16 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE COOLING CONSTANT VALUES.

Parameters for *k*-values		*k*-values and associated cumul fraction			
Input		**0.001**	**0.01**	**0.10**	**1.00**
Layerhouse - off line		0.00	1.00	1.00	1.00
Layerhouse - in line		0.00	1.00	1.00	1.00
OnFarm		0.00	1.00	1.00	1.00
TransportationFromFarm		0.00	1.00	1.00	1.00
PreProcessingOffLine		0.00	1.00	1.00	1.00
PreProcessingInLine		0.00	1.00	1.00	1.00
PostProcessing	Lower bound	0.00	1.00	1.00	1.00
RetailTransportation		0.00	1.00	1.00	1.00
RetailStorage		0.00	1.00	1.00	1.00
HomeTransportation		0.00	1.00	1.00	1.00
HomeStorage		0.00	1.00	1.00	1.00
Layerhouse - off line		0.00	0.00	0.00	1.00
Layerhouse - in line		0.00	0.00	0.00	1.00
OnFarm		0.00	0.01	1.00	1.00
TransportationFromFarm		0.00	0.01	1.00	1.00
PreProcessingOffLine		0.00	0.01	1.00	1.00
PreProcessingInLine		0.00	1.00	1.00	1.00
PostProcessing	Most likely values	0.00	0.99	1.00	1.00
RetailTransportation		0.00	0.99	1.00	1.00
RetailStorage		0.00	0.20	1.00	1.00
HomeTransportation		0.00	0.00	1.00	1.00
HomeStorage		0.00	0.00	0.55	1.00
Layerhouse - off line		0.00	0.00	0.00	1.00
Layerhouse - in line		0.00	0.00	0.00	1.00
OnFarm		0.00	0.00	0.00	1.00
TransportationFromFarm		0.00	0.00	0.00	1.00
PreProcessingOffLine		0.00	0.00	0.00	1.00
PreProcessingInLine		0.00	0.00	0.00	1.00
PostProcessing	Upper bound	0.00	0.00	0.00	1.00
RetailTransportation		0.00	0.00	0.00	1.00
RetailStorage		0.00	0.00	0.00	1.00
HomeTransportation		0.00	0.00	0.00	1.00
HomeStorage		0.00	0.00	0.00	1.00

Figure 5-13 shows that the cooling constant has only a minor effect on the probability of illness. It is important to note that the cooling constant applies only to the central egg of a case or pallet and that most eggs would be near the perimeter with a cooling constant approaching that of exposure to air.

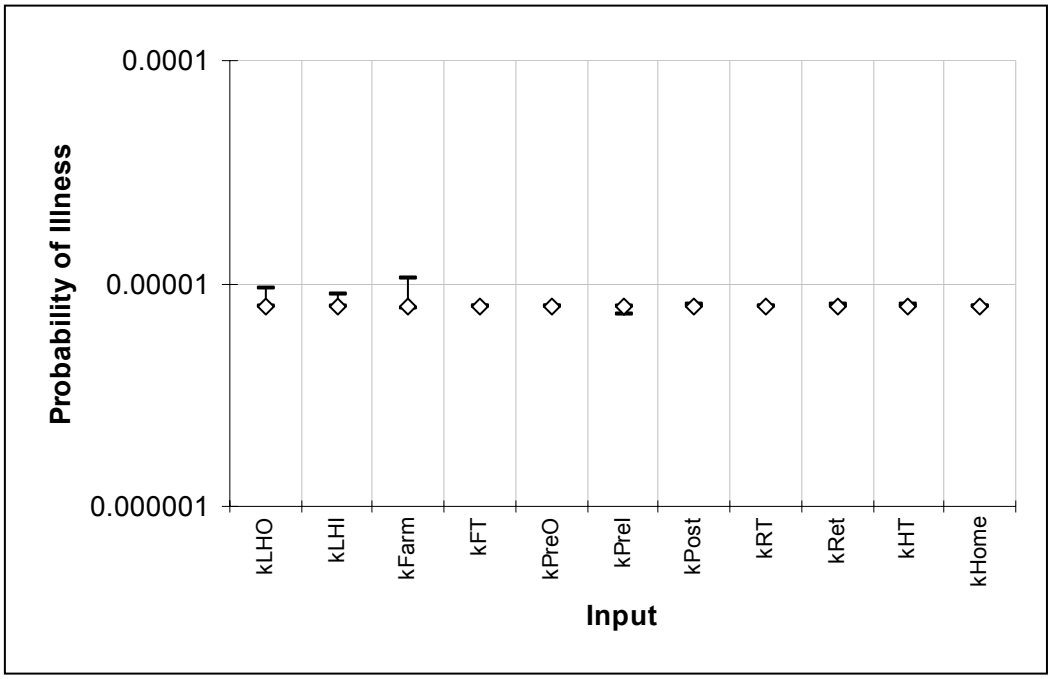

FIGURE 5-13 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR COOLING CONSTANT INPUTS.

Preparation and serving

This category includes fractions for different types of egg servings, $\log_{10}$ reductions for different types of cooking, fractions of eggs cooked in different ways, servings per egg, and dose-response parameters. Table 5-17 shows the bounds for these inputs. As with fractions for contaminated eggs, bounds for fractions in this category represent weights.

Sensitivity for $\log_{10}$ reductions is modeled by adding or subtracting one $\log_{10}$. In the case of soft-boiled eggs and beverages, the most likely value is already less than a $\log_{10}$. The most likely value for the mean of the lognormal distribution for servings per egg is 0.47, or about 1.6 servings per egg. The lower bound is 0, or 1 serving per egg and the upper bound is 1.39, or about 4 servings per egg. Dose-response bounds come from the Hazard Characterization chapter. The dose-response parameters are correlated so the results reflect changing both parameters at the same time. Results are shown in Figure 5-14.

TABLE 5-17 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR COOKING, SERVING SIZE, DOSE RESPONSE, AND MISCELLANEOUS PARAMETERS.

Parameter		LB	ML	UB
Fraction	*Beverages*	0.0017	0.0033	0.0067
	Mixtures	0.2000	0.5304	0.8000
$\log_{10}$ reductions	*Soft boiled and poached*	0.0	0.9	1.9
	Sunny side up	0.8	1.8	2.8
	Scrambled and omelets 1	3.9	4.9	5.9
	Scrambled and omelets 2	5.1	6.1	7.1
	Over easy	5.3	6.3	7.3
	Hard boiled	7.0	8.0	9.0
	Beverages	0.0	0.0	1.0
	Mixtures	11.0	12.0	13.0
Fraction	*Soft boiled and poached*	0.0600	0.12	0.2400
	Sunny side up	0.0675	0.135	0.2700
	Scrambled and omelets 1	0.1175	0.235	0.4700
	Scrambled and omelets 2	0.1175	0.235	0.4700
	Over easy	0.0675	0.135	0.2700
	Hard boiled	0.0700	0.14	0.2800
Fraction	*In-line processed*	0.0%	13.5%	100.0%
	Consumed away from home	0.0%	55.0%	100.0%
Servings per egg (lognormal distribution)	*Mean*	0.00	0.47	1.39
	SD	0.00	1.16	2.08
Dose response (parameters correlated)	*Alpha*	0.0763	0.1324	0.2274
	Beta	38.49	51.45	57.96

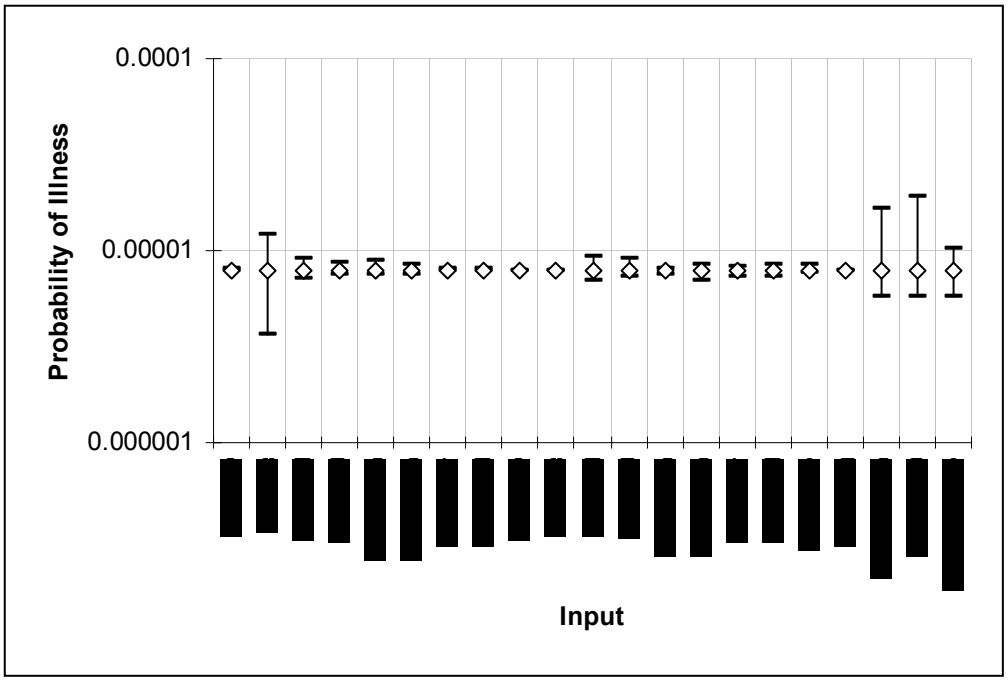

FIGURE 5-14 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR PREPARATION, SERVING, AND DOSE-RESPONSE INPUTS.

Summary of nominal range sensitivity analysis

Figure 5-15 shows the most influential inputs identified by the nominal range sensitivity analysis. Generally, inputs related to storage temperature had the most influence. Since these inputs had relatively wide bounds, it is reasonable that they would have the most influence, given model structure, data, and assumptions.

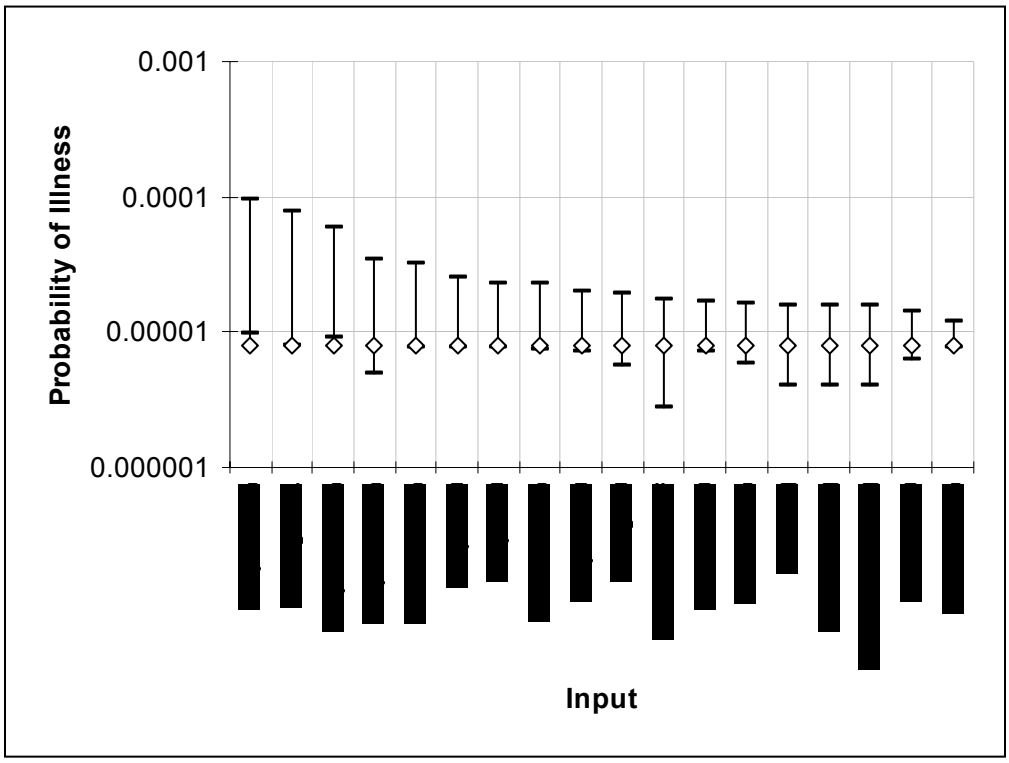

FIGURE 5-15 MOST INFLUENTIAL INPUTS IDENTIFIED BY NOMINAL RANGE SENSITIVITY ANALYSIS.

Difference in log-odds ratio

The difference in log-odds ratio is a special case of the nominal range sensitivity analysis when the model output is a probability.[2] The most influential inputs displayed in Figure 5-15 are shown below in Figure 5-17 in terms of the log-odds ratios.

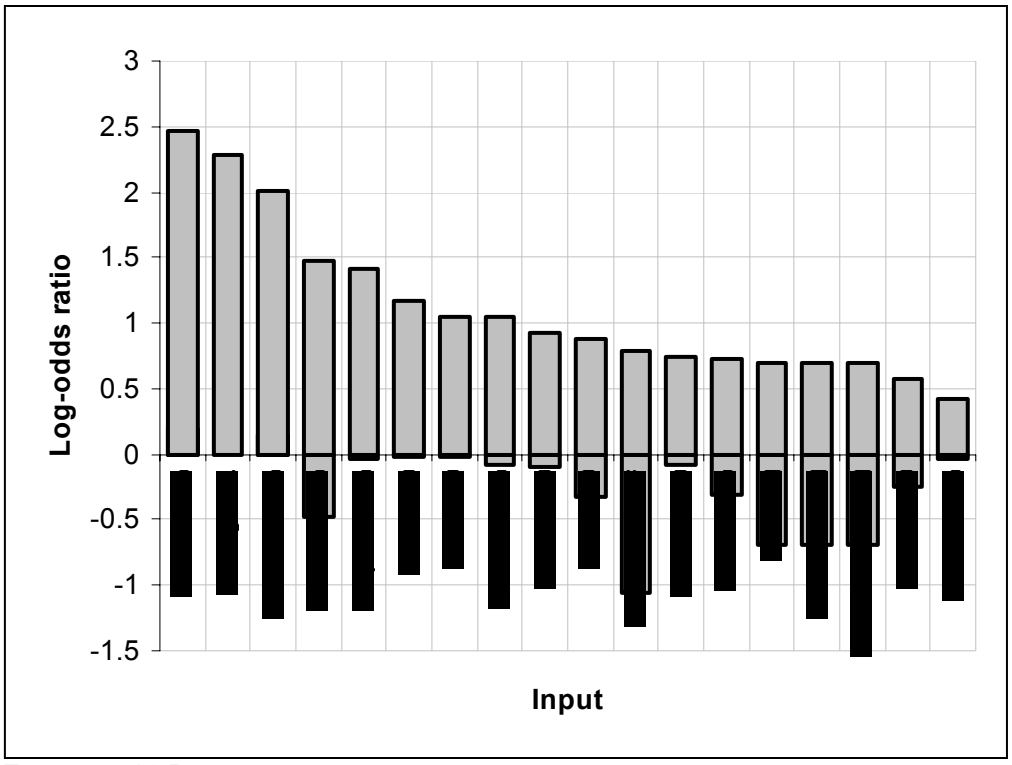

FIGURE 5-16 DIFFERENCE IN LOG-ODDS RATIO FOR MOST INFLUENTIAL INPUTS.

Sensitivity to modeling assumptions

As the baseline model is developed and later run, certain modeling choices influence the output. The effect of some of these modeling assumptions is discussed below.

Stochastic growth modeling versus deterministic growth modeling

The baseline uses a stochastic model in which it is assumed that the event of growth is random and that once growth commences, all bacteria in an egg grow at the same rate. The consequence of stochastic growth is that fewer cells begin to grow, but those that do can grow at faster rates than the expected values from the deterministic model. (Deterministic growth modeling is not random, but is modeled as the expected value of growth of the bacterial population, as described in Annex E). The effect of the stochastic model is that small amounts of contamination (less than 10 bacteria) in simulated eggs are less likely to allow bacterial growth sufficient to cause illness. The corresponding results are shown in Table 5-18.

TABLE 5-18 DIFFERENCES IN DETERMINISTIC VERSUS STOCHASTIC BACTERIAL GROWTH MODELING ON PROBABILITIES OF ILLNESS.

	Deterministic	Stochastic
Probability of Illness	0.0000108	0.0000069
Expected Number of Annual Illnesses	540,000	350,000

Post-pasteurization growth of thermally injured bacteria

The baseline model assumes that SE not killed by pasteurization will be able to grow as well as any bacteria that have not been exposed to pasteurization temperatures. It is possible, however, that these bacteria may have sub-lethal injuries because of exposure to high temperatures. These bacteria would not be expected to grow as well as wild-type bacteria. Thus, the effect of pasteurization would be greater than is modeled in the baseline.

However, the effect of pasteurization on surviving bacteria is not fully elucidated. Smelt et al.[3] demonstrated that lag phase duration increased significantly for injured bacterial cells (*Lactobacillus plantarum*). These researchers assumed that rates of growth were constant for both injured and non-injured bacteria. However, the possibility exists that the rate of growth would decrease for injured cells. Therefore, scenarios were run in which the growth rate for all bacteria after 3 and 5 $\log_{10}$ pasteurization was set to 50% of the growth rate before pasteurization. The results of this scenario were compared to the results of a baseline scenario. Figure 5-17 shows the difference in mean numbers of bacteria at each of the model steps.

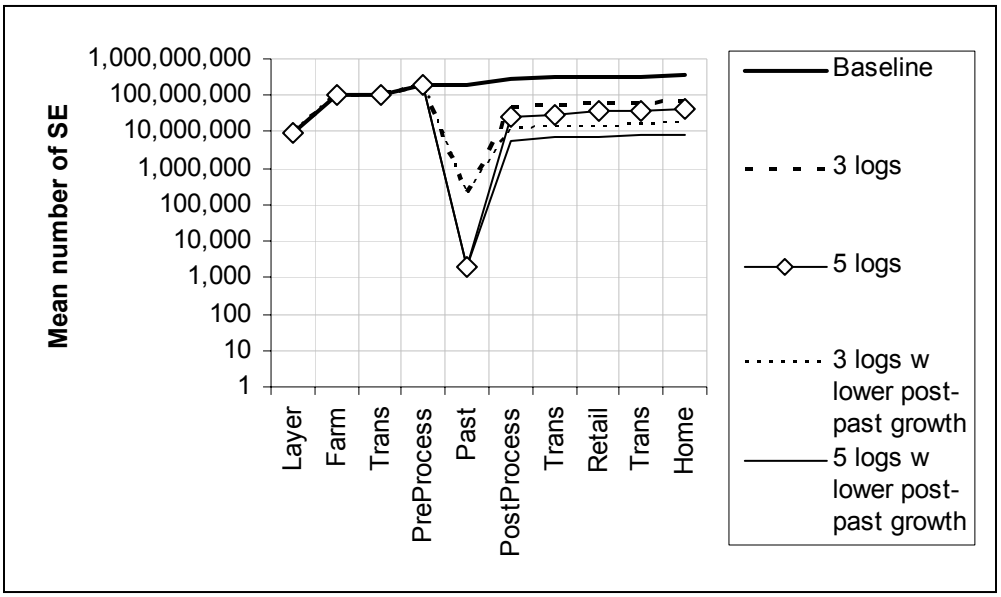

FIGURE 5-17 MEAN NUMBER OF BACTERIA IN BASELINE MODEL WITH 3 LOG10 PASTEURIZATION USING BOTH THE NORMAL GROWTH RATE AND A POST-PASTEURIZATION GROWTH RATE OF 50% OF THE NORMAL FOR INJURED SE CELLS.

The mean number of bacteria assuming 3 $\log_{10}$ pasteurization using the 50% growth rate is about 23% of the mean number of bacteria using the normal growth rate. Assuming 3 $\log_{10}$ it is about 20% when using the 50% growth rate. The expected number of illnesses after 3 $\log_{10}$ pasteurization is about 110,000 (Table 5-5). When using the 50% post-pasteurization growth rate the expected number of illnesses drops to about 81,000 (a 26% reduction). For a 5-$\log_{10}$ reduction after pasteurization, the number of illnesses drops from 52,000 to 32,000 (a 38% reduction).

Validation of the Shell Egg Model

Validation refers to comparison of data and analysis not used in the development of the risk assessment to the results of the risk assessment. This risk estimate predicts the number of human illnesses that would occur from SE infection due to the consumption of shell eggs. Thus, a useful comparison is to the number of human illnesses actually observed. The Hazard Characterization chapter develops a dose-response function for SE. This dose response function is in turn used within the risk characterization to develop estimates of human illness. The Hazard Characterization chapter also presents analyses that estimate the number of human illnesses. These estimates are not used in the development of the risk assessment, and thus, are useful validation tools.

Determining upper and lower bounds for annual number of SE illness in humans

The baseline model predicts about 350,000 human illnesses due to SE infection from shell eggs. The hazard characterization chapter estimates there are 5,896 reported cases of SE in the U.S. annually. The chapter also presents evidence for an underreporting multiplier based on the steps shown in Table 5-19.

TABLE 5-19 *SALMONELLA* SURVEILLANCE UNDERREPORTING MULTIPLIERS.

Surveillance step	Factor Range		Number of Studies
	Low	High	
1. Patient consults a doctor	1.3	12.0	6
2. Doctor obtains culture	1.2	4.3	5
3. Laboratory identifies the organism	1.2	3.6	11
4. Laboratory reports to the health department	1.3	2.4	3
5. Health department reports to CDC	1.0	1.4	1[a]
Salmonella surveillance total multiplier	2.43	624.15	

[a]The factor range includes arbitrary lower and upper bounds assigned to the multiplier from the one listed study.

The multiplier to convert illnesses reported to CDC to all illnesses is given by the product of the multipliers: 1) Patient consults a doctor, 2) Doctor obtains culture, 3) Laboratory identifies the organism, 4) Laboratory reports to the health department, and 5) Health department reports to CDC. The minimum multiplier is 2.43; the maximum is 624. The minimum reasonable number of SE illnesses is thus 5,896 x 2.43 = 14,300. The maximum number is 5,896 x 624 = 3.68 million. The hazard characterization chapter also notes that 80% of these illnesses are due to shell eggs. Therefore, the number of illnesses due to shell eggs is about 11,500 at the lower bound and 2.94 million at the upper bound. The baseline estimate of 350,000 illnesses fits within this range.

Development of a probability distribution function for human illnesses

The appendix to the Hazard Characterization lists the multipliers determined by each of the studies summarized in Table 5-19. It is assumed that for each surveillance step one of the study multipliers is the correct one. Therefore, the total multiplier can be determined by the product of one the multipliers for each of the five steps. The number of possible multipliers is 6 x 5 x 11 x 3 x 3 (step 5 is given 3 multipliers for one study) = 2970. A model was developed by taking all the combinations of multipliers. This resulted in an uncertainty distribution for the number of human illnesses. Figure 5-18 shows the cumulative distribution for the annual number of human illnesses along with upper and lower bounds and the baseline estimates using stochastic growth (Base S) and deterministic (Base D) growth models.

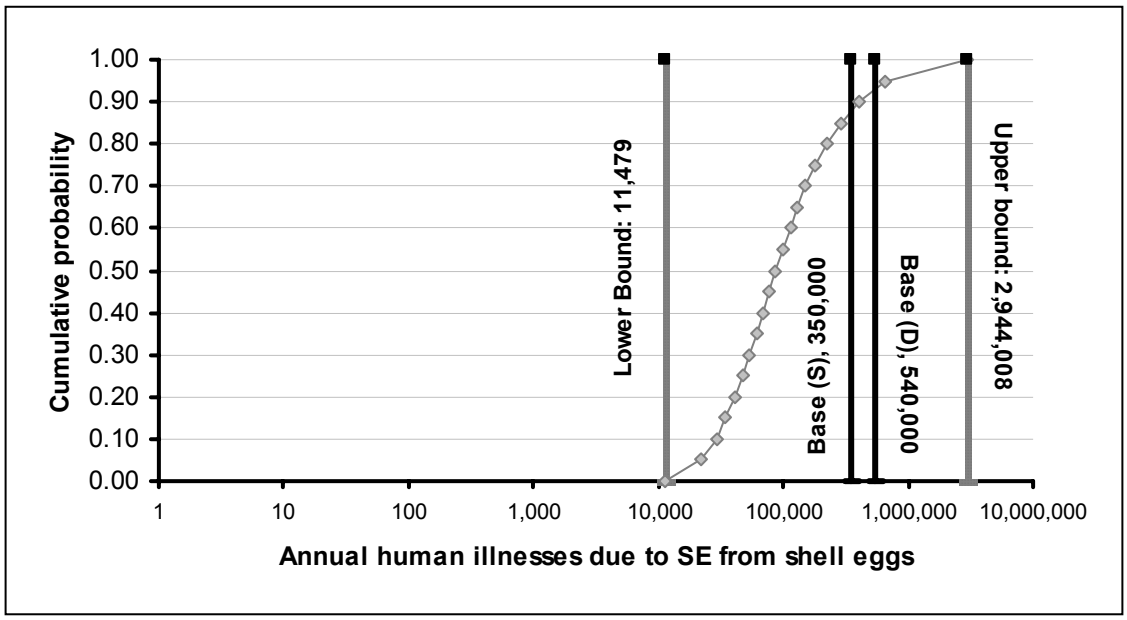

FIGURE 5-18 CUMULATIVE PROBABILITY OF ANNUAL HUMAN ILLNESSES DUE TO SE FROM SHELL EGGS COMPARED TO BASELINE ESTIMATE WITH UPPER AND LOWER BOUNDS.

The baseline estimates for human illnesses are around 90th percentile of the probability distribution for human illnesses. The baseline estimate could thus be considered a relatively conservative estimate.