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The Public Health Impact of Implementing a Concentration-Based Microbiological Criterion for Controlling *Salmonella* in Ground Turkey

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Despite initiatives to improve the safety of poultry products in the United States, progress has stalled, and salmonellosis incidence is still above Healthy People 2020's goal. One strategy to manage *Salmonella* and verify process control in poultry establishments is to implement microbiological criteria (MC) linked to public health outcomes. Concentration-based MC have been used by the food industry; however, the public health impact of such approaches is only starting to be assessed. This study evaluated the public health impact of a concentration-based MC for *Salmonella* in raw ground turkey consumed in the United States using a quantitative risk assessment modeling approach. The distribution of *Salmonella* concentration in ground turkey was derived from USDA-FSIS monitoring surveys. Other variables and parameters were derived from public databases, literature, and expert opinion. Based on considered concentrations, implementing a MC of 1 cell/g led to an estimated 46.1% reduction (preventable fraction, PF) in the mean probability of illness when consumer cooking and cross-contamination were included. The PF was consistent across scenarios including or excluding cross-contamination and cooking, with slightly lower mean PF when cross-contamination was included. The proportion of lots not compliant with the 1 cell/g MC was 1.05% in the main scenarios and increased nonlinearly when higher *Salmonella* concentrations were assumed. Assumptions on concentration variability across lots and within lots had a large impact, highlighting the benefit of reducing this uncertainty. These approach and results can help inform the development of MC to monitor and control *Salmonella* in ground turkey products.

KEY WORDS: Microbiological criteria; performance standards; poultry; risk assessment; risk-based model

1. INTRODUCTION

Every year in the United States (U.S.) foodborne nontyphoidal *Salmonella* spp. causes an estimated 1.2 million illnesses, 19,336 hospitalizations, and 378 deaths (Scallan et al., 2011), costing up to 11 billion dollars (Scharff, 2012). Despite public and private sector efforts, little progress has been made over the last years in reducing the incidence of *Salmonella* infection. In 2018 there were 18.3 salmonellosis cases per 100,000 individuals (Tack et al., 2019), well above the U.S. Centers for Disease Control and Prevention (CDC) Healthy People 2020 objective of 11.4 cases per 100,000 individuals (U.S. Office of Disease Prevention and Health Promotion, 2017). According to outbreak data, poultry is one of the main sources of salmonellosis, being potentially responsible for 10–29% of all *Salmonella* infections during 1998–2008 (Painter et al., 2013). The same study estimated that,

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across all considered pathogens, 19% of deaths were attributed to poultry, and 26% of these deaths were caused by *Salmonella* (Painter et al., 2013). Further, several high-profile multistate outbreaks and recalls involving poultry, specifically ground turkey and chicken parts (CDC, 2011c, 2014, 2019; Grinnell et al., 2013), have highlighted the need for more targeted action to reduce *Salmonella* contamination in poultry products.

To effectively control *Salmonella* in poultry a comprehensive approach throughout the food chain is required, ranging from poultry vaccination to consumer education (CDC, 2011b). One strategy for reducing *Salmonella* contamination is the use of microbiological criteria (MC). According to the Codex Alimentarius, MC define the acceptability of a food batch based on either the presence or absence of microorganisms (prevalence-based), or the number of microorganisms including parasites and/or the quantity of toxins/metabolites per unit of mass, volume, area, or lot (concentration-based) (Codex Alimentarius, 2013). Regulatory agencies often use MC to define and monitor compliance of the products they regulate, at specific points in the supply chain (Codex Alimentarius, 2013). For example, New Zealand established a MC to help control *Campylobacter* contamination in poultry products (New Zealand Ministry for Primary Industries, 2017), while the European Union applies MC for *Salmonella* at farm level (EFSA & ECDC, 2016) and for *Campylobacter* in broilers (European Commission, 2017). Similarly, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), the federal agency overseeing meat and poultry products, established prevalence-based *Salmonella* performance standards for selected meat and poultry products, including ground turkey, as part of the Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP) Final Rule (USDA-FSIS, 1996). MC have also been used by the private sector to verify process control and establish microbiological requirements for raw materials, ingredients, and end-products (Codex Alimentarius, 2013; Yiannas, 2016).

While traditionally MC have focused on the proportion of samples positive for the pathogen of interest (prevalence-based MC), recent studies have highlighted the potential effectiveness of MC based on pathogen concentration in samples (concentration-based MC) (Lambertini, Ruzante, Chew, Apodaca, & Kowalcyk, 2019; Oscar, 2020; Sampedro, Wells, Bender, & Hedberg, 2018). One study focused on chicken parts (Lambertini et al., 2019) while the second, conducted by another research group in parallel with the assessment presented here, examined the public health impact of implementing pathogen enumeration strategies to determine product acceptance in ground turkey (Sampedro et al., 2018). Further, a study from the Netherlands examined the impact of implementing a concentration-based MC for *Campylobacter* in broiler chicken meat (Nauta, Sanaa, & Havelaar, 2012; Swart, Mangen, & Havelaar, 2013). To advance the quantitative evaluation of different process control and MC approaches for poultry in the U.S. context, our study sought to develop and apply a probabilistic quantitative microbial risk assessment (QMRA) modeling approach to evaluate potential public health impacts of a concentration-based MC, specifically of 1 cell/g, for *Salmonella* in raw ground turkey, in conjunction with a lot-based intervention in noncompliant lots.

2. MATERIALS AND METHODS

2.1. Modeling Framework

A probabilistic QMRA forward modeling approach was used to model the major chain of events affecting consumer exposure to *Salmonella* in raw ground turkey (Fig. 1). Two main scenarios were compared: (1) All product is delivered to the market, independently of testing results (baseline scenario); (2) product lots that are not compliant with the concentration-based MC are assumed to undergo an intervention that reduces the associated risk to zero prior to entering the market (intervention scenario). A simulated population of 30,000 lots was modeled from packing to consumption. Model inputs and parameters are shown in Table I. The model, built in the R language (R Core Team, 2019), is available as Supporting Information.

2.2. Product Definition

Raw ground turkey was defined to include ground turkey and ground turkey patties. Mechanically separated turkey (MST) products were not included.

2.3. *Salmonella* Contamination in Product

The concentration of *Salmonella* in ground turkey was estimated using presence/absence and

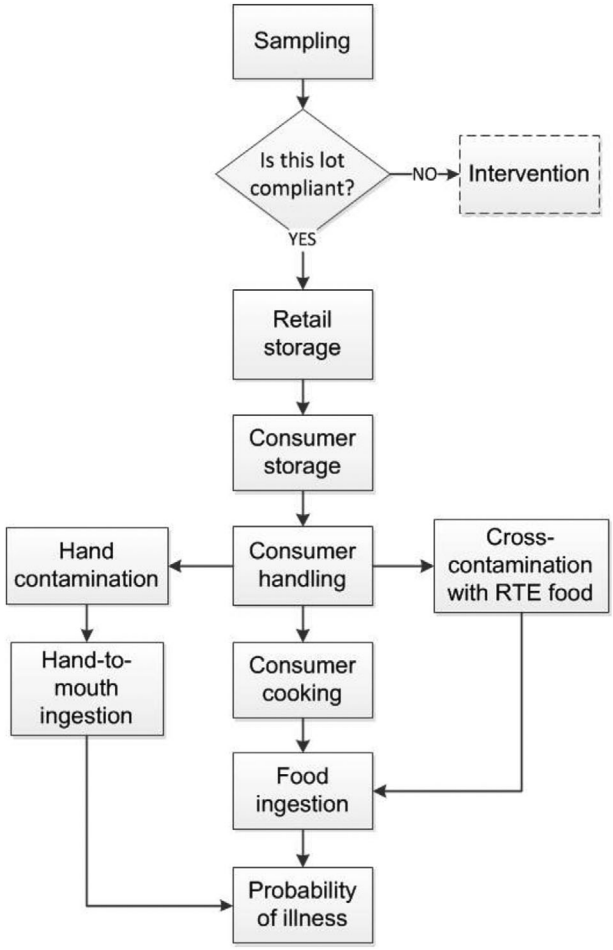

Fig 1. Sequence of events considered in the model.

enumeration data collected by FSIS during either routine inspections or exploratory surveys for comminuted turkey products between 2010 and 2016 (Table II). Concentration data was fit to a lognormal distribution using a Bayesian latent variable hierarchical model analogous to the approach of Williams and Ebel (2012); model code is provided in Supporting Information. Concentration data included: (1) results of presence/absence screening based on a 325 g product sample performed on all samples collected through the FSIS microbiological surveys (N = 4,284), and (2) tube scores from a most probable number (MPN) assay based on five serial dilutions and three replicates per dilution for a subset of samples that tested positive at screening (N = 179, Table II) (USDA-FSIS, 2019). Data were not weighted by establishment production volume, as this information was not available at the time of the study. The variance of the fitted distribution accounts for the combined variability from all sources represented in the data set, including concentration variability across establishments, lot-to-lot variability within each establishment, and variability across individual portions in each lot. The model, coded in JAGS (JAGS, 2016) and R, is available in Supporting Information. Model convergence was tested using the Heidelberger and Welch as well as the Gelman and Rubin diagnostic tests. Throughout the article, parameters of fitted lognormal curves are presented in natural (base e) logarithmic scale (ln) to be consistent with its common parametrization, while output distributions and their summary statistics are presented in either absolute or decimal logarithm (log) scale, for easier interpretation and visualization.

2.4. Portion Size

The distribution of portion sizes (g consumed per ingestion event) were estimated using two-day dietary recall data from the 2013–2014 cycle of the National Health and Nutrition Examination Survey (NHANES) (CDC, 2016). Participants consuming ground turkey (NHANES product code 24207000) and ground turkey patties (NHANES product code 27246300) were identified. NHANES oversamples certain subpopulations and assigns participants sample weights indicating the number of individuals in the U.S. population that the participant represents (Ahluwalia, Dwyer, Terry, Moshfegh, & Johnson, 2016; CDC, 2016). To estimate usual daily intake, NHANES recommends different approaches for foods that are episodically consumed (consumed daily by less than 5% of the population) and ubiquitously consumed (Ahluwalia et al., 2016; CDC, 2011a; Dwyer, Picciano, & Raiten, 2003). Only 75 NHANES participants consumed ground turkey in the 2013–2014 cycle, making it an episodically consumed food. Since only two of the 75 participants consumed ground turkey on both days, we were not able to employ NHANES-recommended methods for episodically consumed foods; hence, mean usual daily intake (total grams consumed in a day) as well as standard error of the mean and selected percentiles were estimated using weighted data from the first day of the dietary recall using PROC SURVEYMEANS in SAS 9.4 (SAS Institute, Cary, NC). Quantiles of the weighted distribution were fitted with a lognormal distribution. In the simulation, the distribution was truncated at the minimum and maximum weighted portion sizes observed (7.9 g and

Table 1. Variables and parameters included in the risk model

Variable	Description	Distribution	Parameters and calculations	Data source
Production and Sampling				
Lot weight	Weight of an average batch of ground turkey	Constant	2000 lb (907.2 Kg)	Industry expert, personal communication
Number of portions per lot	Number of individual ground turkey portions in a 2000-lb lot	Constant	Lot weight/mean portion weight = 9218 (rounded, based on mean portion weight of 98 g)	Calculated, based on portion weight distribution
Salmonella concentration in ground turkey	Number of cells per unit of product (sample or portion) enumerated before packaging. Represents the overall distribution including variability across lots and within lots.	Lognormal ($\mu_{overall}$, $\sigma_{overall}$)	$\mu_{overall}$: −10.724 ln (cells/g) $\sigma_{overall}$: 4.649 ln (cells/g)	Modeled from FSIS data obtained via FOIA
Salmonella concentration variability across lots	Proportion of overall concentration variance attributed to lot-to-lot variability	Constant	$Variance_{lot\text{-}to\text{-}lot}$ = $Coefficient\_Var_{lot\text{-}to\text{-}lot} \times (\sigma_{overall}^2)$ where $Coefficient\_Var_{lot\text{-}to\text{-}lot}$ = 0.7	Model assumption (Swart et al., 2013)
Salmonella concentration variability within lots	Proportion of overall concentration variance attributed to variability within each lot	Constant	$Variance_{within\text{-}lot}$ = $Coefficient\_Var_{within\text{-}lot} \times (\sigma_{overall}^2)$ where $Coefficient\_Var_{within\text{-}lot}$ = 0.3	Model assumption (Swart et al., 2013)
Salmonella concentration parameters for lots	Concentration parameters of lots, accounting for lot-to-lot variability	$\mu_{lot} \sim$ Lognormal ($\mu_{overall}$, $\sigma_{lot\text{-}to\text{-}lot}$)	$\mu_{overall}$: −10.724 ln (cells/g) as defined above $\sigma_{lot\text{-}to\text{-}lot}$ = sqrt($Variance_{lot\text{-}to\text{-}lot}$) = sqrt($0.7 \times \sigma_{overall}^2$)	Calculated
Salmonella concentration in portions within lots	Concentration assigned to portions within a lot, accounting for within-lot variability. $Conc_{sample}$ is also drawn from this distribution.	$Conc_{portion} \sim$ Lognormal (μ_{lot}, $\sigma_{within\text{-}lot}$)	$\sigma_{within\text{-}lot}$ = sqrt($Variance_{within\text{-}lot}$) = sqrt($0.3 \times \sigma_{overall}^2$) $Conc_{portion}$ ceiling: 10^3 cells/g	Calculated
Portion Size	Amount consumed per exposure event (day) by individuals that consumed ground turkey	Portion size ~ Lognormal ($\mu_{consumed}$, $\sigma_{consumed}$)	$\mu_{consumed}$: 4.41 ln g/day $\sigma_{consumed}$: 0.66 ln g/day Truncated at: 7.9 g (min) and 393 g (max)	CDC (2016)
Salmonella dose	Dose ingested with a portion		Dose = $Conc_{portion} \times$ Portion Size	Calculated
Number of samples per lot	Number of distinct samples collected per lot	Constant	1	Model assumption
MC threshold (or detection limit of the semi-quantitative testing assay)	*Salmonella* concentration above which a sample is scored as non-compliant, given a perfect assay	Constant	1 cell/g	Model assumption
Consumer handling/cooking				
Consumer Storage	Fridge temperature; proportion in fridge/freezer; storage duration.	Not applicable	Assumed no growth or decline.	Model assumption
Cooking reduction	Reduction in *Salmonella* cell numbers due to stove-top cooking of a patty	Constant	Complete elimination	Maughan et al. (2016)
Cooking compliance	% of portions cooked to 74°C	Constant	68.3 %	Maughan et al. (2016)

(*Continued*)

Table 1 (Continued)

Variable	Description	Distribution	Parameters and calculations	Data source
Undercooking reduction	Reduction in *Salmonella* cell numbers associated with partial cooking not reaching 74°C	Uniform	[1,7] Log cells/g	Model assumption
Cross-contamination from meat to hands	Probability of transfer	Log(proportion transferred) ~ Normal (μ, σ)	μ: −1.69; σ: 0.81	Hoelzer et al. (2012)
	Proportion of cells in patty available for transfer (extent of contact)	Constant	0.022	Model assumption
Cross-contamination from hands to mouth	Proportion of contamination on fingertips	Constant	0.06	AuYeung et al. (2008) and Rusin et al. (2002)
	Probability of transfer	Uniform	Range: Min 0.34, Max 0.41	AuYeung et al. (2008) and Rusin et al. (2002)
Cross-contamination from meat to board	Probability of transfer	Log(proportion transferred) ~ Normal (μ, σ)	μ: −1.45; σ: 1.39	Hoelzer et al. (2012)
	Proportion of cells in patty available for transfer (extent of contact)	Constant	0.022	Model assumption
Cross-contamination from board to salad	Probability of transfer	Log(proportion transferred) ~ Normal (μ, σ)	μ: −1.42; σ: 0.52	Hoelzer et al. (2012)
	Proportion of cells on cutting board available for transfer (extent of contact)	Constant	1	Model assumption
Risk characterization				
Dose-response and risk estimates	Probability of illness, based on number of *Salmonella* cells ingested (dose)	Beta-Poisson	P(illness) = 1–(1+dose × 0.01/β)^(−α) where $\alpha = 0.1324$, $\beta = 51.45$ 0.01 is a scaling factor	WHO/FAO (2002)
Preventable fraction (PF)	Proportion of the probability of illness that could be eliminated by implementing the MC and associated intervention		1-Mean Prob(Illness)$_{intervention}$/ Mean Prob(Illness)$_{baseline}$	Calculated

392.7 g), which were outside the 1–99% percentile of the fitted distribution. The model code is provided as Supporting Information.

2.5. Simulating Establishments, Lots, and Portions

Based on common industry practices, each lot was assumed to be 2,000 lbs (907.2 kg) and include 9,218 portions (assuming a mean portion size of approximately 98 g based on the truncated portion size distribution). *Salmonella* contamination in all lots was assumed to be nonzero, that is, any lot could potentially harbor some level of contamination, described by the lognormal distribution of concentrations. A separate prevalence parameter was not included, since the concentration distribution was fitted to both detected and nondetected data, with the nondetected assumed to include both "true zeros" and positive but nondetected samples. In simulating lots and portions within each lot, it was assumed that the overall variance observed in the data was the sum of a component (70%) due to variability across lots, and a component (30%) due to variability within lots (Swart et al., 2013). Variability across establishments was not included explicitly. The simulation of lots included three steps (Table I): (1) each simulated lot was randomly assigned the parameters of a lognormal concentration distribution ($\mu_{overall}$ and $\sigma_{lot\text{-}to\text{-}lot}$); (2) each portion within a lot was randomly assigned a concentration from the concentration distribution

Table II. Summary of Two FSIS Datasets Containing *Salmonella* MPN/g Levels, Considered in this Study

Summary statistic	Data Set 1	Data Set 2
FSIS sampling program name	Sampling for ground and other comminuted turkey (not mechanically separated)	NRTE (not-ready-to-eat) comminuted poultry exploratory sampling – turkeys
Collection years	2015–2016	2013–2015
Total no. samples screened[a]	1,361	2,923
No. samples positive at screening (%)[a]	197 (14.5%)	569 (19.5%)
No. MPN-enumerated samples[a]	28	151
No. of MPN-enumerated samples not detected via MPN (< 0.03 MPN/g)[b]	14	73
Mean of enumerated MPN samples (MPN/g)	18.2	1.2
Standard deviation (MPN/g)	63.9	4.9
Median (MPN/g)	0.11	0.09
Minimum (MPN/g)	<0.03	<0.03
Maximum (MPN/g)	240	43

[a]Data for noncomminuted product, such as mechanically separated turkey, were excluded. Samples of product (325 g) were screened and scored as detected or nondetected. A portion of the detected samples were further enumerated with a most probable number (MPN) assay of five dilutions and three replicates per dilution, using a 65 g aliquot of product homogenized in BPW (1:10 proportion). 100 ml aliquots of this homogenate suspension were used as the first MPN dilution. Subsequent MPN tubes were 1:10 dilutions of the first dilution (hence the five MPN dilutions represented 10, 1, 0.1, 0.01, and 0.001 g of the original ground turkey sample) (USDA-FSIS, 2019).
[b]If all tubes in the MPN assay were negative, the sample was considered to be below the lower quantification limit of 0.03 MPN/g (USDA-FSIS, 2014).

for the lot (μ_{lot} and $\sigma_{\text{within-lot}}$); and (3) the number of cells in each portion was derived by multiplying the concentration for the portion ($\text{Conc}_{\text{portion}}$, in cells/g) by the portion's weight (portion size, in g), randomly drawn from its distribution. Portion concentrations were subject to a ceiling of 1,000 cells/g by discarding draws above the ceiling. For computational simplicity, the number of *Salmonella* cells was considered as a continuous real number, that is, the theoretical mean number of cells in a portion was considered instead of a Poisson draw from such mean.

2.6. Sampling Strategy

Sampling and detection steps were modeled to include several elements of monitoring practices currently implemented for ground turkey in the United States. The model assumed that sampling occurred immediately before packing. Sampling frequency was assumed to be one sample per 2,000-lb lot, with all lots being sampled. It was assumed that samples were analyzed individually and not aggregated into a composite sample. Each sample was assumed to first undergo a presence/absence screening test, followed by enumeration if positive. The screening test consisted of the enrichment of an entire 325-g sample in liquid culture medium (USDA-FSIS, 2019). Accordingly, the probability of detection was estimated as the probability of having at least one cell in the sample, assuming the number of cells in a sample follows a Poisson distribution:

$$p_{detection} = 1 - exp\left(-Conc_{sample} * Weight_{sample}\right)$$

where $\text{Conc}_{\text{sample}}$ is the mean sample concentration drawn from the concentration distribution within the lot (lognormal distribution of parameters μ_{lot} and $\sigma_{\text{within-lot}}$), and $\text{Weight}_{\text{sample}}$ is the sample weight, drawn from a uniform distribution of 325 ± 32.5 g (USDA-FSIS, 2019). Sensitivity and specificity of the assay were assumed to be 100%, since this estimates the "upper boundary" of potential risk reduction under ideal testing conditions and avoids making additional confounding assumptions on these parameters.

2.7. MC Compliance Metrics

The MC threshold concentration considered in the intervention scenario was 1 cell/g, which was

set in a range where detection is likely using current assays. Different thresholds were considered as what-if scenarios. A lot was considered compliant without further testing if the sample was nondetected at screening. If the sample screened positive, the sample concentration ($Conc_{sample}$) was compared with the MC threshold (1 cell/g). If the sample concentration exceeded the MC threshold, the lot was considered noncompliant.

2.8. Risk Management Scenarios

Two main scenarios were compared: (1) all product is delivered to the market, independent of testing results (i.e., no intervention); and (2) product lots that are found noncompliant with the MC are treated in a way that cause the associated risk of *Salmonella* illness to become zero. This intervention represents the best-case scenario of the maximum risk reduction attainable with this approach. Computationally, this approach is analogous to partitioning the risk into two components associated with compliant and noncompliant lots.

2.9. Retail Handling and Transportation

As a simplifying assumption, the model assumed no change (i.e., no growth or die-off) in *Salmonella* prevalence or concentration during transportation to retailers, at retail, or transportation from retail to homes. No cross-contamination was assumed to occur across portions, for example, patties, when in the same package.

2.10. Consumer Handling

The main route of exposure considered in the model was ingestion of a ground turkey patty. In selected scenarios, exposure routes associated with cross-contamination in consumers' kitchens were also considered. Upon entering the consumer's home, the raw unfrozen product was assumed to undergo the following steps: (1) refrigeration for a defined time duration (no change in *Salmonella* levels); no freezing or thawing were considered; (2) temporary storage at room temperature before cooking (no change in *Salmonella* levels); (3) touching raw ground turkey with hands and subsequently touching the mouth; (4) cross-contamination between raw ground turkey and a ready-to-eat (RTE) product, such as a vegetable salad, resulting from raw meat touching a cutting board, and subsequent contact between the contaminated board and RTE vegetables; (5) cooking the ground turkey patty, resulting in a reduction in *Salmonella* levels (cooking kill step); (6) eating the cooked ground turkey patty; and (7) eating the RTE food. Steps (3), (4), and (6) were included when secondary exposure routes were included. Transfer coefficients are shown in Table I. It was assumed that only one patty is handled during a preparation event and that only a small proportion of cells are on the surface on the patty and hence available for transfer. The proportion of patty cells available for transfer was assumed based on contact on only one side of the patty, a patty volume of 39 cm^3 and surface area of 172 cm^2 (Schaffner & Schaffner, 2007), and a superficial layer of 10 μm.

2.11. Consumer Cooking Step

It is assumed that ground turkey was cooked as a patty in a stove-top pan, and consumers would cook it analogously to a beef patty. Approximately 68.3% of portions (patties) were assumed to be properly cooked to the recommended internal temperature of 165 °F, that is, 74°C (Maughan et al., 2016) resulting in complete elimination of *Salmonella*. The remaining 31.7% of portions were assumed to be improperly cooked, with a decimal log reduction in *Salmonella* levels uniformly distributed between 1 and 7 log cells/g. These simplified assumptions for cooking reduction were adopted due to the lack of complete data to support a more refined model, in the context of overall model uncertainty, and made acceptable by the fact that relative risk between intervention and baseline scenarios was the primary outcome.

2.12. Risk Characterization

The public health impact associated with each scenario was expressed as the probability of illness per portion for the general U.S. population, estimated as a function of dose using a beta-Poisson dose–response equation (WHO & FAO, 2002) (Table I). Variability in equation parameters was not included. Within the dose–response equation, the dose was multiplied by a scaling factor of 0.01, to match the model risk outcome to the order of magnitude of the incidence of salmonellosis associated with ground turkey consumed in the United States, based on epidemiology data. Specifically, the observed number of cases per million lbs of ground turkey

consumed in the United States was estimated based on the total number of foodborne salmonellosis cases of 1,027,561 (Scallan et al., 2011), a proportion of turkey-associated foodborne salmonellosis cases of 6.2% (IFSAC, 2019), and a proportion of ground turkey to all turkey products consumption of 42% (CDC, 2016). Nation-wide ground turkey consumption was estimated as approximately 2,200 million lbs per year, based on an average individual turkey consumption of 16.1 lbs/year in 2019, a U.S. population of 327 million, and a 42% of turkey consumption attributed to ground turkey products (CDC, 2016; USDA-ERS, 2019). The resulting estimate of 12.1 cases per 1 million lbs corresponded to a probability of illness per portion of 2.6×10^{-6} based on the number of portions in a 2,000-lb lot assumed in the model. A scaling factor of 0.01 was able to match the order of magnitude of this estimate with the risk outcome of the baseline model. We opted for scaling to provide a more intuitive and relatable order of magnitude of absolute risk results, while minimally impacting relative risk. A scaling factor of 0.01 is approximately equivalent to using a less extreme dose–response relationship for *Salmonella* based on feeding study data instead of outbreaks (WHO & FAO, 2002). The mean residual risk remaining when implementing a concentration-based MC and associated intervention was calculated as:

$$\text{Residual Risk} = \frac{\text{Mean (P (illness)}_{\text{intervention}})}{\text{Mean (P(illness)}_{\text{baseline}})}$$

where the numerator is the mean probability of illness per portion after applying an intervention to noncompliant lots, and the denominator is the mean probability of illness per portion without intervention (baseline). The mean preventable fraction (PF) was calculated as (1 − residual risk). Concentrations and probability of illness were compared between compliant and noncompliant lots using an ANOVA approach, with lot status as explanatory variable.

2.13. Sensitivity Analysis

A Spearman correlation analysis was performed between main model outcome (probability of illness per portion) and selected variables (concentration levels, cooking kill step, and cross-contamination transfer coefficients) to assess the impact of these distributed variables on model outcomes. The significance of binary variables (lot compliance status, cooking status, i.e., fully cooked vs. undercooked) was assessed using an ANOVA approach.

2.14. What-if Scenario Analyses

This analysis was carried out on selected variables (MC threshold, *Salmonella* mean concentration, percent of undercooked patties, log reduction associated with cooking/undercooking) to determine how changes in assumptions may affect compliance and public health outcomes. Parameters were varied one at a time within the main scenario including cooking and cross-contamination.

3. RESULTS

3.1. *Salmonella* Contamination in Product

Data from the two USDA-FSIS sampling programs indicate that *Salmonella* was detected at the screening step and enumerated in 4.2% of 4,284 samples; detected and not enumerated in 13.7% of the samples, and not detected in 82.1%. Descriptive statistics for concentration data are presented in Table II. The concentration of *Salmonella* in raw ground turkey portions or samples was modeled with a lognormal distribution of parameters μ: −10.72 ln MPN/g and σ: 4.65 ln MPN/g (mean: 1.087 MPN/g, median: 2.20×10^{-5} MPN/g, Fig. 2).

3.2. Portion Size

Thirty-seven of 8,661 and 40 of 7,573 participants reported consuming ground turkey or ground turkey patties on Day 1 and Day 2, respectively, of the dietary recall assessment in the 2013–2014 cycle of NHANES. Due to the small number of participants consuming the food group on both days (2 of 75), estimates were derived using Day 1 data only. The weighted consumption rate for Day 1 was 0.63%. Only two participants reported consuming more than one portion on Day 1, so the estimated usual daily intake was assumed to be representative of a single consumption event. The weighted mean and median portion size were 107.29 and 75.75 g/day, respectively, with the distribution being approximately lognormal. Quantiles from the empirical distribution of weighted consumption amounts were fitted with a lognormal distribution of parameters $\mu = 4.41$ ln g/day and $\sigma = 0.66$ ln g/day (natural logarithmic scale).

3.3. Risk Scenario Results

Summary results for the main scenarios based on a MC threshold of 1 cell/g are shown in Table III.

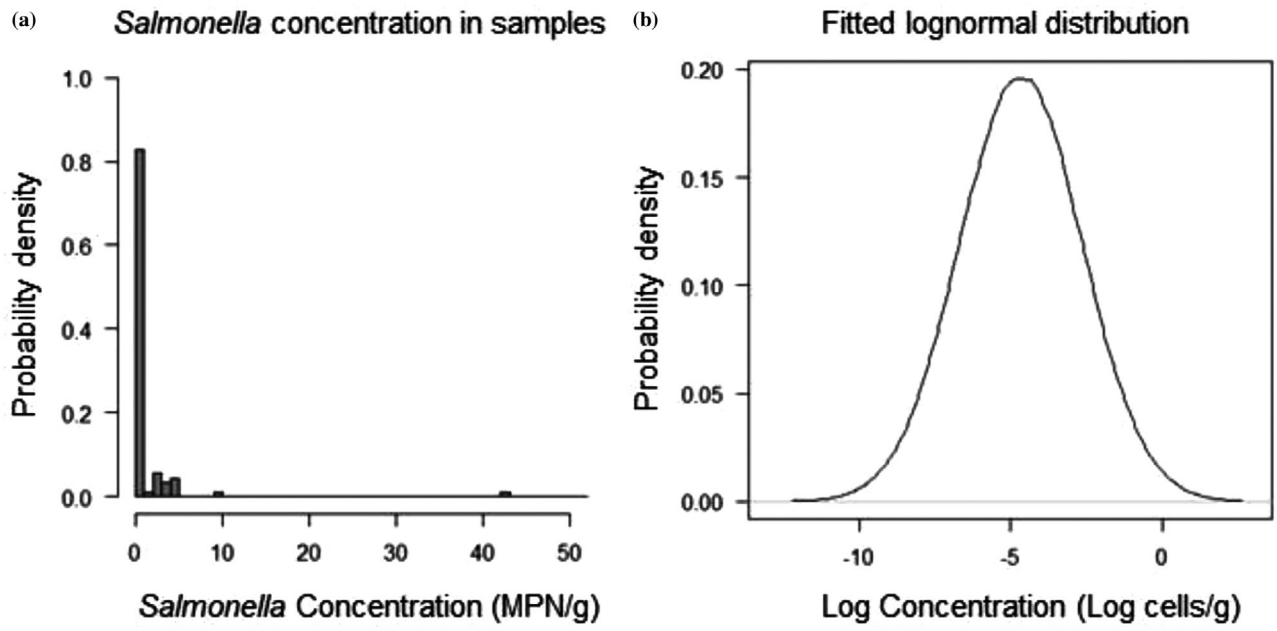

Fig 2. *Salmonella* concentration (MPN/g) in ground turkey samples. (A) Frequency histogram of MPN/g estimates from FSIS data, including only samples that were both screened and enumerated (179 data points, out of 4,284 screened). The horizontal axis was truncated to a maximum value of 50 MPN/g for easier visualization; beyond that range, one data point had a value of 240 MPN/g. Left-censored samples < 0.03 MPN/g were set to 0.03 for visualization purposes. (B) Probability density function of the lognormal distribution (plotted in decimal log scale), fitted to screening-only (presence/absence) and enumerated data (MPN/g) pooled together.

Approximately 1.05% (range: 0.96–1.13% across seven model runs) of lots were noncompliant when applying a detection step followed by enumeration to determine compliance. The distributions of probability of illness were right-skewed; hence, the median risk is representative of the central tendency of the distribution (i.e., the bulk of risk outcomes), while the arithmetic mean risk is representative of the tail of the risk distribution, dominated by extreme values. While only a small fraction of lots were noncompliant in the main scenarios, applying an intervention that reduced their risk to zero resulted in a noticeable decrease of 38.0–48.4% in mean risk (for reference, albeit not a rigorous metric, the preventable fraction calculated using median risk was 11.4–12.5%). When comparing between compliant and noncompliant lots, the distributions of both concentrations (parameter μ for each lot) and probability of illness (means per lot) were significantly different ($p < 0.001$, Fig. 3).

The baseline scenario with no intervention, including a cooking kill step at consumer stage and cross-contamination in the kitchen (scenario 1 in Table III), resulted in an estimated mean probability of illness per portion of approximately 1.30×10^{-6}, or 1.3 illnesses per million exposure events (median: 6.75×10^{-12}, 90% percentile range: 1.67×10^{-15}, 3.87×10^{-8}). Risk distributions had a high variance, with 5–95% percentiles spanning up to 7 logs, albeit this is due to the large portion of the fitted concentration distribution that is so low as to be practically indistinguishable from zero. The coefficient of variation of the mean probability of illness across three model runs was 7.2%. Applying an intervention that reduced risk in noncompliant lots to zero resulted in a mean probability of illness per portion of 7.43×10^{-7} or 0.7 illnesses per million exposure events (median: 5.81×10^{-12}, 90% percentile range: 8.88×10^{-16}, 2.99×10^{-8}). In other words, lots not compliant with the considered MC contributed a mean probability of illness per portion of approximately 0.56×10^{-6}. The associated PF (i.e., the maximum proportion of risk that could be avoided by fully eliminating *Salmonella* from noncompliant lots) was approximately 46.1% when calculated using the ratio of mean risk, with a coefficient of variation of 3.1% across three model runs. Including the cooking reduction or the kitchen cross-contamination component, or both, changed the PF (means) by +2% and −8%, respectively. It is recognized that scenarios without home cooking (3 and 4 in Table III) are not to be considered realistic

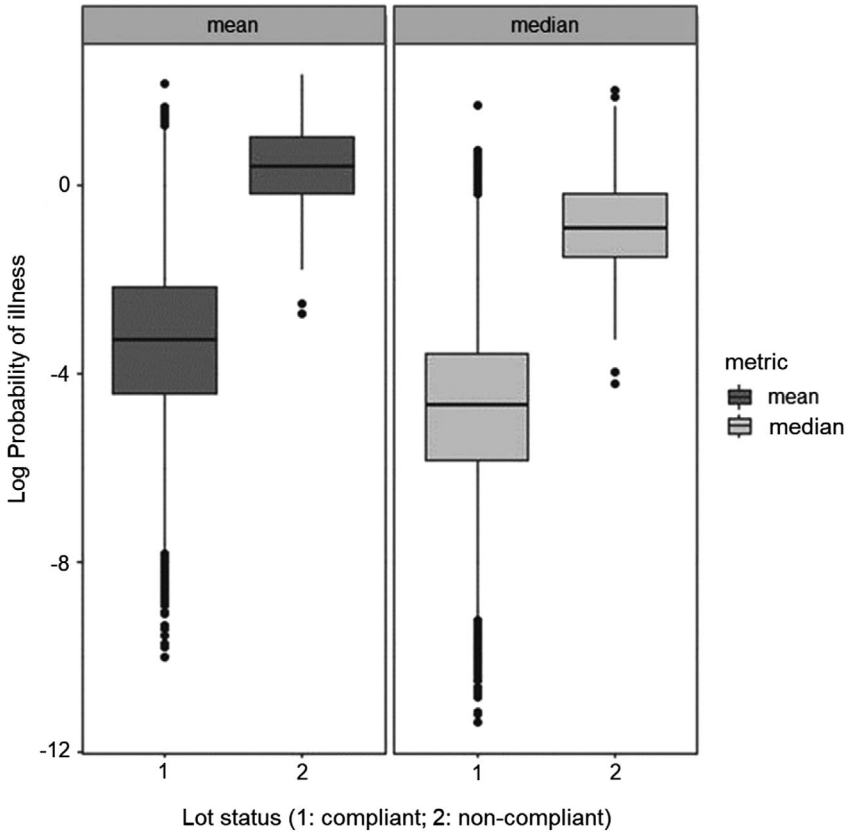

Fig 3. Difference in probability of illness (in decimal log scale) associated with compliant and noncompliant lots (lot status 1 and 2, respectively), in the baseline scenario including cooking and cross-contamination, where probability of illness is expressed as mean or median risk per lot.

and are presented to stress that, even under such extreme assumptions, the PF remains similar to more realistic cases.

3.4. Sensitivity Analysis

For the scenario including cooking and cross-contamination, risk of illness was correlated with cooking status of the portion (fully cooked/non, Spearman correlation coefficient CC: −17.7%), and with the ratio of cross-contamination from meat to cutting board (CC: 22.7%) and from cutting board to RTE food (CC: 10.8%). While these consumer-level variables showed an impact, the probability of illness was most correlated with the initial concentration in a portion (CC: 89.2%). When considering individual exposure routes, the overall probability of illness per event was correlated to different extents to the probability of illness associated with each route (CC: 90.1%, 89.0%, and 30.6% for hand-to-mouth, RTE food, and meat, respectively). As expected, when cooking was considered but no cross-contamination, probability of illness was significantly associated with cooking status of the portion ($p < 0.001$). Risk associated with the hand-to-mouth route was correlated with risk from RTE food (CC: 82.5%), likely due to the meat-to-cutting-board step shared by the two routes. In contrast, risk from the two cross-contamination routes was not highly correlated with risk from meat (CC: 11.1% and 9.4%, respectively). For variables defined at lot level, mean lot risk was highly correlated with the parameter μ (mean in ln scale) and median ($\exp(\mu)$) of the within-lot concentration distribution (CC: 99.4% for both). Lot compliance status was a significant predictor of both dose and probability of illness ($p < 0.001$ for both).

3.5. What-if Analysis: Impact of Concentration Distribution

The distribution of concentration significantly impacted the compliance status of a lot (Table IV). In the main scenarios (Table III) most lots had low levels of contamination and, consequently, a low probability of noncompliance even with a very low MC threshold level. As expected, increasing the mean of the *Salmonella* concentration distribution increased the probability of noncompliance with the

Table III. Summary Risk Outcomes for the Main Scenarios Considered (MC threshold: 1 cell/g)

#	Cooking Step Included?	Cross-Contamination Included?	Probability of Illness per PortionMean (Median;5% and 95% percentiles)[a]		Preventable Fraction (PF)[c]
			Baseline scenario[b]	Intervention scenario[b]	
1	Yes	Yes	1.30×10^{-6} (6.75×10^{-12}; 1.67×10^{-15}, 3.87×10^{-8})	7.43×10^{-7} (5.81×10^{-12}; 8.88×10^{-16}, 2.99×10^{-8})	0.4615
2	Yes	No	1.24×10^{-6} (0; 0, 2.55×10^{-9})	6.39×10^{-7} (0; 0, 2.13×10^{-9})	0.4837
3	No	Yes	2.61×10^{-4} (4.33×10^{-8}; 1.96×10^{-11}, 1.01×10^{-4})	1.62×10^{-4} (3.84×10^{-8}; 1.18×10^{-11}, 7.69×10^{-5})	0.3804
4	No	No	2.61×10^{-4}(4.48×10^{-8}; 2.05×10^{-11}, 1.02×10^{-4})	1.54×10^{-4} (3.97×10^{-8}; 1.22×10^{-11}, 7.67×10^{-5})	0.4106

[a]One million lbs of product corresponds to 500 2,000-lbs lots, or approximately 5,500,000 portions of median weight.
[b]"Baseline" refers to the scenario where no MC and no lot intervention are implemented. "Intervention" refers to the scenario, based on the same variables, where MC and a lot intervention for noncompliant lots are implemented.
[c]The preventable fraction was calculated from the mean probability of illness as: $1 - (\text{Mean P(illness)}_{\text{intervention}}/\text{Mean P(illness)}_{\text{no\_intervention}})$.

considered MC threshold of 1 cell/g (Fig. 4(A)), with a nonlinear relationship between the two variables. There was also a nonlinear relationship between PF and mean (in ln scale) of the concentration distribution (Fig. 4(B)), with the PF exceeding 40% when the mean exceeded −8 ln cells/g, or 0.0003 cells/g (compared to 12.5% when $\mu = -10.72$ ln cells/g). Changing how the overall concentration variance was partitioned between "across lots" and "within lots" noticeably affected risk results (Table IV), although the risk difference remained within one order of magnitude as the default assumption for baseline scenarios, and within two orders of magnitude for intervention scenarios. A substantial decrease in PF was observed when a larger portion of variance was attributed to variability within lots, compared to lot-to-lot.

3.6. What-if Analysis: Impact of the MC Concentration Threshold

Decreasing (or increasing) the MC threshold had a similar impact as decreasing (or increasing) input contamination levels. The probability of noncompliance for a lot was a decreasing, nonlinear function of the decimal log of the MC threshold (Fig. 5(A)). At the MC threshold considered in the main scenarios (1 cell/g, i.e., 0 log cell/g), the probability of noncompliance was approximately 1.05%. By keeping concentration levels fixed and changing the MC threshold, only extremely low theoretical thresholds increased the probability of noncompliance above 15%. In addition, the PF increased the most, by approximately 6–7%, with every decimal log decrease in threshold from 0.1 to 0.001 cells/g, going from 3.5% to 16.1% (based on the scenario including cooking and cross-contamination). This nonlinear relationship flattened out at approximately 18% for (theoretical) thresholds at or below 0.0001 cells/g, with the detection step becoming the limiting factor at these low thresholds. The PF (Fig. 5(B)) increased from 0.005% to a plateau above 90% when the MC concentration threshold was decreased from 2 to −3 log cells/g (100–0.001 cells/g). In a theoretical scenario where the concentration in a portion could be measured accurately without a detection step, probability of noncompliance and risk outcomes did not change compared to the main scenario including a detection step for an MC threshold of 1 cell/g. However, for a lower MC threshold of −5 log cells/g the proportion of noncompliance reached 56.8% with the PF approaching 100% (not shown). The

Table IV. Results of What-if Scenarios. Unless Otherwise Specified, all Scenarios Include Cooking and Cross-Contamination

What-If Scenario	Baseline Scenario[a] P(illness)Mean (median;5–95% Percentiles)	Intervention Scenario[a] P(illness)Mean (Median;5–95% Percentiles)	Preventable Fraction(Means PF)
Input concentration, μ (log cells/g)			
−12	5.29×10^{-7} (1.86×10^{-12}; 4.44×10^{-16}, 1.06×10^{-8})	2.92×10^{-7} (1.75×10^{-12}; 3.33×10^{-16}, 9.18×10^{-9})	0.4470
−10.724 (main scenario)	1.30×10^{-6} (6.75×10^{-12}; 1.67×10^{-15}, 3.87×10^{-8})	7.43×10^{-7} (5.81×10^{-12}; 8.88×10^{-16}, 2.99×10^{-8})	0.4825
−10	2.27×10^{-6} (1.36×10^{-11}; 3.33×10^{-15}, 8.00×10^{-8})	1.04×10^{-6} (1.11×10^{-11}; $1.33 \times 10^{-15,}$ 5.43×10^{-8})	0.5404
−9	4.33×10^{-6} (3.70×10^{-11}; 9.10×10^{-15}, 2.17×10^{-7})	1.85×10^{-6} (2.66×10^{-11}; 1.78×10^{-15}, 1.25×10^{-7})	0.5714
−8	8.00×10^{-6} (1.05×10^{-10}; 2.50×10^{-14}, 6.07×10^{-7})	3.15×10^{-6} (6.15×10^{-11}; 5.55×10^{-16}, 2.77×10^{-7})	0.6061
−7	1.42×10^{-5}(2.74×10^{-10}; 6.72×10^{-14}, 1.57×10^{-6})	4.77×10^{-6} (1.21×10^{-10}; 0, 5.31×10^{-7})	0.6654
−6	2.45×10^{-5} (7.44×10^{-10}; 1.80×10^{-13}, 4.12×10^{-6})	7.18×10^{-6} (2.16×10^{-10}; 0, 9.85×10^{-7})	0.7074
–5	4.04×10^{-5} (2.05×10^{-9}; 4.91×10^{-13}, 1.05×10^{-5})	1.05×10^{-5} (3.44×10^{-10}; 0, 1.74×10^{-6})	0.7412
–4	6.65×10^{-5} (5.73×10^{-9}; 1.38×10^{-12}, 2.55×10^{-5})	1.42×10^{-5} (4.61×10^{-10}; 0, 2.79×10^{-6})	0.7859
MC concentration threshold (cells/g)			
0.000001	1.39×10^{-6} (6.61×10^{-12}; 1.67×10^{-15}, 3.94×10^{-8})	7.89×10^{-8} (6.67×10^{-13}; 0, 4.17×10^{-9})	0.9434
0.00001	1.39×10^{-6} (6.61×10^{-12}; 1.67×10^{-15}, 3.88×10^{-8})	7.89×10^{-8} (6.69×10^{-13}; 0, 4.12×10^{-9})	0.9394
0.0001	1.39×10^{-6} (6.60×10^{-12}; 1.66×10^{-15}, 3.88×10^{-8})	7.91×10^{-8} (6.84×10^{-13}; 0, 4.15×10^{-9})	0.9432
0.001	1.39×10^{-6} (6.60×10^{-12}; 1.66×10^{-15}, 3.88×10^{-8})	8.58×10^{-8} (8.67×10^{-13}; 0, 4.72×10^{-9})	0.9384
0.01	1.39×10^{-6} (6.60×10^{-12}; 1.66×10^{-15}, 3.88×10^{-8})	1.61×10^{-7} (2.07×10^{-12}; 0, 9.36×10^{-9})	0.8841
0.1	1.20×10^{-6} (6.74×10^{-12}; 1.66×10^{-15}, 3.94×10^{-8})	3.83×10^{-7} (4.31×10^{-12}; 1.11×10^{-16}, 1.99×10^{-6})	0.6822
1 (Main Scenario)	1.30×10^{-6} (6.75×10^{-12}; 1.67×10^{-15}, 3.87×10^{-8})	7.43×10^{-7} (5.81×10^{-12}; 8.88×10^{-16}, 2.99×10^{-8})	0.4825
10	1.21×10^{-6} (6.74×10^{-12}; 1.66×10^{-15}, 3.94×10^{-8})	9.72×10^{-7} (6.56×10^{-12}; $1.44 \times 10^{-15,}$ 3.68×10^{-8})	0.1944
Cooking: proportion undercooked			
0%[b]	2.20×10^{-7} (3.66×10^{-12}; 1.11×10^{-15}, 1.39×10^{-8})	1.14×10^{-7} (3.21×10^{-12}; 6.66×10^{-16}, 1.06×10^{-8})	0.4810
50%	2.03×10^{-6} (9.77×10^{-12}; 2.22×10^{-15}, 6.48×10^{-8})	1.03×10^{-6} (8.55×10^{-12}; 1.22×10^{-15}, 4.98×10^{-8})	0.4957
100%	3.77×10^{-6} (2.82×10^{-11}; 5.00×10^{-15}, 1.87×10^{-7})	1.99×10^{-6} (2.45×10^{-11}; 2.78×10^{-15}, 1.44×10^{-7})	0.4725
1 Log	4.40×10^{-5} (4.59×10^{-9}; 1.95×10^{-12}, 1.05×10^{-5})	2.30×10^{-5} (4.05×10^{-9}; 1.14×10^{-12}, 7.82×10^{-6})	0.4771
3 Log	7.84×10^{-7} (5.68×10^{-11}; 2.45×10^{-14}, 1.29×10^{-7})	4.09×10^{-7} (5.01×10^{-11}; 1.43×10^{-14}, 9.75×10^{-8})	0.4784
5 Log	7.78×10^{-7} (5.61×10^{-11}; 2.36×10^{-14}, 1.34×10^{-7})	3.97×10^{-7} (4.89×10^{-11}; 1.31×10^{-14}, 9.81×10^{-8})	0.4901
7 Log	2.19×10^{-7} (3.78×10^{-12}; 1.11×10^{-15}, 1.38×10^{-8})	1.10×10^{-7} (3.35×10^{-12}; 6.66×10^{-16}, 1.06×10^{-8})	0.4951

(*Continued*)

Table IV. (Continued)

What-If Scenario	Baseline Scenario[a] P(illness)Mean (median;5–95% Percentiles)	Intervention Scenario[a] P(illness)Mean (Median;5–95% Percentiles)	Preventable Fraction(Means PF)
0	8.69×10^{-7} (9.21×10^{-14}; 0, 1.12×10^{-8})	4.57×10^{-8} (7.57×10^{-14}; 0, 7.84×10^{-9})	0.9474
0.1	2.32×10^{-6} (1.37×10^{-11}; 3.44×10^{-15}, 7.74×10^{-8})	2.95×10^{-7} (1.13×10^{-11}; 1.44×10^{-15}, 4.45×10^{-8})	0.8731
0.30 (Main scenario)	1.30×10^{-6} (6.75×10^{-12}; 1.67×10^{-15}, 3.87×10^{-8})	7.43×10^{-7} (5.81×10^{-12}; 8.88×10^{-16}, 2.99×10^{-8})	0.4825
0.50	1.38×10^{-6} (6.72×10^{-12}; 1.66×10^{-15}, 3.97×10^{-8})	1.10×10^{-6} (5.93×10^{-12}; 8.88×10^{-16}, 3.37×10^{-8})	0.2090
0.70	1.27×10^{-6} (6.80×10^{-12}; 1.66×10^{-15}, 3.88×10^{-8})	1.18×10^{-6} (6.12×10^{-12}; 8.88×10^{-16}, 3.56×10^{-8})	0.0720
1	1.31×10^{-6} (6.78×10^{-12}; 1.66×10^{-15}, 3.92×10^{-8})	1.30×10^{-6} (6.35×10^{-12}; 9.99×10^{-16}, 3.82×10^{-8})	0.0097

[a]"Baseline" refers to the scenario where no MC and no lot intervention are implemented. "Intervention" refers to the scenario, based on the same variables, where MC and a lot intervention for noncompliant lots are implemented.
[b]0% undercooking corresponds to 100% of portions being fully cooked. Since full cooking was assumed to result in complete *Salmonella* inactivation, this scenario shows the impact of cross-contamination only.

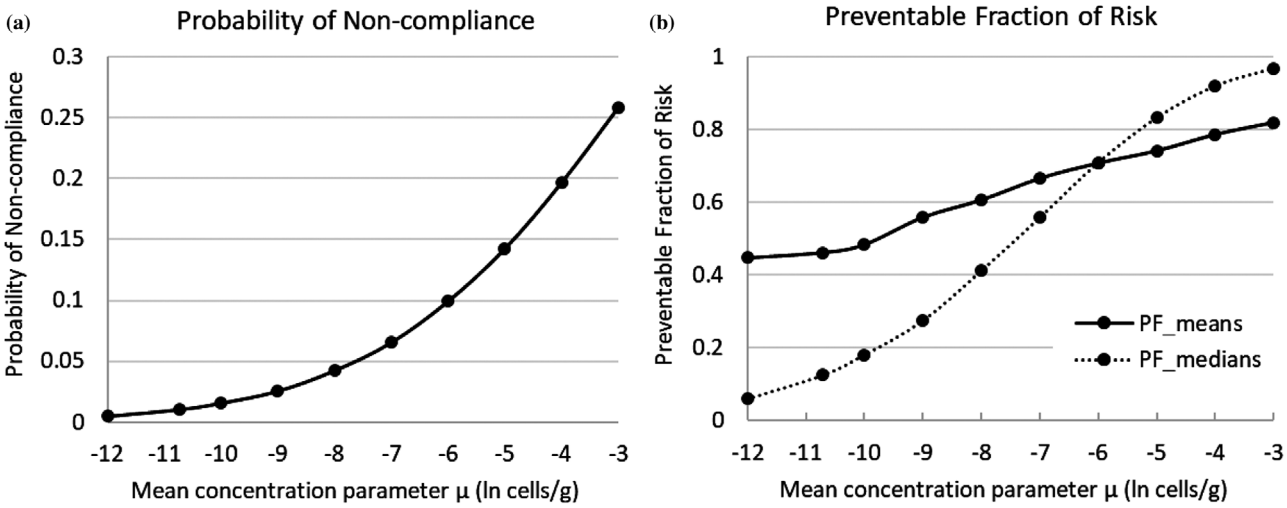

Fig 4. Impact of changes in the mean input concentration (parameter $\mu_{overall}$, in ln cells/g) on the probability of noncompliance (4A) and on the PF of risk (4B). Variance (parameter $\sigma_{overall}$) and all other variables in the scenario were kept constant and as in the main scenario that included cooking and cross-contamination. For reference, the horizontal axis spans from a minimum of −5.2 decimal log cells/g (6.1×10^{-6} cell/g) to a maximum of −1.3 log cell/g (0.05 cell/g). The means PF is the true risk-based metric. The PF based on median outputs is presented for reference to indicate the ratio of the central tendency of the output distributions but is not a rigorous risk metric.

impact of not including a detection step was already visible at an MC threshold of −3 log cells/g (0.001 cells/g), where the proportion of noncompliant lots was 20.7% with PF of 96.1% (compared to ∼16% noncompliance when including a detection step and the same MC threshold, Fig. 5).

3.7. What-if Analysis: Impact of the Cooking Step

The impact of a simplified cooking kill step on absolute risk outcomes was noticeable even at the low concentrations considered in the main scenarios (Table III). The assumption that 31.7% of portions are undercooked means that rare high-impact

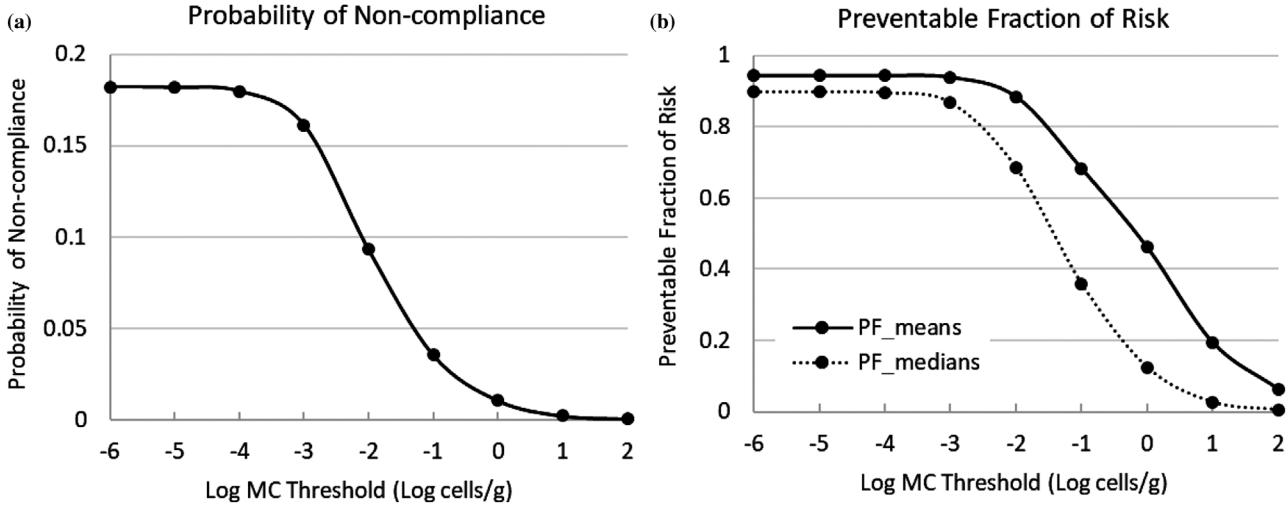

Fig 5. Impact of changes in the MC concentration threshold on the probability of noncompliance (5A) and on the PF of risk (5B). Input concentration parameters and all other variables in the scenario were kept constant and as in the main scenario that included cooking and cross-contamination. The means PF is the true risk-based metric. The PF based on median outputs is presented for reference to indicate the ratio of the central tendency of the output distributions but is not a rigorous risk metric.

undercooking events can occur and influence risk. However, the impact on the PF was minimal, as the cooking step was applied in the same way in both "baseline" and "intervention" scenarios to the majority of product (all but the 1.05% of noncompliant lots). This lack of impact on the PF can also be seen in what-if scenarios that varied the proportion of undercooked product or the degree of cooking reduction (Table IV). When assuming all portions underwent the same decimal log cell/g reduction via cooking, a nonlinear trend was observed between risk and log reduction, with the steepest risk decrease occurring from 1 to 3 log reduction, resulting in a decrease of approximately 2 log in mean probability of illness. When the percent of portions undergoing full cooking (complete elimination of *Salmonella*) was increased incrementally from 0% to 100%, both mean and median risk decreased linearly by one order of magnitude in both baseline and intervention scenarios.

3.8. Impact of Cross-contamination Routes

The contribution of the three considered routes of transmission (ground turkey patty, hands, RTE food) is shown in Table V. In the baseline scenario without cooking and without intervention (i.e., a theoretical extreme scenario where all product is consumed raw), the simplified cross-contamination event from raw meat to RTE food caused by using the same cutting board was responsible for 0.08% of overall mean risk and the hand-to-mouth route for 0.003%, with 99.92% due to meat. The proportion of median risks showed almost identical trends. In the baseline scenario where cooking was included, as expected the proportion of risk due to cross-contamination routes was much higher, with 16.4% of mean risk associated with cross-contamination of RTE food, while the hand-to-mouth route was associated with a lower proportion (0.69% of mean risk). For scenarios with and without cooking, applying the intervention to noncompliant lots reduced absolute risk outcomes for all routes, while the proportion of risk due to cross-contamination routes was conserved (right half of Table V). The PF was also similar in the what-if scenario that assumed full cooking of all portions, that is, when cross-contamination was the only exposure route (Table IV). The proportion of cells on a patty that are available for transfer carries uncertainty and can impact risk outcomes. Changing this proportion from 0.022 to 4.4×10^{-4}, based on different assumptions (Schaffner & Schaffner, 2007) changed the relative importance of different exposure routes, but did not appreciably change the PF (0.49).

4. DISCUSSION

Outcomes of the probabilistic quantitative risk assessment model developed in this study showed

Table V. Relative Impact of Different Routes of Exposure, When Cross-Contamination in Consumers' Kitchen is Included

	Probability of Illness Per Portion					
	Baseline Scenario (No Intervention)			Intervention Scenario		
Exposure Route →	Hand	RTE Food	Ground Turkey	Hand	RTE Food	Ground Turkey
No cooking included						
Mean Prob(illness)	8.83×10^{-9}	2.11×10^{-7}	2.61×10^{-4}	4.70×10^{-9}	1.13×10^{-7}	1.62×10^{-4}
% of total mean risk [a]	(0.003%)	(0.08%)	(99.92%)	(0.003%)	(0.07%)	(99.93%)
Median Prob(illness)	7.26×10^{-13}	1.08×10^{-12}	4.33×10^{-8}	6.43×10^{-13}	9.43×10^{-13}	3.84×10^{-8}
% of total median risk	(0.002%)	(0.003%)	(100.00%)	(0.002%)	(0.002%)	(100.00%)
Cooking included						
Mean Prob(illness)	8.96×10^{-9}	2.13×10^{-7}	1.08×10^{-6}	4.73×10^{-9}	1.13×10^{-7}	5.82×10^{-7}
% of total mean risk	(0.69%)	(16.38%)	(82.94%)	(0.68%)	(16.09%)	(83.23%)
Median Prob(illness)	7.59×10^{-13}	1.13×10^{-12}	0	6.71×10^{-13}	9.80×10^{-13}	0
% of total median risk	(40.17%)	(59.83%)	(0.00%)	(40.64%)	(59.36%)	(0.00%)

[a]Total mean (or median) risk in this table is calculated as the sum of the mean (or median) probability of illness per portion for each of the three exposure routes separately. This sum is in general different from the risk values presented in Table III, where the summed dose from the three routes is inputted in the dose–response relationship.

that a concentration-based MC for *Salmonella* in raw ground turkey, in association with an intervention on noncompliant lots, has the potential to have a substantial positive public health impact across different scenarios. The probability of lot compliance depends on the MC concentration threshold and the distribution of concentrations, as well as parameters of the detection and enumeration assays (e.g., number of samples, sample weight, aliquoting, sensitivity, and specificity). Relatively low concentrations were observed in the microbial surveys used to estimate *Salmonella* concentrations in our model, resulting in a large portion of the distribution being below the threshold of 1 cell/g. As a result, frequency of noncompliance was very low, approximately one in 100 lots (1.05%), with 95% of lots showing a theoretical probability of compliance above 96% (i.e., 4% probability of yielding a sample above the MC threshold). The nonlinear relationship between probability of compliance and both concentration (shown as ln cells/g, Fig. 4) and MC threshold (as log cells/g, Fig. 5) indicate that results should be considered in the context of both variables, as well as their relationship. In addition, the flattening out of the probability of compliance and PF at low MC threshold values, where the detection method becomes the limiting factor, highlights the importance of both detection and enumeration.

Results suggested a concentration-based MC may have a protective impact on public health under a range of consumer behaviors. As expected, the proportion and degree of cooking or undercooking affected risk outcomes. However, in the scenarios considered here differences in cooking parameters did not substantially affect the impact of the MC, that is, the PF. This result was not surprising since the cooking step was applied identically to "baseline" and "intervention" scenarios, with only a minority of lots differing between the two. Analogous considerations can be made for cross-contamination, although its impact is affected by more complex transfer steps and parameters. Naturally, the relative impact of cross-contamination depended on the extent of cooking reduction, with the mean risk due to cross-contamination being 17% of total mean risk when cooking was applied (default scenario with 31.7% undercooked), 30% if all portions underwent a 5 log reduction, and a negligible 0.01% in the theoretical case without any cooking (Table V and data from Table IV). Cross-contamination via hands was minor compared to RTE food (Table V).

This study sought to advance the discussion on the effectiveness of different MC for *Salmonella* in poultry, focusing on a specific concentration-based MC for raw ground turkey. Other studies have considered this issue. For instance, our results are consistent with Swart et al. (2013), who also used a risk-based modeling approach to estimate the public health impact of a concentration-based MC for *Campylobacter* in poultry in the Netherlands, based on a threshold of 1,000 cells/g. Assuming the same best-case intervention as in our study, the PF ranged from 30% to 90% (proportion of noncompliant batches 10–54%) across establishments, which were modeled individually thanks to the availability of detailed data. This study also considered the impact of collecting a higher number of samples per lot ($n =$ 1, 3, or 5, with the results above referring to 5), which increased the impact of a MC. The EU has since adopted a concentration-based MC for *Campylobacter* in poultry (European Commission, 2017).

In the U.S. context, a USDA-FSIS model (USDA-FSIS, 2015) based on a prevalence-based MC estimated that a 25% reduction in *Salmonella* illness incidence could be achieved by reducing prevalence in noncompliant establishments, assuming 40% of noncompliant establishment would achieve the reduction. These estimates formed the basis for the current performance standards for *Salmonella* in comminuted turkey, with noncompliance set as more than 7 detected in 52 samples (13.5%) (USDA-FSIS, 2016). An analogous process was used to set performance standards for comminuted chicken and chicken parts, for *Salmonella* and *Campylobacter*. A follow-up study confirmed the estimates (Ebel & Williams, 2019).

Two recent studies have also taken a risk-based approach to estimate the potential impacts of various MC for poultry. Lambertini et al. (2019) compared prevalence-based and concentration-based MC for *Salmonella* in chicken parts in the United States and estimated that both approaches may yield positive public health impacts, depending on a range of parameters including MC thresholds, concentration inputs, and concentration variability patterns. For a concentration-based MC, they estimated that approximately 60% of illnesses could be prevented with a MC threshold of 0.1 cells/g and 40% with 1 cell/g, which is consistent with the present study. Another study, by Sampedro et al. (2018), was conducted in tandem with the present study with the intent that the two studies would independently estimate the potential impacts of concentration-based MC for ground turkey based on different model structure and assumptions. This study estimated 6.3% of ground turkey lots would be above a MC threshold of 1 cell/g, resulting in a PF of 86–94% based on median risk, which is higher than our estimates but confirms the potential positive impact of a concentration-based MC. As in our study, one sample was assumed to be analyzed for each lot, and noncompliant lots were processed or diverted so that they would pose zero risk. Differently from our study, Sampedro et al. (2018) assumed that lots had a uniform within-lot concentration and that nondetected samples were *Salmonella*-free. At consumer level, their model included undercooking but not cross-contamination and considered a different range of consumer behaviors including eating at restaurants, which was estimated to yield lower risks than consuming ground turkey at home. They also considered the impact of multiple *Salmonella* serotypes and exposed populations using different dose–response relationships to bracket estimates.

The developed model was based on publicly available and published data. Limited data and biases in available data, as well as the need to limit the number of confounding variables and focus on a specific risk management question, required us to make assumptions that may limit the validity of model outcomes beyond the scenarios considered.

First, due to the focus on a specific risk management question, not aiming to develop a novel MC, this study explored only a subset of protocols and parameters relevant to MC development (ICMSF, 2018). For instance, the model assumes collecting one noncomposite sample per lot. In this situation the effectiveness of the testing protocols depends on how representative a sample is of an entire lot, which in turns depends on within-lot variability, that is, the distribution of *Salmonella* concentration in the lot. This assumption was chosen as is reflective of most microbiological testing programs for comminuted poultry products in the United States, which involve collecting a 325 g sample from a lot (USDA-FSIS, 2019). Under the assumption of a lognormal distribution of relatively low mean concentration, only a small proportion of the distribution, that is, a small percent of samples, is likely to be detected and above the MC threshold; hence, contamination is likely to be undetected. Other studies have also highlighted this issue and included scenarios with varying numbers of samples per lot (Swart et al., 2013). Parameters of the testing protocol such as sample weight and assay sensitivity and specificity

also impact sampling outcomes. In this study, we assumed sensitivity and specificity to be 100% to estimate a best-case boundary for the PF and remain assay-agnostic. In practice, estimates including measured assay parameters would be needed to determine the actual PF achievable, or vice versa to design a sampling protocol able to meet the risk-based goals of the MC. In addition, our model assumed that every lot is sampled, which is not current practice. For example, for their verification testing program, the USDA-FSIS generally collects 10–52 samples per establishment per year depending on production volume (USDA-FSIS, 2016). Hence, a concentration-based MC based on the current sampling frequency would have a lower power to detect contamination than estimated in the present study.

Second, the model uses prevalence and concentration data collected in 2013–2016 by USDA-FSIS as part of regulatory initiatives to monitor *Salmonella* in ground turkey. These data were derived by sampling a small number of establishments with minimal replication within establishments and no replication within lots. As a result, it is not possible to characterize different components of the overall variability in *Salmonella* concentrations (and as a result, prevalence) observed in the data, namely variability across establishments, across lots in an establishment, and across individual portions within a lot. Hence, we did not model individual establishments, but considered a population of lots and assumed—as a starting point—that lot-to-lot variability is dominant compared to within-lot variability. Results highlight that the relative magnitude of these two variability components can have a large impact on risk and PF. In theoretical terms, a MC based on one or a small number of samples per lot would be more likely to detect lots of higher contamination levels if product within each lots were well mixed, that is, if bacterial cells were distributed more homogeneously (Jongenburger, Reij, Boer, Zwietering, & Gorris, 2012). However, it is well recognized that foodborne pathogens are heterogeneously distributed in food; bacterial cell clustering can occur at multiple scales and has been observed even in well-mixed foods (Jongenburger, Bassett, Jackson, Gorris, et al., 2012; Jongenburger, Reij, Boer, Gorris, & Zwietering, 2011; Kiermeier, Mellor, Barlow, & Jenson, 2011; Loukiadis et al., 2017; Van Doren et al., 2013). In turn, the spatial features and extent of clustering determine which stochastic distribution of concentrations most accurately represents reality and can be used as a basis to design sampling programs (Jongenburger, Bassett, Jackson, Gorris, et al., 2012; Jongenburger, Bassett, Jackson, Zwietering, & Jewell, 2012; Mussida, Gonzales-Barron, & Butler, 2013). Assessing the impact of clustering requires additional considerations at low contamination levels (Gonzales-Barron, Zwietering, & Butler, 2013; Hoelzer & Pouillot, 2013). There is currently insufficient data to characterize the dispersion or clustering of pathogens within ground turkey lots, making it impossible to estimate within-lot concentration distributions or support the use of more complex stochastic distributions than what adopted in this study. In addition, concentration data do not reflect a static situation, but a complex landscape of production practices that evolve over time. Given these limitations, it is important to keep in mind that concentration data and the fitted distribution used in our analysis may not reflect current levels of contamination in ground turkey products.

Third, for model simplicity we assumed no growth or die-off from the time of sampling to consumption. However, evidence suggests that variations in temperature of retail and home refrigerators could lead to fresh meat being exposed to temperatures that allow for *Salmonella* growth (Bruhn, 2014; EcoSure, 2008; Wang et al., 2015). Other unintentional interruptions of the cold chain could also occur. Our simplified consumer phase also did not consider freezing and thawing steps and the growth and cross-contamination that could be associated with them. While these events impact absolute risk levels, their occurrence in both baseline and intervention scenarios would limit their impact on relative risk and hence the PF, as shown by what-if scenarios. Hence, while a valid goal for future analyses, refinements in the consumer phase model were not prioritized in answering the considered research question.

Fourth, we only modelled three potential exposure pathways. Other exposure or cross-contamination routes are possible (e.g., retail handling, restaurants), but were not included as a more refined consumer stage model was outside the scope of the study. There is also limited information on cooking practices, cross-contamination behaviors, and transfer rates for *Salmonella*. When necessary, data from transfer studies on *Listeria monocytogenes* were used, which may bias estimates of dose. Also, we utilized an existing dose–response model for *Salmonella* scaled to U.S. epidemiological evidence, not including factors such as acquired immunity or increased susceptibility of vulnerable

populations (Havelaar & Swart, 2014), or pathogenicity associated with different strains.

Finally, we assumed that lots exceeding the MC were further processed using *Salmonella* control methods ensuring the complete safety of the product, that is, risk in these lots was reduced to zero. In practice, risk reduction options might be limited by available technology, or dependent on consumer preference for raw versus processed products. We also assumed that 100% of noncompliant lots would undergo an intervention that would bring them to compliance, which may not be true in all establishments. In addition, we assumed that a rapid assay could provide results in time to divert a lot before leaving the plant, which is technologically possible but may not be widely feasible.

This study sought to advance the discussion on developing effective MC for *Salmonella* in poultry and to discuss data needed to accurately assess the range of potential impacts. Several data gaps were identified that, if filled, could improve model estimates and reduce uncertainty. Data needs include: accurate estimates of *Salmonella* concentration distributions, derived from data representative of a wide range of U.S. establishments and weighted by establishment production volume; better estimates of variability in concentration (and hence prevalence) across establishments, across lots, and within lots; data on risk factors and industry practices that could help explain and quantify this variability; data on the effectiveness of actual or potential risk management interventions; better quantification of retail and consumer handling practices; and better quantitative knowledge of the ecology, pathogenicity, and dose–response behavior of different *Salmonella* serotypes. Leveraging data from different sources, including data collected by the industry, could significantly expand the knowledge base available to refine model estimates. Parameters beyond those included here would also need to be considered if a novel MC were to be developed. Overall, we found that implementing a concentration-based MC and associated lot-level interventions could reduce risk of illness. While specific interventions were not explored, this study can inform decision making around the implementation of prevalence-based MC versus concentration-based MC.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Supplementary Material