

Research Paper

Assessment of the Risk of Salmonellosis Linked to the Consumption of Liquid Egg Products Made from Internally Contaminated Shell Eggs Initially Stored at 65°F (18°C) Compared with Eggs Stored at 45°F (7°C)

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ABSTRACT

According to the U.S. Food and Drug Administration's (FDA's) rule on "Prevention of *Salmonella* Enteritidis in Shell Eggs during Production, Storage, and Transportation," shell eggs intended for human consumption are required to be held or transported at or below 45°F (7.2°C) ambient temperature beginning 36 h after time of lay. Meanwhile, eggs in hatcheries are typically stored at a temperature of 65°F (18.3°C). Although most of those eggs are directed to incubators for hatching, excess eggs have the potential to be diverted for human consumption as egg products through the "breaker" market if these eggs are refrigerated in accordance with FDA's requirement. Combining risk assessment models developed by the U.S. Department of Agriculture's Food Safety and Inspection Service for shell eggs and for egg products, we quantified and compared *Salmonella* Enteritidis levels in eggs held at 65°F versus 45°F, *Salmonella* Enteritidis levels in the resulting egg products, and the risk of human salmonellosis from consumption of those egg products. For eggs stored 5 days at 65°F (following 36 h at 75°F [23.9°C] in the layer house), the mean level of *Salmonella* Enteritidis contamination is 30-fold higher than for eggs stored at 45°F. These increased levels of contamination lead to a 47-fold increase in the risk of salmonellosis from consumption of egg products made from these eggs, with some variation in the public health risk on the basis of the egg product type (e.g., whole egg versus whole egg with added sugar). Assuming that 7% of the liquid egg product supply originates from eggs stored at 65°F versus 45°F, this study estimates an additional burden of 3,562 cases of salmonellosis per year in the United States. A nominal range uncertainty analysis suggests that the relative increase in the risk linked to the storage of eggs at higher temperature estimated in this study is robust to the uncertainty surrounding the model parameters. The diversion of eggs from broiler production to human consumption under the current storage practices of 65°F (versus 45°F) would present a substantive overall increase in the risk of salmonellosis.

HIGHLIGHTS

- The level of *Salmonella* contamination is higher when eggs are stored at 65°F than when stored at 45°F.
- This increase in temperature translates to an increased level of contamination of liquid egg products.
- This increase leads to a substantive overall increase in the risk of salmonellosis.

The Centers for Disease Control and Prevention has estimated that nontyphoidal *Salmonella* was the leading cause of death from foodborne illness acquired in the United States by using data from 2000 to 2008 (13). On the basis of the multiyear outbreak data, the U.S. Interagency Food Safety Analytics Collaboration (10) estimated that 7.9% of foodborne, nontyphoidal *Salmonella* illnesses in 2017 were linked to eggs.

Laying hens can produce eggs that are internally contaminated with *Salmonella* Enteritidis if their reproductive tract is colonized (2). The U.S. Department of

Agriculture, Food Safety and Inspection Service (FSIS), and the U.S. Food and Drug Administration (FDA) completed a farm-to-table quantitative microbial risk assessment of *Salmonella* Enteritidis in shell eggs and egg products in 1998, with a focus on internal contamination (9). That assessment found a 12% reduction in human illnesses if all eggs are immediately cooled after lay to an ambient temperature of 45°F (7.2°C) and then maintained at that temperature throughout shell egg processing and distribution, as opposed to the diversity of temperatures that may be experienced throughout this stage of production. In 2005, FSIS conducted an extensive update of the assessment of the risks for *Salmonella* Enteritidis in shell eggs and for *Salmonella* spp. in egg products, focusing on

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the public health impact of (i) pasteurization of shell eggs, (ii) pasteurization of egg products, and (iii) storage time and temperature for shell eggs (11, 14, 16). The questions this assessment answered included the pre- and postpasteurization *Salmonella* numbers in shell eggs and in different types of egg products, the number of illnesses per serving and annual number of illnesses for those products, and the effect of storage time and temperature from laying to further processing on the risk of foodborne illnesses.

Because temperature abuse may permit *Salmonella* populations to reach high concentrations in contaminated eggs, temperature control during egg storage is an important measure to mitigate the risk of salmonellosis associated with the consumption of shell eggs and egg products. On 9 July 2009, the FDA published the final rule, “Prevention of *Salmonella* Enteritidis in Shell Eggs during Production, Storage and Transportation” (now codified at Title 21 of the Code of Federal Regulations at parts 16 and 118 (17), hereafter referred to as the “FDA egg safety final rule”). According to this rule, shell eggs being held or transported for shell egg processing or egg products processing are required to be refrigerated at or below 45°F (~7.2°C) ambient temperature beginning 36 hours after time of lay (section 118.4[e] (17)). FSIS deems egg products with detectable pathogens to be adulterated because FSIS considers egg products to be ready-to-eat products. Any egg product, therefore, “must be free of detectable pathogens” following pasteurization.

In most broiler hatcheries, it is common to store the eggs up to 10 days at a recommended temperature of 60.8 to 64.4°F (16 to 18°C) (15). For a 1- to 3-day storage, the optimal storage temperature condition is 64.4 to 69.8°F (18 to 21°C) for a better hatch rate. Although most eggs originating from hatcheries are directed to incubators for hatching, excess eggs have the potential to be diverted to human consumption as egg products through the “breaker” market if these eggs are refrigerated in accordance with the FDA egg safety final rule. Adapting the risk assessment model developed by FSIS (16), Pouillot et al. (12) quantified human exposure to *Salmonella* Enteritidis and the risk of human salmonellosis if table eggs are held and transported at 65°F (18.3°C) for up to 5.5 days after time of lay rather than held and transported at 45°F within 36 h after time of lay, as required by the FDA egg safety final rule. The predicted risk of salmonellosis from the consumption of pasteurized eggs initially held and transported at 65°F and subsequently diverted to human consumption was estimated to be 25 times higher (i.e., 7.2×10^{-7} versus 2.9×10^{-8} per serving) than the risk when eggs were held and transported at 45°F.

In this study, we assess the risk of salmonellosis linked to various types of egg products made from hatchery eggs diverted for human consumption. Notably, this study estimates and compares the risk of salmonellosis from the consumption of pasteurized liquid egg products made from eggs held at 45 and 65°F during a period of 0 to 9 days post-layer house stage.

MATERIALS AND METHODS

Model overview. The FSIS risk assessment included two separate models: one for *Salmonella* Enteritidis in shell eggs,

referred to as the “shell egg model,” and one for *Salmonella* spp. in egg products, referred to as the “liquid egg product model” (16). Note that in this article, the term “egg products” does not include shell eggs.

The shell egg model predicts the number of human illnesses linked to the consumption of shell eggs. It simulates *Salmonella* Enteritidis contamination of internally contaminated eggs (location of contamination and number of *Salmonella*) and then simulates the movement of those eggs from the farm to the table for consumption through steps of storage, transportation, processing, preparation, and consumption. The number of *Salmonella* Enteritidis in the eggs is estimated at hourly intervals throughout the movement of the eggs along the supply chain.

The liquid egg product model predicts the number of human salmonellosis cases linked to consumption of seven different types of liquid egg products (white, whole egg, yolk, whole egg 10% salt, whole egg 10% sugar, yolk 10% salt, and yolk 10% sugar) potentially contaminated with *Salmonella* spp. Each of these egg products is considered with various bacterial growth, pasteurization efficiency, cooking procedure, and consumption. At hourly intervals, the concentration of *Salmonella* spp. in each type of egg product is estimated from the time eggs are broken into large holding tanks before pasteurization to consumption.

To evaluate the risk of salmonellosis from consumption of egg products made from internally contaminated eggs stored at varying temperatures, we combined these two models. Our model (referred to as the “combined model”) included an additional “pooling” model to link the two previously published models (Fig. 1):

- (i) the shell egg model estimates *Salmonella* Enteritidis contamination of preprocessing eggs as a function of preprocessing storage temperature;
- (ii) we simulated the *Salmonella* Enteritidis contamination of prepasteurization egg products made from the pooling of those eggs in holding tanks (referred to as “vats”); and
- (iii) we used the resulting empirical distribution of *Salmonella* Enteritidis contamination in vats in the liquid egg product model to predict risk of salmonellosis.

To facilitate model use, reproducibility of results, and training in the field of food safety quantitative microbial risk assessment (8), this risk assessment model is available at <https://www.foodrisk.org/resources/display/202> (18).

Contamination of shell eggs. Using the shell egg model, we estimated the number of *Salmonella* Enteritidis (CFU per egg) in 100,000 contaminated shell eggs under 40 different time-temperature scenarios. We considered two alternatives for time at the layer house (uniform(0, 12) h at a varying temperature following a lognormal(4.32, 0.15) (°F) as in FSIS (16); or 36 h, the maximum time by the FDA egg safety final rule at a temperature of 75°F), two alternatives for the temperature of storage before processing (45°F, as required by the FDA egg safety final rule or 65°F), and 10 different times of storage before processing (0, 1, . . . , 9 days) (Table 1). In this article, the lognormal distribution is parametrized as $x \sim \text{lognormal}(m, s)$ if $\ln(x) \sim \text{normal}(m, s)$, where m is the mean and s is the standard deviation of the normal distribution. The lognormal(4.32, 0.15) (°F) distribution has a mean of 75.8°F (24.3°C) and a standard deviation of 11.4°F (6.33°C).

Concentration of *Salmonella* Enteritidis in egg product vats. The shell egg model considers various locations for *Salmonella* Enteritidis contamination within the egg: shell

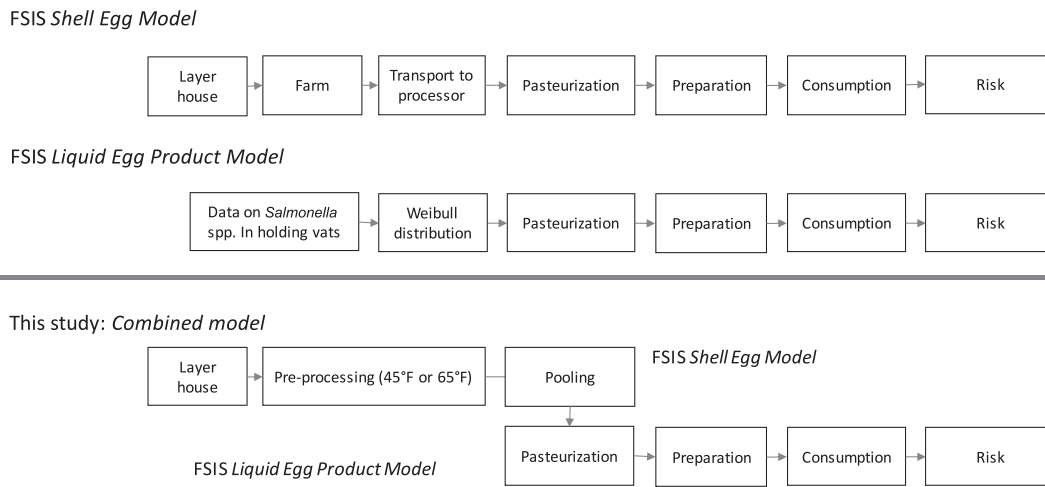


FIGURE 1. Schematic representation of the FSIS shell egg model (16), the FSIS liquid egg product model (16), and the present combined model.

(inside), albumen, vitelline membrane, and yolk (16). To evaluate separately the contamination of white, yolk and whole egg products, we used the following: for whole eggs, eggs contaminated anywhere (shell, albumen, vitelline membrane, or yolk); for white, eggs contaminated on the shell or the albumen; and for yolk, eggs contaminated on the vitelline membrane or the yolk. We used the assumption that eggs are held in egg-processing vats ranging from 22,700 to 158,800 kg (50,000 to 350,000 lb) of each type of egg product (uniform distribution) at the breaker with a weight of 50 g for whole eggs, two-thirds of 50 g for white, and one-third of 50 g for yolk. For a given prevalence of in-shell contaminated eggs, we simulated the number of contaminated parts of eggs (whole eggs, yolk, or white) in the vat, assuming independence of contamination among the eggs in a vat. This assumption is reasonable because of the enormous numbers of eggs contained in each vat. Mathematically, it translates by using a binomial distribution to evaluate the number of contaminated eggs in the vat from the total number of contaminated egg parts and the prevalence of contaminated parts.

From this number of contaminated egg components in the vat and the set of 100,000 simulated values, we simulated a

distribution of the number of *Salmonella* Enteritidis (CFU) in the vat. As an example, if we simulated a value of 120 contaminated eggs in a given vat (this number being a random value, a function of the prevalence of contaminated eggs and the number of eggs present in the vat), we sampled independently 120 values among the 100,000 simulated values of *Salmonella* Enteritidis number in contaminated eggs and added those 120 values. The concentration of *Salmonella* Enteritidis in the vat (CFU per gram) would then be equal to this sum of *Salmonella* CFU divided by the weight of product present in the vat (grams). Repeating this process 1,000,000 times provided us with an empirical distribution of concentration of *Salmonella* Enteritidis in holding tanks of white, yolk, and whole eggs.

Risk assessment linked to the consumption of *Salmonella* Enteritidis in egg products. The liquid egg product model starts from a concentration of *Salmonella* spp. (including all serotypes of *Salmonella enterica* subsp. *enterica*) in egg product vats prior to pasteurization and simulates the pasteurization (inactivation), the storage (potential for growth), and the home cooking (inactivation), the consumption of egg product, and applying the Food and

TABLE 1. Parameters used for the shell egg model; all other parameters are as in (16)

Input	Value	Name of the alternative	Note
Layer house			
Time-temp (2 alternatives)	Uniform(0, 12) h at	FSIS baseline for layer house	As in ref. 16
	lognormal(4.32, 0.15) (°F) (mean, 75.8°F)		
	36 h at 75°F	Limit egg safety final rule	Fixed
Storage on farm before processing			
Temp (2 alternatives)	45°F	45°F	Fixed
	65°F	65°F	Fixed
Time (10 alternatives)	0, 1, 2, . . . , 9 days	0, 1, 2, . . . , 9 days	Fixed
Transportation from farm			
Time	0 days		Included in the previous step
Preprocessing off-line			
Time	0 days		
Proportion of on-line facilities	0%		
Proportion of molted flocks	0%		

TABLE 2. Some parameters used in the liquid egg product model; all other parameters are as in (16)

Product	Contamination level estimated from shell egg contaminated in:	Bacterial growth ^a	Fraction of production (%) ^a	Pasteurization (log reduction) ^a
White	Shell and albumen	As in white	16.9	-5
Whole	Shell, albumen, vitelline membrane, and yolk	As in yolk	45.6	-5.9
Yolk	Vitelline membrane or yolk	As in yolk	4.3	-5.5
Whole 10% salt	Shell, albumen, vitelline membrane, and Yolk	As in yolk	12.7	-6
Whole 10% sugar	Shell, albumen, vitelline membrane, and yolk	As in yolk	12.7	-42
Yolk 10% salt	Vitelline membrane or yolk	As in yolk	3.1	-7.2
Yolk 10% sugar	Vitelline membrane or yolk	As in yolk	4.7	-12.4

^a U.S. Department of Agriculture and Food Safety and Inspection Service (16).

Agriculture Organization of the United Nations and World Health Organization (FAO-WHO) dose-response relationship, evaluates the annual number of cases of salmonellosis from consumption of those egg products in the United States (16). Table 2 reports some parameters of this model for the seven liquid egg products, notably, the pasteurization values and the fraction of production represented by each egg product type in the United States (47,249,212,770 total servings) (16).

The original model specifies the concentration of *Salmonella* spp. in egg products prior to pasteurization by using Weibull distributions estimated from survey data (see Annex F of reference 16). The model was adapted here to incorporate the empirical distributions of contamination of *Salmonella* Enteritidis in egg products obtained from pooling eggs, as described in the previous section. All other parameters from the liquid egg product model (16) were used without any change. Five thousand iterations were run for each of the tested scenarios to provide the estimated number of cases of salmonellosis linked to the consumption of liquid egg products under this scenario.

Aligning the present combined model to survey and epidemiological data. FSIS estimated the prevalence of internally contaminated eggs to be 0.03% (16). This prevalence value leads to much higher *Salmonella* Enteritidis levels in egg product holding tanks than the levels of *Salmonella* spp. used in the liquid egg product model, inferred from bacteriological analysis of 1,034 egg products sampled from the FSIS federally inspected plants (16). As a result, using this prevalence would lead to an estimated number of illnesses much larger than the values estimated in the liquid egg product model and much larger than the epidemiological data reported by the Centers for Disease Control and Prevention at that time (16).

To align the number of salmonellosis cases predicted from combined model to the one predicted from the liquid egg product model, we scaled the prevalence of contaminated eggs entering vats. We simulated the contamination of in-shell contaminated eggs preprocessing by using the baseline parameters (notably the time-temperature profile) from the shell egg model (16). Considering a prevalence of in-shell contaminated eggs of 0.03% (16), we obtained the empirical distribution of *Salmonella* Enteritidis contamination of vats of liquid egg product made by using these eggs. We then used this distribution in the liquid egg product model. The number of cases predicted here was then compared with the liquid egg product model baseline (i.e., with Weibull distributions) to derive a scaling factor of the prevalence of in-shell contaminated eggs.

Additionally, in the shell egg model and liquid egg product risk assessment, model estimates were scaled to align to epidemiological estimates of illnesses attributed to shell eggs from the Centers for Disease Control and Prevention; illness

estimates from the shell egg model and from the liquid egg product model were multiplied by a factor of 0.37 (16). This was not formalized in the model itself nor in many of the tables from the FSIS report (16), so for clarity, we apply the factor to the model results explicitly in the results tables.

Uncertainty analysis. Uncertainty was not specifically modeled in the original model of *Salmonella* Enteritidis in shell eggs because the global uncertainty of the model far exceeded the uncertainty of the illnesses that were attributed to shell eggs from epidemiologic evidence (16). In this study, a nominal range uncertainty analysis (3) was conducted in which inputs were assigned a lower and an upper bound, and the model was rerun to evaluate the effect of the change. Correlated parameters were tested together to avoid any unrealistic sets of parameters. Lower bound and upper bound were specified as in the original FSIS study (16). Of the 97 parameters (or set of correlated parameters) in the original shell egg model (16), 23 were applicable to the output of the current model. Those were the parameters governing the initial level of bacteria in the albumen (two parameters) or in the yolk (two parameters), the localization of the original *Salmonella* contamination within contaminated eggs (nine parameters), the bacterial growth in the yolk (two sets of parameters) or in the albumen (two parameters), the parameters governing the vitellin membrane breakdown (three parameters), the cooling rate of eggs in the layer house and on farm (two parameters), and the dose-response parameters (one set of parameters). The increase in the risk linked to the consumption of liquid egg products when eggs were stored 5 days at 65 versus 45°F after the layer house stage of 36 h at 75°F was evaluated for 46 simulations (23 parameters at lower or upper bound) and compared with the baseline simulation.

RESULTS

Aligning the present combined model to survey and epidemiological data. The number of cases predicted by the original liquid egg product model baseline (i.e., with Weibull distributions) was 5,526 cases, while the one with the combined model with the same in-shell prevalence was 48,106 (Table 3). We scaled the prevalence of contaminated eggs entering vats to align those numbers. The scaling factor was 0.115 (that is, 5,526 of 48,106), leading to an estimated prevalence of internally contaminated eggs entering the egg product line of 0.03% \times 0.115 = 0.00345%. Using this prevalence value of in-shell contaminated eggs entering vats, our combined model leads to a number of cases for egg products comparable to those provided in the liquid egg product model (Table 3).

TABLE 3. Comparison of the liquid egg product model (16) and the combined shell egg model and liquid egg product model (time-temperature profile for eggs baseline (16))

Product	Estimated no. of salmonellosis cases		
	Liquid egg product model	Combined model with in-shell prevalence 0.03%	Combined model with adjusted prevalence of 0.00345%
White	7,125	67,866	7,645
Whole	4,764	37,703	4,219
Yolk	1,914	15,741	1,867
Whole 10% salt	1,101	8,497	967
Whole 10% sugar	0	0	0
Yolk 10% salt	30	210	24
Yolk 10% sugar	0	0	0
Total	14,934	130,017	14,723
Epidemiologically scaled (0.37 × total)	5,526	48,106	5,448

Shell egg contamination. Figure 2 shows the log of the mean number of *Salmonella* Enteritidis per in-shell contaminated egg for 100,000 model iterations, after 36 h of storage in the layer house at 75°F, stored for an additional period at 45°F (i.e., compliant with the FDA egg safety final rule; dashed line, triangles) compared with eggs stored for an additional period of time at 65°F (dashed line, circles) from 0 to 9 days. Additional statistics are provided Table 4, suggesting extremely skewed distributions. After 3 days of storage following layer house storage of 36 h at 75°F, there is about a 1.5-log difference when eggs are stored at 65 versus 45°F, meaning that there are about 30 times more *Salmonella* Enteritidis per egg, on average (Table 5). This difference does not substantially increase over the next few days. If eggs are stored according to the FSIS (16) baseline at the layer house, there is about a 2-log difference

for eggs stored at 65°F (solid line, circles) versus 45°F (solid line, triangles).

Salmonella Enteritidis may initially be deposited in the albumen, in the yolk, in the vitelline membrane, or on the inner shell membranes. For albumen-contaminated eggs, the site of contamination is further distinguished as being close to or far from the yolk. Growth in the albumen of some of these eggs will not occur regardless of how the eggs are stored, while it will grow on some others. Yolk- and vitelline membrane-contaminated eggs can further be separated into those that have a low number of *Salmonella* Enteritidis initially deposited inside them and those with high numbers initially inside them (16). The growth model developed in the shell egg model (16) differs according to the characteristics of this initial contamination. The increase in the mean number of *Salmonella* per egg when eggs are

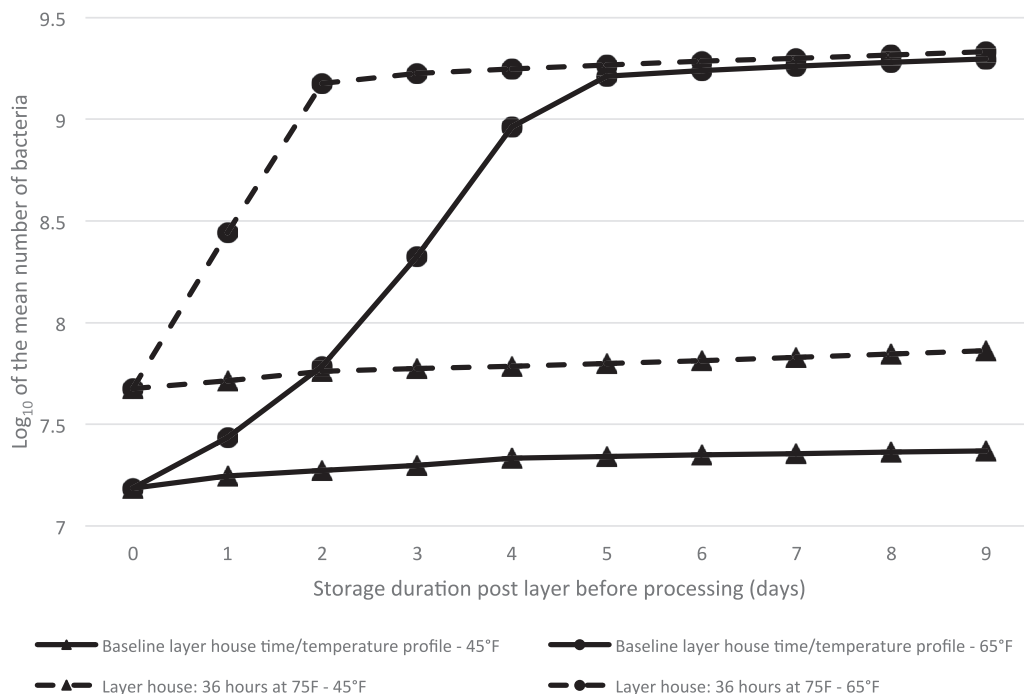


FIGURE 2. Results of simulations showing the log of the mean number of *Salmonella* Enteritidis present at 0 to 9 days of storage at 45°F (7.2°C, triangles) or 65°F (18.3°C, circles) after 36 h in the layer house at 75°F (23.9°C, dashed lines) or after varying time-temperature profiles at the layer house, as considered in FSIS (16) (solid lines).

TABLE 4. Log of statistics of the number of *Salmonella Enteritidis* per in-shell contaminated egg simulated after 0 to 9 days of storage

Statistic		Storage duration (days) post-layer house:									
		0	1	2	3	4	5	6	7	8	9
FSIS (16) baseline layer house time-temp profile											
45°F	Mean	7.18	7.25	7.27	7.30	7.33	7.34	7.35	7.36	7.36	7.37
	SD	8.87	8.90	8.92	8.92	8.95	8.95	8.96	8.96	8.96	8.96
	Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	1st	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	5th	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	10th	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30
	25th	0.60	0.60	0.60	0.60	0.60	0.60	0.60	0.60	0.60	0.60
	Median	1.00	1.04	1.04	1.04	1.04	1.04	1.04	1.04	1.04	1.04
	75th	1.45	1.46	1.46	1.46	1.46	1.46	1.46	1.46	1.48	1.48
	90th	1.83	1.83	1.84	1.84	1.85	1.85	1.85	1.86	1.86	1.87
	95th	2.05	2.07	2.07	2.08	2.08	2.09	2.09	2.10	2.11	2.12
	99th	2.59	2.69	2.72	2.74	2.78	2.83	2.87	2.87	2.96	3.07
	Maximum	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59
	65°F	Mean	7.18	7.43	7.78	8.33	8.96	9.21	9.24	9.26	9.28
Median		1.00	1.08	1.15	1.20	1.26	1.28	1.30	1.32	1.34	1.38
SD		8.87	8.99	9.17	9.42	9.75	9.89	9.90	9.91	9.92	9.93
Minimum		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Maximum		10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59
1st		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5th		0.00	0.00	0.00	0.00	0.00	0.30	0.30	0.30	0.30	0.30
10th		0.30	0.30	0.30	0.30	0.48	0.48	0.48	0.48	0.48	0.60
25th		0.60	0.60	0.70	0.78	0.78	0.85	0.85	0.90	0.90	0.90
75th		1.45	1.54	1.63	1.72	1.79	1.85	1.91	1.98	2.04	2.12
90th		1.83	2.00	2.40	4.21	6.56	7.20	7.20	7.20	7.20	7.20
95th		2.05	2.41	4.60	7.20	7.20	7.20	7.20	7.20	8.31	10.59
99th		2.59	5.16	7.20	8.98	10.59	10.59	10.59	10.59	10.59	10.59
Layer house: 36 h at 75°F (23.9°C)											
45°F	Mean	7.67	7.71	7.76	7.78	7.79	7.80	7.81	7.83	7.84	7.86
	SD	9.12	9.13	9.16	9.16	9.17	9.17	9.18	9.18	9.19	9.19
	Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	1st	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	5th	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	10th	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30
	25th	0.70	0.70	0.70	0.70	0.78	0.78	0.78	0.78	0.78	0.78
	Median	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.20	1.20	1.20
	75th	1.67	1.68	1.68	1.68	1.68	1.69	1.69	1.69	1.69	1.70
	90th	2.83	2.94	2.99	3.06	3.14	3.20	3.27	3.35	3.44	3.54
	95th	5.80	6.05	6.14	6.23	6.32	6.42	6.53	6.64	6.74	6.85
	99th	7.20	7.20	7.23	7.34	7.45	7.56	7.66	7.77	7.89	8.00
	Maximum	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59
	65°F	Mean	7.67	8.44	9.18	9.23	9.25	9.27	9.29	9.30	9.32
SD		9.12	9.44	9.87	9.90	9.91	9.92	9.93	9.93	9.94	9.95
Minimum		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1st		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5th		0.00	0.00	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30
10th		0.30	0.30	0.48	0.48	0.48	0.48	0.48	0.60	0.60	0.60
25th		0.70	0.78	0.85	0.85	0.85	0.90	0.90	0.90	0.95	0.95
Median		1.18	1.23	1.26	1.28	1.32	1.34	1.36	1.38	1.40	1.43
75th		1.67	1.74	1.81	1.88	1.94	2.00	2.07	2.15	2.25	2.37
90th		2.83	5.06	7.19	7.20	7.20	7.20	7.20	7.20	7.20	7.20
95th		5.80	7.20	7.20	7.20	7.20	7.20	9.10	10.59	10.59	10.59
99th		7.20	9.75	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59
Maximum		10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59	10.59

TABLE 5. Increase in the mean number of *Salmonella Enteritidis* per contaminated egg present when eggs were stored at 65 versus 45°C^a

Layer house alternative	Storage temp post-layer house	Statistic	Storage duration (days) post-layer house:									
			0	1	2	3	4	5	6	7	8	9
FSIS (16) baseline layer house time-temp profile ^b	65 vs 45°F	Mean increase (log)	×1.0 (0.00)	×1.5 (0.19)	×3.2 (0.51)	×10.7 (1.03)	×42.7 (1.63)	×74.1 (1.87)	×77.8 (1.89)	×80.5 (1.91)	×82.9 (1.92)	×84.6 (1.93)
Layer house: 36 h at 75°F	65 vs 45°F	Mean increase (log)	×1.0 (0.00)	×5.4 (0.73)	×26.1 (1.42)	×28.2 (1.45)	×28.9 (1.46)	×29.5 (1.47)	×29.7 (1.47)	×29.7 (1.47)	×29.6 (1.47)	×29.5 (1.47)

^a Storage was 0 to 9 days at 45°F (7.2°C) or 65°F (18.3°C) after 36 h in the layer house at 75°F (23.9°C) or after varying time-temperature profiles at the layer house, as considered in (16).

^b Time at the layer house following a uniform(0, 12) h distribution at a varying temperature following a lognormal(4.32, 0.15) (°F) distribution.

stored at 45 or 65°F is not similar for all types of contaminated eggs. Indeed, at 45°F (36 h at 75°F in the layer house, followed by a 5-day storage at 45°F at the farm level before processing), most of the cells (80%) present in contaminated eggs come from the few eggs (0.14%) contaminated in the yolk with high numbers initially inside them (Table 6). At 65°F (36 h at 75°F in the layer house, followed by 5-day storage at 65°F at the farm level before processing), the additional growth for eggs contaminated in the yolk at high initial levels is limited (+0.0 log), while the additional growth ranges from +1.6 to +2.4 log according to the other egg types.

Public health risk linked to liquid egg products.

Using an overall prevalence of contaminated egg of 0.003446%, the estimated number of cases of salmonellosis linked to liquid egg products following various time and temperature storage scenarios are provided (Table 7 and

Fig. 3). The number of cases linked to eggs stored 5 days at 65 versus 45°F after a layer house stage of 36 h at 75°F is multiplied by a factor of about 47. This increase is higher (about 130- to 150-fold) after a layer house stage, with time and temperature as considered in FSIS (16).

Table 8 shows more specifically the increase in public health risk expected per type of egg product for a 5-day storage at 45 or 65°F, after a layer house storage of 36 h at 75°F. This table indicates that the increase in risk varies by type of egg product: substantial increase for egg whites without sugar or salt added and no increase for whole egg products that contain 10% sugar.

For whole eggs, the factor is 29.6 or 1.5 log, which is essentially the same factor as observed for the mean increase in *Salmonella* Enteritidis levels predicted from the shell egg model (×29). The greatest contributor to the increase in the risk of salmonellosis from egg products is primarily from contaminated egg whites. As noted, some

TABLE 6. Total number of *Salmonella Enteritidis* and mean number of *Salmonella Enteritidis* in shell eggs according to the location of the initial contamination^a

Initial contamination ^b	Simulated eggs	Storage at 45°F			Storage at 65°F			Multiplying factor	
		Total no. of <i>Salmonella</i>	%	Mean no. of <i>Salmonella</i> per egg	Total no. of <i>Salmonella</i>	%	Mean no. of <i>Salmonella</i> per egg	(in log)	
Shell	18,576	99,193,577,253	1.6	5,339,878	21,852,241,277,871	11.8	1,176,369,578	×220	+2.3
Alb C G	7,257	63,478,733,970	1.0	8,747,242	6,875,359,490,306	3.7	947,410,706	×108	+2.0
Alb C N	1,932	55,618,474,799	0.9	28,788,030	2,256,944,916,360	1.2	1,168,190,950	×41	+1.6
Alb F G	20,452	104,459,895,487	1.7	5,107,564	23,923,828,314,887	12.9	1,169,754,954	×229	+2.4
Alb F N	31,513	145,010,565,822	2.3	4,601,611	36,429,435,533,862	19.7	1,156,012,932	×251	+2.4
VM low	16,946	242,962,381,347	3.9	14,337,447	18,267,730,938,948	9.9	1,077,996,633	×75	+1.9
VM high	1,248	9,729,027,140	0.2	7,795,695	1,497,031,680,542	0.8	1,199,544,616	×154	+2.2
Yolk low	1,933	554,798,074,862	8.8	287,014,007	68,627,563,577,182	37.0	35,503,136,874	×124	+2.1
Yolk high	143	5,011,731,210,350	79.7	35,047,071,401	5,563,345,573,418	3.0	38,904,514,499	×1	+0.0
Grand total	100,000	6,286,981,941,029	100.0	62,869,819	185,293,481,303,332	100.0	1,852,934,813	×29	+1.5

^a 5-Day storage at 45°F (7.2°C) scenario versus 5-day storage at 65°F (18.3°C) scenario (following 36 h at 75°F [23.9°C] in the layer house; 100,000 simulated eggs).

^b *Salmonella* Enteritidis may initially be deposited in the albumen (Alb), in the yolk, in the vitelline membrane (VM), or on the inner shell membranes (shell). For albumen-contaminated eggs, the site of contamination is further distinguished as being close (C) to or far (F) from the yolk. It is likely that growth in the albumen of some of these eggs will not (N) occur, regardless of how the eggs are stored, while it will grow (G) on some. Yolk- and VM-contaminated eggs are further separated into those that have a low (low) number of *Salmonella* Enteritidis initially deposited inside them and those with high (high) numbers initially inside them. See reference 16 for further details.

TABLE 7. Increase in the estimated number of salmonellosis cases linked to the overall consumption of liquid egg product when eggs were stored at 65 versus 45°C^a

Layer house alternative	Storage temp post-layer house	Statistic	Storage duration (days) post-layer house:									
			0	1	2	3	4	5	6	7	8	9
FSIS (16) baseline layer house time-temp profile ^b	65 vs 45°F	Mean increase (log)	×1.0 +0.00	×1.5 +0.18	×3.9 +0.59	×16.8 +1.22	×73.2 +1.86	×128.9 +2.11	×135.4 +2.13	×140.6 +2.15	×145.4 +2.16	×149.2 +2.17
Layer house: 36 h at 75°F	65 vs 45°F	Mean increase (log)	×1.0 +0.00	×8.8 +0.94	×43.5 +1.64	×46.4 +1.67	×47.0 +1.67	×47.2 +1.67	×47.0 +1.67	×46.4 +1.67	×45.8 +1.66	×45.0 +1.65

^a Number of cases if they were made from eggs stored 0 to 9 days at 65°F (18.3°C) compared with 45°F (7.2°C), after 36 h in the layer house at 75°F (23.9°C), or after varying time-temperature profiles at the layer house, as considered in FSIS (16).

^b Time at the layer house following a uniform(0, 12) h distribution at a varying temperature following a lognormal(4.32, 0.15) (°F) distribution.

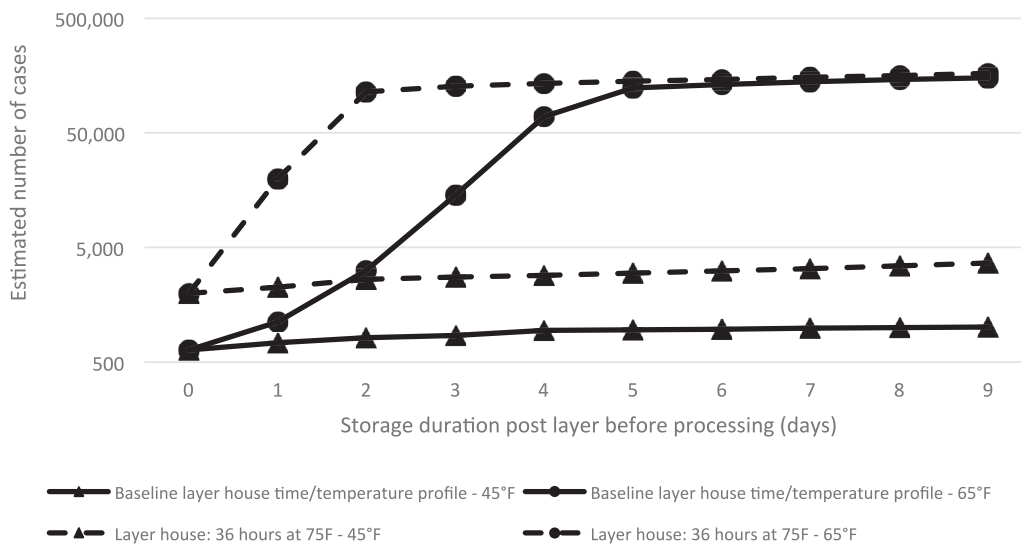


FIGURE 3. Results of simulations showing the estimated number of salmonellosis cases per year in the United States linked to the consumption of all types of liquid egg products (e.g., whole, white, and yolk), if they were made from eggs stored 0 to 9 days at 45°F (7.2°C, triangles) or 65°F (18.3°C, circles) after 36 h in the layer house at 75°F (23.9°C, dashed lines) or after varying time-temperature profiles at the layer house, as considered in FSIS (16) (solid lines).

TABLE 8. Comparison of the estimated number of salmonellosis cases per year in the United States linked to the consumption of various liquid egg products^a

Product	Pasteurization log reduction ^b	Estimated no. of salmonellosis cases		Increase (65 vs 45°F)	
		45°F scenario	65°F scenario		log
White	-5	424	78,057	×184.1	+2.3
Whole	-5.9	1,307	38,701	×29.6	+1.5
Yolk	-5.5	919	15,109	×16.4	+1.2
Whole 10% salt	-6	313	8,468	×27.0	+1.4
Whole 10% sugar	-42	0	0	NA ^c	NA
Yolk 10% salt	-7.2	11	192	×17.2	+1.2
Yolk 10% sugar	-12.4	0	0	NA	NA
Total		2,974	140,528	×47.2	+1.7
Epidemiologically scaled (0.37 × total)		1,101	51,995	×47.2	+1.7

^a Number of cases if they were made from eggs stored 5 days at 45°F (7.2°C) or 65°F (18.3°C) after 36 h in the layer house at 75°F (23.9°C); combined risk assessment model (prevalence of contaminated eggs: 0.003446%).

^b Log reduction values estimated by FSIS (16).

^c NA, 0 of 0.

TABLE 9. Number of cases of salmonellosis linked to the consumption of liquid egg product per year in the United States as a function of layer house and post-layer house storage conditions^a

Layer house	Storage temp	Statistic	Storage time (days):									
			0	1	2	3	4	5	6	7	8	9
F51S (16) baseline layer house time-temp profile ^b	45°F	Estimated no. of cases (unscaled)	639	742	814	857	942	958	973	986	1,000	1,014
		Estimated no. of cases (epidemiologically scaled ^c)	236	275	301	317	349	354	360	365	370	375
		Multiplication factor	×1.0	×1.0	×1.2	×2.1	×6.1	×10.0	×10.4	×10.8	×11.1	×11.4
Layer house: 36 h at 75°F (23.9°C)	65°F	Estimated no. of cases (unscaled)	639	769	979	1,804	5,704	9,533	10,128	10,625	11,109	11,535
		Estimated no. of cases (epidemiologically scaled)	236	285	362	667	2,110	3,527	3,748	3,931	4,110	4,268
		Estimated no. of cases (unscaled)	1,988	2,243	2,628	2,754	2,856	2,974	3,119	3,285	3,460	3,671
Layer house: 36 h at 75°F (23.9°C)	65°F	Estimated no. of cases (epidemiologically scaled)	736	830	972	1,019	1,057	1,101	1,154	1,215	1,280	1,358
		Multiplication factor	×1.0	×1.5	×4.0	×4.2	×4.2	×4.2	×4.2	×4.2	×4.1	×4.1
		Estimated no. of cases (unscaled)	1,988	3,468	10,450	11,510	12,045	12,603	13,157	13,731	14,303	14,985
Layer house: 36 h at 75°F (23.9°C)	65°F	Estimated no. of cases (epidemiologically scaled)	736	1,283	3,867	4,259	4,457	4,663	4,868	5,081	5,292	5,544

^a Number of cases if 7% of eggs are stored at a temperature of 45°F (7.2°C) or 65°F (18.3°C) preprocessing.
^b Time at the layer house following a uniform(0, 12) h distribution at a varying temperature following a lognormal(4.32, 0.15) (°F) distribution.
^c Scaled = 0.37 × unscaled.

types of egg products (e.g., whole egg products with 10% sugar) do not contribute an increase in the risk of salmonellosis when shell eggs are stored at 65 versus 45°F. Overall, the increase in the risk of salmonellosis from egg products produced from contaminated shell eggs stored at 65 versus 45°F is substantive at 47.2-fold.

Expected increase in the risk associated with eggs stored at 65°F as compared with 45°F. The overall risk of salmonellosis from consumption of egg products made from eggs stored at 65°F for 5 days rather than stored at 45°F for 5 days is multiplied by a factor of ×47.2 (Table 7). If only a fraction of the eggs entering the egg product line are stored at 65°F for 5 days, then the expected increase in illnesses will be smaller. As an example, if 7% of the eggs are stored (after 36 h storage in the 75°F layer house) at 65°F for 5 days and 93% of eggs are stored at 45°F for 5 days, then the overall risk of salmonellosis from consumption of egg products is expected to increase by a factor of 4.2 from the value estimated for storage of all eggs at 45°F for 5 days:

$$(7\% \times 47.2X) + (93\% \times 1X) = 4.2X$$

where *X* is the number of cases estimated for storage of all eggs at 45°F.

For 47,249,212,770 servings of egg products per year, predicted illnesses would increase to a total of 12,603 (unscaled) or 4,663 (epidemiologically scaled) compared with 2,974 (unscaled) or 1,101 (epidemiologically scaled) (see Table 8).

$$(7\% \times 47.2 \times 2,974) + (93\% \times 1 \times 2,974) = 4.23 \times 2,974 = 12,603 \text{ (unscaled)}$$

$$(7\% \times 47.2 \times 1,101) + (93\% \times 1 \times 1,101) = 4.23 \times 1,101 = 4,663 \text{ (epidemiologically scaled)}$$

Focusing on the contribution of the 7% of the supply stored at higher temperature in this example, there would be an additional 12,603 – 2,974 = 9,629 (unscaled) or 3,562 (epidemiologically scaled) illnesses per year: a 420% increase. Similar evaluations can be conducted for other storage time-temperature profiles (Table 9).

Uncertainty analysis. The combined model was tested at estimated lower and upper bounds of 23 parameters or set of parameters (Table 10). Most of the tested parameters have a low impact on the number of estimated cases of salmonellosis or on the increase in the estimated number of cases of salmonellosis when eggs are stored at 45 versus 65°F after 36 h in the layer house at 75°F. The model is more sensitive to the parameters governing bacterial growth in yolk: the estimated number of cases ranges from 0 to 125,566, when eggs are stored at 45°F and 0.5 to 154,047 when eggs are stored at 65°F, as a function of the yolk growth parameters. The cooling constant is also of importance, which is expected as the impact of refrigerating the eggs from 75°F to 45 or 65°F is impaired by extreme temperature inertia.

TABLE 10. Results of the nominal range uncertainty analysis^a

Tested parameter ^b	Tested value ^c	Estimated no. of cases when eggs are stored at:		Multiplication factor
		45°F	65°F	
Recall: baseline		2,974	140,528	47.2
Albumen initial contamination				
Mean of the lognormal distribution (ML: 2.6022)	LB: 1.30 UB: 5.2044	2,958 2,978	139,181 144,144	47.0 48.4
SD of the lognormal distribution (ML: 1.2953)	LB: 0.65 UB: 2.5906	2,977 2,964	140,506 143,464	47.2 48.4
Yolk and vitelline membrane initial contamination				
Mean of the Poisson distribution (ML: 1.39)	LB: 0.70 UB: 2.78	2,912 3,003	139,109 142,543	47.8 47.5
Probability of 0 (ML: 0.25)	LB: 0.12 UB: 0.50	2,953 3,000	140,000 142,278	47.4 47.4
Fraction of contaminated egg with initial contamination in the:				
Shell (ML: 0.185)	LB: 0.093 UB: 0.370	3,195 2,645	143,334 136,025	44.9 51.4
Albumen, close to the yolk, with growth (ML: 0.072)	LB: 0.036 UB: 0.145	3,164 2,817	141,932 138,445	44.9 49.1
Albumen, close to the yolk, with no growth (ML: 0.019)	LB: 0.010 UB: 0.039	3,071 2,956	140,891 139,925	45.9 47.3
Albumen, far from the yolk, with growth (ML: 0.205)	LB: 0.102 UB: 0.410	3,225 2,570	143,743 135,591	44.6 52.8
Albumen, far from the yolk, with no growth (ML: 0.315)	LB: 0.157 UB: 0.629	3,363 2,375	145,672 133,632	43.3 56.3
Vitelline membrane, low no. (ML: 0.170)	LB: 0.085 UB: 0.341	3,220 2,665	143,723 134,731	44.6 50.6
Vitelline membrane, high no. (ML: 0.012)	LB: 0.006 UB: 0.025	3,008 2,972	140,860 140,043	46.8 47.1
Yolk, low no. (ML: 0.020)	LB: 0.010 UB: 0.039	2,993 3,093	126,984 167,911	42.4 54.3
Yolk, high no. (ML: 0.001)	LB: 0.001 UB: 0.003	1,739 4,946	139,377 142,776	80.1 28.9
Bacterial growth in the yolk				
Parameters e and f (ML: $e = -1.0063$ and $f = 0.2219$)	LB: $e = -1.5863$ and $f = 0.1954$ UB: $e = -1.1969$ and $f = 0.2484$	687 125,566	10,552 154,047	15.4 1.2
b (ML: 0.4007)	LB: 0.0100 UB: 0.8761	0 3,056	0.5 140,528	NA 46.0
Vitelline membrane breakdown				
d (ML: 1.3103)	LB: 1.0869 UB: 1.5337	3,540 2,577	250,688 75,001	70.8 29.1
Ω (ML: 1)	LB: 1 UB: 2.6	2,974 3,100	140,528 184,460	47.2 59.5
f , g , and k (ML: $f = -1.5087$, $g = 0.0751$, $k = 3.4825$)	LB: $f = -3.2745$, $g = 0.0299$, $k = 2.6227$ UB: $f = -0.010$, $g = 0.1203$, $k = 4.3423$	2,971 20,195	134,590 2,906,549	45.3 143.9
Bacterial growth in the albumen				
SD (ML: 0.3850)	LB: 0.1925 UB: 0.7700	2,961 3,001	140,515 140,631	47.4 46.9
Lag/growth (ML: 5)	LB: 2 UB: 10	2,974 2,974	140,528 140,528	47.2 47.2
Cooling constant				
k -values in layer house (ML: 1)	LB: 0.01 UB: 1	109,316 2,974	204,502 140,528	1.9 47.2
k -values on farm (ML: 1%: 0.01, 99%: 0.10)	LB: 0.01 UB: 1.00	49,008 2,247	144,474 140,267	2.9 62.4

TABLE 10. *Continued*

Tested parameter ^b	Tested value ^c	Estimated no. of cases when eggs are stored at:		Multiplication factor
		45°F	65°F	
Dose-response				
Dose-response (ML: alpha = 0.1324, beta = 51.45)	LB: alpha = 0.10763, beta = 38.49 UB: alpha = 0.22744, beta = 57.96	2,276 4,539	107,289 214,508	47.1 47.3

^a Baseline indicates eggs stored 5 days at 45°F (7.2°C) or 65°F (18.3°C) after 36 h in the layer house at 75°F (23.9°C).

^b See FSIS (16) for a complete definition. ML, most likely value, as used in the baseline model.

^c LB, lower bound; UB, upper bound.

DISCUSSION

In this study, two existing probabilistic risk assessment models, the shell egg model and the liquid egg product model (16), were combined with a third model for egg product pooling. This combined model allows for an evaluation of the public health impact from egg product microbiological load by changing time and temperature profiles for the storage of shell eggs. The nominal range uncertainty analysis developed in this study suggests that the results are robust to the uncertainty, as expected in the various model parameters.

These estimations assume the prevalence and levels of contaminated shell eggs from surplus hatchery lines of production are the same as those for contaminated eggs from the traditional egg product lines, as well as the distribution of the sites of in-shell contamination. This assumption is made in the absence of any directly applicable data. Data on the prevalence of *Salmonella*-positive environments in broiler breeder farms can be found in the literature (1). However, it is yet to be determined if these data could be used to extrapolate a more accurate measure of prevalence and level of contamination in broiler breeder eggs. It could, potentially, be possible to use the breeder environmental data in conjunction with estimated rates of *Salmonella*-positive eggs produced from positive environments to determine a more accurate rate of contamination for broiler breeder eggs. However, because of the low reported frequency of *Salmonella* contaminated eggs (5), it would take a large study to demonstrate a difference that would have a practical effect.

This assumption bypasses most data gaps that would be considered, such as (i) surveillance data, (ii) management differences, (iii) environmental contamination on the farm, (iv) differences in flock types, or (v) egg product pasteurization practices. Note that farms that sell some of their eggs for consumption as shell eggs are bound by the FDA egg safety final rule, including a *Salmonella* Enteritidis prevention plan, and therefore may have different management practices and a different incidence rate of environmental contamination.

Table 6 shows that when eggs are stored at 45°F post-layer house, most of the *Salmonella* Enteritidis cells simulated in the system (80%) originate from the very few (0.143%) eggs that are initially contaminated in the yolk at a “high” initial concentration (“yolk high,” as

defined in reference 16). For these types of contaminated eggs, the *Salmonella* Enteritidis cells can grow immediately (exponentially) without any lag period (16). This immediate exponential growth leads to a very high level of contamination in these eggs in the layer house for the usual time-temperature profile considered in that location (16) and is the major contributor to the mean number of *Salmonella* Enteritidis present in the system when eggs are stored at 45°F (Fig. 2). These specific contaminated eggs lead to a residual risk of salmonellosis in pasteurized egg products when eggs are stored at 45°F (Table 8), as estimated with this model. When eggs are stored 5 days at 45°F post-layer house, the subsequent growth of *Salmonella* is extremely limited for all contaminated eggs, while it is substantial for all (but yolk high when the maximum population density is already reached) contaminated eggs when stored 5 days at 65°F. Table 6 provides an estimated multiplication factor of the mean number of *Salmonella* Enteritidis cells ranging from 41- to 251-fold, according to the type of contaminated egg when eggs are stored 5 days at 65°F versus 5 days at 45°F, following 36 h at 75°F in the layer house.

The increase in the mean level of contamination of eggs when stored at higher temperature directly transfers to an increase in the risk of salmonellosis from consumption of egg product. For whole eggs stored 5 days at 45 versus 65°F (following 36 h at 75°F in the layer house), the factor is, on average, 30-fold or 1.5 log, which is essentially the same factor as observed for the mean increase in *Salmonella* Enteritidis levels predicted in the shell egg model (30-fold). Indeed, for egg products made from whole eggs, the increase in the mean number of *Salmonella* Enteritidis cells per contaminated eggs when stored 5 days at 45 versus 65°F after 36 h of storage at 75°F (+1.5 log or 30-fold) is expected to be equal to the increase in the concentration of *Salmonella* Enteritidis in vat of egg products after pasteurization. Because of the factor of dilution of contaminated eggs in vats of noncontaminated eggs and because of the pasteurization of -5.5 log, the number of *Salmonella* Enteritidis in contaminated vats of egg products following pasteurization will be low. At that low level of contamination, the dose-response relationship for *Salmonella* used in the FSIS risk assessment (16) is linear (6, 19). Therefore, the increase in the mean number of *Salmonella* Enteritidis in the eggs is expected to be translated to the increase in the mean risk per serving of egg products that is 31-fold. Using the combined model, we obtain an increase

in the risk per serving for whole eggs of $\times 30$ (Table 8). Although there would not be an increase in the risk for 10% sugar whole or yolk egg products (no cases of salmonellosis would be expected for those products as a result of the extremely high pasteurization efficiency), the increase in illnesses would be 47-fold overall for egg products, arising from the large contribution of contaminated egg whites to the total ($\times 184$). Note that the absence of increase in the risk for 10% sugar whole eggs or 10% sugar yolk results from the extremely high log reduction (-42 and -12.4 log, respectively) estimated by the FSIS with predictive microbiology models.

These results reinforce the scientific data (for a review, see reference 9) and previous risk assessments (4, 6, 12, 16), showing that an early cooling and a low-temperature storage of shell eggs are highly effective in reducing the level of *Salmonella* Enteritidis in shell eggs. The combined model provides evidence that egg products made from eggs held at 65°F present a significantly higher level of *Salmonella* Enteritidis at the time of consumption. The diversion of eggs held at 65°F beginning 36 h after time of lay to human consumption storage practices of 65°F (versus 45°F) does present a substantive overall increase in the risk of salmonellosis.

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