Public Health Effects of Performance Standards for Ground Beef and Beef Manufacturing Trimmings

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Executive Summary

This risk assessment describes the data sources and analytical methods used in the development of pathogen reduction performance standards for *Salmonella* in ground beef and beef manufacturing trimmings. Collected samples will be used to classify establishments as either meeting or not meeting the performance standards. Reductions in the number of salmonellosis cases are estimated to occur after establishments apply corrective actions that reduce the occurrence of this pathogenic bacteria.

Because relatively few establishments produce the vast majority of ground beef and beef manufacturing trimmings, this analysis proposes performance standards for establishments producing >50,000 pounds per day, while suggesting generic standards that could be applied to establishments producing less than this amount per day.

The performance standards are designed to achieve the Healthy People 2020 goal for *Salmonella* as it relates to beef products, which is a 25% reduction in human *Salmonella* illnesses attributed to ground beef.

The risk assessment model estimates the distribution of within-establishment prevalence of *Salmonella*-positive samples for each industry. It classifies establishments as meeting or not meeting alternative performance standards and assumes that some fraction of those establishments not meeting the standard initially will eventually improve their within-establishment prevalence and meet the performance standard. If the most likely within-establishment distributions for large ground beef and beef manufacturing trimmings establishments are assumed, and it is assumed that 50% of establishments not meeting the standard initially will eventually meet it, then performance standards of 2 allowable positives among 48 samples – applied to large establishments in both industries – are expected to attain the stated public health goal. Alternative assumptions about uncertain inputs could result in different choices for the performance standards.

A standard of 2 allowable positives among any number of samples is proposed for ground beef and beef manufacturing trimmings establishments that are not large.

Introduction

Following implementation of the 1996 Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) System – Final Rule[1], FSIS set pathogen reduction performance standards for *Salmonella* in ground beef (5 positives out of a 53-sample set) and cow/bull (2 positives out of 58) and steer/heifer (1 positive out of 82) carcasses. FSIS collected approximately 30,000 samples per year in the application of these standards. In the years since that program began, the proportion of *Salmonella*-positive samples from carcass testing decreased to such a low frequency that sampling of beef carcasses for *Salmonella* was suspended in 2011 (USDA, 2014).

Since 1994, FSIS has been collecting samples of ground beef for Shiga toxin producing *Escherichia coli* (STEC)[2]. Sampling of beef manufacturing trimmings (BMT) was initiated in 2007. In 2014, FSIS decided to merge its surveillance of *Salmonella* and STEC pathogens by co-analyzing samples collected under its MT43 (ground beef) and MT60 (BMT) programs. One consequence of this change was that, while ground beef samples analyzed for *Salmonella* were 25 grams previously, the MT43 program is based on 325-gram samples. In addition, surveillance of ground beef for STEC was always designed to be conducted continuously across the year, while sampling for the *Salmonella* performance standards was previously clustered in time. These changes to ground beef surveillance – and the absence of any performance standard for BMT – necessitate the development of new performance standards for both product types.

In its *Salmonella* Action Plan, FSIS has committed to the Healthy People 2020 (HP2020) goal of a 25% reduction in annual human *Salmonella* illnesses attributed to its products by the year 2020 (HHS, 2010). Based on published results from CDC (Scallan et al., 2011; Painter et al., 2013), FSIS estimates approximately 80,000 *Salmonella* illnesses are attributed to the consumption of beef. Because a substantial share of beef is consumed as ground beef, these performance standards are expected to reduce ground beef-associated *Salmonella* illnesses.

Although FSIS is also proposing performance standards for BMT, FSIS intends to achieve illness reductions only via the performance standards applied to ground beef. BMT is a primary input to the production of ground beef. It is assumed that purchasers and/or users of BMT will find the performance standard status of BMT-producing establishments useful for managing their ground beef *Salmonella* contamination. For example, a grinding operation may opt to change BMT suppliers if their current supplier is known to not meet the BMT performance standard; this is especially true if the grinding operation is concerned about not meeting the ground beef performance standard and wants to mitigate the chances of that outcome. Nevertheless, though reductions in surface contamination on BMT should reduce contamination of ground beef, the specific magnitude of this reduction is uncertain. For example, recent research on the contribution of contaminated lymph nodes to *Salmonella* contamination of ground beef suggests that the surface contamination detected via testing of BMT may be less important than lymph nodes in explaining ground beef contamination (Li et al., 2015).

[1] Fed Reg Docket No. 93-016F; 1996

[2] At its inception, this program focused specifically on *E. coli* O157:H7, but has expanded to include other STECs subsequently.

Performance standards for ground beef and BMT were developed to be consistent with the resources dedicated to the current MT43 and MT60 programs. Therefore, the number of samples used to determine the performance status of establishments should reflect current practices. In addition, it was preferred that proposed *Salmonella* performance standards allow more than one positive test result as the basis for determining whether establishments meet or do not meet the standards.

Summarization of *Salmonella* Sampling in Ground Beef

Sampling Approach

The ground beef data used in this analysis consists of 23,139 samples collected between August 2014 and July 2016 from 1,240 ground beef producing establishments under FSIS inspection. This date was selected as FSIS began using new laboratory methods to co-analyze MT43 samples for both *Salmonella* and STEC in July 2014. Two years of data were collected and used to increase the sample size for each establishment and account for seasonal and/or annual variability in *Salmonella* occurrence (Williams et al., 2014).

A 325 g portion of each ground beef sample was analyzed for *Salmonella* by FSIS laboratories according to published methods (FSIS, 2011a, 2013, 2014). In the past, a 25 g portion of each ground beef sample was analyzed; this represents a 13-fold increase in sample size from that used previously to establish ground beef performance standards.

The ground beef industry is highly concentrated, with greater than 90% of all production coming from fewer than 100 establishments (Figure 1). Each establishment under FSIS inspection is assigned to one of 7 volume categories based on their average daily production (Table 1). Total annual production for each establishment is estimated using the product of estimates for average daily production and the number of days of production during the year. For this risk assessment, the seven volume categories will be collapsed into three categories representing small, medium, and large producers. Volume categories 1, 2, 3 and 4 represent the small- and medium-sized categories, respectively. The large category comprises volume categories 5, 6 and 7 that produce more than 50,000 lbs. of product per day; this category consists of 75 establishments that account for about 91% of all ground beef produced in the United States (U.S.). The remaining 1,165 establishments account for about 9% of U.S. ground beef.

The assigned frequency of sampling for the MT43 program is based on these volume categories (Table 1). Currently, category 6 and 7 establishments are assigned a maximum of 4 samples per month, while category 5 establishments are assigned a maximum of 3 samples per month. Given the current FSIS sampling algorithm, the actual number of samples assigned to these categories is generally equal to these maxima, but the actual collection rate is somewhat lower. For category 2, 3 and 4 establishments, a maximum of 2 samples per month are assigned, while category 1 establishments are assigned a maximum of 1 sample per month.

Salmonella Findings

Across the 2-year collection period examined, the raw proportion of all samples testing *Salmonella*-positive was low at 0.018. The proportions were not statistically different when comparing the first 12 months to the last 12 months of data collection. The proportion of positive samples also demonstrates a strong seasonal pattern that is consistent with previous analyses of ground beef (Hill et al., 2011; Williams et al., 2014).

The proportion of *Salmonella*-positive samples differ by volume category, with the occurrence of positive samples in the largest volume categories being at least twice that of the small and medium-sized categories[3] (Figure 1). Under the assumption that the proportion of positive samples is directly related to the proportion of contaminated servings of ground beef, FSIS estimates that greater than 95% of all *Salmonella*-contaminated servings can be attributed to the ground beef produced by establishments with daily production volumes of greater than 50,000 pounds a day.

The proportion of *Salmonella*-contaminated ground beef samples varies greatly amongst the group of 75 large establishments, with nearly 1/3 of establishments having no positives out of an average of 74 samples collected during the 2 years of sampling. Three establishments had in excess of 25 percent of their samples *Salmonella*-positive. Ground beef demonstrates the highest degree of concentration of contamination within a small number of establishments among all commodities under FSIS regulation (Lukicheva et al., 2016), which will allow FSIS to effectively focus resources on only a small portion of the industry.

[3] The testing data can be summarized as;

volume categories	total samples	salmonella-pos
1 & 2	11984	167
3 & 4	5564	91
5 - 7	5591	161
total	23139	419

Simple statistical analysis demonstrates that the proportion of positive samples is significantly larger for categories 5-7.

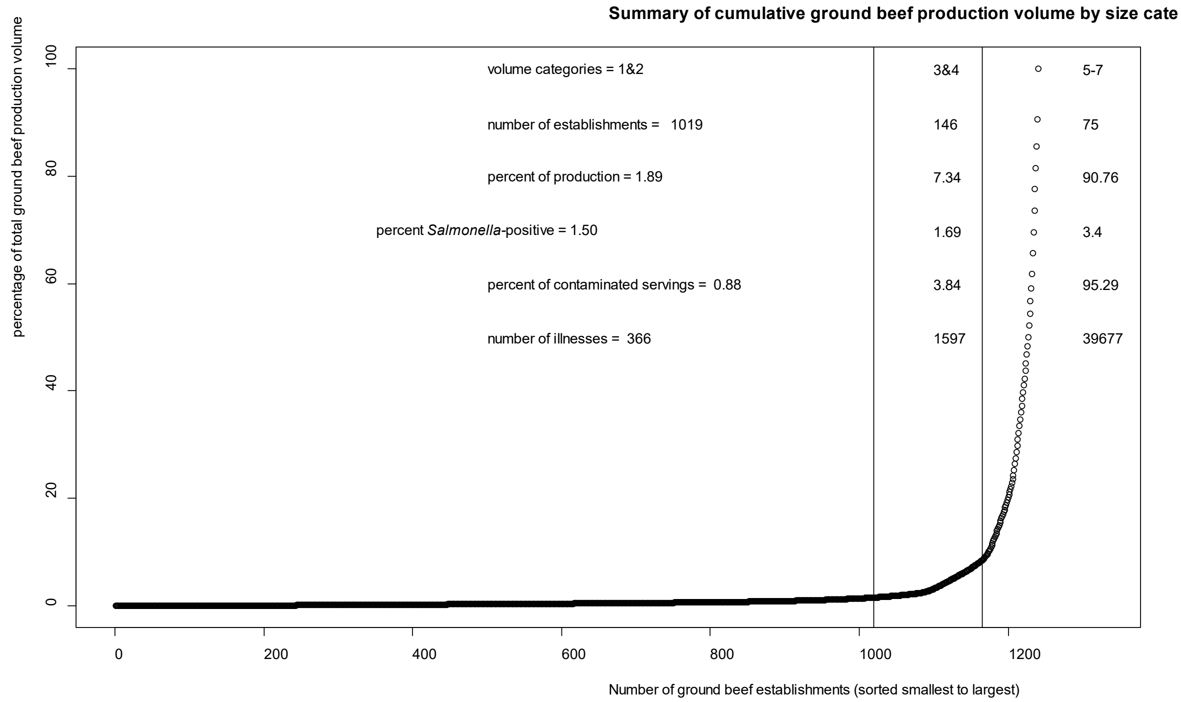

Figure 1. A summary of the U.S. ground beef industry as it relates to *Salmonella* contamination for small (volume categories 1 and 2), medium (volume categories 3 and 4) and large (volume categories 5, 6 and 7) establishments is shown. The shift in the y-axis for each circle on the graph represents the establishments contribution of total ground beef production in the U.S. This graph illustrates that about 91% of all ground beef in the U.S. is produced by establishments in the large volume categories.

Table 1. The size categories defined by FSIS are based on daily production volume. The maximum number of samples assigned per month to each size category is also shown.

FSIS volume category	Product lbs./day	Max. assigned samples per establishment per month
7	>600,000	4
6	250,001 - 600,000	4
5	50,001 - 250,000	3
4	6001 - 50,000	2
3	3001 - 6000	2
2	1001 - 3000	2
1	< 1001	1

Methods for Setting Ground Beef Performance Standards

Given the low overall proportion of *Salmonella*-positive samples in small and medium establishments, the large number of ground beef establishments and the resource constraints placed on the MT43 surveillance program, this analysis examines two performance standards for ground beef. One performance standard will be applicable to small and medium-sized establishments, and the other standard will apply to large-sized establishments.

Compliance with a performance standard will be monitored weekly using a 52-week moving window, as is currently implemented for all poultry performance standards. The annual period obviates the need to account directly for seasonal fluctuations in contamination frequency (FSIS, 2015; Williams et al., 2014).

Consistent with the current sampling frequency for volume category 6 and 7 establishments, the performance standard for large establishments (that also include volume category 5 establishments) will consist of the collection of $n = 48$ samples in a 52-week period (4 samples per month). An establishment will be considered meeting the standard if there are equal to or fewer than s *Salmonella*-positive samples. All illness reduction claims will be derived from the salmonellosis cases attributed to these large establishments because FSIS' adherence to the collection of the requisite number of samples for large establishments allows for more accurate predictions of the effect of the performance standard.

The second performance standard, for small and medium sized establishments, will evaluate results of a variable number of samples per establishment; generally, there will be much less than 48 samples in a 52-week period collected in each of these establishments. The allowable number of positive samples, s, will be the same as that of the primary performance standard described above. This less stringent standard will be referred to as the *generic* performance standard. This performance standard recognizes that, on average, small and medium sized establishments generally have lower contamination rates than large establishments and are therefore likely to meet the standard. The purpose of this standard is to only identify smaller establishments with especially high levels of contamination. FSIS claims no illness reduction benefits from the generic performance standard because small establishments are responsible for very little *Salmonella* exposure to consumers and any reduction in such establishment's prevalence following implementation of this generic performance standard will be negligible.

Methods for Estimating the Effects of the Performance Standard

Consistent with the HP2020 goal for salmonellosis, the ground beef performance standard is designed to achieve a 25% reduction in annual *Salmonella* illnesses attributed to ground beef produced by establishments in the large volume categories. Figure 2 outlines the conceptual framework for deriving a performance standard to achieve a 25% reduction in overall proportion of *Salmonella*-positive samples. A performance standard is chosen such that, following its implementation, some share of ground beef establishments – and their attendant production volume – will be classified as not meeting the standard; and some of those establishments will be compelled eventually to meet the performance standard. This movement of establishments from not meeting to meeting generates a reduction in the overall proportion of *Salmonella*-positive samples in the future (Figure 2).

A risk assessment model estimates the public health effects – measured in annual human *Salmonella* illnesses avoided – from imposing alternative performance standards on large establishments. A critical input to the model is the fraction of ground beef produced by establishments not meeting the standard that will be motivated to become compliant following imposition of the performance standard. This is referred to as the "compliance fraction". Based on previous experience, a baseline assumption is that 50% of production volume not meeting the standard eventually becomes compliant (Ebel et al., 2012; FSIS, 2011b). In the past, FSIS has achieved a 50% compliance fraction by imposing disincentives for establishments not meeting a performance standard. For example, FSIS has posted the names of establishments not meeting the standard on its website. This information might be used by potential customers to influence purchasing or pricing decisions. Nevertheless, the true compliance fraction applicable to ground beef producers is unknown. Therefore, alternative compliance fractions of 40% and 30% are also considered when examining possible choices for a ground beef performance standard.

Model Description

For a performance standard based on $n = 48$ samples collected from each establishment, this analytic approach requires estimating a fraction (ω) of production volume associated with establishments that initially meet the standard (i.e., the establishment has s or fewer positive samples). Before the performance standard is implemented (i.e., the baseline scenario), the overall prevalence of contaminated samples is

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

where P_{pass} and P_{fail} are the prevalence of contaminated samples among all establishments that meet or do not meet the performance standard, respectively.

Once the performance standard is implemented, and establishments not meeting the standard are identified, some fraction α (i.e., the "compliance fraction") of those establishments are expected to change their production practices in order to meet the performance standard. We assume the decision to improve performance among establishments not meeting the standard is independent of the establishment's individual prevalence. Across time, it is likely that these establishments would ultimately attain a prevalence of contaminated ground beef samples that is equal to establishments that meet the performance standard (i.e., P_{pass}). Given this expected change, the estimated overall prevalence following implementation of the performance standard is given by;

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

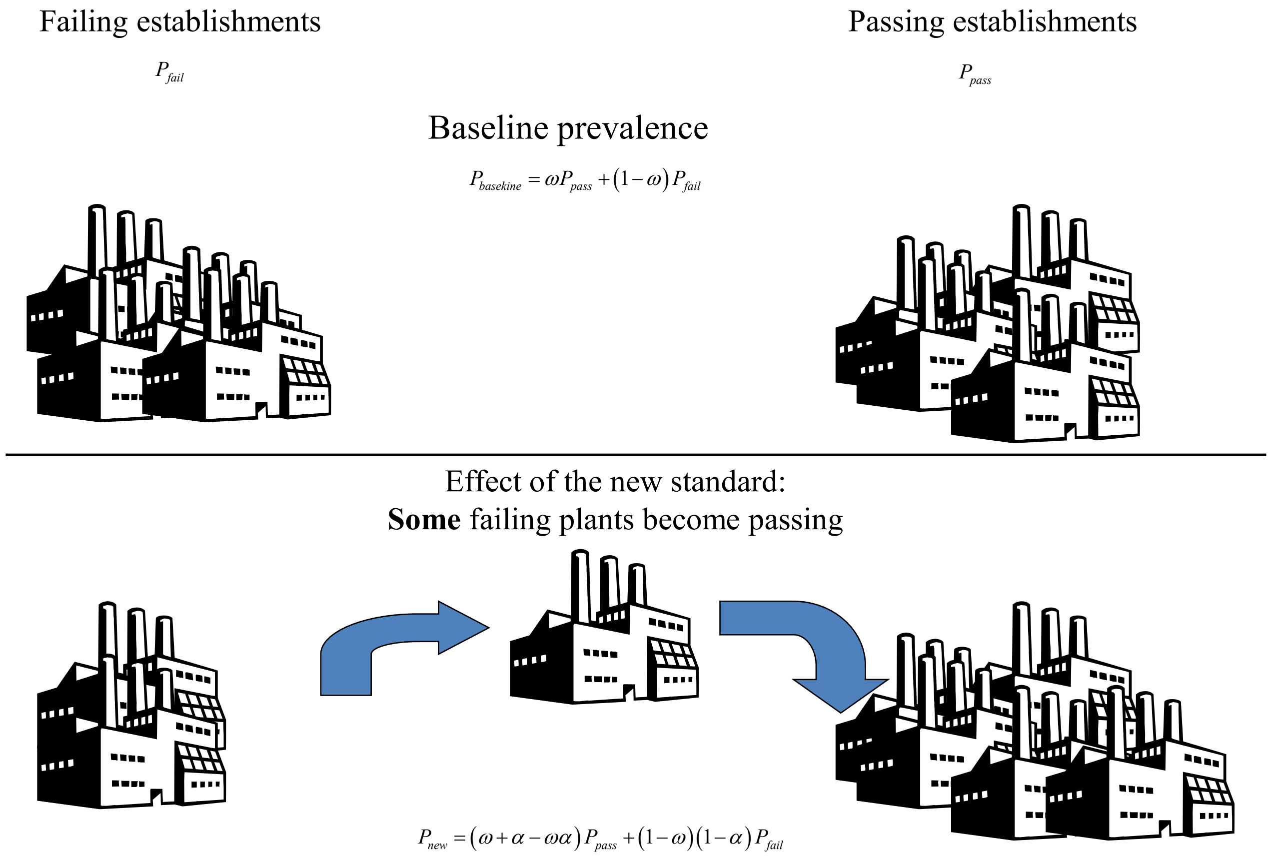

Figure 2. Schematic representation of the 2-strata risk assessment model.

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

$$I_{Avoided} = Poisson\left[\left(1 - \frac{P_{new}}{P_{baseline}}\right)\lambda_{ill} \times Q\right]. \qquad (1)$$

In this equation, λ_{ill} represents the annual rate of illnesses (i.e., cases of salmonellosis attributed to ground beef) 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 $P_{baseline}$, and the prevalence following successful implementation of the performance standard is P_{new} . The value Q represents the fraction of λ_{ill} that is attributed to ground beef produced by volume categories 5, 6 and 7. In other words, the performance standard will only apply to the largest establishments that produce greater than

50,000 pounds per day, so not all illnesses are preventable. The value for Q is assumed to be 95.29% (from Figure 1).

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., density of pathogens per sampled unit) are independent of the prevalence of contamination. If a positive correlation exists between the prevalence of contaminated carcasses and the levels of *Salmonella* on contaminated carcasses, then this assumed independence usually leads to lesser estimates of the reduction in illnesses associated with a reduction in prevalence (Ebel and Williams, 2015).

A performance standard describes the maximum number of allowable positives in a set of 48 samples. Alternative standards imply threshold prevalence levels ($P_{threshold} = {}^{Max\ pos}\!/_{48}$) that discriminate meeting establishments ($P \le P_{threshold}$) from establishments not meeting the standards ($P > P_{threshold}$). The risk assessment model requires estimation of a distribution for the prevalence of *Salmonella*-positive samples per establishment (using production volumes as weights) and estimation of annual human illnesses attributed to consumption of ground beef. Using these inputs, alternative performance standards are examined for achieving a reduction in illnesses relative to the HP2020 goal. In addition, we examine the effects of critical uncertainties affecting the choice of alternative performance standards.

Estimation of Prevalence of *Salmonella*-positive Samples

The values for $P_{baseline}$, P_{pass} and P_{fail} were determined from the MT43 *Salmonella* data. A weighted beta-binomial distribution is used to model how the prevalence of *Salmonella*-positive samples varies across the establishments in the largest volume categories, where s_i and n_i parameters describe the number of positive and total samples collected during the two-year time period in each establishment, respectively. A weighted maximum likelihood method incorporates the estimated total production volume, v_i, of each establishment (Williams et al., 2013).

Once the beta distribution parameters are estimated, these are used to characterize the prevalence of *Salmonella*-positive samples above and below a threshold prevalence $P_{threshold}$, where this prevalence describes the maximum prevalence implied by a performance standard of s allowable positive samples out the $n = 48$ samples in the annual moving window. For example, 4 allowable positives in 48 samples indicate $P_{threshold} = 4/48 = 0.083$.

The beta distribution can then be queried to determine prevalence for the share of the industry above and below $P_{threshold}$. The prevalence above the threshold represents the average prevalence of *Salmonella*-contaminated samples for establishments not meeting the standard (P_{fail}).

Similarly, the prevalence below the threshold represents P_{pass}. Figure 3 illustrates how prevalence in the meeting and not meeting strata changes as a function of the number of allowable positive samples. The figure demonstrates that if no positive samples are allowed, then $P_{fail} = P_{baseline}$ because all establishments do not meet the standard. As the number of allowable positive samples increases, a larger fraction (ω) of the establishments meet the standard and the prevalence of establishments meeting the standard approaches that of the baseline prevalence ($P_{pass} \rightarrow P_{baseline}$) while P_{fail} increases monotonically. For example, as depicted in Figure 3 if the threshold prevalence is $P_{threshold} = 4/48$, then the estimated average prevalence of positive samples for meeting and not meeting establishments is $P_{pass} = 0.023$ and $P_{fail} = 0.115$.

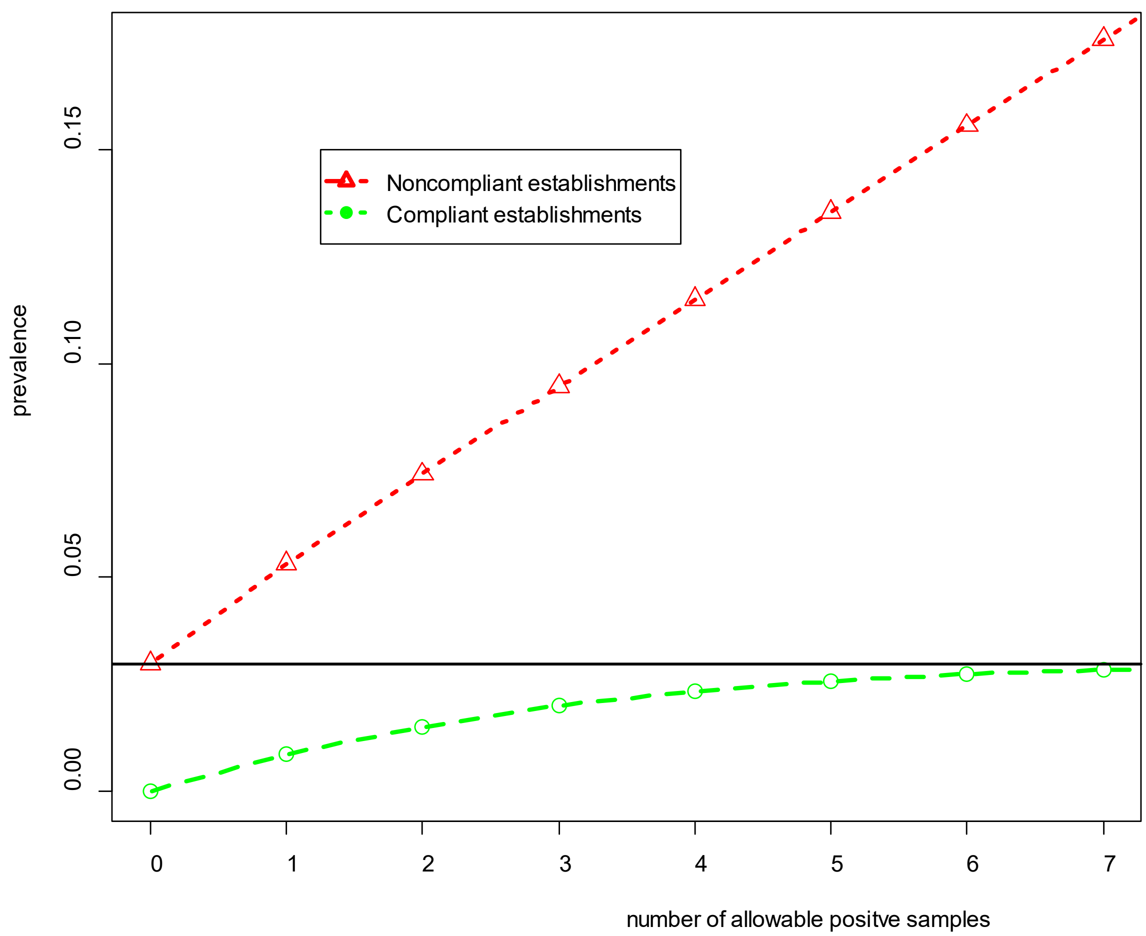

Figure 3. Based on the most likely industry beta distribution, the estimated average prevalence for meeting and not meeting establishments is depicted as a function of the number of allowable positives (*s*) out of *n* = 48 samples. The solid black line represents the average prevalence across the entire population of establishments and an example for *s* = 4 is depicted.

The values of P_{pass} and P_{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,

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

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

where $F(P_{threshold})$ is the cumulative probability of the distribution of p up to value $P_{threshold}$. Because the distribution of p is production volume weighted, the value for ω simply equals $F(P_{threshold})$. The actuar library (Dutang et al., 2008) in the R computer software package (R Development Core Team, 2015) provides simple commands to solve for $E[p \wedge t]$ when p is *beta* distributed.

For a given set of sample data, these equations are approximations that improve as the sampling plan's ability to discriminate prevalence above/below $P_{threshold}$ approaches one. As additional sampling occurs over time, the probability of misclassifying establishments not meeting the standard as above or below the threshold will also decrease, especially so if such establishments take actions to reduce their prevalence such that their probability of compliance increases.

Estimation of Burden of Illness Attributed to Ground Beef

Estimation of the number of illnesses avoided as a consequence of implementing a performance standard requires first estimating the total number of illnesses attributed to consumption of ground beef products. The process begins with the Center of Disease Control and Prevention's (CDC) estimate of the total number of foodborne domestically acquired annual cases of salmonellosis (Scallan et al., 2011). The mean estimate and the 5 and 95% percentiles of the credible interval were used in conjunction with a lognormal distribution to model uncertainty in the estimated annual number of salmonellosis cases. The fraction of those illnesses attributed to beef was based on CDC attribution estimates (Painter et al., 2013). Minimum, most likely, and maximum estimates of the proportion of illnesses attributed to beef were used in a Pert distribution to model uncertainty about this parameter.

No consistent method exists for estimating the proportion of beef-related illnesses to attribute to the consumption of ground beef, so a Pert distribution was constructed to model this uncertain parameter. The minimum estimate relies on outbreak counts in the CDC's Foodborne Disease Outbreak Surveillance System between 1973 and 2011. Those data imply that 23% of all beef-associated outbreaks had ground beef as the most likely food vehicle (Laufer et al., 2015). This estimate is considered a minimum because the denominator used in this estimate includes outbreaks where the type of beef was not identified (i.e., unidentified outbreaks are all attributed to intact beef) and prior to the mid-1990s the majority of beef-associated outbreaks were attributed to undercooked roast beef (Laufer et al., 2015).

The most likely and maximum estimates assume that the proportion of illnesses attributed to ground beef are equal to the proportion of the product consumed (i.e., an equal risk of illness per serving between intact and ground beef). The most likely value of 57% is based on data and analysis of the Beef Checkoff program (Close, 2014). Further analyses of these data, and the incorporation of additional retail sales data collected by RaboBank, generates a maximum value of 62% (Close, 2014).

Quantile information for the components of the illness burden estimates are given in Table 2. Applying a 25% reduction to the annual ground beef-associated illness quantiles suggests that the illnesses prevented by meeting the HP2020 goal might range from about 5,100 to 20,200, with a median of about 10,400 illnesses per year.

Table 2. Burden of illness components are tabulated.

Burden of illness component	5th percentile	50th percentile	95th percentile
Annual number of domestically-acquired foodborne salmonellosis cases	645,370	1,040,695	1,677,198
Attribution fraction for beef[4]	0.047	0.078	0.116
Proportion of beef-associated illness attributed to ground beef	0.399	0.533	0.606
Annual number of ground-beef attributed cases of salmonellosis λ_{ill}	20,425	41,640	80,812

[4] Moving forward, FSIS plans to utilize more recent estimates of foodborne illness source attribution to estimate cases of foodborne illness attributed to FSIS-regulated products. These estimates, produced by the Interagency Food Safety Analytics Collaboration (IFSAC), a tri-agency group with representatives from the CDC, U.S. Food and Drug Administration, and USDA-FSIS, uses foodborne outbreak data to produce harmonized, annual attribution estimates for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter*.

Description of the Ground Beef Performance Standard

The average prevalence of positive samples in establishments in the largest volume categories is currently at least twice that of the establishments in the small and medium volume categories. Furthermore, the small and medium volume category establishments account for less than 9% of total ground beef production. Given the already lower overall risk posed by the small and medium volume category establishments, the generic performance standard exists only to identify those establishments in these volume categories with high levels of contamination.

Currently, FSIS has set upper limits on the number of samples it intends to collect in a given year for each of the seven volume categories. These values are $n_{\max} = 12$ for volume category 1 and 24 samples per year for volume categories 2 through 4. Nevertheless, the actual rate of sample collection in these establishments is uniformly lower than the maximum value ($n_{achieved} = 4$, 15, 17, and 20 on average in volume categories 1 through 4, respectively) because of resource limitations and the sporadic production of ground beef in some small establishments. FSIS also employs a risk-based algorithm to target establishments identified as higher risk.

At this time FSIS intends to maintain its risk-based sampling allocation for establishments assigned to the small and medium volume categories. Therefore, establishments operating under the generic performance standard will be allowed the same number of positive samples as determined by the performance standard, regardless of the number of samples collected each year. Because the number of samples collected in small and medium volume categories will be much less than 48 per year, this generic performance standard implies a very low probability of a small or medium volume category establishment not meeting the standard when their prevalence of positive samples is near the $P_{threshold}$ of the performance standard. Performance characteristics of standards are discussed below.

Results for the Ground Beef Performance Standard (>50,000 lbs/day)

The beta distribution fitted to the 75 ground beef establishments with average daily production of greater than 50,000 pounds generates the most likely distribution shown in Figure 4. Uncertainty about this distribution is illustrated by 5th and 95th percentile distributions that are also shown.

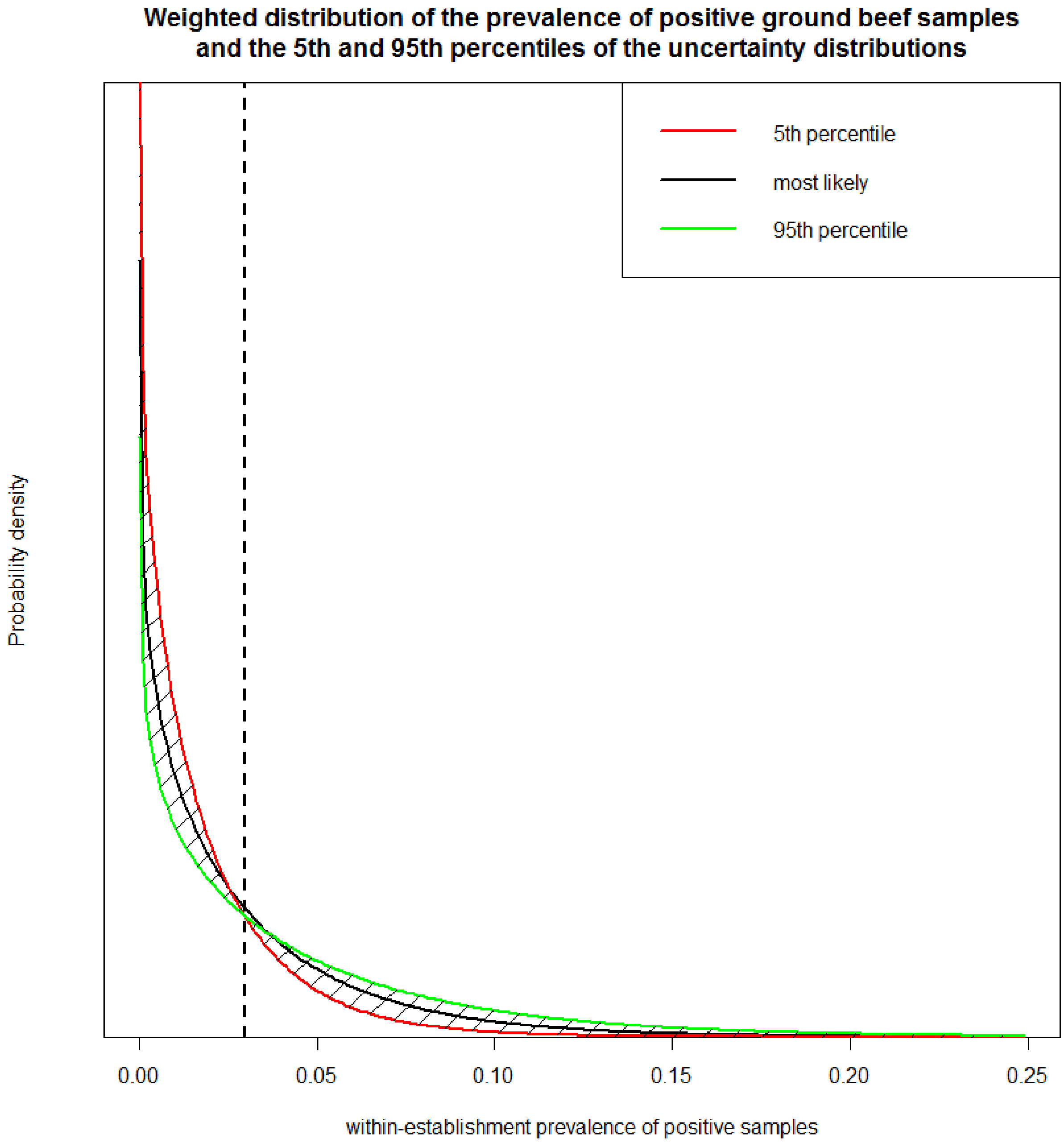

Figure 4. Fitted beta distributions for within-establishment *Salmonella* contamination for ground beef. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Salmonella* contamination across establishments. The uncertainty about the true or actual distribution is illustrated by including bounding distributions—the 5th and 95th percentiles—determined using the statistical fitting algorithm. The vertical line indicates the volume weighted expected value of 0.03 derived from the most likely beta (a=0.82, b=26.79) distribution.

The effectiveness of alternative performance standards is examined by including uncertainty about the beta distribution, as well as uncertainty about the baseline illnesses attributed to consumption of ground beef. To model uncertainty about the beta distribution, the beta-binomial distribution was fit to bootstrap samples of the sampling data to obtain new parameter estimates. Uncertainty about the annual human illness estimate was modeled by random sampling from the distribution described in Table 2.

Figure 5 depicts uncertainty about the proportion of illnesses avoided as a function of the maximum allowable number of positive samples (s) out of $n = 48$ using the default assumption of a 50 percent compliance fraction.[5] This graph illustrates that a 25% reduction in illnesses is most consistent with a performance standard of 2 allowable positive samples. This graph also shows that alternative standards of 1, or 3, allowable positives over-, or under-, shoot the desired reduction goal.

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[5] The estimator for proportional reduction in human illnesses is $\left(1-\frac{P_{new}}{P_{baseline}}\right)\times Q$ where the values of $P_{baseline}$ and P_{new} are determined iteratively via the bootstrap beta distributions.

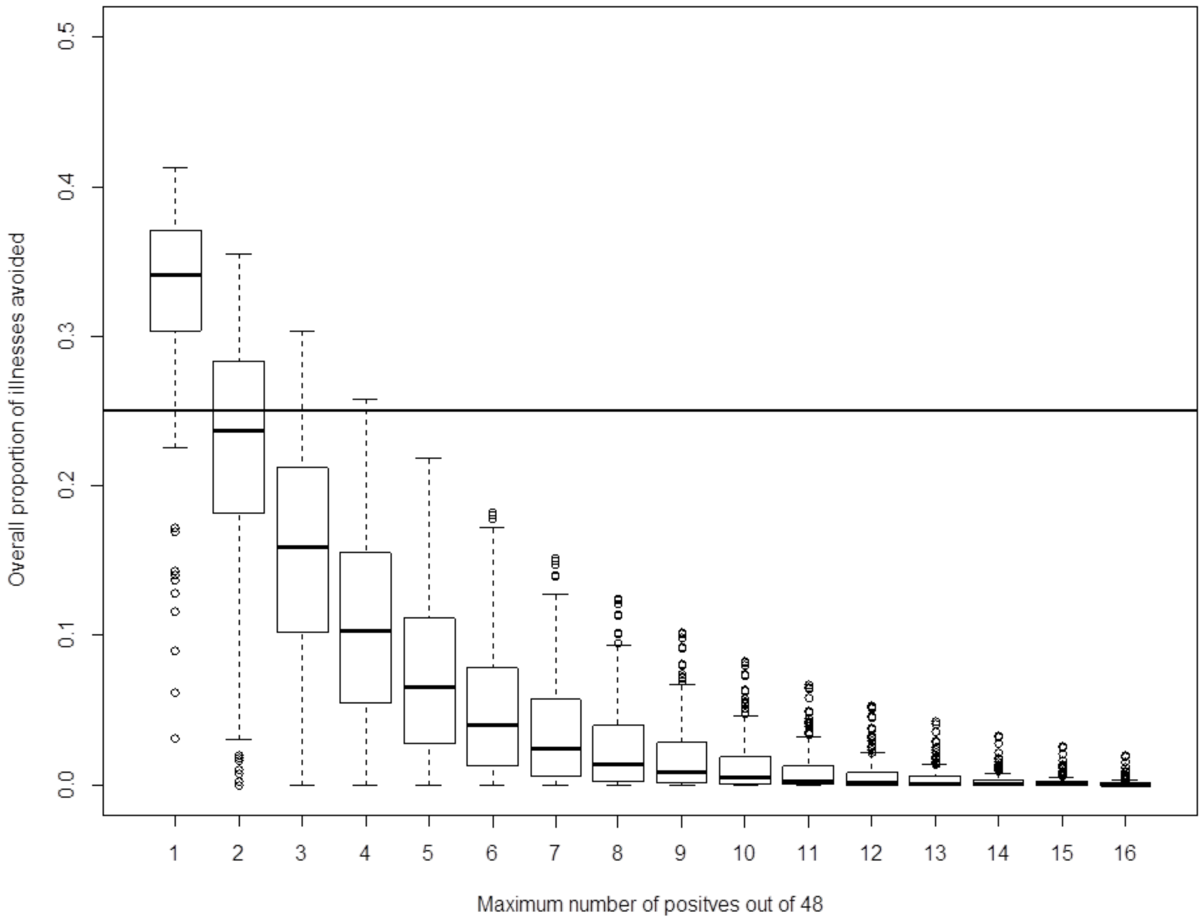

Figure 5. Uncertainty about the proportion of illnesses avoided as a function of the number of allowable positive samples is shown for a compliance fraction of $\alpha = 0.5$. The box and whiskers plots for each alternative number of allowable positive samples demonstrates the 25th, 50th, and 75th percentiles (box), while the whiskers are 1.5 times the interquartile range (i.e., 75th – 25th percentiles). Outliers are shown as open circles.

Figure 6 summarizes the share of the industry under the performance standard that will initially not meet alternative performance standards (i.e., $1-\omega$) while including uncertainty about the industry beta distribution. A median of 24% of all ground beef produced in the U.S. will be from establishments not meeting the standard if a performance standard of 2 allowable positives out of 48 samples is selected.

This share of production volume represents about 14 establishments among the 75 establishments in volume categories 5 – 7 and under the performance standard. This result highlights the fact that the majority of *Salmonella*-contaminated ground beef is generated by a small fraction of the largest producers. Reducing the number of allowable positives to 1 nearly doubles both the proportion of ground beef production, and the number of establishments, which would not meet the standard initially.

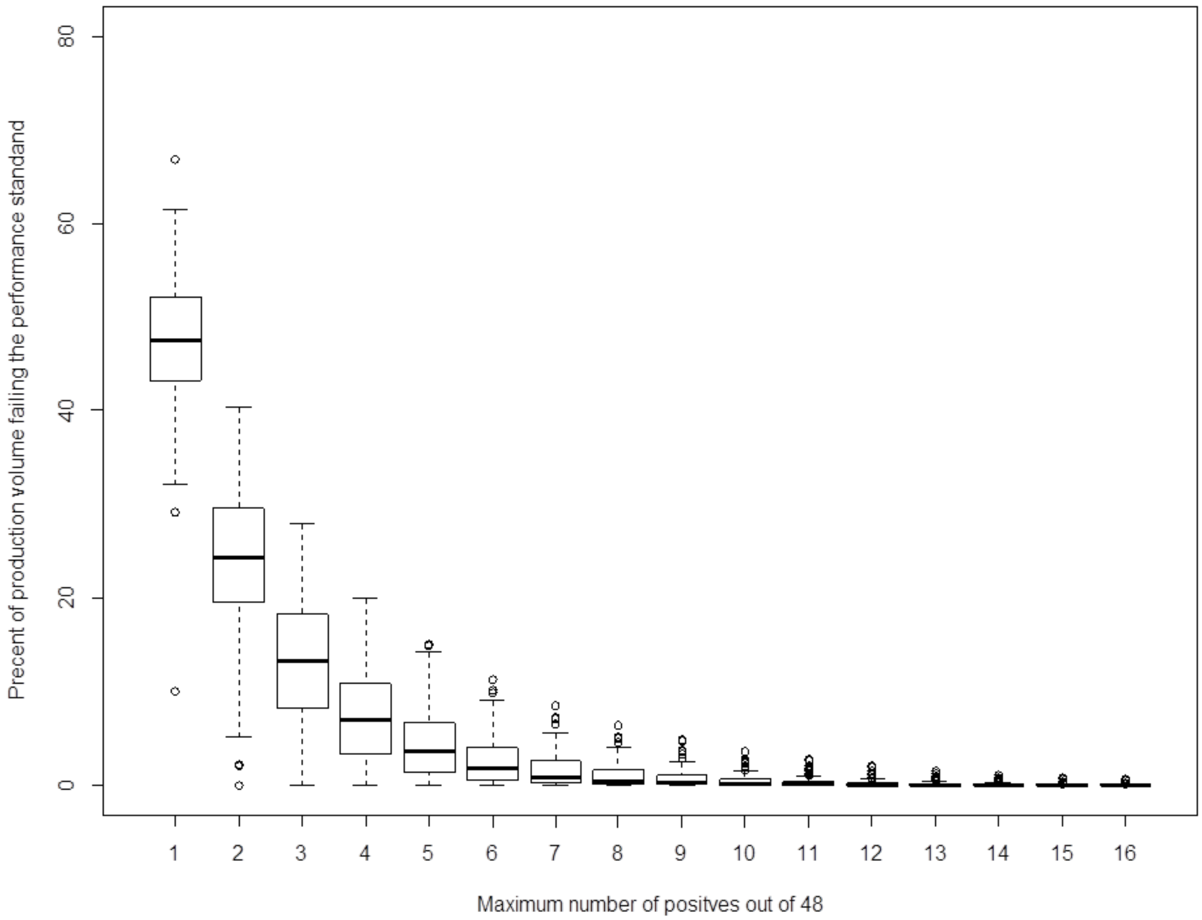

Figure 6.The percentage of production volume under the performance standard that would initially not meet the standard ($1-\omega$) is shown for alternative maximum allowable number of positives. A box and whiskers plot represents uncertainty associated with the industry beta distribution. The initial effect of a ground beef *Salmonella* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 2 allowable positives will result in a median 24% of large establishment production volume not meeting the standard initially.

Table 3 summarizes the preferred performance standards for compliance fractions of 50%, 40% and 30%. Using Equation 1, estimates of the number of illnesses avoided include consideration of the uncertainty about annual illnesses attributed to ground beef consumption. Because the number of establishments expected to not meet the performance standard can only be determined from the available testing, there is no uncertainty about this value.

For a 50% compliance fraction, a performance standard of a maximum of 2 allowable positive samples among 48 samples provides a median 23% reduction in illnesses, a median 24% of production volume not meeting the standard initially and a median 8,900 annual human illnesses prevented (Table 3). For a 40% compliance fraction, a standard of 1 allowable positive sample provides a median 27% reduction in illnesses, a median 48% of production volume initially not meeting the standard and a median 10,700 annual human illnesses prevented. For a 30% compliance fraction, a performance standard of 1 allowable positive sample provides a median 20% reduction in illnesses, a median 48% of production volume initially not meeting the standard and a median 8,000 annual human illnesses prevented.

Given the design objectives of the program, a performance standard of 2 allowable positives from 48 samples is the logical selection. The most-likely prevalence amongst meeting and not meeting establishments at $s = 2$ is $P_{pass} = 0.015$ and $P_{fail} = 0.074$. Coincidentally, the meeting establishment prevalence is equal to that currently achieved by the smallest establishments (as reported for volume categories 1 and 2 in Figure 1) and only slightly lower than the 0.017 of the medium-sized establishments.

Table 3. A summary of possible performance standards for alternative compliance fractions is shown. These standards approximate achievement of the HP2020 goal of a 25% in human illnesses for the compliance fractions. The performance standard only applies to ground beef-producing establishments with average daily volume greater than 50,000 pounds (volume categories 5, 6 and 7).

Compliance fraction	Allowable positives in 48	Proportional reduction in illnesses, median (5% - 95%)	Not meeting production volume share, median (5% - 95%)	Not meeting establishment share (number of establishments)	Illnesses avoided median (5% - 95%)
50%	2	23% (6% - 32%)	24% (7% - 36%)	18% (14)	8,900 (2,000 - 20,000)
40%	1	27% (16% - 31%)	48% (35% - 60%)	35% (26)	10,700 (4,500 - 22,000)
30%	1	20% (12% - 24%)	48% (35% - 60%)	35% (26)	8,000 (3,400 - 16,300)

Results for the Generic Ground Beef Performance Standard

Under the generic performance standard, the data suggest that FSIS will annually classify only about 3 to 5 of the 1,165 small- or medium-sized establishments as not meeting the standard. Available data suggests that establishments not meeting the standard operating under the generic performance standard account for less than 0.05% of total ground beef production.

Figure 8 illustrates the performance characteristics of the performance standard ($s = 2$ allowable positives among 48 samples), as well as some other sample sizes applicable to the generic performance standard. Based on the most-likely industry beta distribution, an establishment currently meeting the standard has an average prevalence of $P_{pass} = 0.015$ and will have a 96.5% chance of meeting the standard. An establishment not meeting the standard with an average prevalence of $P_{fail} = 0.074$ has a 70% chance of not meeting the performance standard during the first year.

The generic performance standard is unlikely to identify small producers as not meeting the standard unless their level of contamination is excessively high, or 12 or more samples are collected annually. Under no scenario will small and medium establishments that perform near the industry average for their volume category have less than a 99% chance of meeting the generic performance standard. Thus, we expect the standard to have very little effect on small and medium producers.

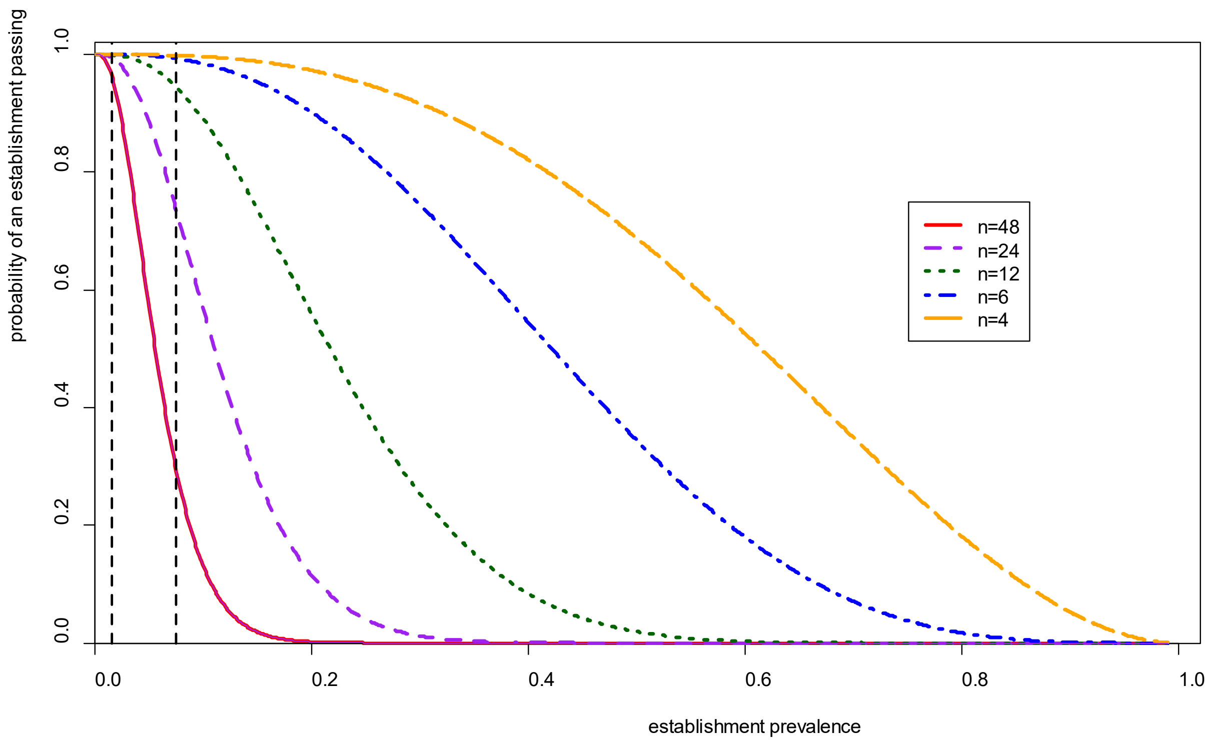

Figure 7. Performance characteristics of the performance standard of 2 allowable positives in 48 samples and a generic performance standard of 2 allowable positives among n < 48 samples. Vertical lines represent P_{pass} and P_{fail} **given the prevalence threshold determined by the performance standard (i.e., 2/48 = 0.042) and the most-likely industry beta distribution.**

One of the design criteria for these performance standards was to allocate the current number of samples more effectively among establishments producing ground beef to achieve the HP2020 reduction in illness goal. Current sampling rates and 3 options for sample allocation are listed in Table 4. Note that even with the smallest allocation of samples to volume categories 1 through 4, more than 50 percent of resources are dedicated to monitoring 9 percent of total annual ground beef production.

Table 4. Ground beef sample allocation options by volume category.

Volume category	Number of establishments	Total production volume[1]	Average samples collected per year	Average collected samples per category	Current annual sampling ceiling	Option 1 annual collection target	Option 1 annual samples per category	Option 2 annual sampling target	Option 2 assigned samples per category	Option 3 annual sampling target	Option 3 annual samples per category
7	12	48%	45	540	48	48	576	48	576	48	576
6	22	28%	42	924	48	48	1056	48	1056	48	1056
5	41	15%	32	1312	36	48	1968	48	1968	48	1968
4	89	7%	20	1780	24	4	356	12	1068	24	2136
3	57	1%	17	969	24	4	228	12	684	12	684
2	139	1%	15	2085	24	4	556	6	834	12	1668
1	880	1%	4	3520	12	4	3520	4	3520	6	5280
Total	1240			11130			8260		9706		13368

[1] Does not add to 100% due to rounding.

Summarization of *Salmonella* Sampling in Beef Manufacturing Trimmings (BMT)

Since 2012, FSIS has been collecting BMT samples under its MT60 program. Although initially designed for *E. coli* O157:H7 surveillance, these samples have been co-analyzed for *Salmonella* since 2014. Nevertheless, FSIS has not established *Salmonella* performance standards for BMT previously.

The BMT data used in this analysis is based on 7,100 samples collected between August 2014 and July 2016 from 509 establishments under FSIS inspection. BMT samples are collected according to the N60 method[6]. This method involves collecting 60 thin slices from the external surface of beef tissues within combo bins of BMT. Each sample slice is about 3 inches long by 1 inch wide and 1/8th inch thick. Microbiologic detection of pathogens from these samples is conducted by FSIS laboratories according to published methods (FSIS, 2011a, 2013, 2014).

About 96% of total annual BMT volume is produced by volume category 5 through 7 establishments (Figure 8). Furthermore, 94% of the estimated *Salmonella* contaminated servings are associated with these large volume establishments; despite the fact that the average proportion of samples that are *Salmonella*-positive is somewhat larger among medium-sized BMT establishments. The average number of BMT samples assigned across volume categories are similar to those observed for ground beef. To create a sampling plan for BMT that requires minimal adjustments to the current sampling assignments, a performance standard is developed for large (volume category 5 – 7) BMT establishments, while a generic standard is applied to medium (volume category 3 and 4) and small (volume category 1 and 2) BMT establishments.

[6] FSIS Directive 10,010.1 (revision 4), 8/20/15

The standard assumes that 48 samples will be collected from large establishments each year (i.e., 4 samples per month).

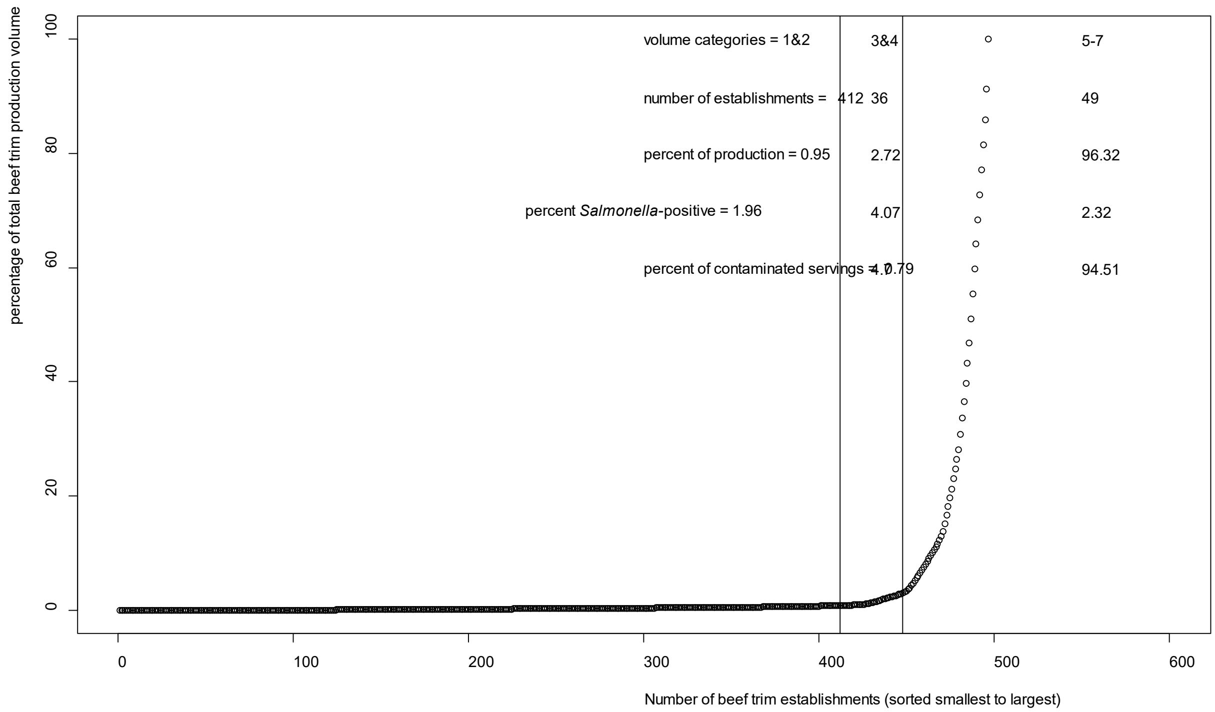

Figure 8. Summary of BMT industry and *Salmonella* testing organized by volume categories 1 through 7.

As mentioned in the introduction, BMT performance standards are intended to provide establishments that produce ground beef with information about their primary input to the grinding process. BMT is created during carcass fabrication and serves solely as a precursor to ground beef. As such, BMT is not consumed without further processing and, therefore, no human illnesses can be attributed directly to this product form.

Although essentially 100% of BMT becomes ground beef, it is not true that 100% of ground beef consists of BMT. Other beef products, including head and cheek meat, heart meat and weasand may be included in finished ground beef products. *Salmonella* contamination of ground beef might result from any of these sources. In addition, recent analysis suggests that large peripheral lymph nodes may harbor *Salmonella* internally and could be an important source of *Salmonella* in ground beef (Li et al., 2015).

Large commercial ground beef operations typically combine units of BMT into grinder loads. A standard unit of BMT is a combo bin consisting of about 2,000 lbs. A standard ground beef unit is a load consisting of about 10,000 lbs. Therefore, a ground beef load is expected to comprise an average of roughly five combo bins. The mixing of BMT from different types of cattle is essential to produce ground beef with precise lean specifications because BMT generated from fed cattle carcasses usually represents 50% lean beef, while BMT generated from culled adult cattle carcasses usually represents 90% lean beef.

If a grinding operation purchases its inputs, then it is expected that the grinding operation would seek combo bins of BMT from multiple slaughter operations that process both types of cattle carcasses. It is assumed that little can be done to change the contamination status of purchased BMT by grinding operations that do not make their own BMT. Instead, operations that strictly grind may be able to manage the likelihood of producing *Salmonella*-positive ground beef by making informed purchasing decisions. Therefore, for example, a grinding operation that wants to reduce the likelihood of *Salmonella*-positive ground beef might prefer suppliers with a lower frequency of *Salmonella*-positive BMT samples rather than suppliers with higher (or unknown) frequencies of *Salmonella*-positive BMT samples.

The purpose of the BMT performance standard is to provide objective information about the *Salmonella*-status of BMT producers to ground beef producers. It is assumed that this information will be useful and will support the objective of the ground beef performance standards (i.e., preventing human illnesses attributed to ground beef consumption). Nevertheless, FSIS does not assert any direct relationship between the effects of BMT performance standards and changes in human illness risk.

The available empiric evidence does not support a direct correspondence between BMT contamination and ground beef contamination. For example, among the 49 BMT-producing establishments with greater than 50,000 pounds average daily production (volume categories 5 through 7), there are 24 establishments that also produce ground beef. For these 24 establishments, the correspondence in *Salmonella*-positive proportions between BMT and ground beef is weak; although the overall positive proportions are very similar for both products (i.e., ~0.023) (Figure 8). Furthermore, the composition of ground beef suggests that other components that are inputs to ground beef could introduce *Salmonella* into ground beef independent of the status of the BMT. For example, we estimate annual production of BMT at roughly 7.2 billion lbs. while other inputs to ground beef produced in the U.S. (e.g., bench trim, heart muscle, head/cheek meat) may constitute another 0.5 to 1 billion lbs. annually. These other inputs are periodically *Salmonella*-positive when tested by FSIS. Head and cheek meat samples are more frequently *Salmonella*-positive than routine BMT samples as shown in Table 5.

Table 5. Summary of FSIS sampling results for the allowable components of beef patty products (July 2014 through September 2016).

Components allowed in beef patties products	Number of positive samples	Total number of samples	Proportion of *Salmonella*-positive samples
Advanced meat recovery (AMR)	2	54	0.037
Cheek meat	27	229	0.118
Head meat	22	143	0.154
Partially defatted beef fatty tissue	0	3	0.000
Partially defatted chopped beef	0	10	0.000
Trimmed beef heart	13	419	0.031
Weasand	5	42	0.119

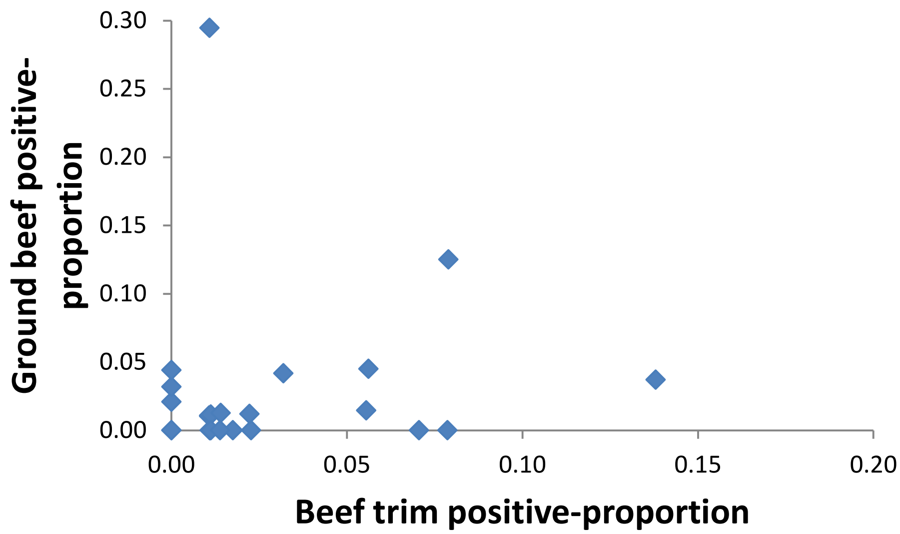

Figure 9. ***Salmonella*** **testing results for BMT and ground beef collected in 24 large establishments that also produced ground beef. There is a weak correspondence between the proportion of samples** ***Salmonella*****-positive from BMT and ground beef across these establishments.**

A performance standard for BMT establishments in volume categories 5 through 7 is proposed such that the classification of such establishments is as concordant as possible with the proposed ground beef performance standard. First, the test results from the 24 BMT establishments in categories 5 through 7 that also produce ground beef (Figure 9) are examined for their meets/not meets classification based on alternative BMT performance standards with an objective of maximizing the concordant pairs. Second, a beta-binomial distribution is fit to *Salmonella* testing data from the 49 BMT establishments with average daily production greater than 50,000 pounds (volume categories 5 through 7). This method is the same as the weighted beta-binomial algorithm described for ground beef data. For this approach, the fraction of the industry that does not meet the alternative performance standards is considered for the most likely distribution.

Given the proposed ground beef performance standard of 2 allowable positives in 48 samples, the first approach suggests that a BMT performance standard that allows a maximum of 2 positives in 48 samples does the best at optimizing the concordance in establishments classified as meeting or not meeting both the ground beef and BMT performance standards (Table 6). This choice of 2 allowable positives generates the largest kappa statistic (0.25) of alternatives from 1 to 10 allowable positives.

Table 6. Classification of 24 large BMT-producing and ground beef-producing establishments with respect to meeting or not meeting performance standards that allow a maximum of 2 *Salmonella*-positives among 48 samples is shown. The BMT standard chosen for this table generates the largest kappa statistic possible while also resulting in similar fractions of establishments not meeting the ground beef and BMT standards (17% and 25%, respectively).

Trim classification \ Ground beef classification	pass	fail	Total
pass	16	2	18
fail	4	2	6
Total	20	4	24

The second approach of fitting a beta distribution to the 49 BMT establishments with greater than 50,000 pounds production daily (volume category 5 through 7) generates the most likely distribution shown in Figure 10. Uncertainty about this distribution is illustrated by 5th and 95th percentile distributions that are also shown. Using the most likely distribution, the fraction of production volume not meeting alternative maximum allowable positives (among 48 samples) is determined (Figure 11). These results show that a standard that allows 1, 2 or 3 positives will result in 36%, 15% and 6% of the BMT industry not meeting the standard, respectively.

If a ground beef standard of 2 allowable positives results in 24% of that industry's production volume not meeting the standard (see Table 3), then the choice of 2 allowable positives for the BMT standard will result in a similar percentage of the BMT industry not meeting the standard without over-condemning BMT establishments relative to ground beef establishments. Similar reasoning would suggest that – if a ground beef standard of 1 allowable positive is chosen and results in 48% of that industry not meeting the standard – then a choice of 1 allowable positive for the BMT standard is preferred.

Based on the available data, a BMT performance standard of 2 allowable positives in 48 samples may result in 10 (20%) of the 49 establishments not meeting the standard initially.

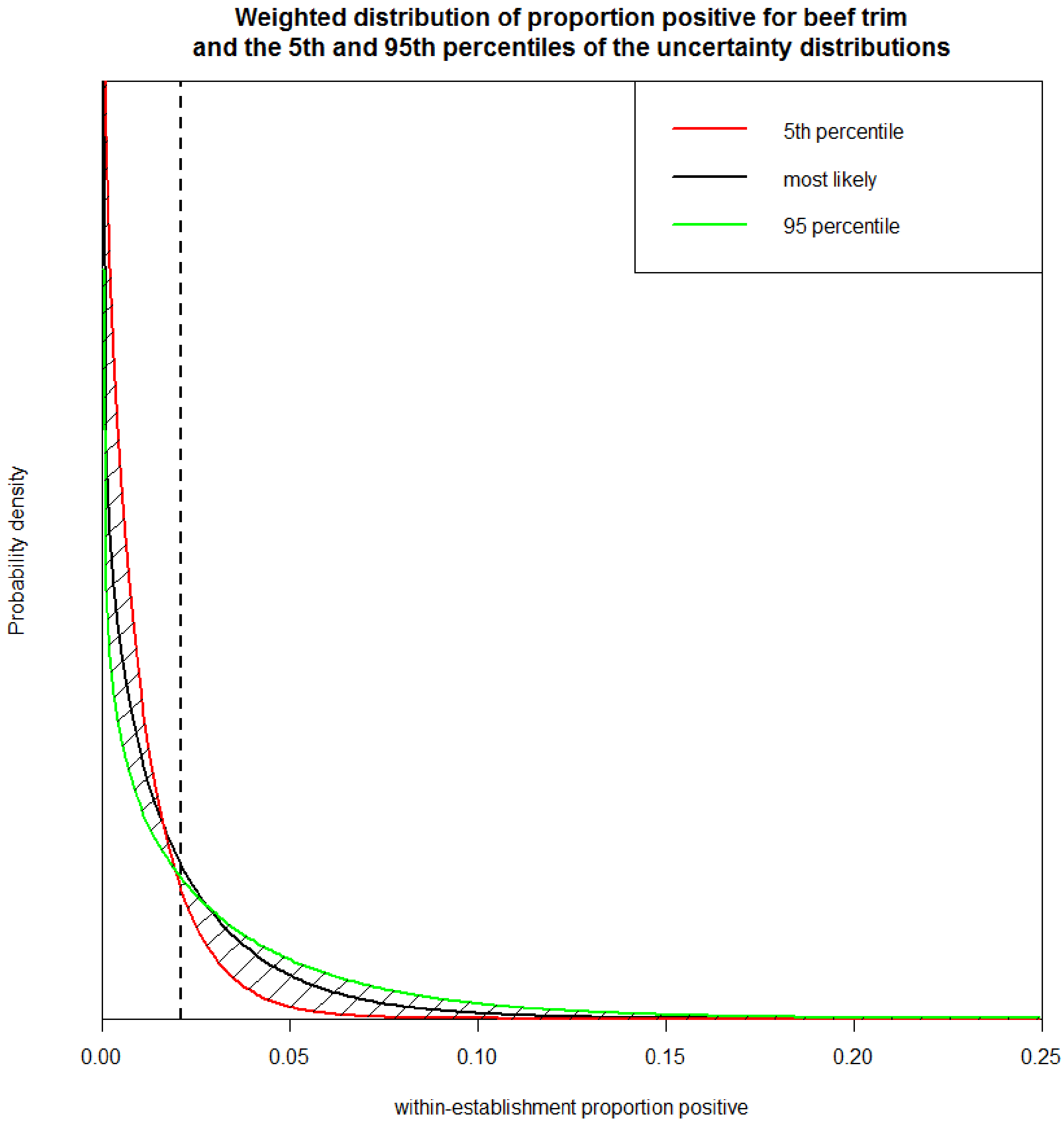

Figure 10. Fitted beta distributions for within-establishment *Salmonella* contamination for BMT among the 49 establishments with average daily volume greater than 50,000 pounds (volume categories 5 through 7). The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Salmonella* contamination in BMT samples across establishments. The uncertainty about the true or actual distribution is illustrated by including bounding distributions—the 5th and 95th percentiles—determined using the statistical fitting algorithm. The vertical dashed line indicates the volume weighted expected value, 2.1%, of the most likely beta (a=0.81, b=37.67) distribution.

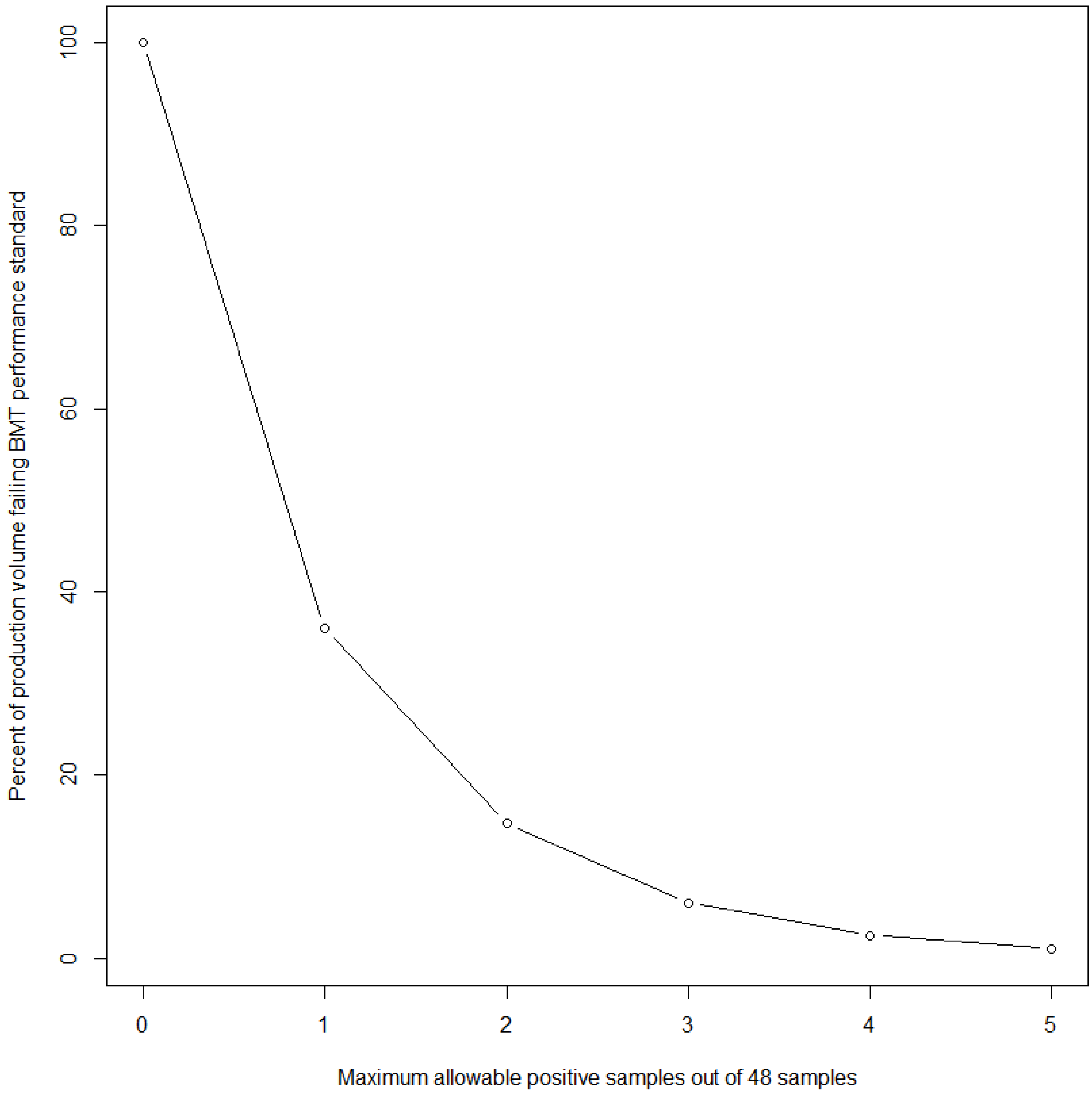

Figure 11. Based on the most likely beta distribution above (Figure 10), the percent of production volume expected to not meet a BMT performance standard that allows 0 to 5 positive samples is shown.

A generic performance standard for BMT of 2 allowable positives per year (regardless of the number of samples collected in the establishment) is proposed for medium and small BMT-producing establishments. This choice of 2 allowable positives matches the proposed standard's number of allowable positives, although the underlying level of contamination necessary to fail to meet this generic standard is generally much larger than expected for most medium and small BMT establishments.

Of the estimated 448 BMT establishments that will fall under the generic performance standard, it is expected that 2 establishments, on average, might not meet this standard each year. These BMT establishments represent 0.1% of total annual BMT production. If a generic standard of 1 allowable positive were to be chosen, then an average of 13 of these BMT establishments, representing about 0.55% of annual BMT production, might not meet the standard each year.

Figure 12 demonstrates the operating characteristics of the BMT performance standard at $s = 2$ allowable, as well as how the generic performance standard operates at various sample numbers less than 48. An establishment currently meeting the standard, with the average prevalence of $P_{pass} = 0.013$, will have a 97.4% chance of meeting the standard. An establishment not meeting the standard with the average prevalence of $P_{fail} = 0.065$ has a 61% chance of not meeting the performance standard during the first year.

Small and medium BMT establishments that perform near the industry average for their volume category have a high chance of meeting the standard. This could allow establishments in the lower volume categories to still operate at higher underlying prevalence levels than establishments with more than 50,000 pounds production daily (volume categories 5 through 7), but egregious offenders should eventually fail to meet the generic standard.

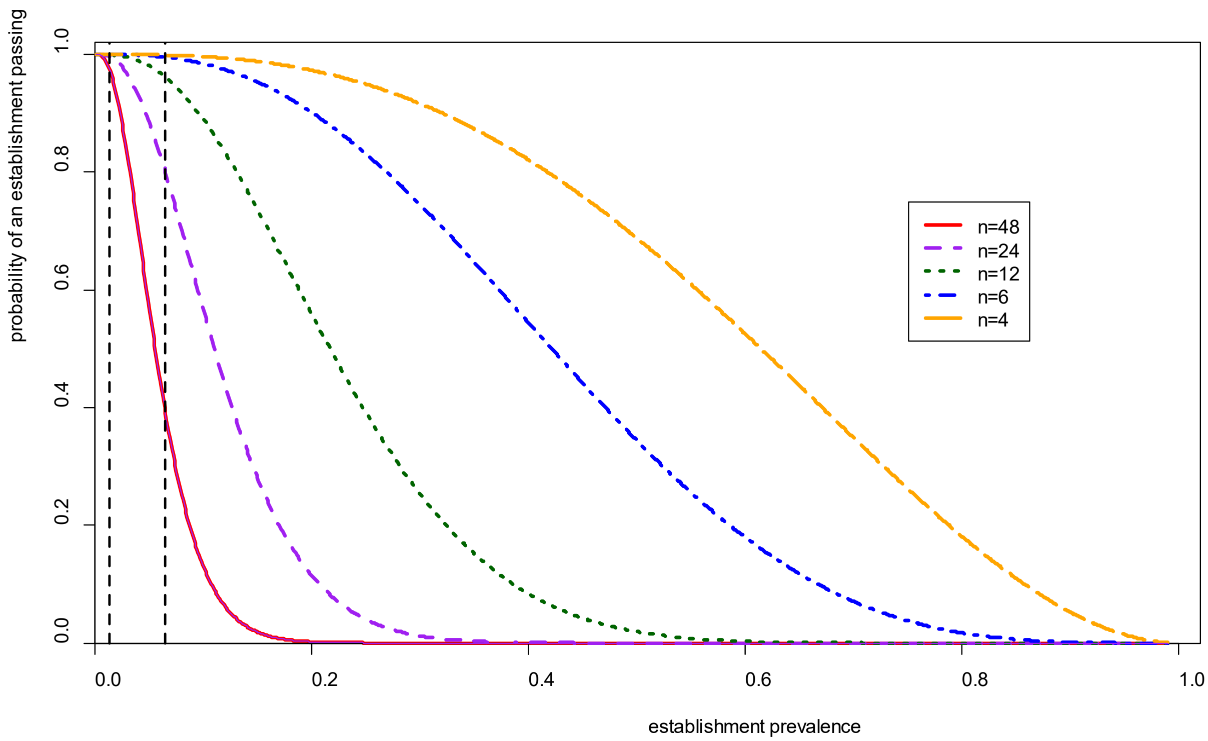

Figure 12. Performance characteristics of the BMT performance standard of 2 allowable positives in 48 samples and a generic performance standard of 2 allowable positives among n<48 samples (n = 24, 12, 6, and 4). Vertical lines represent expected mean prevalence for compliant and noncompliant establishments, which are $P_{compliant} = 0.0133$ and $P_{noncompliant} = 0.0651$ for the prevalence threshold determined by the primary performance standard (i.e., 2/48 = 0.042).

Conclusions

The results of these analyses are conditioned on the assumptions outlined in this report. For example, sample collection will achieve the desired 48 samples needed to categorize large volume establishments accurately and industries are expected to be incentivized to seek improvements in process control.

The goal of the performance standards for ground beef was to meet the agency's illness reduction goals outlined in HP2020. The outputs of these analyses provide FSIS management with information they can use when deciding the most appropriate performance standard and allocation of sampling resources. Decisions about which performance standards to implement are made by FSIS management and these decisions are informed by the outputs of this analysis, a separate economic analysis, and other factors. When interpreting the results, however, it is important to consider the data limitations and uncertainties in the analyses.

In summary, FSIS risk managers considered the results of this analysis to select performance standards for the two products (Table 6). The risk managers preferred the most likely within-establishment contamination distributions and a 50% compliance fraction among establishments that initially do not meet the performances standards. FSIS risk managers opted to not institute the generic performance standards summarized in Table 7.

Table 6. Summary of information about the performance standards (volume categories 5 - 7) selected by FSIS for ground beef and BMT. Results are based on the most-likely within-establishment contamination distributions for each product-pathogen pair and the assumption that 50% of production volume not meeting the standard initially will meet it eventually.

Metric	*Salmonella* ground beef	*Salmonella* BMT
Performance standard	2 of 48	2 of 48
Reduction in illnesses	24%	NA
Illnesses avoided median, (5^{th} – 95^{th} percentiles)	8,900 (2,000 - 20,000)	NA NA
Production volume share initially not meeting performance standard	24%	15%
Number of establishments initially not meeting performance standard initially (% of total)	14 (18%)	10 (20%)

Table 7. Summary of information about the generic performance standards (volume categories 1 - 4) for ground beef and BMT. Results are based on the most-likely within-establishment contamination distributions for each product-pathogen pair.

Metric	*Salmonella* ground beef	*Salmonella* BMT
Performance standard	2	2
Production volume share initially not meeting performance standard	0.05%	0.1%
Number of establishments initially not meeting performance standard initially (% of total)	4 (0.3%)	2 (0.45%)

Literature Cited

Bartholomew, M.J., Vose, D.J., Tollefson, L.R., Travis, C.C., 2005. A linear model for managing the risk of antimicrobial resistance originating in food animals. Risk Analysis 25, 99-108.

Close, D., 2014. Ground Beef Nation: The effect of changing consumer tastes and preferences on the U.S. cattle industry, Raboback AgFocus.

Dutang, C., Goulet, V., Pigeon, M., 2008. actuar: An R package for actuarial science. Journal of Statistical Software 25, 1-37.

Ebel, E.D., Williams, M.S., 2015. When are qualitative testing results sufficient to predict a reduction in illnesses in a microbiological food safety risk assessment? Journal of Food Protection 78, 1451-1460.

Ebel, E.D., Williams, M.S., Golden, N.J., Marks, H.M., 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. Food Control 28, 250-257.

FAO/WHO, 2002. Risk assessment of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood, FAO Food and Nutrition Paper 75, Bangkok.

FSIS, 2011a. Laboratory guidebook notice of change. United States Department of Agriculture, Washington, D.C.

FSIS, 2011b. New performance standards for *Salmonella* and *Campylobacter* in young chicken and turkey slaughter establishments: Response to comments and implementation schedule, Washington, D.C., p. .

FSIS, 2013. Microbiology laboratory guidebook: Appendix 1.08. Media and reagents. United States Department of Agriculture, Washington D.C.

FSIS, 2014. Isolation and identification of *Salmonella* from meat, poultry, pasteurized egg, and catfish products and carcass and environmental sponges United States Department of Agriculture, Washington, DC.

FSIS, 2015. Public health effects of raw chicken parts and comminuted chicken and poultry performance standards. United States Department of Agriculture, Washington, D.C.

HHS, 2010. Healthy people topics & objectives: Food safety, Reduce infections caused by *Salmonella* species transmitted commonly through food Washington, DC.

Hill, W.E., Suhalim, R., Richter, H.C., Smith, C.R., Buschow, A.W., M., S., 2011. Polymerase chain reaction screening for *Salmonella* and Enterohemorrhagic *Escherichia coli* on beef products in processing establishments. Foodborne Pathogens and Disease 8, 1045-1053.

Klugman, S.A., Panjer, H.H., Willmot, G.E., 2012. Loss Models: From Data to Decisions 4ed. John Wiley and Sons, New York.

Laufer, A., Grass, J., Holt, K., Whichard, J., Griffin, P., Gould, L., 2015. Outbreaks of *Salmonella* infections attributed to beef–United States, 1973–2011. Epidemiology and Infection 143, 2003-2013.

Li, M., Malladi, S., Hurd, H.S., Goldsmith, T.J., Brichta-Harhay, D.M., Loneragan, G.H., 2015. *Salmonella* spp. in lymph nodes of fed and cull cattle: Relative assessment of risk to ground beef. Food Control 50, 423-434.

Lukicheva, N., Ebel, E.D., Williams, M.S., Schlosser, W.D., 2016. Characterizing the concentration of pathogen occurrence across meat and poultry industries. Microbial Risk Analysis 4, 29-35.

Painter, J.A., Hoekstra, R.M., Ayers, T., Tauxe, R.V., Braden, C.R., Angulo, F.J., Griffin, P.M., 2013. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities, United States, 1998–2008. Emerging Infectous Diseases 19, 407-415.
R Development Core Team, 2015. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.
Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.-A., Roy, S.L., Jones, J.L., Griffin, P.M., 2011. Foodborne illness acquired in the United States—major pathogens. Emerging Infectious Diseases 17, 7-15.
USDA, 2014. Changes to the *Salmonella* verification sampling program: Analysis of raw beef for Shiga Toxin-producing *Escherichia coli* and *Salmonella*, Washington, D.C.
Vose, D., 2008. Risk Analysis: A Quantitative Guide, 3rd ed. John Wiley & Sons, West Sussex.
Williams, M.S., Ebel, E.D., Cao, Y., 2013. Fitting distributions to microbial contamination data collected with an unequal probability sampling design. Journal of Applied Microbiology 114, 152-160.
Williams, M.S., Ebel, E.D., Golden, N.J., Schlosser, W.D., 2014. Temporal patterns in the occurrence of *Salmonella* in raw meat and poultry products and their relationship to human illnesses in the United States. Food Control 35, 267-273.