Public Health Effects of Performance Standards for Comminuted Pork and Pork Cuts

Prepared by:
Risk Assessment and Analytics Staff
Office of Public Health Science
Food Safety and Inspection Service
U.S. Department of Agriculture

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Executive Summary

The Food Safety and Inspection Service’s (FSIS) Strategic Plan for 2017-2021\(^1\) stated that the Agency would develop *Salmonella* performance standards for raw pork products. This risk assessment report describes the data and analytical methods used in the development of *Salmonella* performance standards for raw comminuted pork and both raw intact and nonintact pork cuts.

Based on analysis of U.S. foodborne disease outbreaks, pork may be responsible for between 8 and 13 percent of roughly 1 million foodborne human salmonellosis cases each year. In the United States, the majority of pork is consumed as pork cuts (e.g., chops, roasts), with the remainder consumed as comminuted pork (e.g., sausage) and ready-to-eat products such as cooked ham.

FSIS inspects 1,110 establishments that slaughter hogs, 1,070 establishments that produce pork cuts, and 1,334 establishments producing comminuted pork. After considering the occurrence of *Salmonella* contamination across these industries and various resource constraints, FSIS decided to apply performance standards to establishments that produce more than 6,000 pounds of comminuted pork per day (138 establishments representing 96 percent of production); or 50,000 pounds of pork cuts per day (38 establishments representing more than 91 percent of production). Most slaughter establishments are not subject to the performance standards, but there are 45 establishments covered by these standards that account for 88 percent of all swine slaughtered in the United States.

Sampling evidence shows that *Salmonella* prevalence varies substantially across the pork industries. On average, 30.3 percent of comminuted pork samples were *Salmonella*-positive. For pork cuts samples, an average of 9.3 percent were *Salmonella*-positive. Contamination tends to cluster among a limited number of establishments in this industry, particularly for pork cuts.

This risk assessment uses a published model to evaluate a range of performance standard options. Each option is defined by the maximum number of allowable *Salmonella*-positive samples among 52 samples collected per 12-month period. For each putative performance standard, the model predicts a) the reduction in annual cases of human salmonellosis and b) the share of the respective industry that will pass the performance standard initially. For a targeted 25 percent reduction (per Healthy People 2030) in human salmonellosis cases attributed to these products, performance standards less than, or equal to, 13 and 6 provide increasing confidence in meeting this goal for comminuted pork and pork cuts, respectively.

For a comminuted pork performance standard of 13 allowable positives, the median (95 percent confidence interval) prediction is that about 8,300 (3,600 – 16,300) fewer *Salmonella* illnesses associated with this product will occur annually following full implementation. Also, an estimated 51 (37 – 67) percent of the production volume – and 56 (49 – 65) percent of

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\(^1\) [Strategic Planning | Food Safety and Inspection Service (usda.gov)](https://www.usda.gov)
establishments – will pass this performance standard initially. Following implementation of a pork cuts performance standard of 6 allowable positives, 21,600 (10,000 – 40,000) fewer Salmonella illnesses associated with these products are predicted, while an estimated 67 (61 – 74) percent of the production volume – and 61 (56 – 67) percent of establishments – will pass this performance standard initially. Of the 20 establishments that produce both pork products and are subject to these performance standards, the model predicts that about 11 will pass both standards, 2 will fail both standards and the remaining 7 will fail one standard.

The risk assessment predictions will hold only if certain assumptions are true. For example, sampling of establishments must be sufficient to classify establishments accurately; and, to generate incentives for passing the standards, information about the classification of individual establishments with respect to the performance standards must be available publicly. Following implementation of the standards, FSIS will periodically analyze the evidence it gathers to determine the accuracy of its predictions.
Introduction

As part of its efforts to reduce pathogen contamination of meat and poultry, the Food Safety and Inspection Service (FSIS) implemented the Pathogen Reduction; Hazard Analysis and Critical Control Points System – Final Rule in 1996 (FSIS, 1996b). That effort included FSIS developing Salmonella performance standards (a.k.a., 2-class attribute sampling plans) for many meat and poultry products. The swine carcass performance standard allowed a maximum of 6 Salmonella-positive carcass swab samples at the post-chill location, out of a set of 55 samples. FSIS also intended to introduce performance standards for fresh pork sausages when data collection for these products was completed (FSIS, 1996b). FSIS found that 30 percent of fresh pork sausage samples were Salmonella-positive and announced a performance standard of 18 allowable positives out of a set of 53 samples (FSIS, 1997). The performance standard was withdrawn and never reconsidered (FSIS, 1998).

In its application of the Salmonella performance standard for swine carcasses, FSIS collected an average of 6,500 samples per year. The baseline survey for market hog carcasses, from which the carcass performance standard was derived, found 8.7 percent of samples positive for Salmonella (FSIS, 1996a). In the years following implementation of the performance standard, the percentage of Salmonella-positive samples from swine carcass testing decreased to less than 3 percent and, as a result, FSIS suspended this sampling program in 2011 (FSIS, 2012; Williams et al., 2014).

The Centers for Disease Control and Prevention (CDC) estimates that there are approximately one million domestically-acquired foodborne cases of salmonellosis each year (Scallan et al., 2011). CDC provided its first estimate of the role of pork products in these cases by analyzing outbreak data collected between 1998 and 2008. The estimated percentage of foodborne salmonellosis cases attributed to pork for this time period was 6.2 percent, with lower- and upper-bound estimates of 3.6 and 11.4 percent respectively (Painter et al., 2013).

The CDC, U.S. Food and Drug Administration (FDA) and FSIS formed the Interagency Food Safety Analytics Collaboration (IFSAC) in 2011. As part of this effort, IFSAC developed estimates of the attribution fractions for 17 broad commodity classes (Richardson et al., 2017). These IFSAC estimates suggest that the percentage of salmonellosis cases attributed to pork has increased, with the most recent estimates being 10.5, 10.8 and 10.3 percent (IFSAC, 2017, 2018, 2019b). Furthermore, the attribution to pork appears to be increasing relative to other commodities, with pork consistently being one of the top five largest contributors to salmonellosis cases in the United States. Higher attribution fractions for pork, coupled with the fact that pork only constitutes about a quarter of the meat and poultry consumed in the United States (ERS, 2018), suggests that the probability of illness per serving for this commodity may be greater than previously realized. For example, a comparative study of meat and poultry products found that the salmonellosis risk per serving for pork was slightly smaller than chicken but larger than that for beef (Hsi et al., 2015). Nevertheless, that study was based on older pork attribution estimates (~6.2 percent) and more recent IFSAC attribution estimates may place pork ahead of both chicken and beef in terms of probability of illness per serving consumed.
In its *Salmonella* Action Plan (FSIS, 2013b), FSIS committed to a 25 percent reduction in annual salmonellosis cases attributed to its regulated products and the Agency has documented recent reductions in comminuted poultry contamination that nearly meet this target (Ebel and Williams, 2019). The 25 percent reduction goal was originally set forth as part of the Healthy People 2020 (HP2020) plan (HHS, 2010). The 25 percent reduction will remain as the intended target for illness reductions unless different targets for HP2030 are proposed and adopted.

This report presents analyses needed to select new performance standards for raw finished pork cuts and raw comminuted (i.e., ground) pork. These products represent the majority of the pork consumed in the United States. Sampling methods differ between these products; a pork cuts sample is a whole-muscle sample (with or without bone), while comminuted product results from the grinding or mincing of trimmings generated during the fabrication of swine carcasses. Sampling evidence suggests that these two forms of pork differ with respect to *Salmonella* occurrence. Therefore, FSIS developed separate performance standards for each of these pork products.

The ham, belly, loin, shoulder, and jowl are pork primal parts (9 CFR 316.9(b)). An intact cut stems from a primal part; its size is equal to, or larger than, ¾ inch in at least one dimension. A non-intact cut differs from an intact cut in that it is further processed (e.g., needle or blade tenderized, injected, pumped or vacuum tumbled). Both intact and non-intact cuts can be either bone-in or boneless.

Following an initial analysis of pork sampling data, and an assessment of the available laboratory resources, FSIS decided to set limits on the production volume of establishments that are eligible for performance standards. This report summarizes *Salmonella* occurrence on pork cuts and comminuted products across the industry to explain these production volume limits.

### Data summarization of *Salmonella*-positive samples from comminuted pork and intact/non-intact pork cuts

#### General Pork Sampling Results

FSIS oversees swine slaughter and/or processing at 2,362 establishments across the United States (Figure 1). There are 1,110 establishments slaughtering hogs, 1,070 establishments that produce pork cuts and 1,334 establishments producing comminuted pork. There are 1,252 establishments that only process pork cuts or comminuted pork.

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2 All data used in the analysis represent the best available data as of January 1, 2020. Any discrepancies between the risk assessment inputs and currently available data represent revisions, updates and/or corrections made to these data at a later date.
The numbers of slaughter, pork cuts and comminuted pork establishments regulated by FSIS are shown. The overlaps in this figure denote establishments that produce more than one product (e.g., slaughter swine, pork cuts or comminuted pork). Overall, 2362 unique establishments constitute the pork industry regulated by FSIS.

The FSIS Phase 2 Pork Exploratory Sampling Program was intended to assess *Salmonella* contamination for three distinct product classes; comminuted pork (i.e., ground or minced), intact pork cuts and non-intact pork cuts. A stratified sampling design was employed to select a sample from the establishments that produced greater than 10,000 pounds per month (i.e., a typical day’s production averaging greater than 500 pounds) of each product. Establishments covered by the survey represented approximately 99 percent of all comminuted pork and pork cuts produced in the United States.

Sampling was conducted from June 2017 through May 2018. There were 1650, 1296, and 1198 samples collected from 141, 130 and 50 establishments producing comminuted, intact and non-intact pork, respectively. Details of the sampling and microbiologic detection methods are described in various FSIS publications (FSIS, 2011a, 2013a, 2014).

Individual samples consist of 2 lbs. (900 g) of product (i.e., either comminuted pork or pork cuts) collected at an establishment and then shipped to one of three FSIS laboratories. Laboratory personnel randomly select a 325 g subsample then add 975 mL of modified Tryptone Soya Broth. The aliquot is mixed by stomaching, blending or hand massaging prior to a 24h incubation period. After incubation, a PCR-based screening test – using the 3M™ Molecular Detection Assay 2 – determines the sample’s initial status. Samples that test positive on the
screening test are subjected to confirmatory testing, serotyping, genotyping and antimicrobial resistance testing according to FSIS methods (FSIS, 2014). The sample aliquot analyzed for each sample implies a limit of detection (LOD) of approximately 0.003 CFU’s per gram.

The average percentage of positive samples across all sampled establishments (i.e., the mean of ratios estimator) for comminuted, intact and nonintact product types was 16.4, 9.4, and 6.3 percent, respectively. A 2-sample test for the equality of the proportions of positive cuts samples found no significant difference in the percentage of positive intact and non-intact samples ($p = 0.167$) across the population of establishments, so these classes were combined into a single category of pork cuts. The average establishment-level percentage of Salmonella-positives samples across the 165 unique establishments producing the combined class of pork cuts was 8.7 percent.

FSIS categorizes establishments using nine strata based on production volume (Figure 2). To facilitate understanding of the relative contribution of different size strata to the total industry, establishments were assigned to small, medium and large production categories. The small production category consists of establishments whose production volume was less than 0.1 percent of the total production volume. Establishments in the medium category have production volumes that constitute between 0.1 and 0.5 percent of the total. Establishments producing greater than 0.5 percent of the total production for the commodity of interest were assigned to the large category.

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3 In a recent publication, FSIS reported the results of the pork baseline (Scott et al., 2020) and estimated the national prevalence of Salmonella in comminuted pork, intact pork cuts and non-intact pork cuts to be 29%, 5% and 4%, respectively. In conducting this risk assessment, FSIS estimated a national prevalence of Salmonella in comminuted pork and pork cuts of 30% and 9%, respectively. This discrepancy in the Salmonella prevalence for pork cuts is due to the following: 1) the risk assessment merged intact and non-intact cuts, 2) performance standard volume cut-offs were imposed (6,000 lbs./day for comminuted and 50,000 lbs./day for cuts) that excluded some establishments’ sampling results from the risk assessment’s estimates, and 3) the publication used baseline production volume data from 2017 while this risk assessment uses 2019 data.
Figure 2. The x-axis of this graph identifies the nine daily production volume bins used in the FSIS database. The vertical bars illustrate the number of pork cuts and comminuted pork establishments as measured along the left y-axis. The symbols connected by lines illustrate the share of total production volume for these commodities as measured along the right y-axis. The greatest number of establishments for both commodities produce between 101 to 1000 lbs. per day, but the greatest share of total production comes from establishments producing 600,000 to 1 million lbs. per day.

Figure 3 summarizes the distribution of production volume and Salmonella contamination across the 400 establishments producing more than 10,000 pounds of comminuted pork per month during the Phase 2 Pork Exploratory Sampling Program. As is typical for United States meat and poultry industries, a relatively small number of establishments produce greater than 95 percent of all comminuted pork. The proportion of Salmonella-positive samples also differ as a function of an establishment’s production volume, with the occurrence of positive samples in the large volume category being roughly three and two times more frequent than that of the small and medium-sized categories, respectively.
Figure 3. Cumulative ground pork production volumes divided into three production volume classes. Summary statistics for each class provide the number of establishments, total share of production volume and percent of samples that were Salmonella-positive in the Phase 2 Pork Exploratory Sampling Program.

Figure 4 summarizes the distribution of production volume and Salmonella contamination across the 387 establishments producing in excess of 10,000 pounds of pork cuts per month during the Phase 2 Pork Exploratory Sampling Program. One notable difference for the pork cuts industry, relative to the comminuted pork industry, is that Salmonella contamination is more similar across the establishment size categories, although the highest proportion of contaminated samples still occurs in the large category. Another difference between these industries is that the large volume category for the cuts industry contains a higher percentage of the total production volume relative to comminuted pork (i.e., 91 versus 78.5 percent).
Characteristics of pork cuts industry
(>10,000 pounds/month)

Small
Estabs= 312
Vol= 2.9%
%pos= 7.6

Medium
Estabs= 42
Vol= 6.1%
%pos= 9.4

Large
Estabs= 33
Vol= 91%
%pos= 9.7

Figure 4. Cumulative production volume of pork cuts by establishment size. The population is divided into three production volume classes. Summary statistics for each class provide the number of establishments, total share of production volume and percent of samples that were *Salmonella*-positive in the Phase 2 Pork Exploratory Sampling Program.

FSIS is limiting the application of performance standards to the larger volume establishments in each of the targeted pork industries. *Salmonella* occurrence across the small volume categories is already substantially less than its occurrence for the medium and large categories for comminuted pork and pork cuts.

After considering FSIS’ available personnel and laboratory resources, in conjunction with the distribution of *Salmonella* contamination across the different size categories, FSIS decided to apply performance standards to establishments that produce more than 6,000 and more than 50,000 pounds of comminuted pork and pork cuts per day. These size classes roughly align with the medium and large strata for comminuted pork and the large strata for establishments that produce pork cuts.

Using these volume limits, the performance standards will apply to 138 comminuted- and 38 cuts-producing establishments (Figure 5). These establishments represent 96 and 91 percent of the total U.S. production volume of comminuted pork and pork cuts, respectively. Twenty establishments produce both of these products and represent 45 percent of all U.S. comminuted pork and pork cuts production.

Although most slaughter establishments are not subject to one or both of the proposed performance standards, the 45 establishments covered by these standards account for 88 percent of all swine slaughtered in the United States (Figure 5). In addition, a few large slaughter establishments do not produce comminuted pork or pork cuts directly but belong to large corporations that process the majority of those establishments’ carcasses. If we add the slaughter
totals for these establishments to those of establishments directly under the standards, then the proposed standards cover about 94 percent of all swine slaughtered in the United States.

Figure 5. The share of the swine slaughter industry covered by the comminuted pork and pork cuts performance standards is shown. Although most slaughter establishments will not be subject to either performance standard, these standards do apply to establishments that represent 88 percent of total swine slaughter.

Because the comminuted pork and pork cuts performance standards do not apply to all of those industries’ establishments, the targeted reduction in occurrence of Salmonella-contaminated samples across the entire industry requires upward adjustment. Therefore, for a 25 percent overall reduction (based on the HP2030 goal), the comminuted pork and pork cuts performance standards should be selected to achieve at least a 26 \( \frac{0.25}{0.96} \) and 27 \( \frac{0.25}{0.91} \) percent reduction, respectively, in Salmonella occurrence from the establishments subject to those performance standards.
Summarizing *Salmonella* contamination across the population of establishments eligible for performance standards

The frequency of contaminated product varies across the establishments that constitute an industry. If $P_j$ is a random variable for within-establishment prevalence of contaminated product $j$ (where $j$ is either pork cuts or comminuted pork), and it is modeled as $P_j \sim \text{beta}(\alpha, \beta)$, then we define $P_{\text{baseline}} = \frac{\alpha}{\alpha + \beta}$.

A beta distribution describes the variability of within-establishment prevalence across an industry. Within-establishment prevalence is the average proportion of sample units collected in an establishment that will be detected positive based on the limit of detection for the sample. For example, a result of 5 positive comminuted pork samples among 52 samples collected across a year suggests that an estimated 9.6% of the 325 g units of comminuted pork produced by the establishment each year are *Salmonella*-positive. Put another way, if the establishment produces 10 million lbs. of comminuted pork per year (roughly 14 million 325 g units), then we would expect that 1.3 million of the 325 g units it produces would be *Salmonella*-positive.

To determine $P_j$, we use maximum likelihood estimation in a weighted beta-binomial fitting algorithm (Williams and Ebel, 2014; Williams et al., 2013). There were 71 comminuted and 41 cuts establishments eligible for the performance standards and sampled in the Phase 2 Pork Exploratory Sampling Program. Their sampling results are summarized as $s_i$ *Salmonella*-positive samples among $n_i$ samples collected in establishment $i$. In addition, each establishment also has a production volume weight assigned based on its share of total product across all establishments, as well as a probability of inclusion associated with the stratified design in the Phase 2 Pork Exploratory Sampling Program (Scott et al., 2020; Williams et al., 2013).

The concept of the beta-binomial fitting algorithm is that there is a beta distribution that describes how the probability of positive samples varies across establishments, but each establishment’s sampling result depends on a binomial process (i.e., $s_i \sim \text{binomial}(n_i, p_i)$, where $p_i$ is the probability of positive samples for establishment $i$). Because the evidence regarding each establishment’s $p_i$ should contribute information to $P_j$ that reflects the establishment’s production volume share, the fitting algorithm is volume-weighted to account for the large differences in the amount of production by each establishment. To estimate uncertainty about the true $P_j$, the maximum likelihood estimates are solved iteratively for 2,000 weighted bootstrap samples of the data (Williams and Ebel, 2014).

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4 To assess the proportion of establishments that will pass alternative performance standards, we also use an unweighted beta-binomial fitting algorithm. The performance standards do not depend on this unweighted fit, but FSIS economists require the proportion of establishments passing and failing a standard to complete a cost-benefit analysis.
A bivariate beta-binomial distribution (Bibby and Væth, 2011) is also fitted to the data to describe the effect of different performance standards on the subpopulation of establishments that produce both pork cuts and comminuted pork.

The estimated beta distributions show that within-establishment *Salmonella* prevalence varies substantially across the pork industry (Figures 6 and 7). For both commodities, most of the mass of the distribution is below the mean ($P_{baseline, comm} = 30.3\%$, $P_{baseline, cuts} = 9.3\%$), but these distributions also suggest that a number of establishments have contamination levels that are multiple times higher than the modal values.

There is much more uncertainty about the true distribution of within-establishment *Salmonella* prevalence for comminuted pork than pork cuts. Two factors explain this difference in the magnitude of the uncertainty. The first is the larger average number of samples per cuts establishment versus comminuted establishment ($\bar{n}_{cuts} = 35$ versus $\bar{n}_{comm} = 18$). The second is that all cuts establishments that will be subject to the standard were selected with certainty in the Phase 2 Pork Exploratory Sampling Program. In contrast, only about 50 percent of establishments in the medium-sized strata were selected for comminuted pork.

**Figure 6.** The variability of within-establishment prevalence across the comminuted pork industry is modeled using a beta distribution. This figure includes a bootstrap depiction of uncertainty about the beta distribution using 200 bootstrap replicates (2000 replicates are used for the full analyses). The most likely distribution is based on the maximum likelihood estimates ($beta(1.134, 2.608)$); bootstrap sampling of the data generate alternative distributions that reflect the uncertainty associated with the fitting algorithm to the available sampling data. The population mean is the expected value of the most likely distribution.
Figure 7. The variability of within-establishment prevalence across the pork cuts industry is modeled using a beta distribution. This figure includes a bootstrap depiction of uncertainty about the beta distribution using 200 bootstrap replicates (2000 replicates are used for the full analyses). The most likely distribution is based on the maximum likelihood estimate ($\text{beta}(0.492, 4.823)$); bootstrap sampling of the data generate alternative distributions that reflect the uncertainty associated with the fitting algorithm to the available sampling data. The population mean is the expected value of the most likely distribution.

Salmonella contamination is clustered in a relatively small fraction of the pork industry. The Gini coefficient quantifies this phenomenon. This coefficient is a number between 0 and 1 that describes how concentrated contamination is amongst a small portion of establishments (Beach and Davidson, 1983; Bishop et al., 1991; Lukicheva et al., 2016). A Gini coefficient near 0 suggests that contamination is spread evenly across establishments (i.e., all establishments have similar contamination). A Gini coefficient near 1 implies that only a small number of establishments are responsible for most of the contamination (i.e., most of the contaminated pork is produced by a small number of establishments). A Gini coefficient of $\frac{1}{3}$ describes a uniform distribution. The Gini coefficients for comminuted pork and pork cuts are 0.39 and 0.61, respectively. These indicate some clustering of contamination among establishments in the comminuted pork industry, but a somewhat high degree of clustering of contamination among cuts establishments. Gini coefficients estimated for other FSIS meat and poultry commodities range from 0.19 (comminuted chicken-Salmonella) to 0.71 (pre-chill beef carcasses-Salmonella) (Lukicheva et al., 2016).
Methods

Figure 8 outlines a conceptual framework for deriving a performance standard to achieve a reduction in overall occurrence of *Salmonella*-positive product. A performance standard is chosen such that, following its implementation, some share of establishments – and their attendant production volume – will be classified as failing the standard; and some of those establishments will be compelled eventually to pass the performance standard. This movement of establishments from failing to passing generates a reduction in the overall occurrence of *Salmonella*-positive product in the future.

A risk assessment model estimates the public health effects – measured in annual human *Salmonella* illnesses avoided – from imposing performance standards. This model assumes that reductions in human illnesses will be proportional to the reduction in the prevalence of *Salmonella*-positive samples (Ebel and Williams, 2015). A critical input to the model is the fraction of pork products – produced by establishments not meeting the standard initially – that will eventually become compliant following imposition of the performance standard. This proportion is referred to as the compliance fraction. Some establishments not meeting a standard at the start are motivated to reduce contamination. For example, FSIS has posted the names of establishments not meeting the standard on its website (FSIS, 2011b). This information might be used by potential customers to influence purchasing or pricing decisions (Golan et al., 2004; Ollinger and Moore, 2009). This risk assessment uses information from an analysis of other FSIS performance standards to model the effect of the compliance fraction across a plausible range of values.
Failing establishments $P_{\text{fail}}$  

Baseline prevalence  

$$P_{\text{baseline}} = \omega P_{\text{pass}} + (1 - \omega)P_{\text{fail}}$$

Passing establishments $P_{\text{pass}}$

Effect of the new standard:  

Some failing plants become passing

$$P_{\text{pass}} = (\omega + \alpha - \omega \alpha)P_{\text{pass}} + (1 - \alpha)(1 - \omega)P_{\text{fail}}$$

Figure 8. Schematic representation of the 2-strata risk assessment model.

**Model Description**

A mathematical model predicts the effects of alternative performance standards (Ebel, Williams, Golden, et al., 2012; FSIS, 2016; Williams et al., 2011). Estimates for many of the parameters in the model are derived from the beta-binomial distribution fitted to the volume-weighted sampling data. The resulting beta distribution models how the prevalence of *Salmonella*-positive samples varies across the industry’s establishments, where $s_i$ and $n_i$ parameters describe the number of positive and total samples collected in establishment $i$, respectively.

The performance standard development assumes FSIS will collect $n = 52$ samples annually from each establishment (weekly sampling). A performance standard is defined by choosing the number of maximum allowable positive samples ($s$) out of $n$. The ratio of $s$ to $n$ defines a threshold prevalence $P_{\text{threshold}} = s / n$. Establishments whose prevalence of positive samples exceeds the threshold value are defined as failing the performance standard. This analytic approach requires estimating a fraction ($\omega$) of production volume associated with establishments that initially meet the standard (i.e., the establishment has $s$ or fewer positive samples). The estimate of $\omega$ is derived from the cumulative probability of the beta distribution up to the threshold prevalence.

Before the performance standard is implemented (i.e., the baseline scenario), the overall prevalence of contaminated samples is
\[ P_{\text{baseline}} = \omega P_{\text{pass}} + (1 - \omega) P_{\text{fail}}, \]

where \( P_{\text{pass}} \) and \( P_{\text{fail}} \) are the average prevalence of contaminated samples among establishments that would pass or fail the performance standard, respectively.

The values of \( P_{\text{pass}} \) and \( P_{\text{fail}} \) are derived from the beta distribution using conditional expected value theory (Klugman et al., 2012). These values depend on a calculation for the limited expected value of a random variable \( p \), \( E[p \wedge t] \), such that \( p = P \) for values less than \( t \) but \( p = t \) for all values larger than \( t \). Therefore,

\[
P_{\text{pass}} = \frac{E[p \wedge P_{\text{threshold}}] - P_{\text{threshold}} (1 - F(P_{\text{threshold}}))}{F(P_{\text{threshold}})}
\]

\[
P_{\text{fail}} = \frac{E[p] - (E[p \wedge P_{\text{threshold}}] - P_{\text{threshold}} (1 - F(P_{\text{threshold}})))}{1 - F(P_{\text{threshold}})}
\]

where \( F(P_{\text{threshold}}) \) is the cumulative probability of the distribution of \( p \) up to value \( P_{\text{threshold}} \).

Because the distribution of \( p \) is production volume weighted, the value for \( \omega \) equals \( F(P_{\text{threshold}}) \).

The actuar library (Dutang et al., 2008) in the R computer software package (R Development Core Team, 2018) provides simple commands to solve for \( E[p \wedge t] \) when \( p \) is beta distributed.

Uncertainty in the various prevalence estimates is derived using a bootstrap resampling routine on the data collected for each establishment (Efron and Tibshirani, 1994). For this analysis, a bootstrap sample size of 2,000 was used to provide sufficient demonstration of the uncertainty in the distributions.

Once the performance standard is implemented, and establishments failing the standard are identified, some fraction (i.e., \( \alpha \), the “compliance fraction”) of those establishments are expected to change their production practices in order to pass the performance standard. Across time, it is likely that these establishments would ultimately attain a prevalence of contaminated samples that is equal to establishments that meet the performance standard (i.e., \( P_{\text{pass}} \)). Given this expected change, the estimated overall prevalence following implementation of the performance standard is given by;

\[
P_{\text{new}} = (\omega + \alpha - \omega \alpha) P_{\text{pass}} + (1 - \omega)(1 - \alpha) P_{\text{fail}}.
\]

In previous FSIS risk assessments, the compliance fraction has been a decision variable with alternative values of 30, 40 and 50% (FSIS, 2011b, 2015). A recent study of the comminuted turkey and chicken performance standards estimated that the most likely compliance fraction values were approximately 40 and 50%, respectively (Ebel and Williams, 2019). The number of comminuted chicken establishments roughly approximates the numbers of pork-producing
establishments, and the lower and upper bounds of uncertainty about the compliance fraction for comminuted chicken were approximately 20% and 60%.

In the current risk assessment, the compliance fraction is modeled as an uncertain parameter with a \textit{Pert}(minimum, mode, maximum) distribution. For both pork cuts and comminuted pork, the compliance fraction’s modal value is the average of modal values for comminuted chicken and turkey (i.e., $45\% = \frac{40\% + 50\%}{2}$) and the minimum and maximum values are those observed for comminuted chicken (i.e, $\alpha \sim \text{Pert}(0.2, 0.45, 0.6)$).

To estimate the annual average number of illnesses avoided ($I_{\text{Avoided}}$) by a performance standard that reduces the prevalence of contaminated units, the following model can be used as adapted from Ebel et al., 2012

$$I_{\text{Avoided}} \sim \text{Poisson} \left[ \left(1 - \frac{P_{\text{new}}}{P_{\text{baseline}}} \right) \lambda_{\text{ill}} \right]. \quad \text{(Equation 1)}$$

In this equation, $\lambda_{\text{ill}}$ represents the annual rate of illnesses (i.e., cases of salmonellosis attributed to a pork product) occurring before the performance standard is implemented. Estimation of this parameter is explained below. In this formula, the prevalence of contaminated samples prior to implementing the performance standard is $P_{\text{baseline}}$ and the prevalence following successful implementation of the performance standard is $P_{\text{new}}$.

This approach suggests that the number of human illnesses avoided by a prevalence-based performance standard is proportional to the number of illnesses that occurred prior to implementation. Such an approach has been used previously to estimate changes in sporadic illnesses within populations when prevalence of contamination changes (Bartholomew et al., 2005; FAO/WHO, 2002; Vose, 2008). This model assumes that the levels of contamination (i.e., concentration of pathogens per sampled unit) are independent of the prevalence of contamination. If a positive correlation exists between the prevalence of contaminated samples

---

5 All calculations for illness reduction were based on 2 million iterations; this was sufficient to provide stability in the median estimate within 0.5 percent.

6 The Phase 2 Pork Exploratory Sampling Program data support assumptions of either independence, or a positive correlation, between concentration and prevalence. Those data include MPN analyses on about one-third of the \textit{Salmonella-positive samples}. For the comminuted pork industry, using $P_{\text{threshold}} = \frac{13}{52} = 0.25$ results in an average concentration of 0.15 CFU’s per gram (range is <0.03 – 4.3 CFU’s) among positive samples collected in establishments above this threshold, wherein the average prevalence is 48 percent. Among positive samples collected in establishments below this threshold, wherein the average prevalence is 10 percent, the average concentration is 0.04 CFU’s per gram (range is <0.03 – 0.07 CFU’s). For the pork cuts industry, using $P_{\text{threshold}} = \frac{6}{52} = 0.115$ results in an average concentration of 0.06 CFU’s per gram (range is <0.03 – 0.43 CFU’s) among positive samples collected in establishments above this threshold, wherein the average prevalence is 24 percent. Among positive samples collected in establishments below this threshold, wherein the average prevalence is 3 percent, the average concentration is 0.04 CFU’s per gram (range is <0.03 – 0.07 CFU’s).
and the levels of *Salmonella* on the end product, then this assumed independence usually leads to a conservative estimate of the reduction in illnesses associated with a reduction in prevalence (Ebel and Williams, 2015).

**Estimation of Burden of Illness (\(\lambda_{ill}\)) Attributed to Ground Pork and Pork Cuts**

The annual number of *Salmonella* illnesses attributed to pork is an uncertain parameter. Prior to implementing a performance standard, the annual *Salmonella* illnesses in the United States attributed to different pork products can be modeled as:

\[
\lambda_{ill\_j} = \lambda_{salm\_tot} \times a_{pork} \times a_{pork\_j}
\]

where \(\lambda_{ill\_j}\) is total annual illnesses associated with pork product \(j\) (where \(j\) is indexed as pork cuts, comminuted pork or ready-to-eat (RTE) pork), \(\lambda_{salm\_tot}\) is the total U.S. foodborne *Salmonella* illnesses per year from all sources, \(a_{pork}\) is the attribution fraction of all *Salmonella* illnesses associated with pork consumption and \(a_{pork\_j}\) is the attribution fraction of pork illnesses associated with product \(j\) such that \(a_{pork\_RTE} + a_{pork\_cuts} + a_{pork\_comminuted} = 1\), where pork cuts constitute intact and non-intact whole cuts of pork.

To estimate the annual rate of total foodborne *Salmonella* illnesses (\(\lambda_{salm\_tot}\)) from all sources, we use CDC’s approach (Scallan et al., 2011). This approach begins with the number of *Salmonella* cases reported to the FoodNet surveillance system, then adjusts that number to account for FoodNet’s catchment area and an under-diagnosis multiplier.

The most recent number of FoodNet cases reported is for surveillance year 2015; for *Salmonella*, there were 7719 cases identified in the 10 FoodNet sites (CDC, 2017). FoodNet’s catchment area represents 0.15 of the U.S. population, so we calculate total reported cases as

\[
\frac{7719}{0.15} = 51,460
\]

but, this number does not account for under-diagnosis of *Salmonella* cases.

The under-diagnosis multiplier for *Salmonella* was estimated to be approximately 24 undiagnosed domestic, foodborne cases for each reported case (Scallan et al., 2011). Uncertainty about this multiplier can be modeled using a *Gamma*(32.83,0.74) distribution (Ebel, Williams and Schlosser, 2012). Therefore, \(\lambda_{salm\_tot} \sim 51,460 \times *Gamma*(32.83,0.74)\) with an expected value of about 1.25 million *Salmonella* cases per year.

To model uncertainty about the attribution fraction for pork, we assume

\(a_{pork} \sim Pert(0.036,0.103,0.16)\). CDC estimated an attribution fraction for pork based on analysis of *Salmonella* outbreaks from 1998 to 2008; this estimate had a most likely value of 6.2 percent with a minimum to maximum range of 3.6 to 11 percent (Painter et al., 2013). IFSAC estimated pork attribution based on analysis of *Salmonella* outbreaks from 1998 to 2017 (IFSAC,
The IFSAC estimate for $a_{pork}$ was centered at 10.3 percent with 90 percent credibility bounds of 7.77 and 13.21 percent. A Pert(minimum, mode, maximum) distribution was defined for $a_{pork}$ by assuming the minimum value from Painter et al. (2013), the modal value from IFSAC and a maximum value of the 99.9% upper bound from the IFSAC results. This latter value was calculated by using the interval between IFSAC’s reported 95th percentile ($x_{0.95}$) and modal value ($\bar{x}$) to impute a standard error for application to more extreme values.

Attributing pork-associated Salmonella illnesses to either cuts of pork (e.g., roasts, chops, ribs) or comminuted (e.g., ground) pork is accomplished by considering the outbreak evidence from IFSAC, consumption information from the National Health and Nutrition Examination Survey (NHANES)(CDC, 2012), and pork production evidence from FSIS. Although the IFSAC analysis reports attribution fractions for 17 general food categories, the dataset can be queried to examine more detailed descriptions of the foods implicated in outbreaks. For pork, outbreaks were associated with pork cuts, ground pork, RTE pork and unknown pork products (IFSAC, 2019a). The latter category was assumed to comprise either pork cuts or ground pork in proportions consistent with the outbreaks for which pork cuts and ground pork were identified.

The IFSAC analysis of subcategories of pork provided most likely (90% credibility bounds) estimates for attribution of pork cuts, ground pork and RTE pork of 8.32 (6.96, 9.94), 2.51 (1.54, 4.00) and 0.54 (0.28, 1.05), respectively. The most likely values imply approximately 73, 22 and 5 percent of pork-associated Salmonella illnesses were attributed to pork cuts, ground pork and RTE pork, respectively. Uncertainty for the attribution fraction of pork illnesses associated with RTE pork products is modeled as $a_{pork \_ RTE} \sim Pert(0.02, 0.05, 0.09)$, where the minimum and maximum values roughly correspond to the RTE bounds divided by the total attribution for pork.

NHANES analysis of 10 years of consumption data suggests the average daily consumption of pork comprises pork cuts, ground pork, RTE pork and pork dishes (Appendix A). This analysis suggests that 53, 19 and 28 percent of pork consumed in the United States comes from pork cuts, ground pork and RTE pork, respectively. Furthermore, these results imply that 73 and 27 percent of raw pork (i.e., not RTE) consumption in the United States is represented by pork cuts and ground pork, respectively. This implies that the ratio of pork cuts consumption to ground pork consumption is about 2.7:1.

FSIS data for total raw pork production suggests 61 and 39 percent shares for pork cuts and ground pork; a 1.6:1 ratio for cuts to ground (Scott et al., 2020). Recall that the IFSAC analysis

\[ x_{0.999} = \bar{x} + \frac{Z_{0.999} - \bar{x}}{Z_{0.95}} \times Z_{k} \]

\[ Z_{k} \] is the $k^{th}$ quantile of a Normal(0,1) distribution.

\[ 7 \]

\[ 8 \]

This analysis included outbreaks involving multiple Salmonella etiologies, unlike the annual report that only includes outbreaks with one etiology. Therefore, the implied total attribution for pork using this approach is 11.4 percent (8.32%+2.51%+0.54%) rather than the prior IFSAC estimate of 10.3 percent.
\[
\left(\frac{73}{73 + 22}\right) \text{ and 23 percent of raw pork outbreak illnesses are associated with pork cuts and ground pork, respectively; a 3.3:1 ratio for cuts to ground.}
\]

To model uncertainty about the attribution shares for pork cuts and ground pork, we define the ratio \( m = \frac{a_{\text{pork cuts}}}{a_{\text{pork comminuted}}} \) and further assume \( m \sim \text{Pert}(1.6, 2.7, 3.3) \) based on the values derived above. For a given value of \( a_{\text{pork rte}} \), we know that

\[
(1 - a_{\text{pork rte}}) = m \cdot a_{\text{pork comminuted}} + a_{\text{pork comminuted}} = (m + 1) a_{\text{pork comminuted}}
\]

\[
\frac{(1 - a_{\text{pork rte}})}{(m + 1)} = a_{\text{pork comminuted}}
\]

\[a_{\text{pork cuts}} = m \cdot a_{\text{pork comminuted}}\]

to maintain the identity \( a_{\text{pork rte}} + a_{\text{pork cuts}} + a_{\text{pork comminuted}} = 1 \).

Outputs of this analysis are summarized in Table 1. At the median, approximately 69 and 26 percent of all pork Salmonella illnesses are attributed to pork cuts and comminuted pork, respectively.
Table 1. Burden of illness components for pork cuts and comminuted pork are shown.

<table>
<thead>
<tr>
<th>Burden of illness component</th>
<th>2.5\textsuperscript{th} percentile</th>
<th>50\textsuperscript{th} percentile</th>
<th>97.5\textsuperscript{th} percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual number of domestically-acquired foodborne salmonellosis cases, $\lambda_{salm_tot}$</td>
<td>859,000</td>
<td>1,238,000</td>
<td>1,714,000</td>
</tr>
<tr>
<td>Attribution fraction for pork, $a_{pork}$</td>
<td>0.06</td>
<td>0.11</td>
<td>0.15</td>
</tr>
<tr>
<td>Proportion of pork-associated illness attributed to RTE pork, $a_{pork_rte}$</td>
<td>0.03</td>
<td>0.05</td>
<td>0.08</td>
</tr>
<tr>
<td>Proportion of pork-associated illness attributed to pork cuts, $a_{pork_cuts}$</td>
<td>0.63</td>
<td>0.69</td>
<td>0.73</td>
</tr>
<tr>
<td>Proportion of pork-associated illness attributed to comminuted pork, $a_{pork_comminuted}$</td>
<td>0.23</td>
<td>0.26</td>
<td>0.32</td>
</tr>
<tr>
<td>Annual number of attributed cases of salmonellosis pork cuts $\lambda_{ill_cuts}$</td>
<td>45,000</td>
<td>88,000</td>
<td>145,000</td>
</tr>
<tr>
<td>Annual number of attributed cases of salmonellosis for comminuted pork $\lambda_{ill_ground}$</td>
<td>17,000</td>
<td>34,000</td>
<td>57,000</td>
</tr>
</tbody>
</table>
Results

The model estimates the percentage reduction in human illnesses \( 1 - \frac{P_{\text{new}}}{P_{\text{baseline}}} \), and the fraction of the industry’s production volume that initially passes \( \omega \), for alternative performance standards of \( s \) positive samples among 52 total samples. These functional relationships are uncertain because of uncertainties about the distributions of within-establishment prevalence (Figures 6 and 7) and the compliance fraction.

Comminuted Pork Performance Standard

Figure 9 illustrates the trade-off between percentage reduction in human illnesses and the percent of production volume initially passing for a range of performance standards applied to the comminuted pork industry. The public health estimates are represented by box-and-whiskers plots that imply greater reductions in illnesses with decreasing (more stringent) performance standards. The horizontal line within each box represents the estimated median reduction in illnesses for a maximum number of allowable positive samples \( s \) out of \( n = 52 \). The lower and upper edges of each box represent the 25th and 75th percentile values of the range of uncertainty about reduction in illnesses while the whiskers extend to values that are no more than 1.5 times the length of the box. Estimates that are more extreme deviations appear as separate dots.

The percent of production volume initially passing is represented by the maximum likelihood estimate and 95 percent uncertainty bounds (in red). This percentage increases with increasing (less stringent) performance standards. The blue line denotes the 26 percent overall reduction objective, based on the Healthy People goal (adjusted for comminuted pork production under the performance standard).

If the performance standard is \( s = 13 \), the median estimated reduction in human illnesses is 26.5 percent. This estimate implies a slightly greater than 50 percent confidence in meeting or exceeding the targeted 26 percent reduction in human illnesses for this product. For this performance standard, an estimated 51 (37 – 67) percent of the production volume is expected to pass the performance standard initially (i.e., our median predicts that about 49 percent of production volume would fail the standard initially).

Performance standards with \( s < 13 \) have a larger probability of achieving a 26.5 percent reduction in human illnesses, but more stringent standards also imply less of the industry will initially pass. Performance standards \( s > 13 \) are progressively less likely to achieve the 26 percent reduction in human illnesses. For example, uncertainty about a performance standard of \( s = 17 \) implies there is less than 25 percent confidence of meeting or exceeding the targeted reduction.

If the performance standard achieves the estimated 26.5 percent reduction in Salmonella-contamination, then the prevalence in the portion of the industry covered by the performance standard will be reduced from the baseline prevalence of \( P_{\text{baseline,comm}} = 30.3\% \) to \( P_{\text{new,comm}} = 22.3\% \).
This average prevalence, however, is still greater than the 11.2 and 14.5% observed in the small and medium size strata for this commodity (Figure 3).

Figure 9. The estimated illness reductions and the percentage of comminuted pork production volume that is expected to pass a performance standard initially are shown for a range of performance standard options. The box-and-whiskers plots represent uncertainty about illness reduction; these refer to values along the left y-axis. The dashed red lines represent most likely and 95 percent uncertainty bounds for the share of the industry that will pass performance standards initially; these lines refer to values along the right y-axis. The solid horizontal blue line indicates the targeted reduction in illnesses.

Figure 10 compares the proportion of production volume that will initially pass the performance standard and the proportion of establishments that will initially pass. Both curves are simply representations of the cumulative probabilities of beta distributions based on volume weighted (production volume curve) or unweighted (establishments curve) fits. A larger proportion of establishments are expected to initially pass the standard, relative to the proportion of production volume passing. This result is expected because the lower volume establishments generally have much lower contamination rates; therefore, performance standards based on small numbers of allowable positives will result in small establishments passing the standard, but the production volume associated with those establishments is not large. For a performance standard of \( s = 13 \), an estimated 51 (37 – 67) percent of the production volume – and 56 (49 – 65) percent of establishments – will pass the performance standard initially.
Figure 10. Comparison of the proportion of establishments and the proportion of production volume for comminuted pork likely to be affected by the performance standard. The red curve represents the share of production volume that will pass alternative performance standards; dashed lines represent 95 percent confidence boundaries. The black line represents the share of establishments that will pass alternative performance standards (with corresponding 95 percent confidence boundaries). This curve is estimated using an unweighted beta-binomial fitting algorithm.

We use Equation 1 to estimate the number of illnesses avoided from alternative comminuted pork performance standards (Figure 11). In addition to the uncertainty in the percent reductions in proportion of *Salmonella*-positive samples depicted in Figure 9, the estimate of illnesses avoided includes uncertainty about the total number of salmonellosis cases, as well as the fraction of cases attributed to comminuted pork ($\lambda_{il}^*$). For a performance standard of $s = 13$, the median prediction is that about 8,300 fewer *Salmonella* illnesses associated with consuming comminuted pork will occur annually following full implementation of this performance standard. The 95 percent confidence interval spans 3,600 – 16,300 such illnesses avoided.
Figure 11. The estimated number of annual salmonellosis cases that would be avoided by implementing alternative comminuted pork performance standards is shown. Box and whiskers plots illustrate uncertainty about these estimates.

**Pork Cuts Performance Standard**

For pork cuts, a performance standard of $s = 6$ has an estimated median reduction in human illnesses of 27.5 percent (Figure 12). This implies 50 percent confidence in meeting or exceeding the targeted 27 percent reduction in human illnesses for this product. For this performance standard, an estimated 67 (61 – 74) percent of the production volume is expected to pass the performance standard initially (i.e., our median predicts 33 percent of production volume would fail the standard initially). Because the distribution of within-establishment prevalence for pork cuts is less variable, more right-skewed, and contamination is more highly clustered (Figure 7 and the higher Gini coefficient), a higher percent of this industry’s production volume (relative to the comminuted pork industry) will pass initially for performance standards around $s = 6$.

If the performance standard achieves the desired 27 percent reduction in *Salmonella*-contamination on cuts, then the average prevalence across the portion of the industry covered by the performance standard will be reduced from $P_{\text{baseline,cuts}} = 9.3\%$ to $P_{\text{new,cuts}} = 6.7\%$. This is slightly less than the 7.6 and 9.4% observed in the small and medium size strata for this commodity (Figure 4).
Figure 12. The estimated illness reductions and the percentage of pork cuts production volume that is expected to pass a performance standard initially are shown for a range of performance standard options. The box-and-whiskers plots represent uncertainty about illness reduction; these refer to values along the left y-axis. The dashed red lines represent most likely and 95 percent uncertainty bounds for the share of the industry that will pass performance standards initially; these lines refer to values along the right y-axis. The solid horizontal blue line indicates the targeted reduction in illnesses. Percent reduction in illnesses and the estimated percentage of production volume that is expected to pass a performance standard based on the existing industry contamination distribution.

Figure 13 compares the proportion of production volume that will initially pass the performance standard and the proportion of establishments that will initially pass. The lines depicting these estimated proportions are similar because the production volumes of the establishments eligible for this performance standard are also more similar than those producing comminuted pork. For a performance standard of \( s = 6 \), an estimated 67 (61 – 74) percent of the production volume – and 61 (56 – 67) percent of establishments – will pass the performance standard initially.
Figure 13. Comparison of the proportion of establishments and the proportion of production volume for pork cuts likely to be affected by the performance standard. The red curve represents the share of production volume that will pass alternative performance standards; dashed lines represent 95 percent confidence boundaries. The black line represents the share of establishments that will pass alternative performance standards (with corresponding 95 percent confidence boundaries). This curve is estimated using an unweighted beta-binomial fitting algorithm.

We use Equation 1 to estimate the number of illnesses avoided from alternative pork cuts performance standards (Figure 14). In addition to the uncertainty depicted in Figure 12, the estimate of illnesses avoided includes uncertainty about the number of salmonellosis cases attributed to pork cuts (\( \lambda_{\text{at}} \)). For a performance standard of \( s = 6 \), the median prediction is that about 21,600 fewer *Salmonella* illnesses associated with consuming pork cuts will occur annually following implementation of this performance standard. The 95 percent confidence interval spans 10,000 – 40,000 such illnesses avoided.
Effects of Performance Standards on Establishment Producing Cuts and Comminuted Pork

There were 20 establishments sampled for both comminuted (350 samples) and pork cuts (587 samples). From these data, we estimate the proportion of establishments that are likely to pass both standards. This estimate is derived by fitting a bivariate beta-binomial distribution (Figure 15) (Bibby and Væth, 2011) to these data and integrating the joint probability density function. Table 2 provides estimates for the proportion of establishments expected to pass for a range of possible performance standards that are near the most likely choices of 6 and 13 allowable positives for cuts and comminuted pork, respectively. In general, the proportion of establishments expected to pass any of the presented combinations in Table 2 is reasonably high compared to the estimates provided for the comminuted standard, which is the standard with the lowest proportion of establishments expected to initially pass. This phenomenon occurs because the prevalence of positive comminuted samples for establishments that produce both products is only 16.2 percent, which is lower than for the population at large.

For illustration, consider establishments producing both products and standards of $s_{\text{comm}} = 13$, $s_{\text{cuts}} = 6$. In this case, we expect 56 percent of such establishments (e.g., roughly 11 of 20) will pass both standards. Of the remaining 44 percent of these establishments, our bivariate beta-binomial distribution predicts 8 percent will fail both standards, while approximately 14 percent and 22 percent will fail the comminuted and cuts standards only, respectively. The univariate marginal distributions predict higher passing rates for the individual commodities of 75 and 72 percent for the comminuted and cuts standards, respectively. If these variables were completely
independent, then we would expect a probability of failing both standards of 7 percent 
\((1 - 0.75)(1 - 0.72) \times 100\).

Figure 15. Joint distribution of the prevalence of *Salmonella* contamination for establishments that produce both cuts and comminuted product.

Table 2. Proportion of establishments that produce both comminuted pork and pork cuts that are expected to pass a range of possible standards. This table summarizes a bivariate beta-binomial distribution shown graphically in Figure 15.

<table>
<thead>
<tr>
<th><em>s</em>&lt;sub&gt;cuts&lt;/sub&gt;</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>0.439</td>
<td>0.459</td>
<td>0.476</td>
<td>0.491</td>
<td>0.505</td>
</tr>
<tr>
<td>5</td>
<td>0.482</td>
<td>0.503</td>
<td>0.522</td>
<td>0.539</td>
<td>0.554</td>
</tr>
<tr>
<td>6</td>
<td>0.516</td>
<td>0.539</td>
<td>0.560</td>
<td>0.578</td>
<td>0.595</td>
</tr>
<tr>
<td>7</td>
<td>0.546</td>
<td>0.570</td>
<td>0.592</td>
<td>0.612</td>
<td>0.629</td>
</tr>
<tr>
<td>8</td>
<td>0.571</td>
<td>0.596</td>
<td>0.619</td>
<td>0.640</td>
<td>0.659</td>
</tr>
</tbody>
</table>
Discussion

The evidence analyzed in this risk assessment suggests *Salmonella* occurrence on pork is substantial. Comparing the estimated occurrence of *Salmonella* in pork to other commodities finds that pork cuts and chicken parts are equally likely to be *Salmonella*-positive. The occurrence for comminuted pork falls between that of comminuted turkey and chicken (Ebel and Williams, 2019) and is approximately 10 times higher than ground beef (FSIS, 2019).

This risk assessment provides an array of performance standards options for risk managers to consider. The outputs for each of the performance standards, comminuted pork and pork cuts, illustrate the trade-offs between public health benefits and the share of the industry passing (or failing) initially. Ultimately, risk managers will decide the performance standards for each commodity. To inform those decisions, FSIS economists will use the outputs of the risk assessment in their benefit-cost analysis.

For comminuted pork, selection of performance standards with $s \leq 13$ increases our confidence in meeting the HP2030 goal for reducing salmonellosis among consumers of this product. Nevertheless, tighter performance standards will result in more of the industry failing. For example, a standard of $s = 13$ is expected to result in a 26.5 percent reduction in illnesses, while 49 percent of the industry will fail initially. In contrast, a standard of $s = 10$ increases the expected reduction in illnesses to 30.4 percent, while 58 percent of the industry will fail initially. Therefore, selecting $s = 10$ instead of $s = 13$ could generate a 3.9 percent gain in the illness reduction for a 9 percent increase in the failing share of the industry.

For pork cuts, selection of performance standards $s \leq 6$ imply increased confidence in meeting the HP2030 goal for this product. Any reduction in the standard, however, will result in more of the industry failing. For example, a standard of $s = 6$ is expected to result in a 27.5 percent reduction in illnesses while 33 percent of the industry will fail initially. In contrast, a standard of $s = 4$ increases the expected reduction in illnesses to 33 percent while 44 percent of the industry will fail initially. Therefore, selecting $s = 4$ instead of $s = 6$ could generate a 5.5 percent gain in the illness reduction for an 11 percent increase in the failing share of the industry.

We expect the results of these analyses to hold only if the assumptions outlined in this report are true. For example, sampling of establishments must be sufficient to categorize establishments accurately (i.e., the intended 52 samples per year are collected in nearly all large establishments). Furthermore, information about the classification of individual establishments with respect to these performance standards must be available to consumers of these commodities (e.g., via public posting) so that incentives to pass the standards are evident. The analysis also depends on the respective industries maintaining a structure that is similar to the period during which the sampling data were collected. If the composition of these industries fluctuates (e.g., a large turnover of establishments, with many new establishments entering and others exiting), then predictions regarding the occurrence of *Salmonella* across the industries are less accurate.
Ultimately, accomplishing the public health goals outlined here will depend on private incentives for establishments to maintain or attain passing status with respect to any performance standard selected. Because the swine industry has not been scrutinized for *Salmonella* as much as other meat and poultry industries historically, the incentive structure may take time to develop. Nevertheless, evidence suggests that customers, who become aware of the status of establishments with respect to performance standards, tend to prefer to purchase products from those companies that are passing FSIS performance standards (Ollinger and Moore, 2009; Ollinger et al., 2017). As is the case with other FSIS performance standards, the Agency intends to monitor each of the pork industries for evidence of progress toward meeting the HP2030 goals and will periodically assess the performance of the predictive model using established methods (Ebel and Williams, 2019).
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Appendix A

Average US Domestic Consumption of Pork – Determination of the Cuts to Ground Products Ratios

Background: To support the Agency’s efforts to develop new *Salmonella* pathogen reduction performance standards for pork, FSIS must determine the allocation of pork-associated *Salmonella* illnesses. Further, pork-associated *Salmonella* illnesses must be attributed to either cuts of pork (e.g., roasts, chops, ribs) or comminuted (e.g., ground) pork to develop accurate performance standards. FSIS accomplished this by considering the foodborne illness outbreak evidence from a variety of sources and analyses. This analysis focused on using consumption information from the National Health and Nutrition Examination Survey (NHANES) (CDC, 2012) to estimate pork consumption in the United States.

Purpose: The purpose of this analysis was to obtain accurate US population average daily consumption estimates for FSIS-inspected pork products categorized as not ready-to-eat (NRTE) ground pork, NRTE pork cuts, and RTE pork products, based on 10 years of the most recent National Health and Nutrition Examination Survey (NHANES) datasets. The estimation of the average ratio of NRTE pork cuts to NRTE ground pork was the primary goal.

Conclusion: About 75% of NRTE pork is consumed as cuts while about 25% is consumed as ground.

Data: The average daily consumption of pork products from the unstratified US population was estimated from the 10 year average over five two year cycles of NHANES data.\(^1\) Data sets were created from dietary interviews that contained individual food codes and first day for survey cycles for NHANES 2007-2008, NHANES 2009-2010, NHANES 2011-2012, NHANES 2013-2014, and NHANES 2015-2016\(^2\). Therefore, data from 2007 through 2016 was utilized in this analysis.

Methods/Approach: The CDC-approved methods\(^3\) for combining and weighting multiple NHANES cycles using SAS software\(^4\) were followed. Additional demographics information from the respective demographics variables and sample weights data sets\(^5\) were merged with the dietary interview and body measures\(^6\) data sets. All estimates correspond to the US population unadjusted for age over the 2007 through 2016 time period.

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\(^1\) The National Health and Nutrition Examination Survey (NHANES); NHANES is a major program of the National Center for Health Statistics (NCHS). NCHS is part of the Centers for Disease Control and Prevention (CDC) and has the responsibility for producing vital and health statistics for the Nation.

\(^2\) NHANES Data files: DR1IFF_E Data; DR1IFF_F Data; DR1IFF_G Data; DR1IFF_H Data; and DR1IFF_I Data.

\(^3\) ANALYTIC AND REPORTING GUIDELINES The National Health and Nutrition Examination Survey (NHANES), versions 2006 -2018, National Center for Health Statistics Centers for Disease Control and Prevention Hyattsville, Maryland; NHANES Tutorials Modules 1-7 (SAS code).

\(^4\) SAS 9.4 X64 8PRO platform, Copyright (c) 2002-2012 by SAS Institute Inc., Cary, NC, USA. NOTE: SAS (r) Proprietary Software 9.4 (TS1M2), Licensed to USDA-FOOD SAFETY & INSPECTION SERVICE, Site 70050709

\(^5\) NHANES Data files: DEMO_E_Data, DEMO_F_Data, DEMO_G_Data, DEMO_H_Data, and DEMO_I_Data.

\(^6\) NHANES Data files: BMX_E_Data, BMX_F_Data, BMX_G_Data, BMX_H_Data, and BMX_I_Data.
The merged and survey design weighted daily averages were computed for all pork products with 200 pork food codes\(^7\) over the 10-year survey period. Daily averages for pork cuts, ground pork, and RTE pork were analyzed using SAS proc survey means with programming for daily averages and ratio estimates. Food codes with multiple meat ingredients were excluded.

Additional analysis was done because of uncertainty in quantities of pork consumed reported for certain food codes with multiple species ingredients. This uncertainty was compensated for by creating a fourth consumption category -- called DISH -- where the approximate percentage of pork was consumed divided equally among the different species ingredients, as previously done\(^8\).

**Results:** Analytic daily means and ratios for total grams and grams per kilogram per day were estimated, as shown in Table 1.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>With RTE Uncertainty</th>
<th>Without RTE Uncertainty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Analytic Daily Means</td>
<td>Ratio Estimates</td>
</tr>
<tr>
<td>Pork Cuts</td>
<td>31.47 grams/day (0.47 grams/kg/day)</td>
<td>45.14% (44.76%)</td>
</tr>
<tr>
<td>Ground Pork</td>
<td>12.02 grams/day (0.17 grams/kg/day)</td>
<td>17.24% (16.19%)</td>
</tr>
<tr>
<td>RTE Pork</td>
<td>26.22 grams/day (0.41 grams/kg/day)</td>
<td>37.61% (39.05%)</td>
</tr>
<tr>
<td>DISH</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Total</td>
<td>69.71 grams/day (1.05 grams/kg/day)</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Table 2: Normalized Ratio Estimates**

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Original Ratios</th>
<th>Normalized Ratio Estimates</th>
<th>Normalized Ratio Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>gram/day</td>
<td>in grams/day</td>
<td>in grams/kilogram/day</td>
</tr>
<tr>
<td>Pork Cuts</td>
<td>41.03% (41.18%)</td>
<td>73.07%</td>
<td>74.24%</td>
</tr>
<tr>
<td>Ground Pork</td>
<td>15.12% (14.29%)</td>
<td>26.93%</td>
<td>25.76%</td>
</tr>
<tr>
<td>Total</td>
<td>56.15% (55.47%)</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Conclusions:** The best estimate of the US population average consumption in categories of pork cuts, ground pork, and RTE were obtained from the estimates accounting for uncertainty.

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\(^7\) Exactly 200 NHANES food codes were identified as containing key words for pork or pork products to also include recipes listing pork products; these codes were used to identify subjects reporting pork consumption.

\(^8\) If a code reported pork or beef, then one half pork was assumed, or if pork, beef, or chicken was reported then one third pork was assumed.
(inclusion of DISH food codes). These provide a lower bound for the average consumption uncertainties due to a lack of specificity for pork in multiple species recipe designations in the NHANES food codes. The best estimates for ratios were based on these lower bounded uncertainties. See Table 2 for normalized ratio estimates for pork cuts and ground pork. This suggests that about 75% of NRTE pork is consumed as cuts while about 25% of NRTE pork is consumed as ground.