Journal of Food Protection, Vol. 80, No. 5, 2017, Pages 863–878
doi:10.4315/0362-028X.JFP-16-403
Published 2017 by the International Association for Food Protection

Research Paper

A Quantitative Assessment of the Risk of Human Salmonellosis Arising from the Consumption of Almonds in the United States: The Impact of Preventive Treatment Levels

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MS 16-403: Received 26 September 2016/Accepted 15 December 2016/Published Online 17 April 2017

ABSTRACT

The presence of *Salmonella* on almonds continues to result in product-related outbreaks and recalls in the United States. In this study, the impact of microbial reduction treatment levels (1 to 5 log CFU) on the risk of human salmonellosis from the consumption of almond kernels in the United States was evaluated. An exposure model, including major steps in almond processing, was used to estimate prevalence and levels of contamination of *Salmonella* on almonds at the point of consumption. A *Salmonella* dose-response model and consumption data for almonds in the United States were used to assess risk of illness per serving and per year, quantifying variability and uncertainty separately. A 3-log reduction treatment resulted in a predicted mean risk of illness of two cases per year for almonds consumed as a core product not cooked at home (95% confidence interval [CI], one to four cases), one case per year for almonds consumed as an ingredient not cooked at home (95% CI, one to two cases), and less than one case per year for almonds consumed as an ingredient cooked at home (95% CI, 7×10^{-7} to 3×10^{-6} cases). A minimum 4-log reduction treatment resulted in an estimated mean risk of illness below one case per year in the United States. This study also includes an assessment of the risk of human salmonellosis as a result of an exceptional situation, which results in higher risk estimates compared with the baseline model. The exceptional situations modeled posttreatment resulted in estimates of mean risk that were not significantly affected by treatment level. Sensitivity analysis results showed initial *Salmonella* contamination level to be the factor with the most impact on risk per serving estimates, given a certain treatment level. The risk assessment also includes a simulation of the events that occurred in 2001. Treatment levels with a minimum 4-log microbial reduction would have been sufficient to prevent the outbreak cases. The uncertainty range in the estimates indicates that additional information is needed to make more precise predictions of this specific outbreak event.

Key words: Low moisture; Risk Assessment; *Salmonella*; Tree nuts; Uncertainty; Variability

The United States is the largest producer of almonds in the world *(20),* with almond production constituting an estimated 6 billion dollar industry *(42)*. In the United States, almonds are predominantly grown in the Central Valley of California *(20)*. During the past 15 years, a number of human salmonellosis outbreaks associated with the consumption of almonds or almond products in the United States (in 2000 to 2001, 2004, and 2014) have been documented *(24)*. *Salmonella* has been shown to be occasionally present on almonds and almond products, leading to various U.S. product recalls in 2001, 2004, 2012, and 2014 *(30)*. An overview of the U.S. production process for almonds is outlined in Figure 1 *(20, 23)*.

Under a marketing order issued by the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (CFR Title 7 Part 981, "Almonds Grown in California," 2015), handlers must (with certain exceptions) subject their almonds to a treatment process or processes that achieve in total a minimum 4-log reduction of *Salmonella* (7 CFR 981.442(b), "Quality Control"—"Outgoing," 2017; available at https://www.gpo.gov/fdsys/pkg/CFR-2011-title7-vol8/pdf/CFR-2011-title7-vol8-sec981-442.pdf).

Quantitative risk assessment is a tool to estimate the risk of adverse health effects from exposure to a hazard in the food supply and the associated burden of illness for a specific population. It can be used to evaluate potential risk reduction strategies, to determine the adequacy and predicted efficacy of preventive controls, and to guide risk management policies. Published risk assessments for *Salmonella* on almonds include those developed by Danyluk et al. *(14)* and Lambertini et al. *(26)*. The U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition built a quantitative risk assessment model to estimate the risk of human salmonellosis arising from the consumption of almonds in the United States. This newly developed risk assessment model for *Salmonella* on almonds

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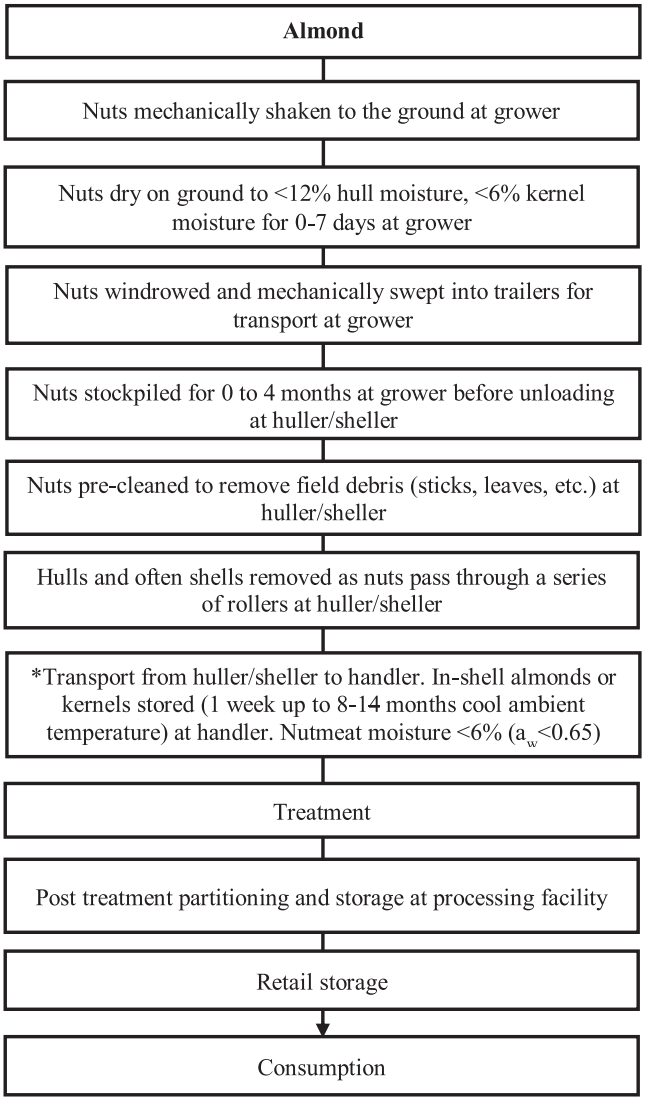

FIGURE 1. *Steps in production process for almonds (modified from Frelka and Harris (20) according to Harris (23)).*

includes a novel mathematical analysis of updated data sets for *Salmonella* probability of contamination (prevalence), *Salmonella* concentration levels, and U.S. almond consumption patterns. Additionally, the model considers variability and uncertainty of parameters separately, to accurately estimate risk and to provide a measure of the uncertainty of the estimated number of salmonellosis cases per year *(21, 29)*. Probability of contamination and *Salmonella* concentration levels for each step throughout the production process from harvest to consumption were also evaluated separately, for better accuracy *(11, 34)*. The model includes the results of a recent study on modeling *Salmonella* survival on tree nuts, quantifying variability and uncertainty *(37)* and providing parameters that are used in this risk assessment. The model includes microbial reduction treatment levels from 1 to 5 log CFU during processing. It also includes consumer cooking as a step for those products (e.g., cookies with almonds) that are consumed after cooking at home (e.g., through baking). This article presents the results of the quantitative risk assessment model of human salmonellosis arising from the consumption of almonds in the United States and evaluates the impact of preventive treatments. Throughout this article, the word "almond" refers to an "almond kernel" unless specified otherwise.

MATERIALS AND METHODS

Overview of exposure assessment for *Salmonella* on almonds. The exposure assessment module estimates the likelihood and level of *Salmonella* contamination on or in almonds at consumption and includes the processing steps corresponding to the major stages in almond production from harvest to consumption (Fig. 1). The following major steps and associated basic processes in almond processing were included in the baseline exposure assessment model for almonds *(23)*: (i) pretreatment storage (survival during storage), (ii) inactivation treatment (from no reduction to 5-log reductions, including 1-, 2-, 3-, and 4-log reductions), (iii) posttreatment partitioning into lots and bags (partitioning into smaller lot sizes), and (iv) posttreatment and retail storage (survival during storage). The exposure assessment considered whether the product was consumed without further cooking ("uncooked at home") or was cooked at home by the consumer ("cooked at home"). The probability of contamination (having at least one *Salmonella* cell in the given food unit) and the level of contamination in positive food units (discrete number of CFU per unit of almonds restricted to levels higher than or equal to 1) were estimated separately. A unit refers to the amount of almonds (in grams) in a lot, sublot, or consumer package, as applicable to each stage of the almond production process. A unit is considered contaminated ("contaminated unit") when there is a minimum of one *Salmonella* cell per unit. Contamination level is defined as the number of *Salmonella* cells per contaminated unit or per unit (includes contaminated and noncontaminated units).

Estimating initial frequency and levels of contamination of almonds at the handler. Data from the 2001, 2002, 2003, 2004, 2005, 2006, 2010, and 2013 surveys conducted by the Almond Board of California to determine *Salmonella* contamination on almonds were submitted to the FDA docket in response to Federal Register Notice FDA-2013-N-0747 *(43)* (Table 1). These data were collected at the handler stage of the almond production process (data preceded by asterisk in Fig. 1). These data include findings published in peer-reviewed journal articles *(3, 15, 26),* as well as unpublished data submitted to the docket only (e.g., survey year 2013). A comprehensive description of the sampling design is provided in Bansal et al. *(3),* Danyluk et al. *(15),* and Lambertini et al. *(26)*. The unpublished data were collected using the same sampling design as outlined in the published studies *(3, 15, 26)*. Briefly, almonds were collected directly after receipt at the handler. Handlers in this survey were located throughout California's almond growing region, and samples were collected throughout the harvest season. Microbiological testing followed the AOAC Official Method 2001.09 *(2),* and the FDA's *Bacteriological Analytical Manual* (BAM) method was used to determine most-probable-number (MPN) levels of *Salmonella (44)*. The frequency of *Salmonella* contamination (i.e., detection in at least a 100-g sample) on almonds during this period (2001 to 2013) was approximately 1%, with small variations in observed values among years. To better characterize the MPN data received through the Federal Register Notice, a rarity index was determined for each MPN pattern, as described in Blodgett *(7)*. The rarity index is defined as the probability of observing a given pattern for the MPN, divided by the probability of observing the most probable pattern for that MPN. A pattern is defined as rare if the rarity index is below 0.05 *(8)*. Two MPN patterns were categorized as rare

(Table 1). Patterns defined as rare were included in the analysis, noting that the maximum likelihood method to derive the *Salmonella* distribution naturally provided a lower weight for these rare patterns.

Multiple models assuming either a Poisson or a lognormal distribution were fit to the MPN dilution assay patterns (number of tubes, grams per tube, number of positive tubes) to determine the best-fit model for describing the probability of contamination and distribution of *Salmonella* concentrations in the almond samples from year to year, according to the methods described in Pouillot et al. *(36)* and Van Doren et al. *(45)*. Parameter estimation was performed using maximum likelihood directly from the dilution assay patterns, and the model fit was compared using the Akaike Information Criterion and likelihood ratio tests (for nested models). A lognormal model with a common mean for all years, and a standard deviation varying by year, was found to be the best-fit model. The best-fit model was translated in a Bayesian framework (where each iteration draws from the distribution of a specific year), using JAGS through rJAGS R library *(31)*. Uninformative priors were used for the mean (Normal (0,10) log CFU/g) and the standard deviations (independent uniform distribution from 0 to 10 log CFU/g). Table 2 provides the statistics of the lognormal model outcome of the Bayesian model distributions representing *Salmonella* contamination at the handler, including the variability and uncertainty distributions of the mean and standard deviation (σ). The Bayesian step was carried out to provide correlated pairs of uncertain parameters to be used in the second-order Monte Carlo simulation *(33)*.

***Salmonella* survival during storage.** It was assumed that *Salmonella* is introduced as soon as an almond falls on the ground. A Weibull survival model that includes a fixed and random variation of δ per tree nut (which is the model parameter that represents the time it takes for the first log reduction) and a fixed variation of ρ per tree nut (which is the model parameter that defines the shape of the curve) was used to predict survival of *Salmonella* on almonds at 20 to 25°C *(37)*. It was assumed that population levels of *Salmonella* on almonds stored at refrigeration and freezing temperatures do not decline *(9, 23, 25, 40)*. A binomial process restricted to positive values was used to evaluate the number of *Salmonella* cells in contaminated units at the end of each stage of the exposure assessment model, and a parallel decrease in prevalence was modeled *(11, 34)*. As documented in the peer-reviewed literature *(16, 28, 33),* tracking pathogen prevalence and level separately is a more efficient approach when prevalence and levels are expected to be or to become very small. The binomial model assumes that each *Salmonella* cell has an independent probability of survival.

Handler step. The exposure assessment model requires estimating lot size at the handler. In 64% of the cases, the almond lot size at the handler follows a triangular distribution, with a minimum of 1,000 kg, a mode and maximum of 11,350 kg, and in 36% of the cases, a uniform distribution between 11,350 and 22,700 kg *(3, 23)*.

The time from initial contamination to sampling (i.e., the time almonds spend at the grower and huller) is between 0 and 16 weeks at 23°C, with a mode of 2 weeks *(23)*. The almond survival data used to develop the Santillana Farakos et al. *(37)* survival model used 1 week as the survival start time. The starting time of the survival curve was, thus, set to follow a triangular distribution, with minimum = −1, mode = 1, and maximum = 15 weeks, with negative values set to 0. Statistical analysis results showed that it was not possible to reject the assumption of a Poisson distribution from sample to sample for the *Salmonella* contamination data collected at the handler step. Therefore, this assumption stands during survival and partitioning because the survival and partitioning process used a binomial process (if $X \sim$ Poisson (λ) at time 0 and $Y \sim$ binomial (X, p) during survival or partitioning, then $Y \sim$ Poisson (λp)).

Preprocess storage. It is estimated that 5% of occurrences follow a triangular distribution (minimum = 0, mode = 2, maximum = 2 weeks), 90% follow a uniform distribution (minimum = 2, maximum = 49 weeks), and 5% follow a triangular distribution (minimum = 49, mode = 49, maximum = 73 weeks) *(23, 26)*. The preprocessing temperature was 23°C *(23)*.

Inactivation during treatment. Six different treatment levels, ranging from no treatment to 5-log reductions and including 1-, 2-, 3-, and 4-log reductions, were modeled. The performances of the specific treatments available for reducing *Salmonella* on almonds (e.g., oil roasting, dry roasting, blanching, treatment with propylene oxide) were not evaluated. The log-reduction treatment levels in *Salmonella* cells are defined in CFU per unit of product being treated (i.e., the lot size). It was assumed that each *Salmonella* cell had an identical and independent probability of inactivation. To evaluate the change in *Salmonella* as a result of treatment in contaminated units, a binomial process restricted to positive values was used. Note that, for treatments with a high log reduction, the contamination level in *Salmonella*-positive lots posttreatment is typically the minimum number of cells in the contaminated units (1 CFU).

Postprocess partitioning into smaller lots and consumer packages. Posttreatment, the lots are partitioned into lots varying in size from 45 to 45,000 kg *(23)*. The maximum size of the lots after partitioning was set to a size equivalent to the size of the lot before partitioning. The lots are then partitioned into individual bags. Consumer packages range in size from an 18-g snack pack to a 454-g bag *(8)*. The change in *Salmonella* levels per unit as a result of partitioning was evaluated by following one subunit (at random) per iteration, and the probability of contamination and number of *Salmonella* cells in contaminated units for each step was estimated using a binomial process restricted to positive values *(34)*.

Postprocess storage. Posttreatment storage occurs at 23°C (80%) and at 4°C (20%) *(26)*. The storage duration was assumed to be 3 weeks *(26)*. The storage time at retail follows a triangular distribution, with minimum = 1/7, mode = 2, and maximum = 6 weeks *(26)*.

Consumer cooking. In addition to almonds being consumed directly from the retail package ("out of hand"), many consumers also use almonds as an ingredient in products that are further cooked at home (e.g., cookies, cakes, chicken, fish dishes). The term "uncooked at home" or "cooked at home" for almonds in this study refers to a cooking step at home. Cooked almonds are those purchased as an "uncooked at home" ingredient (e.g., which might have been roasted, treated with propylene oxide) that are further cooked by the consumer (e.g., through baking, broiling, frying) at home. To account for the log decrease in *Salmonella* levels for almonds that receive a cooking step at home, data from a study by Lathrop et al. *(27)* were used, where a minimum 4.8-log CFU decrease in *Salmonella* population per gram of cookie after 10 min of baking at 177°C was observed. Cookies baked for 15 min had no detectable levels of *Salmonella (27)*. In the absence of

TABLE 1. *MPN dilution assay patterns of* Salmonella *contamination at the handler stage of the almond production process observed during nine harvest seasons*[a]

	Frequency of contamination		MPN patterns					
Year	No. of samples	Positive samples (%)	No. of samples	g/tube	No. of tubes	No. of positive tubes	MPN	Rarity index[b]
2001	2,003	0.60	1,991	100	1	0	—	—
			12	100	1	1	—	—
2002	2,012	1.19	1,988	100	1	0	—	—
			4	100/25	1/1	1/0	1.61	1
			17	100/25/2.5/0.25	1/3/3/3	1/0/0/0	0.79	1
			2	100	1	1	—	—
			1	100/25/2.5/0.25	1/3/3/3	1/1/1/0	3.15	0.21
2003	1,764	0.85	1,749	100	1	0	—	—
			11	100/23/2.5/0.25	1/3/3/3	1/0/0/0	0.79	1
			3	100/23/2.5/0.25	1/1/0/0	1/1/100	1.91	1
			1	100	1	1	—	—
2004	1,643	0.73	1,631	100	1	0	—	—
			8	100/25/2.5/0.25	1/3/3/3	1/0/0/0	0.79	1
			3	100/12.5/1.25/0.125	1/3/3/3	1/0/0/0	1.22	1
			1	100/25/2.5/20.25	1/3/3/3	1/1/0/0	1.91	1
2005	1,852	0.97	1,834	100	1	0	—	—
			8	100/25/2.5/0.25	2/3/3/3	1/0/0/0	0.44	1
			4	100/25/2.5/0.25	1/3/3/3	1/0/0/0	0.79	1
			1	100/25/2.5/0.25	2/3/3/3	2/0/0/0	1.22	0.93
			1	100/48	1/1	1/0	1.13	1
			1	100/25/2.5/0.25	2/3/3/3	2/1/0/0	2.22	1
			1	100/95	1/1	1/0	0.72	1
			1	100/70	1/1	1/0	0.89	1
			1	100/75	1/1	1/0	0.85	1
2006	1,899	1.58	1,869	100	1	0	—	—
			19	100/25/2.5/0.25	1/3/3/3	1/0/0/0	0.79	1
			7	100/25/2.5/0.25	1/3/3/3	1/1/0/0	1.91	1
			1	100/25/2.5/0.25	1/3/3/3	1/2/0/0	3.84	1
			1	100/25/2.5/0.25	1/3/3/3	1/1/2/0	4.63	0.02[c]
			1	100/25/2.5/0.25	1/3/3/3	1/3/0/0	9.25	1
			1	100/25/2.5/0.25	1/3/3/3	1/3/0/1	15.4	0.08
2007	1,799	0.83	1,784	100	1	0	—	—
			15	100	1	1		—
2010	1,000	1.0	918	100	1	0	—	—
			6	100	1	1		—
			2	100	13	1	0.08	1
			1	100	11	1	0.10	1
			1	100	14	4	0.34	1
			1[d]	100	12	1	0.09	1
			1[d]	100	13	1	0.08	1
			1[d]	100	13	2	0.17	1
			2[d]	100	14	1	0.07	1
			1[d]	100	15	1	0.07	1
			1	100	6	0	—	—
			3	100	9	0	—	—
			2	100	10	0	—	—
			5	100	11	0	—	—
			6	100	12	0	—	—
			18	100	13	0	—	—
			10	100	14	0	—	—
			8	100	15	0	—	—
			2	100	16	0	—	—
			7	100	17	0	—	—
			2	100	18	0	—	—
			2	100	19	0	—	—
2013	977	1.02	867	100	1	0	—	—
			2	100	6	0	—	—
			1	100	8	0	—	—

TABLE 1. *Continued*

Year	Frequency of contamination		MPN patterns					
	No. of samples	Positive samples (%)	No. of samples	g/tube	No. of tubes	No. of positive tubes	MPN	Rarity index[b]
			95	100	11	0	—	—
			1[d]	100/25/2.8/0.28	11/3/3/3	4/0/0/0	0.41	1
			1[d]	100/25/2.8/0.28	11/3/3/3	1/0/0/0	0.09	1
			1	100/50/25/2.8/0.29	36/16/3/3/3	1/0/0/0/0	0.02	0.82
			1	100/50/25/2.8/0.28	19/10/3/3/3	7/8/1/3/1	1.09	0.00[c]
			1	100/50/25/2.8/0.28	11/5/3/3/3	2/0/0/0/0	0.15	0.81
			1	100/25	1/2	1/0	1.10	1
			1	100/25	1/2	1/1	3.17	1
			1	100/50/25/2.8/0.28	1/13/3/3/3	1/0/0/0/0	0.13	0.14
			1	100/50/25/2.8.0.28	1/12/3/3/3	1/1/0/0/0	0.15	0.33
			1	100/50/25/2.8/0.28	1/11/3/3/3	1/0/0/0/0	0.15	0.16
			1	100/50/25/2.8/0.28	1/3/3/3	1/1/0/0	1.89	1
			1	100/50/25/2.8/0.28	1/10/3/3/3	1/3/0/0/0	0.73	1

[a] MPN, most probable number; —, not applicable.
[b] The probability of observing the specific (observed) pattern for the estimated MPN value divided by the probability of the most probable pattern for the estimated MPN value.
[c] A rare pattern. A pattern is defined as "rare" if the rarity index is <0.05.
[d] Samples were negative on initial sampling but positive on resampling.

additional data, it was assumed that the expected log decrease in *Salmonella* levels during baking of almonds approximates that of the minimum level seen in baking of peanut butter cookies, and a fixed value of 5 log per unit was used.

Consumption. We distinguished between three types of consumed almond products: (i) core almond product (>80% of the product is almond [including whole almonds]) consumed uncooked at home, (ii) almond as an ingredient (<80% of the product ingredients are almonds) consumed uncooked at home, and (iii) almond as an ingredient (<80% of the product ingredients are almonds) consumed cooked at home (e.g., in home-baked, home-fried, or home-boiled products). Consumption of almonds by the U.S. population (e.g., intake per serving for each product type) was estimated using data originating from "What We Eat in America" (WWEIA), the dietary survey portion of the National Health and Nutrition Examination Survey (NHANES) (https://www.ars.usda.gov/northeast-area/beltsville-md/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweianhanes-overview/), 2003 to 2004, 2005 to 2006, 2007 to 2008, and 2009 to 2010 cycles. Empirical distributions representing serving sizes among consumers and weighted by the NHANES dietary statistical sampling weights were used for almonds consumed as a core product not cooked at home, as an ingredient not cooked at home, and as an ingredient cooked at home. These data are representative of the total U.S. population of consumers. Assuming that data reported in the NHANES-WWEIA 24-h dietary recalls (two per survey respondent, conducted 3 to 10 days apart) are representative of consumption over the whole year, and considering that there are approximately 320 million individuals in the United States, the number of servings per year was estimated. The estimated number of cases per serving and per year corresponds to an "average serving" and an "average year" because the variability introduced in the probability of contamination study is integrated in the procedure.

Hazard characterization. The dose-response model used in this risk assessment is equivalent to the beta-Poisson dose-response model, with parameters $\alpha = 0.1324$ (95% confidence interval [CI], 0.094 to 0.1817) and $\beta = 51.45$ (95% CI, 43.75 to 56.39) derived

TABLE 2. *Lognormal model outcome distributions representing* Salmonella *contamination on almonds at the handler*

Parameter[a]	Year	Lot concn (log/g)	Uncertainty distribution				
			2.5%	25%	50%	75%	97.5%
μ	All	−4.968	−5.289	−5.071	−4.961	−4.861	−4.690
σ	2001	0.806	0.544	0.731	0.809	0.888	1.044
	2002	0.967	0.778	0.900	0.966	1.034	1.159
	2003	0.922	0.731	0.856	0.922	0.987	1.121
	2004	0.855	0.639	0.782	0.855	0.928	1.065
	2005	0.917	0.732	0.850	0.917	0.981	1.105
	2006	1.121	0.954	1.063	1.117	1.177	1.287
	2007	0.900	0.673	0.823	0.902	0.977	1.125
	2010	0.915	0.686	0.836	0.914	0.994	1.148
	2013	0.943	0.764	0.877	0.939	1.006	1.141

[a] Mean (μ) (common mean for all years) and standard variation (σ) (varying by year) of the lognormal model.

by the Food and Agriculture Organization of the United Nations, World Health Organization (FAO/WHO) *(18)* and adapted to the number of *Salmonella* cells, which in our model is an exact integer value (dose-response model, sometimes called a beta-binomial dose-response *(22)*). The risk estimates obtained when using the 2.5th and 97.5th percentile of the FAO/WHO *(18) Salmonella* dose-response curve resulted in mean estimated risks that were on the same order of magnitude as that when using the expected values. No uncertainty in the dose-response was considered.

Modeling exceptional situations that could occur during almond processing. In many instances, contamination of low–water activity foods with pathogenic bacteria is reported to be the result of cross-contamination *(10, 32)*. The main sources for cross-contamination in the processing facility include raw materials and the environment (which includes personnel, equipment, pests, dust, water, and air) *(4)*. The following types of root causes have been previously identified *(32)*: poor sanitation practices, poor facility and equipment design, lack of good manufacturing practices, and poor ingredient control and handling. Three scenarios to determine the impact of rare events with potentially high public health consequences were modeled as an exceptional situation. The scenarios examined both pretreatment and posttreatment events and were modeled for almonds consumed as a core product not cooked at home.

In the first exceptional situation (a rain event with almonds on the orchard floor [pretreatment event]), one in-shell almond was soaked with *Salmonella*-contaminated water on the orchard floor (e.g., localized issue, such as following a rain or flood irrigation). The in-shell nut stayed on the ground under these relatively wet conditions for 1 to 7 days. This was assumed to lead to growth of *Salmonella* on the hull. The hulls were then dried, leading to a decrease in population. A (stochastic) growth modeled as a Yule process was considered *(46)*. The *Salmonella* growth rate on the almond hull per 24 h ranged from 1 log at 15°C to 4 log at 24°C *(41)*. In-shell almonds are dried on the ground after they drop to the orchard floor *(41)*. The expected decrease of *Salmonella* during drying was estimated to range from 1 to 3 log *(41)*. *Salmonella* may migrate across the intact almond shells into the kernel *(13)*. Quantitative data are not available for almonds, but there are data for *Salmonella* migration on pecan shells *(5)*. Based on the data for pecans *(5)*, transfer rates across the hull and shell for almonds were modeled with a triangular distribution, with minimum = 1 log and a mode and maximum as an uncertain parameter *m* ranging from 2 to 4 log. At the processing facility, for the purpose of modeling this particular exceptional situation, the shell and hull were discarded, assuming there was no cross-contamination from the shell and hull to other nuts or the environment (necessary assumption only for this particular exceptional situation to estimate risk per serving due to contaminated kernels with origin in the orchard floor). Cross-contamination between the contaminated kernel and other kernels (previously considered *Salmonella* free) was modeled. Suehr et al. *(39)* showed that 38% of *Salmonella* cells were transferred homogeneously to 1,000 g of kernels from 50 g of inoculated almond kernels when they were mixed in a cylindrical drum. The proportion of *Salmonella* transferred was considered independent of the number of almonds being mixed within the cylinder. The amount of almonds to which *Salmonella* cells were transferred was modeled as a triangular distribution, with a minimum of 100 g, a mode of 1,000 g, and a maximum value being uncertain around 10,000 to 100,000 g (10 to 100 kg) (assumed arbitrarily as a subset of the true almond lot sizes). The initially contaminated almond was assumed to have been removed from the process (as it was visibly altered) and to have been discarded by classical visual or mechanized imaging quality control processes in place (a necessary assumption; this is a common, but not necessarily standard, practice). The rest of the model stages would follow similar to the baseline scenario.

In the second exceptional situation (*Salmonella* transfer from the environment to a lot of processed almonds during storage before packaging), we assumed that all steps through treatment were similar to the ones in the baseline scenario, followed by environmental contamination (posttreatment). As an example, a roof leak allows droppings from a bird shedding *Salmonella* to fall directly into storage bins, where the almonds are not protected from direct exposure to the environment during storage before packaging. We assumed a fixed recontamination level of 0.5 to 2 log CFU per lot going directly into the lot at storage just before packaging. We assumed that *Salmonella* was transferred to a subset of the almond lot ranging in size from 100 g to 100 kg (modeled as a triangular distribution, with minimum = 100 g, mode = 1,000 g, and maximum uniformly sampled from an uncertainty distribution with minimum = 10,000 g and maximum = 100,000 g) (lot sizes were assumed arbitrarily as a subset of the true almond lot sizes). The remainder of the process was assumed to occur similarly to the baseline model.

In the third exceptional situation (lot of raw almonds mixed with lot of treated almonds before packaging), all steps through treatment are the same as the baseline scenario, and there is improper separation of raw untreated almonds and treated almonds such that one untreated almond lot is mixed with one treated almond lot and the almonds are then packaged. The level of contamination of the raw untreated almond lot is equal to the level estimated in the model for the handler stage in the baseline model scenario. The level of contamination of the raw treated almond lot was taken from the results of the baseline scenario, with *Salmonella* levels corresponding to each of its treatment levels (after treatment). The mixed treated and untreated almonds are then packaged and the remainder of the process is modeled identically to the baseline scenario. The final lot size will be twice the size of the postprocessing lot.

Sensitivity analysis. Spearman's rho statistic was determined, with risk per serving being the outcome variable and looking at risk estimates arising from consumption of almonds as a core product uncooked at home for no treatment and a 4-log reduction treatment level. Factors considered were those for which variability and uncertainty were estimated, and they included initial contamination levels, the time it takes to reduce the *Salmonella* population by 1 log CFU (δ), pretreatment and posttreatment storage times, and consumption patterns.

Simulating the second phase of the 2001 salmonellosis outbreak from almonds. A simulation of the second phase of the 2001 salmonellosis outbreak due to almonds produced in the United States was recreated. Recalled boxes of raw almonds from the 2001 salmonellosis outbreak were sampled using the FDA-BAM method, and a *Salmonella* prevalence of 65% was found *(14, 15, 26)*. Among the 50 recalled boxes sampled, MPN levels were calculated from the 26 positive boxes, of which 21 boxes showed *Salmonella* levels of 3.4 MPN/100 g, one box showed levels of 5.6 MPN/100 g, and four boxes showed levels of 7.9 MPN/100 g. These samples were analyzed 6 months after the almonds were shipped to retail establishments. The total amount of contaminated almonds consumed was estimated to be in the range of 2,000 to 30,000 kg, which was modeled as a uniform distribution. The source of the 2001 salmonellosis outbreak is still unknown. With the data available, and without giving any weight to the actual origin of the contamination, the second phase of the outbreak event was rebuilt, assuming that the origin of the contamination and

TABLE 3. *Mean* Salmonella *probability of contamination and concentration levels for each stage of the exposure assessment model for log reduction treated almonds*[a]

		Exposure assessment stage				
Salmonella	Treatment (log reduction)[b]	Pretreatment storage	Posttreatment	Partition into lots	Partition into packages	Posttreatment and retail storage
Mean unit size (g)		10,161,226	10,161,226	4,715,836	224	224
Mean probability of contamination[c]	0	0.7	0.7	0.64	0.003	0.002
	1		0.5	0.37	0.0004	0.0002
	2		0.2	0.14	0.00004	0.00002
	3		0.06	0.04	0.000004	0.000002
	4		0.01	0.01	0.0000004	0.0000002
	5		0.002	0.0008	0.00000004	0.00000002
Mean concn (CFU/contaminated unit)[d]	0	185	185	93.5	1	1
	1		19	10	1	1
	2		2.7	1.8	1	1
	3		1	1	1	1
	4		1	1	1	1
	5		1	1	1	1

[a] Almonds were treated with a simulated 0-, 1-, 2-, 3-, 4-, or 5-log reduction treatment.
[b] The log reduction treatment levels in *Salmonella* cells are defined in CFU per unit of product being treated.
[c] Probability that a unit is contaminated with *Salmonella,* a contaminated unit being defined as a lot having at least 1 CFU per unit.
[d] Number of *Salmonella* cells in each contaminated unit at the end of the exposure assessment model (the minimum value is 1).

subsequent processing steps were similar to those described in the rain event with almonds on the orchard floor. The difference between the simulated 2001 salmonellosis outbreak event and the exposure assessment steps in the exceptional situation is that the batch size of *Salmonella*-free almonds to which the *Salmonella* cells are transferred at the processing facility was set at 500 g (to be able to reach the prevalence levels found in the outbreak) for the simulated outbreak event (instead of using a triangular distribution with a minimum of 100 g, a mode of 1,000 g, and a maximum value being uncertain around 10,000 to 100,000 g [10 to 100 kg]). The batch size was set to a fixed value of 500 g for the model to estimate the prevalence and concentration levels as found in the 2001 recalled lots. We only considered consumption levels for almonds not cooked at home (i.e., not further cooked at home by the consumer). The data obtained from NHANES-WWEIA showed that 90% of almonds are consumed uncooked at home by the consumer and, of these, 41% are consumed as a "core product" (product with $\geq$80% content of almonds) and 59% are consumed as an ingredient (product with $<$80% content of almonds). The number of servings in this outbreak event was equivalent to the total intake of contaminated almonds not cooked at home (i.e., "core product" and "as an ingredient") divided by the corresponding serving size.

The variability dimension was set to 10,001 replicates and the uncertainty dimension to 501 replicates (i.e., we have 501 replicates to evaluate uncertainty and, within each uncertainty loop, 10,001 replicates to characterize variability in model parameters). Monte Carlo simulations were developed in R using the *mc2d* package *(35),* and convergence was graphically checked using the *mc2d* package. The R code is available upon request by sending an email to FDAFoodSafetyRiskModel@fda.hhs.gov.

RESULTS

Exposure assessment for *Salmonella* on almonds. Mean *Salmonella* probability of contamination and concentration levels (for contaminated units) at the end of each stage of the exposure assessment model for no treatment and for 1-, 2-, 3-, 4-, and 5-log reduction treatments show that there is a decrease in both probability of *Salmonella* contamination and *Salmonella* concentration levels (of contaminated units) throughout exposure (Table 3). As the levels of reduction increase from 1 to 5 log, the levels of *Salmonella* per unit decrease, with approximately a 10-fold decrease for every additional log reduction (Fig. 2). Treatment, rather than storage time, is shown to have the greatest impact on the decrease in probability of contamination and *Salmonella* concentration levels in contaminated units (Table 3). The fact that the mean concentration level is 1 CFU per contaminated unit for all treatment levels at the stage of partitioning into packages does not mean that the levels are independent of treatment or that partitioning results in a decrease in *Salmonella* numbers. Contamination levels are expressed per contaminated unit, and the units are partitioned to such a degree that they contain the minimum *Salmonella* concentration to be considered positive, which is 1 CFU. The impact of the treatment is, thus, also reflected in the probability of contamination (Table 3). The lower probability of contamination after partitioning (Table 3) is a result of the increase in the number of units that contain zero *Salmonella* cells (which results from the redistribution of low *Salmonella* concentrations into a higher number of units of smaller unit size).

Risk estimates per serving. The distribution of the estimated risk per serving of almonds represents the probability of acquiring human salmonellosis due to the consumption of an almond serving in the U.S. population (Table 4). It results from combining the FAO/WHO *(18)* dose-response function with the results of the exposure assessment module (concentration levels of *Salmonella* per contaminated serving) and the prevalence of contaminated servings. The mean intake per serving ($\pm$standard deviation) for almonds (based on NHANES-WWEIA data) consumed as

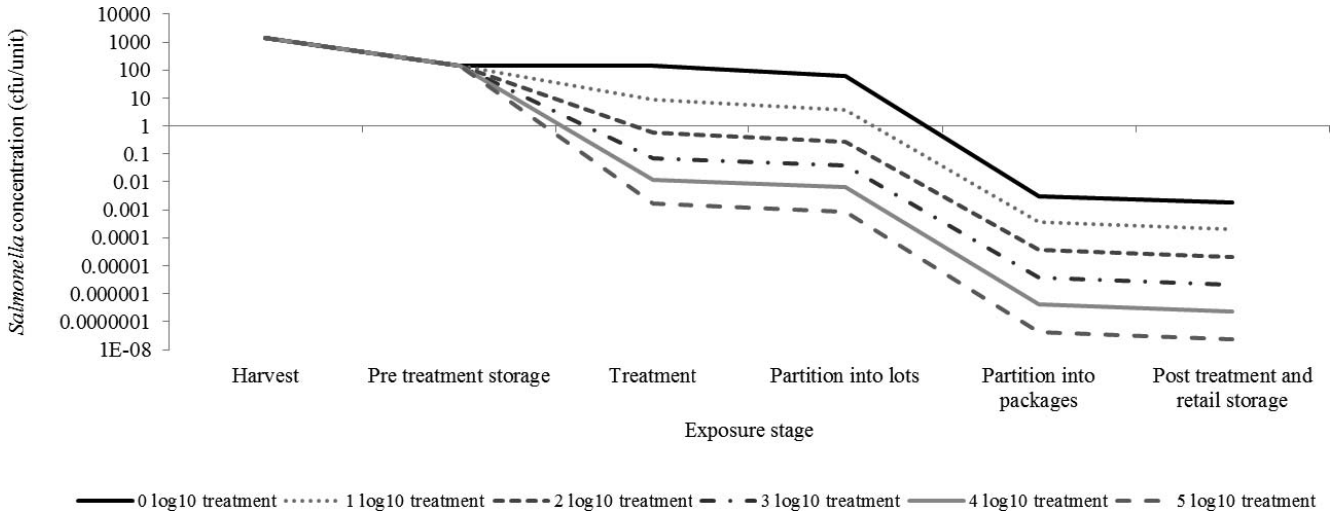

FIGURE 2. *Mean* Salmonella *concentration levels in each of the exposure assessment stages for a simulated no treatment and for 1-, 2-, 3-, 4-, and 5-log reduction treatments (where the log reduction treatment levels in* Salmonella *cells are defined in CFU per unit of product being treated).*

a core product not cooked at home is 26.3 (±30.1) g, 5.21 (±8.1) g for almonds consumed as an ingredient not cooked at home, and 1.58 (±4) g for almonds consumed as an ingredient cooked at home. Table 4 represents the risk characterization results and contains six sets of statistics (one for each treatment level, i.e., no treatment and 1-, 2-, 3-, 4-, and 5-log reduction) on the risk from consuming three different almond products: almonds consumed as a core product not cooked at home, almonds consumed as an ingredient not cooked at home, and almonds consumed as an ingredient cooked at home. Variability represents the heterogeneity of the data (irreducible by increased data collection), whereas uncertainty is an expression of the lack of knowledge and can be reduced by additional data *(29)*. The impact of variability (e.g., from serving to serving, from lot to lot, from year to year) is much higher than the impact of the considered uncertainty in the risk assessment model (Table 4). Variability in estimated risk (from the 50th to the 97.5th quantile of variability) spans over 2 to 3 log, whereas the uncertainty (from the 2.5th to the 97.5th quantile of uncertainty) for a given statistic spans over roughly 1 log (Table 4). The considered uncertainty included uncertainty in the probability of contamination, the *Salmonella* contamination levels, the survival model parameters, and all process conditions that are part of the exposure assessment model (e.g., time and temperature during storage). The highest risk is seen for almonds consumed as a core product not cooked at home (do not receive a cooking step at home), followed by almonds consumed as an ingredient not cooked at home, and to a lower extent, almonds that are cooked at home before consumption (Table 4). As the treatment increases from 1- to 5-log reduction, the mean risk of salmonellosis per serving in the U.S. population decreases significantly for all three types of almond products consumed. The differences in estimated risk for the different types of almonds consumed can be attributed to the *Salmonella* reduction step when consuming almonds cooked at home and, to a lesser degree, to the differences in serving size when consuming almonds as a core product or ingredient. Differences in the estimated risk per contaminated serving among the U.S. population within the same type of product result from varying levels of *Salmonella* in a contaminated serving.

These mean risk estimates per contaminated serving among the contaminated servings eaten by individuals in the U.S. population correspond to one case of salmonellosis per 1,061 million (95% CI, 1,567 to 505 million), 10,493 million (95% CI, 16,025 to 4,672 million), and 105 billion (95% CI, 155 to 47 million) servings for a 3-, 4-, and 5-log reduction treatment, respectively, for almonds consumed as a core product not cooked at home; 7,352 million (95% CI, 11,013 to 3,412 million), 74 billion (95% CI, 109 to 32 billion), and 740 billion (95% CI, 1,098 to 316 billion) servings for a 3-, 4-, and 5-log reduction treatment, respectively, for almonds consumed as an ingredient not cooked at home; and 5 quadrillion (95% CI, 8 to 2 quadrillion), 52 quadrillion (95% CI, 84 to 21 quadrillion), and 520 quadrillion (95% CI, 833 to 172 quadrillion) servings for a 3-, 4-, and 5-log reduction treatment, respectively, for almonds consumed as an ingredient cooked at home. The estimated mean risk per serving is approximately 10 times higher for a log reduction treatment of 3 versus 4 and 4 versus 5 log. The mean risk per serving is, on average, seven times higher for almonds consumed as a core product not cooked at home compared with almonds consumed as an ingredient not cooked at home, a reflection of the differences in serving sizes. The mean risk per serving is 5×10^6 times higher for almonds consumed as a core product not cooked at home versus almonds consumed as an ingredient cooked at home and 7×10^5 times higher for almonds consumed as an ingredient not cooked at home versus almonds consumed as an ingredient cooked at home.

Risk estimates per year. As estimated by NHANES-WWEIA, 3.13% of individuals consume almonds as a core product not cooked at home (1.8×10^9 servings), 10.72% of individuals consume almonds as an ingredient cooked at

TABLE 4. *Salmonellosis risk per serving for consumption of almonds in the U.S. population*[a]

		Almonds consumed as core product not cooked at home				Almonds consumed as ingredient not cooked at home				Almonds consumed as ingredient cooked at home			
				Quantiles of variability				Quantiles of variability				Quantiles of variability	
Treatment (log)		Mean	SD	50%	97.5%	Mean	SD	50%	97.5%	Mean	SD	50%	97.5%
0	Estimate	9.3E−07	1.3E−05	1.2E−08	4.9E−06	1.4E−07	1.9E−06	1.6E−09	7.0E−07	1.9E−13	3.4E−12	7.3E−16	7.7E−13
	95% CI[b]	6.4E−07	5.4E−06	3.8E−09	3.3E−06	9.0E−08	7.9E−07	5.5E−10	4.8E−07	1.2E−13	1.2E−12	2.5E−16	4.8E−13
		1.9E−06	8.0E−05	2.4E−08	6.7E−06	2.7E−07	1.2E−05	3.3E−09	9.7E−07	5.0E−13	3.2E−11	1.5E−15	1.1E−12
1	Estimate	9.3E−08	1.2E−06	1.1E−09	5.0E−07	1.4E−08	1.8E−07	1.5E−10	7.1E−08	1.9E−14	3.5E−13	7.0E−17	7.8E−14
	95% CI	6.5E−08	5.5E−07	3.7E−10	3.4E−07	9.2E−09	8.5E−08	5.3E−11	4.9E−08	1.2E−14	1.2E−13	2.4E−17	4.8E−14
		1.9E−07	9.2E−06	2.3E−09	6.6E−07	3.2E−08	1.5E−06	3.1E−10	9.7E−08	5.2E−14	3.0E−12	1.4E−16	1.1E−13
2	Estimate	9.5E−09	1.3E−07	1.2E−10	4.8E−08	1.4E−09	1.9E−08	1.6E−11	7.0E−09	1.9E−15	3.5E−14	7.4E−18	7.4E−15
	95% CI	6.4E−09	5.7E−08	3.9E−11	3.1E−08	9.2E−10	8.4E−09	5.6E−12	4.5E−09	1.2E−15	1.3E−14	2.5E−18	4.4E−15
		2.0E−08	9.8E−07	2.4E−10	6.5E−08	2.8E−09	1.3E−07	3.3E−11	9.6E−09	5.0E−15	3.2E−13	1.5E−17	1.0E−14
3	Estimate	9.4E−10	1.3E−08	1.2E−11	4.6E−09	1.4E−10	1.9E−09	1.6E−12	6.5E−10	1.9E−16	3.5E−15	7.5E−19	7.4E−16
	95% CI	6.4E−10	5.9E−09	4.0E−12	3.0E−09	9.1E−11	8.6E−10	5.7E−13	4.4E−10	1.2E−16	1.3E−15	2.5E−19	4.6E−16
		2.0E−09	1.1E−07	2.5E−11	6.2E−09	2.9E−10	1.4E−08	3.5E−12	8.9E−10	5.0E−16	2.9E−14	1.6E−18	1.0E−15
4	Estimate	9.5E−11	1.5E−09	1.2E−12	4.9E−10	1.4E−11	2.0E−10	1.7E−13	6.9E−11	1.9E−17	3.7E−16	7.6E−20	7.7E−17
	95% CI	6.2E−11	5.7E−10	4.0E−13	3.3E−10	9.1E−12	8.1E−11	5.7E−14	4.8E−11	1.2E−17	1.3E−16	2.6E−20	4.8E−17
		2.1E−10	1.1E−08	2.5E−12	6.5E−10	3.1E−11	1.5E−09	3.5E−13	9.5E−11	4.6E−17	2.6E−15	1.6E−19	1.1E−16
5	Estimate	9.5E−12	1.3E−10	1.2E−13	4.9E−11	1.4E−12	1.9E−11	1.7E−14	7.0E−12	1.9E−18	3.4E−17	7.6E−21	7.8E−18
	95% CI	6.4E−12	5.4E−11	4.0E−14	3.3E−11	9.1E−13	8.3E−12	5.7E−15	4.8E−12	1.2E−18	1.3E−17	2.6E−21	4.8E−18
		2.1E−11	1.1E−09	2.5E−13	6.7E−11	3.2E−12	1.6E−10	3.5E−14	9.6E−12	5.8E−18	3.5E−16	1.6E−20	1.1E−17

[a] Core almond product (>80% of the product is almond [including whole almonds]); almond as an ingredient (<80% of the product ingredients are almonds). CI, confidence interval. The columns (e.g., Mean, SD, 50 and 97.5%) represent variability, and the rows (Estimate, CI 95%) represent the uncertainty of the estimates.

[b] 95% CI, the values in the top row represent the lower limits and the values in the lower row the upper limits of values in which we have 95% probability of finding the true value.

TABLE 5. *Estimated mean number of salmonellosis cases per year for consumption of almonds in the United States*[a]

Log reduction treatment (log)	Estimated mean no. of cases/yr								
	Almonds as core product not cooked at home (2×10^9 servings/yr)			Almonds as ingredient not cooked at home (7×10^9 servings/yr)			Almonds as ingredient cooked at home (6×10^9 servings/yr)		
	Estimate	95% CI		Estimate	95% CI		Estimate	95% CI	
0	1,697	1,162	3,501	906	604	1,817	<1	<1	<1
1	170	119	339	91	62	212	<1	<1	<1
2	17	12	36	9	6	19	<1	<1	<1
3	2	1	4	1	1	2	<1	<1	<1
4	<1	<1	<1	<1	<1	<1	<1	<1	<1
5	<1	<1	<1	<1	<1	<1	<1	<1	<1

[a] 95% CI, the values in the left column represent the lower limits and the values in the right column the upper limits of values in which we have 95% probability of finding the true value.

home (6.7×10^9 servings), and 11.48% of individuals consume almonds as an ingredient not cooked at home (6.2×10^9 servings). The estimated number of cases of salmonellosis per year in the United States (Table 5) decreases roughly 10-fold as the *Salmonella* reduction treatment level is increased by 1 log, for all almond products. Cooking almonds at home significantly decreases the risk estimate, with the number of cases per year estimated below one for all treatment levels (Table 5). For almonds consumed uncooked at home that have gone through a 4- or 5-log reduction treatment, the number of mean (±uncertainty) estimated cases per year is less than one (Table 5). If almonds receive a 3-log reduction level treatment, then the model estimates a mean of two cases per year for almonds consumed as a core product not cooked at home (95% CI, 1 to 4) and one case per year for almonds consumed as an ingredient not cooked at home (95% CI, 1 to 2) (Table 5).

Estimated risk of human salmonellosis arising from the modeled exceptional situations. The estimated risk of salmonellosis arising from consumption of almonds as a core product not cooked at home under any of the modeled exceptional situations is higher than that seen for the baseline model (model with no exceptional situation) (Tables 6 and 7 and Fig. 3). The number of cases per year linked to this kind of exceptional situation would be equal to the number of cases linked to one exceptional situation multiplied by the number of such exceptional situations (currently unknown).

In the case of the rain event with almonds on the orchard floor, where cross-contamination occurs prior to treatment, there is a significant difference in the risk

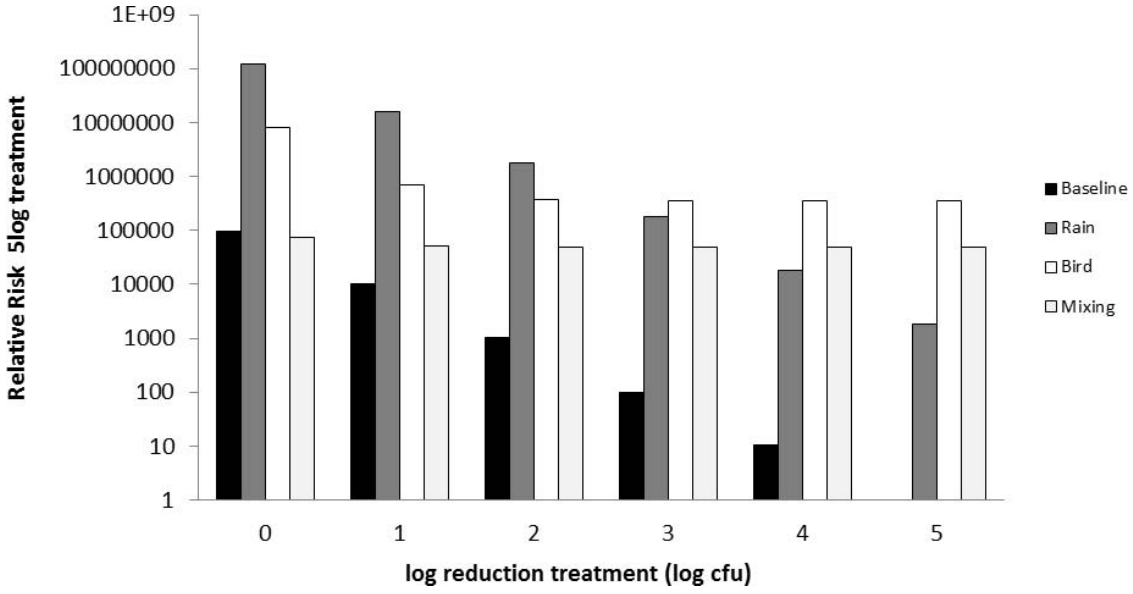

FIGURE 3. *Mean risk per serving of almonds consumed as a core product uncooked at home relative to the mean risk per serving in the baseline model, assuming a 5-log CFU reduction treatment and given an exceptional situation. Rain, a rain event with almonds on the orchard floor; bird,* Salmonella *transfer from the environment to a lot of processed almonds during storage before packaging; and mixing, a lot of raw almonds mixed with a lot of treated almonds before packaging.*

TABLE 6. *Salmonellosis risk per serving for consumption of almonds (as a core product not cooked at home) in the U.S. population given three different exceptional situations*[a]

		Pretreatment				Posttreatment							
		Rain event with almonds on orchard floor				Environmental contamination				Mixing of processed and unprocessed lots			
				Quantiles of variability				Quantiles of variability				Quantiles of variability	
Reduction treatment (log)[b]		Mean	SD	50%	97.5%	Mean	SD	50%	97.5%	Mean	SD	50%	97.5%
0	Estimate	1.21E−03	8.01E−03	1.71E−05	1.65E−04	8.17E−05	2.33E−03	2.77E−07	8.67E−05	7.37E−07	9.01E−06	1.71E−08	4.16E−06
	95% CI[c]	4.02E−04	4.02E−03	2.27E−06	2.83E−05	2.94E−05	5.80E−04	2.17E−07	4.31E−05	5.04E−07	3.77E−06	7.07E−09	3.02E−06
		4.25E−03	1.74E−02	1.11E−04	1.20E−03	2.02E−04	5.66E−03	4.08E−07	2.59E−04	1.57E−06	6.55E−05	3.14E−08	5.55E−06
1	Estimate	1.60E−04	1.67E−03	1.61E−06	1.83E−05	6.76E−06	1.33E−04	1.78E−07	2.35E−05	5.06E−07	7.03E−06	8.69E−09	2.67E−06
	95% CI	4.93E−05	6.16E−04	2.14E−07	2.72E−06	3.04E−06	2.93E−05	1.55E−07	1.58E−05	3.46E−07	2.93E−06	3.45E−09	1.87E−06
		6.14E−04	4.32E−03	1.25E−05	1.15E−04	2.91E−05	2.05E−03	2.36E−07	6.15E−05	1.17E−06	5.81E−05	1.63E−08	3.52E−06
2	Estimate	1.72E−05	2.30E−04	1.69E−07	1.83E−06	3.60E−06	4.74E−05	1.55E−07	1.92E−05	4.81E−07	6.83E−06	6.43E−09	2.48E−06
	95% CI	5.02E−06	6.51E−05	2.24E−08	2.83E−07	2.30E−06	1.90E−05	1.39E−07	1.33E−05	3.23E−07	2.84E−06	2.33E−09	1.72E−06
		7.33E−05	7.92E−04	1.28E−06	1.25E−05	8.53E−06	1.69E−04	2.01E−07	4.85E−05	9.99E−07	4.67E−05	1.28E−08	3.31E−06
3	Estimate	1.76E−06	2.26E−05	1.74E−08	1.93E−07	3.49E−06	4.29E−05	1.51E−07	1.88E−05	4.82E−07	6.75E−06	5.84E−09	2.46E−06
	95% CI	5.05E−07	5.73E−06	2.26E−09	2.92E−08	2.27E−06	1.79E−05	1.36E−07	1.30E−05	3.25E−07	2.93E−06	2.02E−09	1.71E−06
		6.86E−06	1.06E−04	1.33E−07	1.33E−06	8.00E−06	1.31E−04	1.93E−07	4.65E−05	1.15E−06	6.46E−05	1.20E−08	3.28E−06
4	Estimate	1.75E−07	2.04E−06	1.75E−09	1.97E−08	3.45E−06	4.28E−05	1.51E−07	1.85E−05	4.83E−07	6.63E−06	5.75E−09	2.47E−06
	95% CI	5.20E−08	6.32E−07	2.27E−10	2.94E−09	2.26E−06	1.84E−05	1.35E−07	1.31E−05	3.25E−07	2.83E−06	1.93E−09	1.69E−06
		6.83E−07	1.15E−05	1.36E−08	1.38E−07	8.10E−06	1.46E−04	1.92E−07	4.73E−05	1.11E−06	5.72E−05	1.19E−08	3.29E−06
5	Estimate	1.76E−08	2.11E−07	1.75E−10	1.97E−09	3.56E−06	4.41E−05	1.51E−07	1.88E−05	4.80E−07	6.85E−06	5.74E−09	2.46E−06
	95% CI	5.23E−09	6.43E−08	2.27E−11	2.94E−10	2.26E−06	1.78E−05	1.36E−07	1.32E−05	3.25E−07	2.92E−06	1.92E−09	1.69E−06
		7.22E−08	9.93E−07	1.36E−09	1.39E−08	8.20E−06	1.36E−04	1.93E−07	4.67E−05	1.17E−06	5.20E−05	1.18E−08	3.34E−06

[a] See the text for more details about the exceptional situations.

[b] The log reduction treatment levels in *Salmonella* cells are defined in CFU per unit of product being treated.

[c] 95% CI, the values in the top row represent the lower limits and the values in the lower row the upper limits of values in which we have 95% probability of finding the true value.

TABLE 7. *Human salmonellosis cases per exceptional situation from consumption of almonds as a core product not cooked at home, including the 2.5 and 97.5% uncertainty distribution percentages*[a]

Log reduction treatment (log)[b]	Pretreatment			Posttreatment					
	Rain event with almonds on orchard floor			Environmental contamination			Mixing of processed and unprocessed lots		
	Estimate	95% CI[c]		Estimate	95% CI		Estimate	95% CI	
0	0.4	0.2	1.1	0.03	0.01	0.1	0.7	0.5	1.4
1	0.04	0.02	0.1	0.002	0.001	0.01	0.5	0.3	1.1
2	0.004	0.002	0.01	0.001	0.001	0.002	0.4	0.3	0.9
3	0.0005	0.0002	0.001	0.001	0.001	0.002	0.4	0.3	1.0
4	0.00004	0.00002	0.0001	0.001	0.001	0.002	0.4	0.3	1.1
5	0.000005	0.000002	0.00001	0.001	0.001	0.002	0.4	0.3	1.0

[a] See text for details about the exceptional situations.
[b] The log reduction treatment levels in *Salmonella* cells are defined in CFU per unit of product being treated.
[c] 95% CI, the values in the left column represent the lower limits and the values in the right column the upper limits of values in which we have 95% probability of finding the true value.

estimates for the different log-reduction treatments, with the risk decreasing as the treatment level increases from 1- to 5-log reduction (Fig. 3), resulting in an average 1,000-times-higher mean risk per serving compared with the baseline model, irrespective of treatment level (Fig. 3). Note that this exceptional situation modeled one single contaminated almond. In reality, the amount of contaminated almonds as a result of a rain event could be higher, leading to higher risk estimates.

In the case of exceptional situations that occur posttreatment (mixing of raw and processed almond lots, as well as recontamination), the estimated mean risk of illness when almonds are treated to obtain a 3-, 4-, or 5-log reduction are nearly identical (Table 6). This indicates that the contribution of pretreatment contamination to the overall risk is small compared with the contribution of posttreatment contamination. For exceptional situations occurring post-treatment, the small differences in risk estimates for almonds that have not been treated versus those that have been treated to obtain up to a 1- or 2-log reduction arise from those minor differences in pretreatment contamination (Table 6).

The mixing of a treated and an untreated lot of almonds can lead to a significant risk (Table 6). The mean risk per serving from this exceptional situation is similar to that obtained using the baseline model when no treatment is in place but has a gradual 10-fold relative increase for every log reduction increase in treatment level (compared with the baseline model) (Fig. 3). Thus, an almond process that usually undergoes a 4-log reduction treatment would, under an exceptional situation where there is mixing of processed and unprocessed lots of product after treatment, have a 10,000-times-higher mean risk per serving from consumption of almonds as a core ingredient not cooked at home. Similarly, cross-contamination and/or recontamination after treatment reduces the apparent effectiveness of the treatment *(38)*. As an example, the mean risk per serving of the exceptional situation where a bird sheds *Salmonella* into a lot of finished product can result in risk estimates that are 100 times higher compared with a baseline model with no treatment or a treatment of 1-log reduction, and this risk increases gradually (10 times) up to 1,000,000 times compared with a baseline model that applies a 5-log reduction treatment (Fig. 3). These results serve to demonstrate that preventive controls impact the safety of a food product *(38)*. The level of reduction that a treatment achieves is very dependent on both the relative contributions of pre- and posttreatment contamination levels and the dose consumed (Fig. 3).

Sensitivity analysis results. The results of the sensitivity analysis indicate that, for a given treatment level, initial *Salmonella* contamination level is the factor with greatest impact on mean risk per serving estimates, followed by pretreatment storage time at any treatment level (Fig. 4). Longer storage times result in decreasing levels of mean estimated risk per serving (*Salmonella* tends to decrease at 20 to 25°C), which is the reason for the negative Spearman rho statistic values found for these factors (i.e., pretreatment and posttreatment storage). The U.S. consumption patterns for almonds as a core product not cooked at home, and the time it takes to reduce the population by 1 log CFU (δ), follow in decreasing order of impact, with a similar effect on mean risk estimates per serving (Fig. 4). Postprocess storage time is shown to have the lowest impact on risk estimates (Fig. 4).

Rebuilding the second phase of the almond salmonellosis outbreak of 2001. Using 500 g as the set lot size, the mean prevalence was estimated as 56%, and the mean contamination level of positive samples for almonds after 6 months of storage at ambient temperature (assuming no preventive treatments were in place) was 5.5 CFU/100 g. These prevalence and contamination levels are in line with those found in the recalled samples of the 2001 outbreak. The mean salmonellosis risk estimates for this rebuilt 2001 second-phase salmonellosis outbreak show an estimated number of cases that decrease from a mean of 5,665 cases (95% CI, 905 to 21,331 cases) to a mean of 814 cases (95%

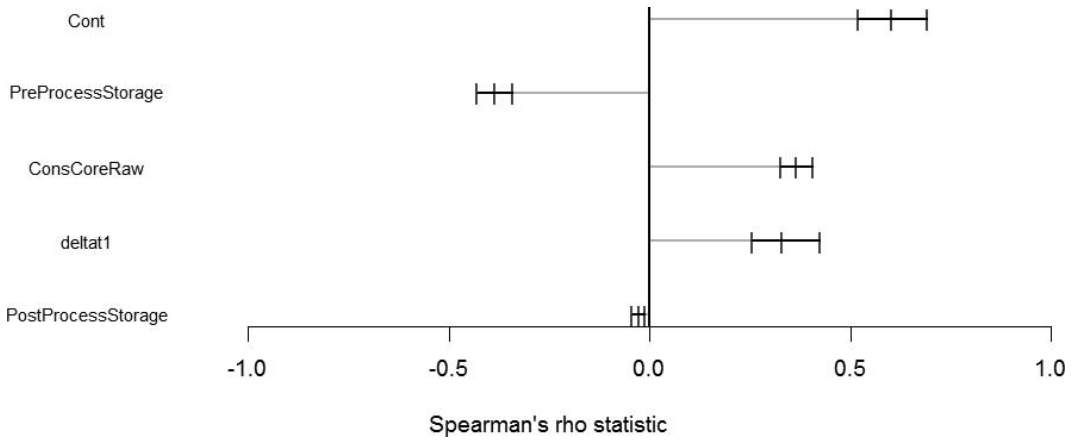

FIGURE 4. *Spearman's rho statistic for the baseline risk assessment model, considering a 4-log reduction treatment (sensitivity analysis considering no treatment showed the same rank) with risk per serving from consumption of almonds as a core product consumed uncooked at home as the outcome variable. Cont, initial* Salmonella *contamination; PreProcessStorage, pretreatment storage time (weeks); ConsCoreRaw, serving sizes for almonds consumed as a core product uncooked at home; delta1, time (weeks) it takes to reduce the* Salmonella *population by 1 log CFU per contaminated unit at 23°C; PostProcessStorage, posttreatment storage time (weeks).*

CI, 126 to 3,376) with a 1-log reduction treatment and that decrease 10 times for every additional log reduction level applied (Table 8). In the second phase of the 2001 outbreak, approximately 2,800 cases were predicted, including the underreporting factor (the Centers for Disease Control and Prevention estimates that there are 29 cases for each case of illness that is reported) *(26)*. Whereas the estimated mean number of cases is in line with the predicted cases of the actual 2001 outbreak, the uncertainty of the estimates with this simulation are high, as seen from the 95% CI estimates (Table 8).

DISCUSSION

Danyluk et al. *(14)* developed a model to calculate the risk associated with the consumption of raw almonds in the United States, using prevalence data from 2000 to 2004. The risk assessment model included steps from harvest to consumption, including consumer handling of the product. Results showed a high variability of the predicted number of cases from one year to another, with a 78% chance of one or more cases of salmonellosis per year, an overall predicted mean of eight cases per year, and a maximum of 4.4×10^5 cases per year from consumption of raw almonds *(14)*. Simulating a processing treatment with propylene oxide, as characterized by their experiments, or a theoretical 5-log reduction step, reduced the chance of acquiring salmonellosis from consumption of almonds significantly. Results showed an estimated chance of observing one or more illnesses from consumption of almonds per year in the United States to be 0.01% when treating almonds with propylene oxide and 0.69, 0.35, 0.30, and 0.21% for log reduction treatments of 5 ± 1, 5 ± 0.5, 5 ± 0.1, and 5 ± 0 log, respectively. Total handler storage time, consumer storage conditions, and consumer storage time were the main factors driving the variability surrounding the risk estimate for raw almonds. In the Danyluk et al. *(14)* study, it was assumed that only 5% of the total almonds consumed in the United States (those consumed raw) contribute to foodborne illness. The remaining 95% were assumed not to contribute to illness because they were either roasted or blanched (treatments by which a 5-log reduction is usually achieved) *(14)*. Lambertini et al. *(26)* conducted a risk assessment building upon the published Danyluk et al. *(14)* risk assessment. With this updated model, the estimated mean risk of illness from consumption of almonds, given a 4-log reduction mandatory treatment, was 0.0084 ± 0.35 cases per billion servings, resulting in an average 0.06 cases per year *(14)*. The incidence of salmonellosis with this model was represented by a highly skewed distribution. In all, the Lambertini et al. *(26)* model predicted risks that were 2.6-fold higher compared with the Danyluk et al. *(14)* model. Our current model (for consumption of almonds as a core product not cooked at home) predicts mean risk estimates per serving that are 11 times higher and mean risk

TABLE 8. *Estimated salmonellosis cases for consumption of almonds not cooked at home during the simulated second phase of the 2001 outbreak event and the impact of preventive treatments*[a]

Log reduction treatment (log)[b]	Estimated mean no. of outbreak cases[c]		
	Estimate	95% CI[d]	
0	5,665	905	21,331
1	814	126	3,376
2	93	15	400
3	10	1	43
4	1	<1	4
5	<1	<1	<1

[a] Treatments ranged from no treatment to a 5-log reduction.
[b] The log reduction treatment levels in *Salmonella* cells are defined in CFU per unit of product being treated.
[c] Outbreak due to consumption of almonds as a core product not cooked at home and of almonds as an ingredient not cooked at home.
[d] 95% CI, the values in the left column represent the lower limits and the values in the right column the upper limits of values in which we have 95% probability of finding the true value.

estimates per year that are three times higher than those obtained with the Lambertini et al. *(26)* model (for consumption of almonds not cooked at home). This unequal difference when comparing mean risk per serving and mean risk per year estimates of the current model and that of Lambertini et al. *(26)* arises from the fact that the amount of almond servings not cooked at home in the Lambertini et al. *(26)* model was a fixed value of 6.6 billion servings based on almond production data in the United States (500 to 600 million lb [227 to 270 thousand metric tons] per year). The current model obtained a distribution of consumption data from NHANES-WWEIA and made a distinction of whether the product was consumed as an ingredient or as a core almond product, both consumed uncooked at home, and accounting for an average 8.3 billion servings. Using almond sales data to account for consumption would not change the risk per serving estimates but would overestimate the risk per year by two- to threefold. The differences in the risk estimates obtained with the current model as compared with the Lambertini et al. *(26)* model are the result of the fact that the current model does not include consumer home storage, does not assume log-linear declines of *Salmonella* during storage at 20 to 25°C, has a different model to estimate initial prevalence and contamination levels, and separates variability and uncertainty in its risk estimates. Consumer home storage is not included in the current exposure assessment model because consumer storage practices do not serve as risk mitigation for regulatory purposes. As such, the exposure assessment model assumes that almonds are consumed immediately after purchase, with no further storage. This is considered a fail-safe model assumption because, if the consumer stored almonds at room (20 to 25°C), refrigeration, or freezing temperatures after purchase and before consumption, *Salmonella* levels on almonds would be decreased or maintained, making the estimated risk of salmonellosis lower. Additionally, survival curves for *Salmonella* on almonds have been shown to be nonlinear *(1, 6, 25, 40)*. The Lambertini et al. *(26)* risk model for *Salmonella* on almonds assumes log-linear declines of *Salmonella* during storage at room temperature. Decreasing levels of *Salmonella* in the Lambertini et al. *(26)* risk assessment were estimated by using a log-linear survival model and an additional storage step (consumer). Mean risk is highly influenced by the right-hand tail of the distribution, because although most servings may have a low risk, most cases might be linked to a few extreme situations *(47)*. Separating uncertainty and variability within risk assessments is a recurring recommendation in national and international guidelines, such as Codex Alimentarius Commission *(12),* and FAO/WHO *(17, 19)*. This is the first risk assessment for *Salmonella* on tree nuts that is able to separate variability and uncertainty in its risk estimates.

Similar to that presented in this study, Lambertini et al. *(26)* also conducted a simulation of the events that occurred in 2001, leading to a salmonellosis outbreak of an estimated 2,800 cases in the second phase (95 cases reported). The results of the outbreak simulation of the second phase using both the current model and the Lambertini et al. *(26)* model showed that preventive treatment levels of a minimum 4-log reduction would have been sufficient to prevent the outbreak. However, the uncertainty range in the estimates indicates that additional information is needed to make more precise predictions of this specific outbreak event. Uncertainty in the input variables (e.g., *Salmonella* concentration levels and amount of almonds consumed as well as the infectious dose) is a major contributor to the rightly skewed and highly variable risk outcomes. Knowledge of the exact conditions, amount of contaminated product consumed, and the *Salmonella* prevalence and concentration levels that led to the 2001 outbreak would aid in making more precise predictions of the risk outcomes and of the possible effect that preventive treatments could have had on the risk estimates.

In summary, the impact of preventive treatments to reduce *Salmonella* concentration levels on the risk of human salmonellosis arising from the consumption of almonds in the United States has been evaluated. A minimum 4-log reduction treatment results in an estimated number of cases of salmonellosis (including uncertainty) that is below one case per year for consumption of almonds in the United States. The risk assessment also includes an assessment of the risk of human salmonellosis as a result of exceptional situations during almond production, pretreatment or posttreatment. The exceptional situations modeled include a rain event with almonds on the orchard floor (pretreatment) and two cross-contamination events during processing (posttreatment). Results of modeling such events showed that the mean risk of illness estimates per serving increased compared with the baseline model. Even though exceptional situations occurring pretreatment (e.g., rain event with almonds on orchard floor) can result in significantly higher risk estimates per serving compared with the baseline model (for any treatment level), these estimates decreased as the treatment level increased from 1- to 5-log reduction (similar to the baseline model). However, the exceptional situations modeled to occur posttreatment (e.g., environmental contamination during postprocess storage, mixture of a lot of treated and untreated almonds) resulted in estimates of mean risk of illness per serving that were not significantly affected by treatment level. This highlights the fact that process control through preventive treatments becomes insufficient when contamination occurs posttreatment (e.g., cross-contamination).

The model, the results, and the conclusions of this assessment are limited to *Salmonella,* almonds, and the United States. With additional data on different types of "exceptional situations," the frequency with which they occur, and how these situations impact the probability of contamination, as well as *Salmonella* levels, the risk assessment could be enhanced. Data on transfer rates of *Salmonella* across the hull and shell of in-shell almonds would also aid in estimating risk arising from these exceptional situations. Understanding the cooking processes at the consumer level, which reduce the number of viable *Salmonella* cells, and the reduction levels the processes achieve would provide a better means of estimating the risk of salmonellosis caused by consumption of almonds as an ingredient in products cooked at home. As data become available on the specific log reduction achieved for a targeted treatment level, the effect of the variability in the treatment level achieved could be quantified in the risk estimations.

ACKNOWLEDGMENTS

The authors thank Karin Hoelzer and John Larkin for their contribution to the early development of the *Salmonella* on almonds risk assessment model. The authors thank Dr. Linda Harris for providing raw data and information. The authors thank Versar, Inc., for managing the external peer review process (Versar contract HHSF223201210011B) and the external peer reviewers Dr. Donald Schaffner, Dr. Larry Beuchat, Dr. Lawrence Goodridge, Dr. Amir Mokhtari, and Dr. Elliot Ryser for their comments on earlier versions of the risk assessment model and draft report. The authors thank Dr. Sherri Dennis and Jenny Scott for their careful review of the current and previous versions of this manuscript. This work was supported, in part, by appointments to the Research Participation Program at the Center for Food Safety and Applied Nutrition administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S Department of Energy and the U.S. Food and Drug Administration.

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