

Research Paper

A Quantitative Assessment of the Risk of Human Salmonellosis Arising from the Consumption of Pecans in the United States

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ABSTRACT

A quantitative risk assessment was conducted to assess the risk of human salmonellosis acquired from consumption of pecans in the United States. The model considered the potential for *Salmonella* survival, growth, and recontamination of pecans from the sheller to the consumer, including steps such as immersion in water, drying, conditioning, cracking, partitioning, and storage. Five theoretical microbial reduction treatment levels (1 to 5 log CFU) were modeled. Data from the 2010 to 2013 surveys by the National Pecan Shellers Association were used for initial prevalence and contamination levels. The impacts of atypical situations in the pecan production system were also evaluated. Higher initial contamination levels, recontamination during processing, and a delay in drying postconditioning were the modeled atypical situations. The baseline model predicted a mean risk of salmonellosis in the United States from consumption of in-shell and shelled pecans processed by cold conditioning with no microbial reduction treatment and no further home cooking as 1 case per 775,193 servings (95% confidence interval [CI]: 1 case per 1,915,709 to 178,253 servings). This predicted risk per serving was estimated as a mean of 529 cases of salmonellosis per year (95% CI: 213 to 2,295 cases). Hot conditioning for shelled pecans and microbial reduction treatment of both shelled and in-shell pecans had a significant impact on the predicted mean risk of illness. Assuming 77% of the shelled pecans sold at retail (i.e., 80% of the retail supply) received hot conditioning, the mean estimated salmonellosis cases per year from consumption of in-shell and shelled pecans uncooked at home was 203 (95% CI: 81 to 882 cases) if no additional microbial reduction treatment were applied. The predicted risk of illness per serving was higher for all atypical situations modeled compared with the baseline model, and delay in drying had the greatest impact on risk.

Key words: Dry food; Low moisture; Microbial reduction treatment; Risk assessment; Tree nuts

The United States is the primary producer of pecans in the world, with a yearly production of 264 million lb (120 million kg) in 2014 and 254 million lb (115 million kg) in 2015 (34). During harvest, pecans are mechanically shaken to the ground, swept into windrows, and transferred into trailers. The nuts are then transported to holding locations where they can be dried at ambient temperature to reduce the moisture level before shelling (37). Further steps in pecan production include immersion in a dump tank with water at ~23°C for debris removal, two drying steps (at ~60°C), conditioning (typically performed using steam or hot water or using cold chlorinated water to soften the shell so that the kernel is less likely to be damaged during cracking), cracking, and storage (3, 6).

The presence of *Salmonella* on in-shell pecans and pecan kernels can arise from various environmental contamination routes. In-shell pecans come into contact with the soil during harvest as they are shaken to the ground.

Even though soil is partially removed before receipt at the sheller, significant amounts of soil and dust can remain and be brought into sheller storage and processing facilities (15, 17). Potential sources of *Salmonella* contamination in the soil include wildlife, grazing animals, raw manure, and contaminated irrigation water (2, 17). Other potential sources of *Salmonella* contamination include exposure to contaminated water through rainfall or in the facility, pests (including wildlife), air, cross-contamination between treated and untreated pecans (both in-shell and kernels), poor ventilation, leaks in roofs where birds congregate, and insufficient or lack of cleaning and sanitation resulting in various kinds of cross-contamination (2, 17). No outbreaks of salmonellosis have been linked to pecans, but pecans have been involved in recalls due to potential *Salmonella* contamination (11).

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. The assessment can be used to predict the adequacy and efficacy of microbial reduction treatments. Previous published risk assessments for *Salmonella* on tree

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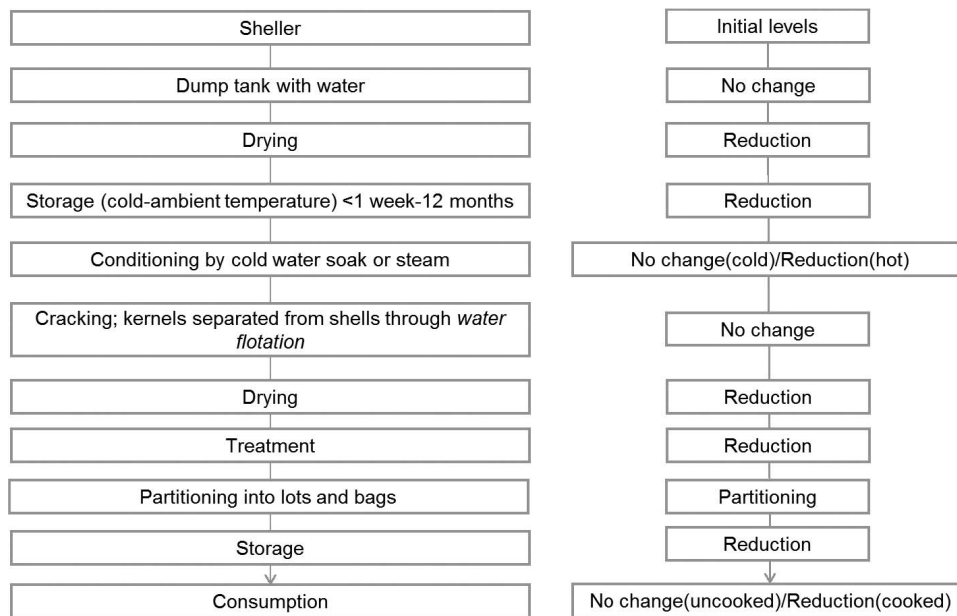


FIGURE 1. Pecan production process steps (left) and expected change in *Salmonella* levels as a result of the corresponding process step (right). Adapted from Beuchat and Mann (6).

nuts include those developed for almonds by Santillana Farakos et al. (33), Lambertini et al. (22), and Danyluk et al. (14). The objectives of the present study were to conduct a quantitative risk assessment of human salmonellosis cases arising from the consumption of pecans in the United States and to evaluate the impact of microbial reduction treatments and atypical situations in pecan processing to inform risk management decisions. To our knowledge, this article is the first published quantitative microbiological risk assessment for *Salmonella* contamination and consumption of pecans.

MATERIALS AND METHODS

Overview of the exposure assessment model for *Salmonella* on pecans. The prevalence and levels of *Salmonella* on in-shell pecans and/or pecan kernels were assessed starting from the sheller to the point of consumption (Fig. 1). The assessment included the major steps in a pecan production process, such as immersion in a dump tank with water at $\sim 23^{\circ}\text{C}$ for debris removal, two drying steps at $\sim 60^{\circ}\text{C}$, conditioning (typically using steam or hot water or using cold chlorinated water to soften the shell so the kernel is less likely to be damaged during cracking), cracking (including a water flotation step in which pecan pieces and a portion of the shells pass through chlorinated water), a microbial reduction treatment, partitioning, and storage both before and after the microbial reduction treatment. Figure 1 (adapted from Beuchat and Mann (6)) includes the most common steps in pecan processing. Minor variations to this scheme can exist and are dependent on the processor (37). In the absence of more detailed information, it was assumed that minor processing variations between individual shellers would not significantly change the prevalence or levels of *Salmonella* on in-shell pecans or pecan kernels and thus would not impact the estimated risk as obtained in this assessment. Consumer home storage was not included in the exposure assessment model because these practices do not serve as risk mitigation for regulatory purposes. The exposure assessment model thus assumes pecans are consumed after purchase with no further storage. However, if the consumer stored pecans at room

(20 to 25°C), refrigeration, or freezing temperatures at the home after purchase, *Salmonella* levels would be maintained (under refrigeration or freezing) or decreased (under ambient) depending on the time-temperature characteristics of storage. The model does consider whether the product is consumed raw or is used as an ingredient in a food that is cooked by the consumer (e.g., a pecan pie).

Some exposure assessment process steps will affect the *Salmonella* prevalence and/or level on in-shell pecans and/or pecan kernels (Fig. 1). In several studies, *Salmonella* was reduced after dry storage at ambient temperature (~ 20 to 25°C) and a water activity (a_w) of <0.7 (3–5, 10), hot air drying (7), and a microbial reduction treatment (e.g., oil roasting) (7). No change in *Salmonella* level is expected as a result of immersion in unchlorinated water for <24 h at 20 to 25°C , immersion in chlorinated water (when *Salmonella* is present at low levels) containing up to 400 $\mu\text{g}/\text{mL}$ free chlorine for <24 h (6), or partitioning (*Salmonella* cells are only redistributed). The *Salmonella* level is expected to be maintained postpurchase (at the home) when pecans are consumed without further cooking. Consumer home storage practices were not modeled here, although we expect the *Salmonella* level to remain the same or to decline over time, depending on the storage temperature and time, in a model that considers home storage.

Estimating prevalence and level of *Salmonella* on pecans at the sheller. Data from the 2010 to 2013 surveys collected by the National Pecan Shellers Association (NPSA) to determine *Salmonella* contamination on pecans were submitted to the U.S. government in response to U.S. Food and Drug Administration (FDA) notice FDA-2013-N-0747 (37). The data and a comprehensive description of the sampling design were provided by Brar et al. (11). In that study, 500-g samples of in-shell pecans of four broad varieties were collected from seven U.S. shellers at receipt. Each sheller collected a number of samples proportional to their production volume. In-shell subsamples of 100 g were screened for *Salmonella* using the AOAC official method 2001.09 (the mini VIDAS assay system) (1). Positive results were confirmed using standard culture methods, and *Salmonella* levels were determined

TABLE 1. Models fitted to MPN patterns of *Salmonella* contamination on pecans at the sheller

Model name	Description	Comparison model ^a
Poisson 1	Single Poisson distribution for all lots and sampling years	
Poisson 2	Single Poisson distribution for all lots with mean λ_y allowed to differ from year to year	Poisson 1
Zero-inflated (ZI) Poisson 3	One Poisson distribution accounts for the <i>Salmonella</i> level in only contaminated lots; other lots are not contaminated as measured by the prevalence estimate; prevalence of contamination and mean level λ in contaminated lot is constant for all survey years	Poisson 1 and Poisson 2
ZI Poisson 4	Same assumptions as ZI Poisson 3 but prevalence and level are allowed to vary by sample year	Poisson 2 and ZI Poisson 3
Lognormal 1	One lognormal distribution ^b describes the lot-to-lot variability in the mean contamination level; within a given lot, the contamination is Poisson distributed	
Lognormal 2	Same assumptions as lognormal 1, but mean and standard deviation of the lognormal distribution are allowed to differ from year to year	Lognormal 1
Lognormal 3	Same assumptions as lognormal 2, but the standard deviation is held constant from year to year	Lognormal 1 and lognormal 2
Lognormal 4	Same assumptions as lognormal 2, but the mean is held constant from year to year	Lognormal 1, lognormal 2, and lognormal 3
ZI lognormal 5	Same assumptions as lognormal 1, but some uncontaminated lots are included	Lognormal 4
ZI lognormal 6	Same assumptions as lognormal 2, but some uncontaminated lots are included (see ZI lognormal 5) and the prevalence is allowed to differ from year to year	Lognormal 4 and ZI lognormal 5

^a Model(s) provided in this column are nested in the model given in that row.

^b $X \sim \text{lognormal}(\mu, \sigma)$ if $\log(X) \sim \text{Normal}(\mu, \sigma)$.

using a most-probable-number (MPN) method. Two three-tube MPN analysis methods were used. With one method, four 25-g subsamples were removed from the original 100-g sample without blending; three of these subsamples were used for the 25-g MPN tubes and one was portioned into three 2.5-g and three 0.25-g tubes. With the other method, the original 100-g sample was blended together before distribution into the three MPN tubes. All samples were further enriched following the guidelines in the FDA *Bacteriological Analytical Manual* (38). To better characterize the MPN data received in response to the FDA notice, a rarity index was determined for each MPN pattern as described by Blodgett (9). 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 when the rarity index is <0.05 (8). The MPN data were received in response to the FDA notice corresponding to *Salmonella* contamination at the sheller. Five MPN patterns were categorized as rare. To eliminate the possibility of transcription error, the submitters were asked to check the raw data, and each pattern was confirmed. This result suggests that there might have been a nonhomogeneous distribution of the pathogen in those five pecan samples tested (13). Patterns defined as rare were included in the analysis, but the maximum-likelihood method used to derive the *Salmonella* distribution naturally provided a lower weight for these rare patterns.

Multiple models of *Salmonella* contamination distribution were fit to the MPN patterns, using a maximum-likelihood method (Table 1). Models were compared based on a maximum-likelihood ratio test when nested. When models were not nested, the Akaike information criterion was used to determine the best applicable model (30), which was translated in a Bayesian framework using JAGS through the rJags R library (26). This approach allowed for a simpler specification of the credible intervals surrounding the parameter estimate given the sampling design (27, 32, 33). Uninformative priors were used for the mean (normal distribution with a mean of 0 and a standard deviation 10 log CFU/g) and for the standard deviation (independent uniform distribution from 0 to

10 log CFU/g). Convergence was confirmed using Gelman and Rubin's convergence diagnostic, and a value of <1.1 was used as a sign of convergence (19).

In this assessment, a lot was defined as a unit quantity of pecans (in-shell or kernels) in mass and was measured in grams. For each iteration of the simulation, one mean and standard deviation of the level of *Salmonella* per lot was sampled from a coupled mean–standard deviation (μ_u, σ_u , to keep the correlation structure) of the Monte Carlo Markov chain to represent uncertainty. The size of a lot at the sheller step of the pecan production process is estimated to follow a triangular distribution with a minimum of 1,000 kg, a mode of 11,350 kg, and a maximum of 11,350 kg (21).

Estimates for the prevalence (probability of having at least one *Salmonella* cell in the given food unit) and level of contamination (modeled as a discrete CFU per contaminated unit, i.e., a unit containing >0 *Salmonella* cells) were tracked separately throughout the simulation. It was assumed that the *Salmonella* cells were Poisson distributed in a given lot (homogeneous distribution). The prevalence was defined as

$$1 - \exp(-\lambda \times s)$$

where $\log(\lambda)$ is the level of *Salmonella* per gram in the lot and follows a normal distribution $N(\mu_u, \sigma_u)$ and s is the size of the lot (g).

Removal of orchard debris and drying. In-shell pecans typically arrive at the sheller facility without the husk that surrounds the shell, which is the part of the nut that surrounds the kernel (21). In-shell pecans are then typically immersed in a dump tank to separate the nuts from inedible material; in some cases air is used to blow off the material (6). The time-temperature combination at the dump tank ($\approx 23^\circ\text{C}$ for less than 1 min) is not relevant for growth or inactivation of *Salmonella* (21). As such, no change in *Salmonella* level per lot was assumed as a result of pecans being immersed in the dump tank.

TABLE 2. Descriptive statistics of the distributions from the inference model describing *Salmonella* survival at temperatures of 21 to 24°C on pecans (in-shell and kernels) at $a_w < 0.7$

Variable	Mean	Quantile (uncertainty distribution)				
		2.5%	25%	50%	75%	97.5%
δ^a	15.6	11.4	14.1	15.5	16.9	20.0
ρ^b	0.61	0.55	0.59	0.61	0.63	0.67
Standard deviation of δ from replicate to replicate	0.37	0.36	0.37	0.37	0.38	0.38
Residual	4.05	3.02	3.62	3.99	4.43	5.36

^a Time (weeks) to the first log reduction.

^b Parameter defining the shape of the curve.

Following immersion in the dump tank, in-shell pecans are dried before storage (3, 6). In 2013, NPSA conducted a survey on *Salmonella* control and inactivation during pecan processing. The survey instrument was completed by 22 pecan shellers, which is the majority of U.S. pecan shellers. Their responses were submitted to the FDA in response to notice FDA-2013-N-0747 (37). In this survey, 20 (91%) of the 22 respondents reported use of an air drying process (kernels) in one or more of their plants. The minimum reported air temperature was 25 to 93°C, and 10 (50%) of these 20 respondents reported air temperatures of $\leq 65^\circ\text{C}$. The reported exposure time to these temperatures was < 1 h for 10 (50%) of the 20 respondents. The drying step was validated by a third party to achieve a reduction in *Salmonella* of up to 2 log CFU for 2 (10%) of the 20 the respondents. Log-linear declines of *Salmonella* during drying of wet pecan nutmeats at 60°C, as collected by Beuchat and Mann (7), were used in this risk assessment to account for the effect of drying on *Salmonella* survival before (in-shell) and after (kernels) shelling. In the absence of additional data, it was assumed that the effect of drying was the same for *Salmonella* on in-shell pecans and on pecan kernels. A bootstrap procedure was used to estimate the uncertainty around the log-linear estimate for *Salmonella* inactivation during drying.

Salmonella survival during storage. A mathematical model to predict survival of *Salmonella* on almonds, pecans, pistachios, and walnuts at ambient storage temperature that considers variability and uncertainty separately was developed by Santillana Farakos et al. (32). This model is a Weibull survival model that includes a fixed and random variation of δ per tree nut (time to the first log reduction) and a fixed variation of ρ per tree nut (parameter defining the shape of the curve) (Table 2). The Weibull model survival parameters as estimated exclusively for pecans were used in this risk assessment (Table 2). The probability that a *Salmonella* cell selected at random will survive from time t_1 to time t_2 (a specified storage time) is defined as

$$P_{\text{surv}} = 10^{-\left(\frac{t_2 \rho - t_1 \rho}{\delta \rho}\right)}$$

where t_1 and t_2 are the time since the beginning of the survival step (t_0), which is considered in this assessment as the arrival of pecans at the sheller. A binomial process restricted to positive values was used to evaluate the level of *Salmonella* in contaminated units at the end of each stage of the exposure assessment model:

$$N_2 \sim \text{Binomial}(N_1, P_{\text{surv}}), \text{ with } N_2 > 0$$

where N_2 is the level of *Salmonella* in the contaminated unit at the end of the survival period (t_2) and N_1 is the level of *Salmonella* in the contaminated unit at the beginning of the survival period (t_1).

The binomial model assumes that each *Salmonella* cell has an independent probability of survival. The probability of contamination is accordingly adjusted to (28)

$$P_2 = P_1 \left[1 - (1 - P_{\text{surv}})^{N_1} \right]$$

accounting for lots in which there is no *Salmonella* ($N_2 = 0$). Where P_{surv} and N_1 are defined as above, P_2 is the probability of contamination at the end of the survival period (t_2) and P_1 is the probability of contamination at the beginning of the survival period (t_1).

Storage conditions in pecan processing. Once pecans are dried they are typically stored either at ambient temperatures (~ 20 to 25°C) when storage is planned for less than 2 weeks or under refrigeration when storage is planned for more than 2 weeks. Storage times vary: 5% of storage times follow a triangular distribution (minimum = 0, mode = 2, maximum = 2 weeks), 90% of storage times follow a uniform distribution (minimum = 2, maximum = 49 weeks), and 5% of occurrences follow a triangular distribution (minimum = 49, mode = 49, maximum = 73 weeks) (21). In a study published by Beuchat and Heaton (3), the decrease in the levels of *Salmonella* inoculated on the surface of in-shell pecans and pecan kernels after storage at 4°C for up to 32 weeks was minimal (4). Thus, it was assumed that for pecans stored under refrigeration (95% of the occurrences) no decrease in *Salmonella* levels per lot (in grams) would occur.

Following conditioning, drying, a microbial reduction treatment, and partitioning into lots and bags, pecans are stored for 3 weeks (Fig. 1); 80% of them at $\approx 23^\circ\text{C}$ and 20% of them at refrigeration temperatures (21).

Conditioning and second drying. According to Beuchat and Mann (6), conditioning is commonly carried out by one of two means: (i) using cold water (usually chlorinated) for 8 h and then draining for 16 to 24 h or (ii) using hot water or steam for 6 to 8 min. The results of the 2013 NPSA survey (37) revealed that the majority of the pecan processors use a hot water bath conditioning step (17 of 22, 77%) with temperatures $> 81^\circ\text{C}$ for 1 to 8 min and an average dwell time of 3.5 min. Fourteen (82%) of 17 respondents indicated that the hot water bath conditioning step was validated by a third party to achieve a minimum 4-log reduction in *Salmonella* per unit of product being treated (i.e., the lot size in grams). Of those processors that reported the use of a chlorinated water bath (in-shell; 11 of 22, 50%), all indicated water temperatures of 15 to 30°C ; 64% of these processors used a minimum free chlorine concentration of 200 ppm. For the majority (55%) of these 11 respondents, the minimum exposure time for the in-shell pecans in chlorinated water was 2 min. Two (18%) of the

11 respondents indicated that the chlorinated water bath was validated by a third party to achieve a maximum 2-log reduction in *Salmonella* per unit of product being treated. Beuchat and Mann (6) collected data on the survival of *Salmonella* in water at 21°C containing up to 400 µg/mL free chlorine for 1, 2, 8, 16, and 24 h. *Salmonella* populations were not significantly reduced from an initial level of 0.63 log CFU/g; levels were higher levels after 16 and 24 h. When initial levels were higher (5.62 log CFU/g), decreases of 0.41 to 0.98 log CFU/g were observed within 1 h. Gradual increases in levels occurred during subsequent soaking (6). Two conditioning processes were applied in the model: cold conditioning with no change in *Salmonella* levels and a hot conditioning with a minimum of 4-log and maximum of 5-log reduction per unit of product being treated. To evaluate the change in *Salmonella* levels as a result of conditioning, a binomial process restricted to positive values was used to evaluate the *Salmonella* levels at the end of each stage:

$$P_{\text{surv}} = 10^{-L}$$

$$N_2 \sim \text{Binomial}(N_1, P_{\text{surv}}), \text{ with } N_2 > 0$$

$$P_2 = P_1 \left[1 - (1 - P_{\text{surv}})^{N_1} \right]$$

where L is the log reduction $\sim \text{Uniform}(4, 5)$.

Following conditioning and subsequent cracking, pecan kernels are separated from the shells through water flotation (at 23°C). No change in *Salmonella* levels is expected in the water flotation step; thus, no change in *Salmonella* level was assumed at this step of the exposure assessment model (21). A second drying step takes place following water flotation. To account for *Salmonella* reduction during drying of pecan kernels, the same reduction estimate as described for drying during preconditioning was applied (see details in "Removal of orchard debris and drying"). Pecans that are sold in the shell at retail do not undergo conditioning or cracking but follow the rest of the process steps in the same way as pecans that are sold shelled (6, 37). According to NPSA, 80% of the pecan supply is sold shelled and 20% is sold in-shell (24).

Microbial reduction treatment. Six microbial reduction treatments (no treatment and 1-, 2-, 3-, 4-, and 5-log reductions) were modeled on 100% of the product and with no process variance. The log reduction microbial treatment levels were defined per unit of product being treated (i.e., the lot size in grams), which differed depending on the sheller. The evaluation of the performance of specific microbial reduction treatments for *Salmonella* on pecans (e.g., oil roasting, dry roasting, blanching, steam, and propylene oxide) is beyond the scope of this risk assessment. For the microbial reduction treatment step, it was assumed that each *Salmonella* cell had an identical and independent probability of inactivation. A binomial process restricted to positive values was used to evaluate the level of *Salmonella* at the end of this stage (see details in section "Conditioning and second drying"). For microbial reduction treatments with a high log reduction, the contamination in *Salmonella*-positive lots after the microbial reduction treatment was the minimum level in positive units, i.e., 1 CFU.

Partitioning. Following the microbial reduction treatment, the lots are redistributed into lots of 45 to 45,000 kg (21). The lot size after partitioning was set to have a maximum equivalent to the size of the lot before partitioning. The lots are then further partitioned into consumer packages. Consumer packages range in

size from an 18-g snack pack to a 224- or 454-g bag (10). To evaluate the change in *Salmonella* levels per subunit as a result of partitioning, one subunit (at random) was followed per iteration, and the probability of contamination and the *Salmonella* level for each step was estimated as follows (31):

$$N_2 \sim \text{Binomial} \left(N_1, \frac{S_2}{S_1} \right), \text{ with } N_2 > 0$$

$$P_2 = P_1 \left[1 - \left(1 - \frac{S_2}{S_1} \right)^{N_1} \right]$$

where N_2 is the *Salmonella* level in the considered subunit of size S_2 (after partitioning), N_1 is the *Salmonella* level in the considered unit of size S_1 (before partitioning), P_2 is the probability of contamination in the considered subunit of size S_2 (after partitioning), and P_1 is the probability of contamination in the considered subunit of size S_1 (before partitioning).

Cooking. U.S. consumers use pecans as an ingredient in cooked products at home (e.g., pecan pie) (36). These pecans are purchased by the consumer as an uncooked ingredient. To account for the log decrease in *Salmonella* levels for pecans used as an ingredient in cooked products, a literature search was conducted to obtain data on the fate of *Salmonella* on pecans during baking. No references were found with data specifically on *Salmonella* survival on pecans during baking. Lathrop et al. (23) collected survival data for *Salmonella* in peanut butter during baking of cookies. Commercial peanut butter was artificially inoculated with a five-serovar cocktail of *Salmonella* (Tennessee, Tornow, Hartford, Agona, and Typhimurium), the inoculated peanut butter was used to prepare peanut butter cookies using a standard recipe, and cookies were baked at 177°C for various times (10 to 15 min). Results revealed a minimum 4.8-log decrease in *Salmonella* levels per 25-g cookie after 10 min at 177°C (detection limit, 0.04 CFU/g) (23). Cookies baked for 15 min had no detectable *Salmonella* (23). Similar to pecans, peanut butter is a low- a_w nut product. Although the composition of peanuts and peanut-related products is different from that of pecans, the main parameters influencing survival of *Salmonella* during heating of foods are temperature and a_w , which is assumed to be similar (within 0.1 standard deviation). The *Salmonella* inoculant used by Lathrop et al. was reduced by 4.8 log CFU per 25-g cookie after baking. However, this *Salmonella* inoculant did not undergo a microbial reduction treatment step prior to baking. In the absence of available data and for the purpose of this risk assessment, it was assumed that the expected log decrease in *Salmonella* levels during baking of pecans approximates that of the minimum level found in baking of peanut butter cookies. A fixed value of 5 log CFU per unit (consumer packages after processing and retail storage) was used for pecans that are included as an ingredient in food products that undergo a cooking step in the home.

Modeling atypical situations in pecan processing. Atypical situations in the food production system can lead to individual illnesses and outbreaks. As part of this risk assessment, the impacts of three atypical situations on foodborne illnesses were evaluated. The first atypical situation (cattle grazing) assumed that cattle grazing on the pecan orchard floor would lead to higher initial levels of *Salmonella* on pecans. Initial *Salmonella* contamination levels at the pecan sheller were modeled to increase by a minimum of 2 log CFU and a maximum of 4.5 log CFU per lot, using a uniform distribution and to obtain mean initial contamination levels that were sixfold higher than the baseline model. The rest of

the pecan processing steps were assumed to be the same as those described for the baseline process model. A pecan lot at this step of the process consists of a mean of 8,328 kg of in-shell pecans. The objective of the cattle grazing atypical situation was to model a situation in which the initial *Salmonella* contamination level on pecans is increased (without increasing the prevalence) to understand the impact on the risk per serving from pecan consumption.

The second atypical situation (recontamination) was modeled to include a recontamination event at the processing facility during cracking (after conditioning and before the microbial reduction treatment). This event assumed that *Salmonella*-contaminated water (e.g., water not properly disinfected) was used to separate kernels from shells during cracking, leading to a *Salmonella* minimum of 0.5 log CFU and a maximum of 3 log CFU per lot of cross-contaminated pecan lots (an increase in *Salmonella* levels of 0.5 to 3 log CFU per lot due to cross-contamination). This increase in levels was assumed and only affects the contaminated lots of the baseline process model. The prevalence remains the same as that established in the baseline process model. The rest of the pecan processing steps were assumed to be the same as those described for the baseline process model.

The third atypical situation (delay in drying) modeled a delay in drying pecan kernels that have been separated from the shells through water flotation after conditioning and before microbial reduction treatment. The kernels were assumed to be moist and held at 21°C after conditioning, allowing for growth of *Salmonella* on the kernel. The a_w of moist kernels was assumed to be 0.95 to 0.98 based on data from Beuchat and Mann (5). For this atypical situation, it was assumed that pecans were held in these high moisture conditions (a_w 0.95 to 0.98) for a minimum of 6 h and a maximum of 24 h. The growth per hour was determined based on data from Beuchat and Mann (5), i.e., a maximum of approximately 5 log CFU in 48 h or ~ 0.1 log CFU/h for pecans at 21°C. The rest of the pecan processing steps were assumed to be the same as those described for the baseline process model.

Consumption. Consumption of pecans in the U.S. population was estimated using data originating from What We Eat in America (WWEIA), the dietary survey portion of the National Health and Nutrition Examination Survey in the 2003 to 2004, 2005 to 2006, 2007 to 2008, and 2009 to 2010 cycles (12). Proportions of pecan ingredients in WWEIA foods used in these analyses were based on recipes developed for U.S. Environmental Protection Agency's Food Commodity Intake Database (36). Empirical distributions representing serving sizes among consumers (eaters) and weighted by the WWEIA dietary statistical sampling weights were used for pecans consumed as a core product uncooked, as an ingredient uncooked, and as an ingredient cooked. Assuming that data reported in the WWEIA 24-h dietary recalls (two per survey respondent, conducted 3 to 10 days apart) are representative of consumption over the entire year and considering that there are approximately 320 million individuals in the United States (35), the number of servings per year was estimated. The estimated number of illness cases per serving and per year correspond to an average serving and an average year, respectively, as the variability introduced in the probability of contamination study was integrated in the procedure. We distinguished among three types of pecan products consumed, for which the cooking step, if present, was assumed to happen at the home: (i) core pecan product ($\geq 80\%$ of the product ingredients are pecans, including whole pecans) consumed uncooked, (ii) pecan as an ingredient ($< 80\%$ of the product ingredients are pecans) consumed uncooked, and (iii) pecan as an ingredient

($< 80\%$ of the product ingredients are pecans) consumed cooked (e.g., in baked, fried, or boiled products). The empirical cumulative distribution function for consumption of pecans as an uncooked core product, as an uncooked ingredient, and as a cooked ingredient is presented in Figure 2. The cooking step in cooked pecans means cooking by the consumer and would not include, for instance, pecans sold as roasted pecans (see "Cooking" section for details). The number of pecan servings per year in the United States was estimated from the WWEIA data; 0.7% of the population (~ 2 million individuals) reported consuming uncooked pecans as a core product, 3% of the population (~ 9 million individuals) reported consuming uncooked pecans as an ingredient, and 6% of the population (~ 18 million individuals) reported consuming cooked pecans as an ingredient.

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 from the Food and Agriculture Organization of the United Nations and World Health Organization (FAO-WHO) data (16), adapted to the number of *Salmonella* cells, which in our model is an exact value (beta-binomial dose-response model (20)). The risk estimates obtained when using the 2.5 and 97.5 percentiles of the FAO-WHO *Salmonella* dose-response curve resulted in mean estimated risks that were in the same order of magnitude as those when using the FAO-WHO expected values. Thus, no uncertainty in the dose-response was considered.

Sensitivity analyses. To evaluate the factors with the greatest impact on the estimated risk of human salmonellosis from consumption of pecans, a sensitivity analysis was conducted on the baseline risk assessment model (considering a hot or cold conditioning process and a 0- or 5-log microbial reduction treatment) and the three modeled atypical situations (considering a cold conditioning process with a 0-log microbial reduction treatment). Spearman's rho statistic was determined, with risk per serving as the outcome variable, examining risk estimates arising from consumption of pecans as a core product uncooked. Factors considered were those for which variability and uncertainty were estimated and include initial contamination levels (Contamination), drying time (TimeDrying; in minutes and for the first drying), the time to reduce the *Salmonella* population by 1 log CFU (Delta), consumer package sizes (SizePack), preprocess storage time (PrePStorage), postprocess storage time (PostPStorage), and consumption patterns (ConsCoreRaw). The impact on estimated risk of the *Salmonella* contamination due to cattle grazing (CattleContamination) to recontamination postconditioning (Recontamination) in the atypical situations was evaluated compared with the impact on risk of the other factors. Similarly, the impact of *Salmonella* growth due to a delay in drying after conditioning (Growth, Time; in the atypical situation of delay in drying) on estimated risk also was evaluated. The use of Spearman rank coefficients, rather than more complex statistical methods, is sufficient to explore the model because relationships between factors and output are monotonic and no interaction between the factors is expected.

The variability dimension was set to 10,001 replicates and the uncertainty was set to 501 replicates, i.e., 500 replicates to evaluate uncertainty and within each uncertainty loop 10,000 replicates to characterize variability in model parameters. The risk was assessed using a second-order Monte Carlo simulation (18) developed in R using the mc2d package (29). The R code is available upon request (FDAFoodSafetyRiskModel@fda.hhs.gov).

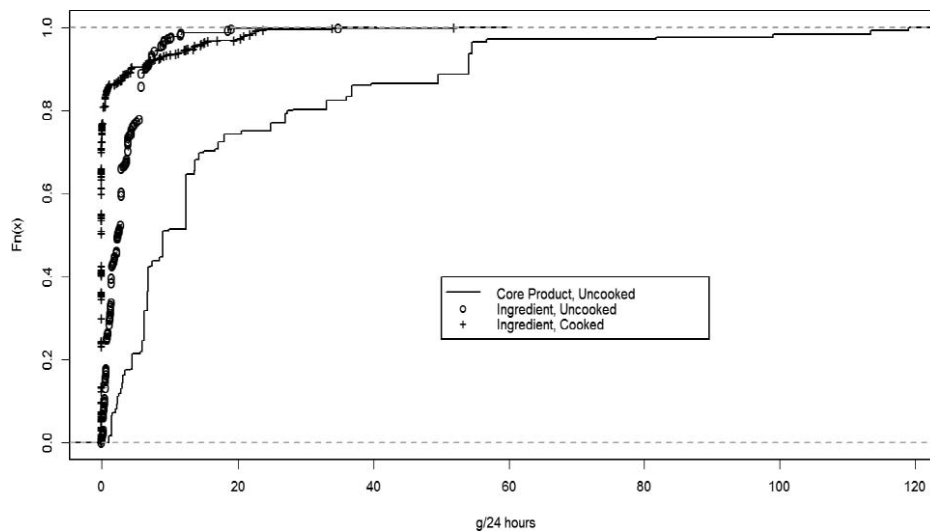


FIGURE 2. Empirical cumulative distribution function for daily U.S. consumption of pecans. The solid line represents core product (>80% of the product is pecans) consumed uncooked, + represents pecans consumed as an ingredient (<80% of the product is pecans) in an uncooked product, and ○ represents pecans as an ingredient (<80% of the product is pecans) in a cooked product.

RESULTS AND DISCUSSION

Salmonella contamination levels at the sheller. The model fitting results for data for *Salmonella* contamination on in-shell pecans at the sheller are presented in Table 3. All lognormal and zero-inflated (ZI) lognormal models tested were shown to fit better (had lower Akaike information criterion values) than the models assuming a Poisson distribution of the contamination data. Within the lognormal models, lognormal 2 was the best fitting model to describe the MPN contamination patterns for *Salmonella* (Table 3). The σ value for survey year 2012 was unidentifiable (estimated to be 0 and thus the minimum value 0.10 was used), presumably because of the data, but the evidence from the other years suggests variation between lots (Table 3). The lognormal 3 and lognormal 4 models were comparable in their prediction potential but not better than lognormal 1. The ZI lognormal 5 model degenerated to lognormal 1 (P was estimated to be 1), and ZI lognormal 6 did not have a significantly better prediction potential than did lognormal 4 (given there were more parameters in the model). Thus, lognormal 1, which assumes a lot-to-lot variation of the mean contamination and follows a lognormal distribution with parameters $\mu = -5.72 \log \text{CFU/g}$ and $\sigma = 1.32 \log \text{CFU/g}$, was the best model to describe *Salmonella* contamination on pecans at the sheller.

Salmonella prevalence and contamination throughout exposure. The exposure assessment model for pecans tracks *Salmonella* contamination from the arrival of pecans at the sheller to the point of consumption and includes estimates of prevalence and level at the dump tank, after the first drying, after preprocess storage, after conditioning, after the second drying, after microbial reduction treatment, after partitioning into lots and individual bags, after postprocess storage, and after retail storage at consumption (Fig. 1). Table 4 provides the mean probability of *Salmonella* contamination and the levels (per contaminated unit) at the

end of each stage of the exposure assessment model for 0- (no microbial reduction treatment), 4-, and 5-log microbial reduction treatments, considering both a conditioning step using steam or hot water and one using cold chlorinated water. The mean *Salmonella* level at the end of each stage of the exposure assessment model for 0- (no microbial reduction treatment), 4-, and 5-log reduction treatments and both hot and cold conditioning steps are presented in Figure 3. A decrease in both the probability of *Salmonella* contamination and the levels (in contaminated units) is seen throughout the exposure assessment model for pecans that undergo both a cold and a hot conditioning step for the three microbial reduction treatment levels shown (Fig. 3 and Table 4). Lower probability of contamination and lower contamination levels (in contaminated units) were observed for pecans that undergo hot conditioning compared with those that undergo a cold conditioning step to soften the kernel so that it is less prone to shatter during the shelling process (Table 4 and Fig. 3).

Both hot conditioning and microbial reduction treatment had the greatest impact on the decrease in probability of contamination and *Salmonella* levels in contaminated units throughout exposure (Table 4 and Fig. 3). Drying and storage (Table 4 and Fig. 3) result in a lower probability of contamination and a decrease in *Salmonella* levels per contaminated lot. However, the reductions achieved during drying and storage are much smaller in magnitude than those obtained through a hot conditioning step or when implementing a microbial reduction treatment. Partitioning shows an apparent decrease in probability of contamination and *Salmonella* concentration (Table 4 and Fig. 3). However, this apparent lower probability of contamination after partitioning is a result of the redistribution of low *Salmonella* levels into a high number of units of smaller size. For example, if a 10,000-kg lot contains 100 CFU, the prevalence is 100% and the *Salmonella* level is 100 CFU per contaminated lot. After partitioning into 454-g bags, the per

TABLE 3. Model fitting results for *Salmonella* contamination at the pecan sheller

Model ^a	Parameter estimate	Log likelihood	AIC ^b	LRT ^c
Poisson 1	$\lambda = -3.61 \log \text{CFU/g}$	-786	1,574	NA ^d
Poisson 2	2010: $\lambda = -3.61 \log \text{CFU/g}$ 2011: $\lambda = -3.54 \log \text{CFU/g}$ 2012: $\lambda = -4.13 \log \text{CFU/g}$ 2013: $\lambda = -3.49 \log \text{CFU/g}$	-776	1,561	Better than Poisson 1 ($P = 0.0002$)
ZI Poisson 3	$\lambda = -2.0 \log \text{CFU/g}$; prevalence = 1.4%	-558	1,120	Better than Poisson 1 ($P < 0.0001$)
Poisson 4	2010: $\lambda = -2.22 \log \text{CFU/g}$; prevalence = 3.0% 2011: $\lambda = -1.44 \log \text{CFU/g}$; prevalence = 0.49% 2012: $\lambda = -4.13 \log \text{CFU/g}$; prevalence = 100% 2013: $\lambda = -2.02 \log \text{CFU/g}$; prevalence = 2.2%	-522	1,060	Better than Poisson 2 ($P < 0.0001$) and ZI Poisson 3 ($P < 0.0001$)
Lognormal 1	$\mu = -5.72 \log \text{CFU/g}$ $\sigma = 1.32 \log \text{CFU/g}$	-434	874	NA
Lognormal 2	2010: $\mu = -5.25 \log \text{CFU/g}$; $\sigma = 1.19$ 2011: $\mu = -7.67 \log \text{CFU/g}$; $\sigma = 1.99$ 2012: $\mu = -4.14 \log \text{CFU/g}$; $\sigma = 0.10^e$ 2013: $\mu = -5.49 \log \text{CFU/g}$; $\sigma = 1.32$	-426	868	Better than lognormal 1 ($P = 0.007$)
Lognormal 3	$\sigma = 1.312$ 2010: $\mu = -5.49 \log \text{CFU/g}$ 2011: $\mu = -6.01 \log \text{CFU/g}$ 2012: $\mu = -5.91 \log \text{CFU/g}$ 2013: $\mu = -5.48 \log \text{CFU/g}$	-431	872	Lognormal 2 is better ($P = 0.02$); not better than lognormal 1 ($P = 0.05$)
Lognormal 4	$\mu = -5.65 \log \text{CFU/g}$ 2010: $\sigma = 1.38$ 2011: $\sigma = 1.21$ 2012: $\sigma = 1.15$ 2013: $\sigma = 1.39$	-432	873	Not better than lognormal 1 ($P = 0.08$); lognormal 2 is better ($P = 0.01$); log likelihood is better than lognormal 3 for a similar number of parameters
ZI lognormal 5	Degenerates to Lognormal 1	NA	NA	NA
ZI lognormal 6	2010: $\mu = -3.31$; $\sigma = 0.68$; prevalence = 11% 2011: $\mu = -7.67$; $\sigma = 1.98$; prevalence = 100% 2012: $\mu = -3.83$; $\sigma = 0.10$; prevalence = 100% 2013: $\mu = -5.49$; $\sigma = 1.31$; prevalence = 100%	-428	880	Not better than lognormal 4 ($P = 0.87$)

^a Models described in detail in Table 1.

^b Akaike information criterion.

^c Likelihood ratio tests.

^d NA, not applicable.

^e Unidentifiable, used the minimum value.

bag mean prevalence and level of *Salmonella* will be lower because some bags will contain no *Salmonella* and the 100 CFU will be distributed among multiple bags. The minimum mean level reported in the results (e.g., Table 4) is 1 CFU per contaminated unit because the unit must contain at least 1 CFU to be considered contaminated. However, this result does not mean that levels are independent of microbial

reduction treatment or conditioning type, nor does it mean that partitioning decreases mean *Salmonella* levels. Rather, this result is due to the model characterizing contamination levels for only contaminated units. The estimates of the probability of contamination for pecan kernels are slightly lower (for any processing condition except cold conditioning and no treatment) than those for shelled pecans at retail

TABLE 4. Probability of *Salmonella* contamination and *Salmonella* levels for each stage of the exposure assessment model for a 0-, 4-, and 5-log reduction treatment with both hot and cold conditioning steps

Parameter	Upon arrival at sheller	After dump tank	After drying 1 ^a	Storage ^b	Type of conditioning ^c	Postconditioning
Mean unit size (kg)	8,328	8,328	8,328	8,328		8,328
Probability of <i>Salmonella</i> contamination (mean ± SD)	0.82 ± 0.31	0.82 ± 0.31	0.79 ± 0.34	0.79 ± 0.34	Hot	0.015 ± 0.078
					Cold	0.79 ± 0.34
<i>Salmonella</i> level (CFU) per contaminated unit (mean ± SD)	1,558 ± 31,548	1,558 ± 31,548	1,073 ± 20,734	1,054 ± 19,999	Hot	1.03 ± 0.8
					Cold	1,054 ± 19,999

^a First drying step was 60°C, 11.2% moisture, 5 to 10 min.

^b Preprocess storage where 90% of occurrences follow a uniform distribution with minimum = 2 weeks, maximum = 49 weeks; 5% follow a triangular distribution with minimum = 49 weeks, mode = 49 weeks, maximum = 73 weeks; and 5% follow a triangular distribution with minimum = 0 weeks, mode = 2 weeks, maximum = 2 weeks. If pecans are stored for more than 2 weeks, storage is at refrigeration temperature.

^c Whether the conditioning process was done using steam or hot water (hot), thus assuming a 4- to 5-log reduction in *Salmonella*, or by immersion in chlorinated water (cold), thus assuming no reduction in *Salmonella*.

^d Second drying step was 60°C, 11.2% moisture, 5 to 10 min.

^e Microbial reduction treatment resulting in 0-, 4-, or 5-log reductions in *Salmonella*.

^f Pecans were partitioned into lot sizes of 45 to 45,000 kg.

^g Lots were partitioned into individual packages of 18, 224, and 454 g.

^h Postprocessing for 3 weeks and retail storage following a triangular distribution (minimum = 1 day, mode = 2 weeks, maximum = 6 weeks); 80% of product stored at 23°C and 20% stored at 4°C.

ⁱ Minimum level of *Salmonella* for the unit to be considered contaminated is 1 CFU.

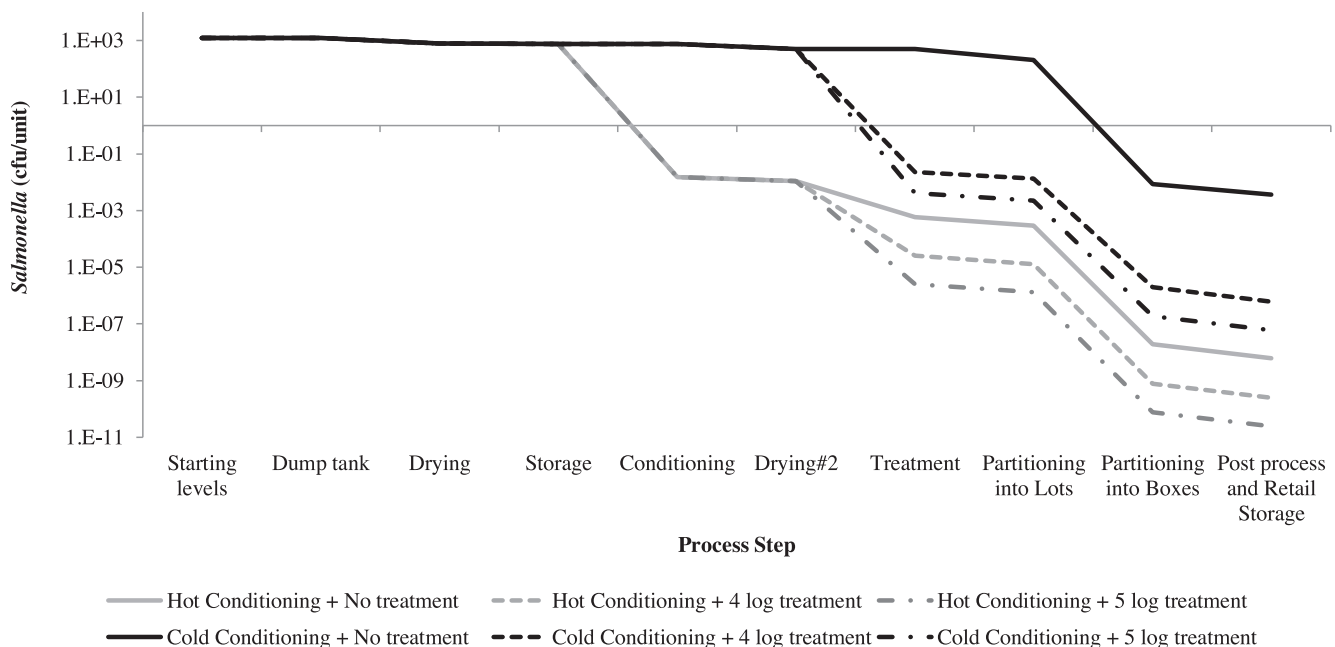


FIGURE 3. *Salmonella* levels (CFU per unit) in each exposure assessment stage including a 0-, 4-, and 5-log reduction treatment and two types of conditioning: hot (steam or hot water, assuming a 4- to 5-log reduction in *Salmonella*) and cold (immersion in chlorinated water, assuming no reduction occurs).

TABLE 4. *Extended*

Drying 2 ^d	Microbial reduction treatment ^e	Posttreatment	Postpartitioning into lots ^f	Postpartitioning into packages ^g	Postprocessing and retail storage ^h
8,328		8,328	3,547	0.224	0.224
0.011 ± 0.066	0	0.001 ± 0.009	0.0003 ± 0.0055	1.9E-08 ± 3.6E-07	6.04E-09 ± 1.14E-07
	4	2.5E-05 ± 5.2E-04	1.3E-05 ± 2.8E-04	7.7E-10 ± 1.6E-08	2.43E-10 ± 5.31E-9
	5	2.5E-06 ± 5E-05	1.3E-06 ± 2.8E-05	7.6E-11 ± 1.6E-09	2.43E-11 ± 5.38E-10
0.748 ± 0.364	0	0.749 ± 0.364	0.643 ± 0.407	8.6E-03 ± 5.6E-02	0.0037 ± 0.0335
	4	0.0217 ± 0.095	0.0129 ± 0.0712	1.9E-06 ± 4.1E-05	6.17E-07 ± 1.27E-05
	5	0.0041 ± 0.034	0.00227 ± 0.024	1.9E-07 ± 4.2E-06	6.10E-08 ± 1.23E-06
1.02 ± 0.534	0	1 ± 0.02	1 ± 0.01	1 ⁱ	1
	4	1	1	1	1
	5	1	1	1	1
724 ± 13,176	0	659 ± 12442	321 ± 6438	1.01 ± 0.39	1 ± 0.12
	4	1.05 ± 1.2	1.02 ± 0.612	1	1
	5	1 ± 0.12	1 ± 0.058	1	1

as published by the U.S. Food and Drug Administration from a 1-year survey (October 2014 to October 2015) of 623 samples (38). *Salmonella* was not detected in any samples of shelled pecans at retail, with a prevalence 95% CI of 0 to 0.59% (39).

Risk estimates per serving. The distribution of the estimated risk per contaminated serving of pecans (Table 5) represents the probability in the U.S. population of acquiring salmonellosis due to the consumption of a *Salmonella*-contaminated pecan serving. These estimates come from combining the FAO-WHO (16) dose-response function with the results of the exposure assessment module (levels of *Salmonella* per contaminated serving, Table 4). Table 5 shows the estimated mean risk per serving due to the consumption of pecans in the United States based on the two conditioning processes (cold and hot) and the six log-reduction levels (0-, 1-, 2-, 3-, 4-, and 5-log reductions) for pecans consumed as a core product uncooked, as an ingredient in uncooked products, and as an ingredient in cooked products. These results contain 12 sets of statistics: six microbial reduction treatment levels each for the cold and hot conditioning process. The columns (mean, standard deviation, and 95% CI) represent variability, and the rows (mean estimate with 95% CI) represent the uncertainty of the estimates. The interval between the 2.5% and the 97.5% quantiles may be considered the 95% CI of uncertainty in the estimates. Variability represents the heterogeneity of the data (and is thus cannot be reduced by increased data collection), and uncertainty is an expression of the lack of knowledge and can be reduced by adding data (25). The impact of variability on the risk estimates per serving is much larger than that of uncertainty (Table 5). For example, the mean risk estimate per serving for consumption of pecans as an uncooked core product processed without a microbial reduction treatment with cold conditioning has a 6-log variability span (8.5×10^{-12} to 4.2×10^{-6}) and a 1-log uncertainty span (5.2×10^{-7} to 5.6×10^{-6}). Similarly, the mean risk estimate per serving for consumption of pecans as an uncooked core product processed without a microbial

reduction treatment with a hot conditioning step is 5.3×10^{-11} with a 6-log variability span (2.3×10^{-16} to 1.5×10^{-10}) and a 1-log uncertainty span (2.1×10^{-11} to 2.4×10^{-10}). The risk at random varies among contaminated servings by about 6 log units (2.5 to 97.5% quantile risk estimates) across all microbial reduction treatment levels and both conditioning processes for consumption of pecans as an uncooked core product and as an ingredient in an uncooked product (Table 5). Higher levels of variability, which have an 8-log span on average, are seen for the risk at random arising from the consumption of pecans as an ingredient in a cooked product. The reasons for the higher variability for cooked pecans could be the variable *Salmonella* levels in contaminated servings as a result of cooking. The uncertainty span is approximately 1 log CFU over all microbial reduction treatment levels, conditioning processes, and types of pecan products consumed (Table 5). Uncertainties considered include uncertainty in the probability of *Salmonella* contamination, contamination levels, the survival model parameters during storage, conditioning, and drying, and process conditions that are part of the exposure assessment model (e.g., time and temperature). No uncertainty in the dose-response was included in these results.

The highest mean risk per serving was found for pecans consumed uncooked with a process that involved a cold conditioning step (use of chlorinated water at ambient temperature of ~20 to 25°C) with no microbial reduction treatment (Table 5). The relative risk of salmonellosis per 100,000 servings for consumption of pecans with either a hot or a cold conditioning step and all log microbial reduction treatment levels is presented in Figure 4 relative to the risk per 100,000 servings from consumption of pecans as an ingredient in a cooked product that had received a 5-log reduction treatment (i.e., the lowest mean risk estimate across all conditions). Decreasing mean risk estimates are found as the microbial reduction treatment level increases, the conditioning process is hot (steam or hot water), and/or the pecans are consumed as an ingredient in cooked products (Table 5 and Fig. 4). The mean risk per serving for pecans that undergo a hot conditioning process is higher (at any

TABLE 5. *Salmonellosis risk per serving for consumption of pecans in the U.S. population^a*

Conditioning ^b	Microbial reduction treatment ^c	Risk measure ^d	Core uncooked					Ingredient uncooked					Ingredient cooked																
			Mean	SD	2.5% quantile	97.5% quantile	95% CI	Mean	SD	2.5% quantile	97.5% quantile	95% CI	Mean	SD	2.5% quantile	97.5% quantile	95% CI												
Cold	0	Estimate	1.3E-06	2.7E-05	8.5E-12	4.2E-06	2.1E-07	4.5E-06	1.0E-12	7.0E-07	8.0E-13	2.5E-11	2.8E-20	1.1E-12	95% CI	5.2E-07	6.6E-06	4.6E-13	2.0E-06	8.6E-08	1.1E-06	6.1E-14	3.2E-07	2.8E-13	5.0E-12	1.5E-21	4.0E-13		
		Estimate	5.6E-06	4.1E-04	6.8E-11	8.0E-06	1.1E-06	6.5E-05	8.1E-12	1.3E-06	8.1E-12	7.0E-12	5.1E-10	2.3E-19	1.1E-13	95% CI	1.3E-07	2.6E-06	8.5E-13	4.3E-07	2.1E-08	4.4E-07	1.0E-13	7.1E-08	8.2E-14	2.4E-12	2.8E-21	1.1E-13	
		Estimate	5.5E-08	6.7E-07	4.6E-14	2.0E-07	8.9E-09	1.1E-07	6.1E-15	3.4E-08	6.1E-15	3.4E-08	2.9E-14	1.5E-22	3.9E-14	95% CI	5.7E-07	3.6E-05	7.0E-12	8.4E-07	9.8E-08	5.6E-06	8.1E-13	1.4E-07	7.5E-13	5.2E-11	2.3E-20	2.6E-13	
		Estimate	1.3E-08	2.8E-07	8.5E-14	4.3E-08	2.1E-09	4.4E-08	1.0E-14	7.2E-09	8.2E-15	2.5E-13	2.8E-22	1.0E-14	7.2E-09	95% CI	5.6E-09	7.1E-08	4.6E-15	2.0E-08	9.1E-10	1.1E-08	6.1E-16	6.1E-16	3.3E-09	2.9E-15	5.4E-14	1.5E-23	3.6E-15
		Estimate	6.3E-08	4.0E-06	7.0E-13	8.4E-08	1.1E-08	6.3E-07	8.1E-14	1.4E-08	6.5E-14	4.9E-12	2.3E-21	2.3E-21	2.3E-21	95% CI	1.3E-09	2.9E-08	8.5E-15	3.9E-09	2.2E-10	4.5E-09	1.0E-15	6.5E-10	6.5E-10	8.3E-16	2.5E-14	2.8E-23	1.1E-15
	1	Estimate	5.5E-10	7.2E-09	4.6E-16	1.9E-09	9.0E-11	1.1E-09	6.1E-17	3.1E-10	2.8E-16	5.6E-15	1.5E-24	1.5E-24	95% CI	6.5E-09	4.0E-07	7.0E-14	7.7E-09	1.0E-09	5.6E-08	8.1E-15	1.3E-09	6.6E-15	4.9E-13	2.3E-22	2.4E-15		
		Estimate	1.3E-10	2.9E-10	8.5E-16	4.1E-10	2.2E-11	4.7E-10	1.0E-16	6.8E-11	8.4E-17	2.6E-15	2.8E-24	1.1E-16	95% CI	5.4E-11	7.2E-10	4.6E-17	2.0E-10	8.9E-12	1.2E-10	6.1E-18	3.2E-11	2.7E-17	5.0E-16	1.5E-25	4.0E-17		
		Estimate	6.2E-10	4.1E-08	7.0E-15	7.7E-10	9.6E-11	6.0E-09	8.2E-16	1.3E-10	6.7E-16	5.1E-14	2.3E-23	2.5E-16	95% CI	1.3E-11	2.9E-10	8.5E-17	4.3E-11	2.2E-12	4.6E-11	1.0E-17	7.0E-12	7.8E-18	2.4E-16	2.8E-25	1.1E-17		
		Estimate	5.5E-12	7.3E-11	4.6E-18	2.0E-11	8.8E-13	1.2E-11	6.1E-19	3.4E-12	3.0E-18	5.1E-17	1.5E-26	4.0E-18	95% CI	6.8E-11	4.2E-09	7.0E-16	8.2E-11	9.8E-12	6.5E-10	8.2E-17	1.3E-11	5.7E-17	4.4E-15	7.8E-24	2.6E-17		
		Estimate	5.3E-11	1.2E-09	2.3E-16	1.5E-10	8.4E-12	1.8E-11	2.9E-17	2.5E-11	3.2E-17	1.0E-15	7.3E-25	3.9E-17	95% CI	2.1E-11	3.2E-10	1.2E-17	7.3E-11	3.4E-12	5.1E-11	1.7E-18	1.2E-11	3.2E-17	1.0E-15	7.8E-24	2.6E-17		
	2	Estimate	2.4E-10	1.9E-08	1.8E-15	2.8E-10	4.1E-11	2.5E-09	2.3E-16	4.7E-11	1.8E-16	4.2E-26	6.0E-26	1.4E-17	95% CI	5.1E-12	1.2E-10	2.3E-17	1.5E-11	8.4E-13	1.9E-11	2.9E-18	4.7E-11	3.2E-18	1.0E-16	7.8E-26	3.9E-18		
		Estimate	2.1E-12	2.9E-11	1.2E-18	7.4E-12	3.3E-13	4.4E-12	1.7E-19	1.2E-12	1.1E-18	1.9E-17	4.2E-27	1.4E-18	95% CI	2.6E-11	1.9E-09	1.8E-16	2.8E-11	4.3E-12	3.2E-10	2.3E-17	4.6E-12	2.8E-17	2.1E-15	6.0E-25	9.1E-18		
		Estimate	5.2E-13	1.2E-11	2.3E-18	1.5E-12	8.4E-14	1.8E-12	2.9E-19	2.5E-13	3.2E-19	1.0E-17	7.8E-27	3.9E-19	95% CI	2.1E-13	3.1E-12	1.2E-19	7.4E-13	3.4E-14	5.0E-13	1.7E-20	1.2E-13	1.1E-19	2.0E-18	4.2E-28	1.4E-19		
		Estimate	2.6E-12	1.6E-10	1.8E-17	2.9E-12	4.2E-13	2.4E-11	2.3E-18	4.7E-13	2.7E-18	2.0E-16	6.0E-26	9.1E-19	95% CI	5.3E-14	1.2E-12	2.3E-19	1.5E-13	8.5E-15	1.9E-13	2.9E-20	2.5E-14	3.2E-20	1.0E-18	7.8E-28	3.9E-20		
		Estimate	2.1E-14	3.2E-13	1.2E-20	7.4E-14	3.4E-15	5.1E-14	1.7E-21	1.2E-14	1.1E-20	2.0E-19	4.2E-29	1.4E-20	95% CI	2.2E-14	1.5E-11	1.8E-18	2.9E-14	3.9E-14	2.4E-12	2.4E-19	4.7E-14	2.4E-19	1.8E-17	6.0E-27	9.1E-20		
	3	Estimate	5.3E-15	1.2E-13	2.3E-20	1.5E-14	8.4E-16	1.9E-14	2.9E-21	2.5E-15	3.2E-21	1.0E-19	7.8E-29	3.9E-21	95% CI	2.1E-15	3.2E-14	1.2E-21	7.4E-15	3.4E-16	5.0E-15	1.7E-22	1.2E-15	1.1E-21	2.0E-20	4.2E-30	1.4E-21		
		Estimate	2.1E-15	3.2E-14	1.2E-21	7.4E-14	4.1E-15	2.5E-13	2.3E-20	4.7E-15	2.4E-20	1.9E-18	6.0E-26	9.1E-19	95% CI	2.3E-14	1.8E-12	1.8E-19	2.9E-14	4.1E-15	2.5E-13	2.3E-20	4.7E-15	2.4E-20	1.9E-18	6.0E-28	9.1E-21		
		Estimate	5.3E-16	1.2E-14	2.3E-21	1.5E-15	8.4E-17	1.9E-15	2.9E-22	2.5E-16	3.2E-22	1.0E-20	7.8E-28	3.9E-22	95% CI	2.1E-16	3.2E-15	1.2E-22	7.4E-16	3.4E-17	5.0E-16	1.7E-23	1.2E-16	1.1E-22	2.0E-21	4.2E-31	1.4E-22		
		Estimate	2.4E-15	1.9E-13	1.8E-20	2.9E-15	4.2E-16	2.5E-14	2.3E-21	4.7E-16	2.4E-21	1.9E-19	6.0E-29	9.1E-22	95% CI	2.4E-15	1.9E-13	1.8E-20	2.9E-15	4.2E-16	2.5E-14	2.3E-21	4.7E-16	2.4E-21	1.9E-19	6.0E-29	9.1E-22		
		Estimate	2.1E-16	3.2E-15	1.2E-22	7.4E-16	3.4E-17	5.0E-16	1.7E-23	1.2E-16	1.1E-22	2.0E-21	4.2E-31	1.4E-22	95% CI	2.4E-16	3.2E-15	1.2E-22	7.4E-16	3.4E-17	5.0E-16	1.7E-23	1.2E-16	1.1E-22	2.0E-21	4.2E-31	1.4E-22		

^a Pecans were consumed as a core product uncooked, an ingredient in an uncooked product, or an ingredient in a cooked product.
^b Whether the conditioning process was done using steam or hot water (hot), thus assuming a 4- to 5-log reduction in *Salmonella*, or by immersion in chlorinated water (cold), thus assuming no reduction in *Salmonella*.
^c Microbial reduction treatment resulting in 0-, 4-, or 5-log reductions in *Salmonella*.
^d 95% CI (confidence interval) representing the lower (top) and upper (bottom) range of values within which there is a 95% probability of finding the true value.

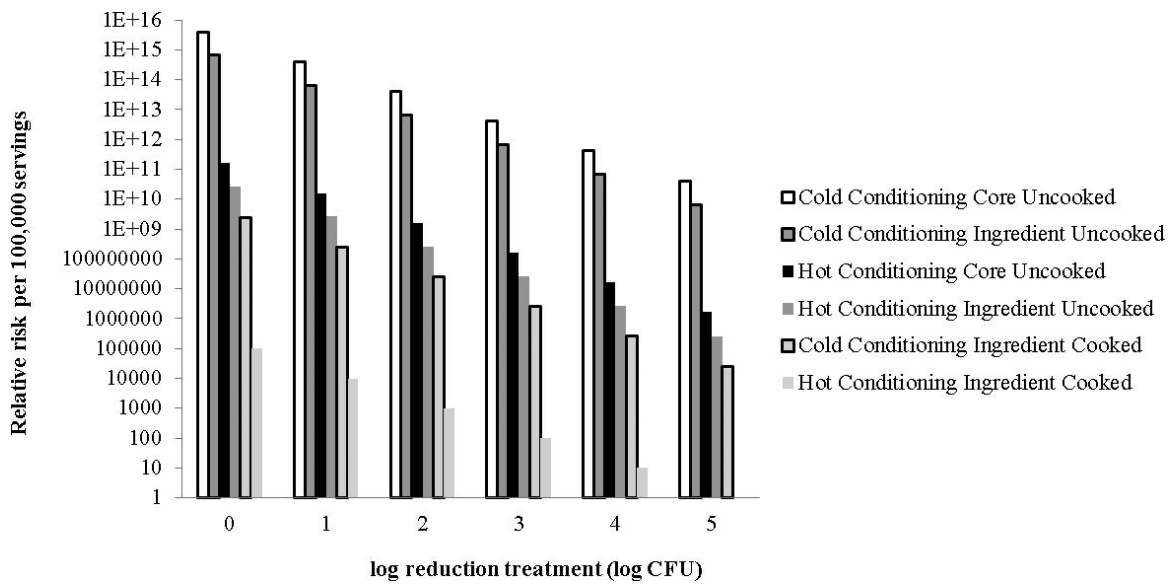


FIGURE 4. Relative risk of salmonellosis per 100,000 servings of pecans processed with a hot (steam or hot water, assuming a 4- to 5-log reduction in *Salmonella*) or a cold (immersion in chlorinated water, assuming no reduction occurs) conditioning step and various microbial reduction treatments relative to the risk per 100,000 servings of pecans as an ingredient cooked after having received a 5-log reduction treatment. Core, pecan product in which $\geq 80\%$ of the ingredients are pecans (including whole pecans); ingredient, pecan products in which $< 80\%$ of the ingredients are pecans; uncooked, pecans that are not further cooked at home; cooked, pecans that receive a cooking step at home (assuming a 5-log reduction in *Salmonella*).

microbial reduction treatment level) for pecans consumed as a core product uncooked followed by pecans consumed as an ingredient in an uncooked product and pecans consumed as an ingredient in a cooked products. Similarly, the mean risk per serving is higher for those pecans that receive a lower microbial reduction treatment level, assuming the conditioning step and type of pecan product consumed remain the same. Differences in estimated risk for the different types of pecan products consumed can be attributed to the *Salmonella* reduction step when consuming cooked pecans and, to a lesser degree, to differences in the pecan serving size when consuming pecans as a core product or ingredient (Fig. 4).

For the cold conditioning process, the mean risk values correspond to approximately one case of salmonellosis per 100 million, 1 billion, 10 billion, and 100 billion servings for a 2-, 3-, 4-, and 5-log reduction treatment, respectively, for pecans consumed as a core product uncooked; 1 billion, 10 billion, 100 billion, and 1 trillion servings, respectively, for pecans consumed as an ingredient in an uncooked product; and 100 trillion, 1,000 trillion, 10,000 trillion, and 100,000 trillion servings, respectively, for pecans consumed as an ingredient in a cooked product. For the hot conditioning process, these mean risk estimate values correspond to approximately one case of salmonellosis per 1 trillion, 10 trillion, 100 trillion, and 1,000 trillion servings for a 2-, 3-, 4-, and 5-log reduction treatment, respectively, for pecans consumed as a core product uncooked; 10 trillion, 100 trillion, 1,000 trillion, and 10,000 trillion servings, respectively, for pecans consumed as an ingredient in an uncooked product; and 1 million trillion, 10 million trillion, 100 million trillion, and 1,000 million trillion servings, respec-

tively, for pecans consumed as an ingredient in a cooked product.

Risk estimates per year. The estimated number of servings of pecans consumed as a core product uncooked, an ingredient in an uncooked product, and an ingredient in a cooked product were 4.1×10^8 , 1.8×10^9 , and 3.5×10^{10} , respectively. These data combined with the estimated risk per serving provided the estimates for salmonellosis cases per year in the United States from consumption of pecans as a core product uncooked, an ingredient in an uncooked product, and an ingredient in a cooked product shown in Table 6. The type of conditioning process, the microbial reduction treatment level, and the use of a cooking step before consumption of the final product all have an impact on the number of estimated salmonellosis cases. For postprocess storage at temperatures at which *Salmonella* levels do not decrease (refrigeration or freezing), a threefold increase in predicted risk was observed. For pecans that have undergone a hot conditioning step and/or a cooking step before consumption, less than one salmonellosis case per year is the mean estimate for all microbial reduction treatment levels. For pecans that have undergone a conditioning step in chlorinated water at ambient temperature (~ 20 to 25°C) with no microbial reduction treatment, a mean of 529 salmonellosis cases per year (95% CI: 213 to 2,295 cases) is estimated for those pecans consumed as a core product uncooked and 373 cases per year (95% CI: 150 to 1,961 cases) is estimated for pecans consumed as an ingredient in an uncooked product. Addition of a microbial reduction treatment to cold conditioning decreases the mean estimated cases per year significantly; a minimum 3-log reduction treatment resulted in an estimated mean risk of

TABLE 6. Estimated salmonellosis cases per year from consumption of *U.S. pecans*^a

Conditioning ^b	Microbial reduction treatment ^c	No. of cases measure ^d	Core uncooked	Ingredient uncooked	Ingredient cooked
Cold	0	Estimate	529	373	<1
		95% CI	213	150	<1
	1	Estimate	2,295	1,961	<1
		95% CI	54	37	<1
		Estimate	22	16	<1
	2	95% CI	235	172	<1
		Estimate	5	4	<1
		95% CI	2	2	<1
	3	Estimate	26	18	<1
		95% CI	<1	<1	<1
		Estimate	<1	<1	<1
	4	95% CI	3	2	<1
		Estimate	<1	<1	<1
		95% CI	<1	<1	<1
	5	Estimate	<1	<1	<1
95% CI		<1	<1	<1	
Estimate		<1	<1	<1	
Hot	0	95% CI	<1	<1	<1
		Estimate	<1	<1	<1
	1	95% CI	<1	<1	<1
		Estimate	<1	<1	<1
		95% CI	<1	<1	<1
	2	Estimate	<1	<1	<1
		95% CI	<1	<1	<1
		Estimate	<1	<1	<1
	3	95% CI	<1	<1	<1
		Estimate	<1	<1	<1
		95% CI	<1	<1	<1
	4	Estimate	<1	<1	<1
		95% CI	<1	<1	<1
		Estimate	<1	<1	<1
	5	95% CI	<1	<1	<1
Estimate		<1	<1	<1	
95% CI		<1	<1	<1	

^a Pecans were consumed as a core product uncooked (0.7% of individuals, 4.09E+08 servings), an ingredient in an uncooked product (3% of individuals; 1.75E+09 servings), or an ingredient in a cooked product (6% of individuals; 3.54E+10 servings).

^b Whether the conditioning process was done using steam or hot water (hot), thus assuming a 4- to 5-log reduction in *Salmonella*, or by immersion in chlorinated water (cold), thus assuming no reduction in *Salmonella*.

^c Microbial reduction treatment resulting in 0-, 1-, 2-, 3-, 4-, or 5-log reductions in *Salmonella*.

^d 95% CI (confidence interval) representing the lower (top) and upper (bottom) range of values within which there is a 95% probability of finding the true value.

less than one case of salmonellosis (95% CI: less than one to three cases) per year for pecans consumed uncooked both as a core product and as an ingredient in the absence of any atypical situations, such as those described below.

Assuming 80% of the pecans sold at retail are sold shelled and 77% of these undergo a hot conditioning step

with no additional microbial reduction treatment, the model estimates 203 cases of salmonellosis per year (95% CI: 82 to 881 cases) for pecans (in-shell and shelled) consumed uncooked. A 4-log reduction treatment would reduce the number of cases of salmonellosis per year to less than one, including uncertainty.

Estimated risk from the modeled atypical situations. As expected, the estimated risk of salmonellosis arising from consumption of pecans as a core product uncooked under any of the modeled atypical situations is higher than that seen for the baseline model (assuming equal conditioning type and microbial reduction treatment level; Table 7 and Fig. 5). The atypical situation that had the greatest impact on risk for all processing conditions is delay in drying (Table 7 and Fig. 5), where the growth of *Salmonella* after conditioning leads to risks per serving that are approximately 10-fold higher than those for the baseline model with any microbial reduction treatment level and conditioning type. Recontamination and cattle grazing had decreasing impacts on risk. The increase in initial *Salmonella* contamination levels in pecans was directly proportional to the estimated increase in the risk estimates per serving. Even though there is an approximately sixfold increase in initial *Salmonella* levels in the cattle grazing exceptional situation, conditioning and microbial reduction treatment have an impact on risk estimates per serving (Table 7). In the recontamination atypical situation, a mean (\pm standard deviation) increase of 174 (\pm 239) CFU per contaminated lot after conditioning results in risk estimates that are fourfold higher than those with the baseline cold conditioning process at any microbial reduction treatment level. However, this increase in *Salmonella* levels in the recontamination event results in risk estimates that are 4-log higher than baseline for pecans that undergo a hot conditioning process at any microbial reduction treatment level because recontamination is modeled to occur post-conditioning, when the *Salmonella* level in the baseline model tends to be lower. Risk estimates per serving in the recontamination event are influenced by the microbial reduction treatment level, each increasing level reducing the risk 10-fold (Table 7). However, because of the recontamination event, the conditioning step does not have as large an effect on risk estimates; the risk estimates for pecans under cold conditioning are only sixfold higher than those for pecans under hot conditioning after the recontamination event, when a 5-log decrease in risk level is observed for the baseline process model. This is an example of the possible outcome from an atypical situation in the processing system when it occurs postconditioning (and pecans undergo no further microbial reduction treatment).

The number of cases per year linked to this kind of atypical situation is equal to the number of cases linked to the situation multiplied by the number of situation events in that year. Although it is not possible to predict the number of cases per year for each atypical situation because it is not known how many such events occur in a year, the risk estimates obtained from the modeled atypical situations provide an estimate of the significance of such a situation

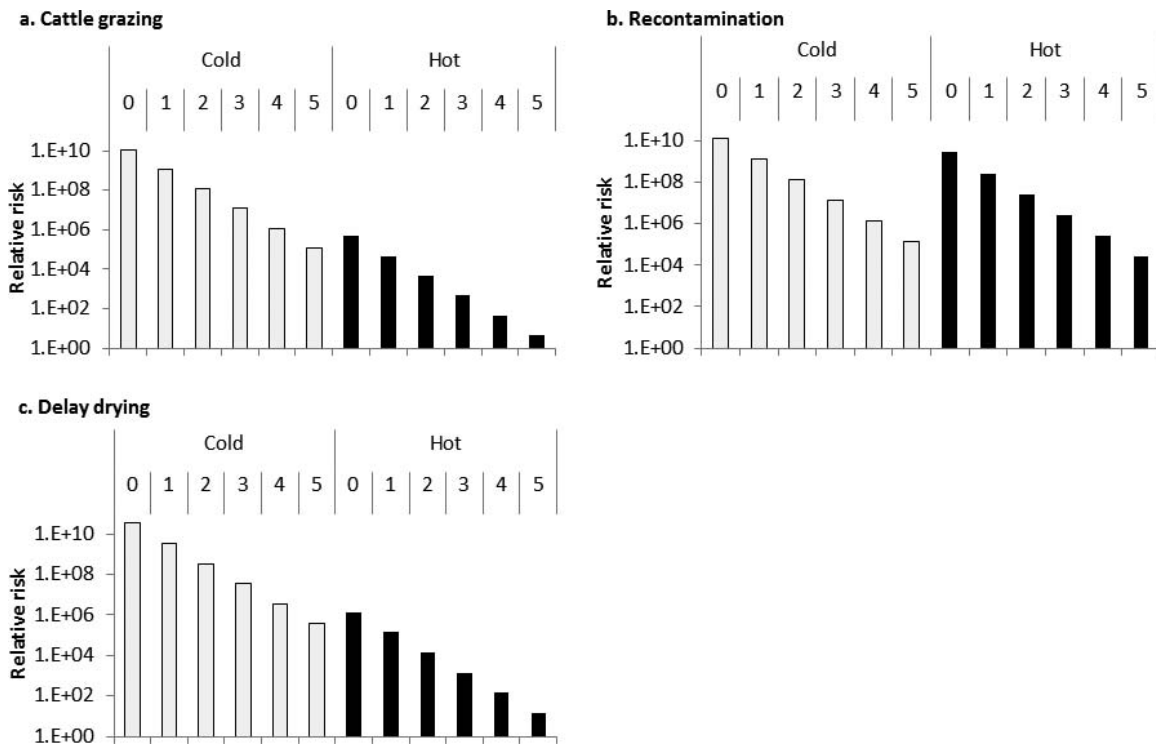


FIGURE 5. Risk per serving of pecans consumed as a core product uncooked assuming either a hot (4- to 5-log reduction) or a cold (no reduction) conditioning step and various microbial reduction treatments (0, 1, 2, 3, 4, and 5 log CFU) relative to the risk per serving in the baseline model assuming hot conditioning and a 5-log reduction treatment. (a) Atypical situation assuming that cattle grazing at the pecan orchard floor would lead to sixfold higher initial levels of *Salmonella* on pecans; (b) atypical situation assuming a recontamination event occurs postconditioning during cracking (resulting in *Salmonella* recontamination at 0.5 to 3 log CFU); (c) atypical situation assuming a postconditioning delay in drying pecan kernels that have been separated from the shells through water flotation.

TABLE 7. *Salmonellosis* risk per serving in the U.S. population for consumption of pecans as a core product uncooked after three atypical situations

Conditioning ^a	Microbial reduction treatment ^b	Cattle grazing ^c		Recontamination ^d		Delay in drying ^e	
		Mean	SD	Mean	SD	Mean	SD
Cold	0	61,200	3.4	74,000	14.8	179,700	46.8
	1	6,200	3.1E-01	7,360	1.5	18,600	4.9
	2	616	3.1E-02	733	1.4E-01	1,800	4.7E-01
	3	61.6	3.3E-03	75.7	1.4E-02	187	4.8E-02
	4	6.2	3.4E-04	7.6	1.6E-03	19	5.1E-03
Hot	5	6.2E-01	3.2E-05	7.5E-01	1.5E-04	1.9	5.0E-04
	0	2.4	1.5E-04	14,500	9.5E-01	7.49	2.1E-03
	1	2.4E-01	1.5E-05	1,450	8.6E-02	7.4E-01	2.1E-04
	2	2.4E-02	1.5E-06	146	9.2E-03	7.4E-02	2.2E-05
	3	2.4E-03	1.5E-07	14.5	8.8E-04	7.2E-03	2.1E-06
	4	2.4E-04	1.5E-08	1.5	8.4E-05	7.4E-04	2.1E-07
	5	2.4E-05	1.5E-09	1.5E-01	8.4E-06	7.5E-05	2.1E-08

^a Whether the conditioning process was done using steam or hot water (hot), thus assuming a 4- to 5-log reduction in *Salmonella*, or by immersion in chlorinated water (cold), thus assuming no reduction in *Salmonella*.
^b Microbial reduction treatment resulting in 0-, 1-, 2-, 3-, 4-, or 5-log reductions in *Salmonella*.
^c Atypical situation assuming that cattle grazing at the pecan orchard floor would lead to sixfold higher initial levels of *Salmonella* contamination on pecans.
^d Atypical situation assuming a recontamination event occurs postconditioning during cracking, resulting in *Salmonella* recontamination at 0.5 to 3 log CFU.
^e Atypical situation assuming a postconditioning delay in drying pecan kernels that have been separated from the shells through water flotation.

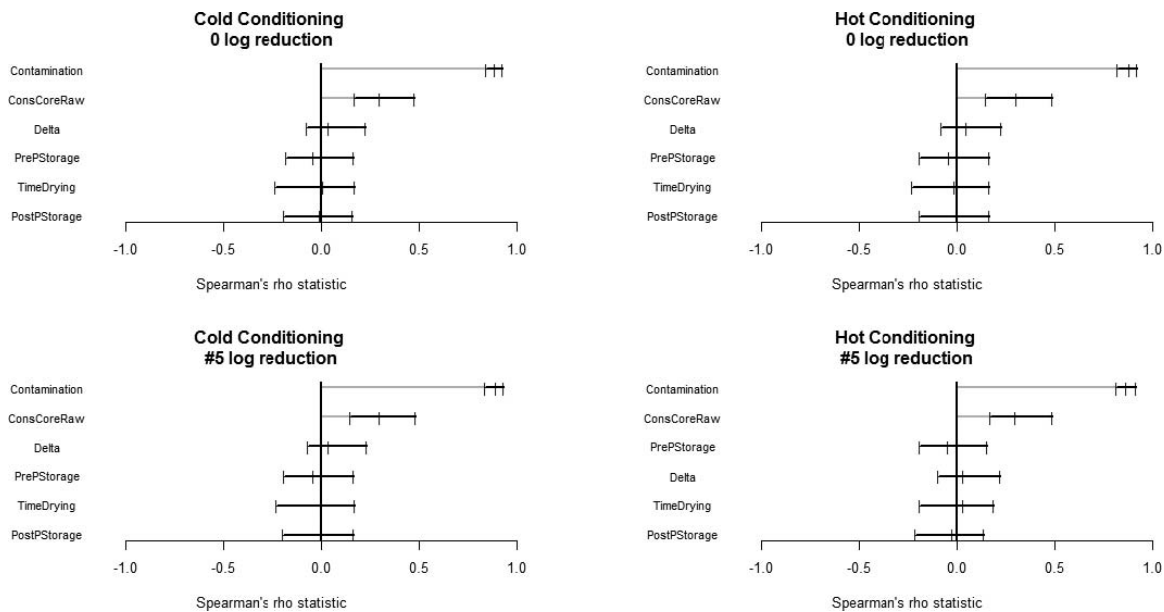


FIGURE 6. Spearman rho statistic for the baseline risk assessment model (hot and cold conditioning and 0- and 5-log microbial reduction treatment) with risk per serving from consumption of pecans as a core product consumed uncooked as the outcome variable. Contamination, initial *Salmonella* contamination; ConsCoreRaw, serving sizes for pecans consumed as a core product uncooked; Delta, time (weeks) to reduce the *Salmonella* population by 1 log CFU per contaminated unit at 23°C; PrePStorage, preprocess storage time (weeks); TimeDrying, drying time (min) for the first drying step; PostPStorage, postprocess storage time (weeks).

compared with the baseline model scenario and the impact such an atypical situation could have on risk (changes in the order of magnitude).

Even though the atypical situation (e.g., cattle grazing) occurred before conditioning and before the microbial reduction treatment and thus resulted in higher risk estimates per serving compared with the baseline model (for any microbial reduction treatment level or conditioning process), these risk estimates decreased as the microbial reduction treatment level increased from 0 to 5 log CFU and with a hot conditioning process (similar to the trend seen with the baseline model). However, the atypical situations modeled to occur after conditioning (delay in drying and recontamination) resulted in mean risk estimates of illness per serving that were not significantly affected by microbial reduction treatment or conditioning (other than how those processes affect the background levels of *Salmonella* up to the point of the event). This finding highlights the fact that process control through microbial reduction treatments may be insufficient when the atypical situation in the system occurs after treatment (e.g., cross-contamination).

Sensitivity analysis. The sensitivity analysis results of the baseline risk assessment model indicate that the main variable affecting the risk outcome is the initial distribution of *Salmonella* levels on pecans in the shell (Contamination; Fig. 6). The Spearman rho statistic for initial contamination at any microbial reduction treatment level and conditioning process is close to 1: 0.90 with cold conditioning and 0-log reduction treatment (i.e., no treatment), 0.91 for cold conditioning and 5-log reduction treatment, 0.89 for hot conditioning and 0-log reduction treatment, and 0.89 for hot conditioning and 5-log reduction treatment. Consumption

patterns (ConsCoreRaw) significantly influence the risk estimate but to a smaller extent (Spearman $\rho < 0.5$). Other factors such as PostPStorage (postprocess storage time), Delta (time associated with *Salmonella* survival kinetics required to reduce the population by 1 log CFU), and PrePStorage (preprocess storage time) and the time pecans are dried in-shell (first drying) have less influence on the risk estimate. Increasing drying and storage times result in decreased levels of risk, which is the reason for the negative Spearman rho values found for these factors (Fig. 6).

The Spearman rho statistic for the factors specific to each atypical situation are presented in Figure 7 for pecan kernels produced with cold conditioning and a 0-log microbial reduction treatment and consumed as a core product uncooked. The added contamination level at the initial step of the process in the cattle grazing atypical situation and after conditioning and cracking in the recontamination atypical situation are the main drivers of risk in both atypical situations modeled. Background *Salmonella* levels (Contamination factor) in the cattle grazing and recontamination atypical situations have less influence on risk estimates than do factors such as consumption patterns. In the modeled atypical situation of delay in drying, initial contamination levels are still the main factor influencing the risk estimate, followed by consumption patterns. The growth rate of *Salmonella* on pecans per day in the delay in drying event (Growth) is the third major influence factor on risk estimates (Fig. 7). The duration of the delay in the delay in drying atypical situation (Time) does not have a major influence on risk estimates (Fig. 7).

In conclusion, we evaluated the impact of microbial reduction treatments, which reduce *Salmonella* levels on pecans, on the risk of human salmonellosis cases arising

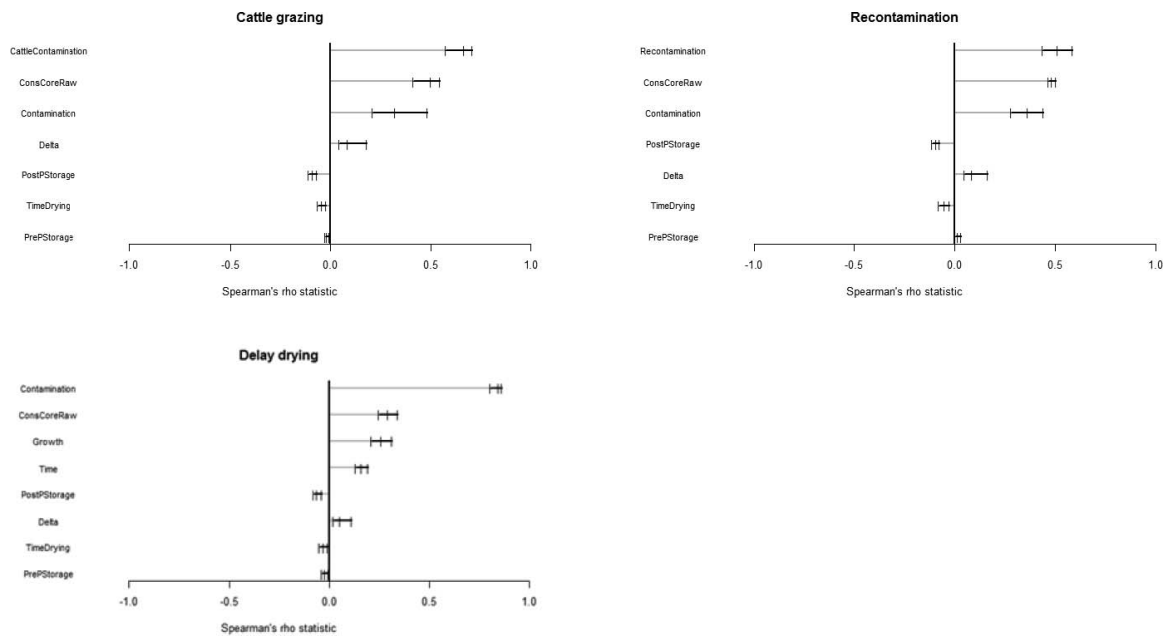


FIGURE 7. Spearman rho statistic for the atypical situations of cattle grazing, recontamination, and delay in drying considering a cold conditioning process and a 0-log microbial reduction treatment with risk per serving from consumption of pecans as a core product consumed uncooked as the outcome variable. Contamination, Delta, ConsCoreRaw, SizePack, PostPStorage, TimeDrying and PrePStorage are defined as in Figure 6. CattleContamination, added initial Salmonella contamination due to cattle grazing; Recontamination, added Salmonella contamination due to recontamination; Growth, growth per day of Salmonella on pecan kernels; Time, duration (days) of the delay in drying.

from the consumption of pecans in the United States. Other risk assessments of *Salmonella* on tree nuts include those for almonds (13, 22, 33). In the most recent almond risk assessment, Santillana Farakos et al. (33) found that a 3-log reduction treatment of U.S. almonds resulted in a predicted mean risk of salmonellosis of two cases per year for almonds consumed as a core product uncooked at home (95% CI: one to four cases), one case per year for almonds consumed as an ingredient in an uncooked product at home (95% CI: one to two cases), and less than one case per year for almonds consumed as an ingredient in a cooked product 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 of less than one case per year for U.S. almonds consumed as a core product or as an ingredient in an uncooked product at home. The risk of consuming almonds as an ingredient of a product cooked at home was less than one case per year, including uncertainty for all microbial reduction treatment levels modeled.

The estimated annual public health burden from consumption of pecans as a core product uncooked at home is highly dependent on whether the pecans have been shelled and if so what type of conditioning process they have undergone. Similar to the results for almonds (33), assuming all pecans are sold in-shell or have been shelled using cold conditioning, a 4-log reduction treatment would reduce the number of salmonellosis cases per year to less than one, including uncertainty for consumption of pecans as a core product or as an ingredient in an uncooked product at home. Pecans consumed cooked at home have an estimated risk of less than one case per year regardless of treatment level.

Hot conditioning and microbial reduction treatment have a significant impact on the predicted mean risk of illness from consumption of U.S. pecans. A hot conditioning process decreases the predicted risk by an average of 4 log units, assuming the rest of the process remains the same. The predicted salmonellosis risk per serving for pecans consumed uncooked decreases even more when the process includes a microbial reduction treatment. The microbial reduction treatment proportionally decreases predicted risk estimates as the microbial reduction treatment level increases from 1 to 5 log CFU. For instance, a 1-log CFU microbial reduction treatment level reduces the predicted risk estimate by 10-fold, and a 5-log CFU microbial reduction treatment level decreases the predicted risk estimate by 100,000-fold (5 log units). When the process includes a hot conditioning step and a microbial reduction treatment, the predicted risk is reduced by a minimum of 5 log units (when the microbial reduction treatment level is 1 log CFU) and the predicted risk decreases by up to 9 log units when the microbial reduction treatment level increases up to a 5-log reduction. For pecans consumed as an ingredient in cooked products (e.g., a pecan pie), the predicted risk decreases by 6 log units (1,000,000-fold) compared with pecans consumed as a core product uncooked following a cold conditioning process with no additional microbial reduction treatment.

The impact of variability (e.g., from serving to serving, from lot to lot, and from year to year) on predicted risk is much larger than the impact of the considered uncertainty in the model (e.g., *Salmonella* survival parameters, contamination levels, and process conditions). Initial *Salmonella* contami-

nation levels were the main driver of risk for all evaluated conditioning processes and microbial reduction treatments for pecans consumed as a core product uncooked, followed by serving size, and the size of the consumer package.

This risk assessment also included an assessment of the risk of salmonellosis cases as a result of a possible atypical situation in the production system before and/or after conditioning and/or microbial reduction treatment. Results of modeling such events serve to quantify the increased risk per serving from consumption of U.S. pecans in atypical situations that can occur after microbial reduction treatments in pecan processing compared with risk estimates associated with typical pecan processing.

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