Public Health Effects of Raw Chicken Parts and Comminuted Chicken and Turkey Performance Standards

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Executive Summary

FSIS announced its *Salmonella* Action Plan on December 4, 2013[1]. In the plan, FSIS stated that it would complete a risk assessment and develop *Salmonella* performance standards for comminuted poultry during fiscal year 2014. In addition, FSIS stated that it would announce and request comment in the Federal Register on the setting of pathogen reduction performance standards for *Salmonella* and *Campylobacter* during fiscal year 2014 for raw chicken parts. This risk assessment describes the motivation, data sources, and analytical methods used in the development of the new pathogen reduction performance standards for *Salmonella* and *Campylobacter* for these products.

The new and revised performance standards are designed to achieve The Healthy People 2020 (HP2020) goal for *Salmonella* as it relates to poultry products, which is to achieve a 25% reduction in human illnesses attributed to poultry by the year 2020 (HHS 2010). The HP2020 goal for *Campylobacter* is to achieve a 33% reduction during the same time period (HHS 2010). The 25% and 33% reduction targets represent FSIS policy choices. Healthy People 2020 does not provide product-specific goals. The *Salmonella* and *Campylobacter* goals are with respect to a 2006-08 baseline. Therefore, any reductions achieved through the 2011 *Salmonella* and *Campylobacter* performance standards for young chicken and turkey would apply to meeting the Healthy People goal. FSIS predicted that the 2011 performance standards would reduce *Salmonella* illnesses by 12% and *Campylobacter* illnesses by 3%.

The risk assessment describes how counts of the *Salmonella*- and *Campylobacter*-positive samples, collected at a rate of roughly once per week, will be used to categorize establishments as either passing or failing the performance standard. Reductions in the number of salmonellosis and campylobacteriosis cases are estimated to occur after establishments apply corrective actions that reduce the occurrence of these pathogenic bacteria.

[1] http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/salmonella/sap.

A common analytical framework is used to estimate the improvements in public health associated with six performance standards. Following implementation of the performance standards, the model presents different scenarios under which a 25% reduction in salmonellosis cases attributed to chicken and turkey could occur. The model also describes different scenarios under which reductions in *Campylobacter* illnesses could occur, but the full 33% reduction could not be achieved for all products types using existing sampling methods and under the assumed response by industry.

Introduction

Performance standards have been applied to meat and poultry slaughter establishments since the inception of the PR/HACCP rule (FSIS 1996). Under a performance standard, each establishment is subjected to a series of sampling occasions. If the number of positive samples in a set of samples is less than or equal to a maximum allowable number of positive samples, then the establishment is considered to be passing the performance standard. If the number of positive samples exceeds the maximum allowable, then the establishment is considered to be failing the performance standard. For the performance standards considered here, we assume a set size of 52. If available resources permit weekly sampling of establishments, a set size of 52 would therefore cover a year period.

FSIS plans to revise the current *Salmonella* performance standards for comminuted chicken and turkey, as well as establish new *Campylobacter* standards for each of these products. FSIS also plans to establish new performance standards for chicken parts. Separate standards will be examined for *Salmonella* and *Campylobacter*.

The purpose of this report is to explain the estimated public health effects of alternative performance standards applied to raw chicken parts and comminuted poultry (i.e., chicken and turkey). For our purposes, a performance standard constitutes the maximum number of allowable positive samples within a fixed number of samples (i.e. a sample set). These numbers also generate a value for the maximum allowable fraction of positive samples that constitutes passing the performance standard.

Public health improvements are assumed to be generated from the establishment of performance standards if those standards motivate an industry to reduce the occurrence of pathogens in/on the commodities produced by that industry. FSIS wants to establish performance standards that achieve The Healthy People 2020 (HP2020) goal for *Salmonella,* which is to a 25% reduction in human illnesses by the year 2020 (HHS 2010). The HP2020 goal for *Campylobacter* is to achieve a 33% reduction (HHS 2010).

The FSIS recently announced a *Salmonella* Action Plan (FSIS 2013) that includes provisions for establishing performance standards that are linked to the Healthy People 2020 goals. Therefore, the performance standards detailed in this report are intended to be examined with respect to their expected public health effects. Specifically, the analysis considers alternative performance standards where the maximum number of allowable positives varies from 1 to 52 out of each n = 52 sample set per establishment to assess the likelihood of achieving the intended reduction in illnesses across all establishments.

This report develops and assesses six performance standards:

- *Salmonella* on chicken parts
- *Campylobacter* on chicken parts
- *Salmonella* in comminuted chicken
- *Campylobacter* in comminuted chicken
- *Salmonella* in comminuted turkey
- *Campylobacter* in comminuted turkey

The remainder of this report presents the methods used, the results of the analyses and a discussion of the results and a characterization of how the results can be interpreted. The methods employed here allow FSIS to develop performance standards for multiple FSIS-regulated commodities. The proposed performance standards are designed to help FSIS achieve its public health goals, but when estimating the public health benefits from all the performance standards it is important to consider the relationship of the benefits in the different commodities. Currently, FSIS does not have sufficient data to determine how pathogen contamination occurrence on poultry carcasses, poultry parts and comminuted poultry products might be related to each other within establishments that produce these products (i.e., at present, the data do not permit rejecting the hypothesis that contamination occurrences are independent across products). Also, sufficient data do not exist to assess how performance standards for *Salmonella* or *Campylobacter* might affect industry's accomplishments with regard to the other pathogen. Although we address the possible relationship between carcasses and parts for the *Salmonella* performance standard for chicken parts, we otherwise assume that the effectiveness of performance standards for one commodity-pathogen pairing is independent of any other commodity-pathogen pairing. Nevertheless, successful control of one pathogen's contamination might influence the occurrence of contamination with the other pathogen.

The methods used for estimating the public health effects of performance standards are common across pathogens and commodities. Therefore, a single methods section is included as applicable for all analyses. The data for these analyses, however, differ and are presented separately for each type of analysis. Some sources of uncertainty differ across the analyses and are discussed separately.

Results are organized to support decision-making with respect to each of the six performance standards. Finally, a discussion section summarizes the conclusions of this assessment and highlights important caveats to these conclusions.

Methods

Mathematical model

Equations for predicting the public health effect of a performance standard have been described previously (FSIS 2011, Ebel, Williams et al. 2012). Briefly, the annual rate of illnesses avoided is estimated as;

$$\lambda_{ill\ avoided} = \left(1 - \frac{p_{new}}{p_{baseline}}\right)\lambda_{ill}, \tag{1.1}$$

where λ_{ill} represents the annual rate of illnesses occurring before the proposed performance standard is implemented, $p_{baseline}$ is the prevalence of contaminated sample units prior to implementing the performance standard and p_{new} is the prevalence of contamination following successful implementation of the performance standard.

The prevalence parameters are estimated as follows:

$$p_{baseline} = \omega p_{passing} + (1-\omega)\, p_{failing} \tag{1.2}$$

$$p_{new} = \left(\omega + \alpha - \omega\alpha\right) p_{passing} + \left(1 - \omega\right)\left(1 - \alpha\right) p_{failing} \qquad (1.3)$$

where $p_{passing}$ and $p_{failing}$ are the volume-weighted expected prevalence of contamination levels among establishments passing or failing the performance standard, ω is the fraction of production volume associated with establishments that initially pass the performance standard and α is the production volume fraction of initially failing establishments that would change their production practices in order to pass the performance standard.

Statistical fitting

In order to determine the current status of the industries with respect to *Salmonella* and *Campylobacter* prevalence, statistical distributions were fitted to FSIS sampling results (data collected from the raw chicken parts baseline survey or the exploratory sampling program for comminuted poultry). These statistical distributions describe how the prevalence of contamination within establishments varies across the population of all establishments producing the various commodities. To estimate $p_{passing}$, $p_{failing}$ and ω, we fit a distribution to available data to describe how within-establishment prevalence of contamination $\left(p\right)$ varies across the industry prior to implementing the performance standard. A *beta-binomial* fitting algorithm is employed to derive weighted maximum likelihood estimates (MLE) of the parameters of a *beta* distribution (Williams, Ebel et al. 2013). The *beta-binomial* is a mixture distribution that generalizes the binomial distribution. For a fixed prevalence value (p), the binomial distribution accounts for random variability arising from a binomial process in the number of positives (x) in sample of size n. However, because prevalence varies among establishments, the beta distribution represents this variability: x~Binomial(n,p) , with p ~ Beta (a,b).

The MLE parameters of the distribution for p define its most likely shape. Furthermore, the parameter values of the beta(a,b) distribution are uncertain. We illustrate uncertainty about the best-fitting *beta* distribution by defining 5th and 95th confidence boundaries. These boundaries are derived by locating distributions with the same coefficient of variation as the MLE distribution, but with means that are shifted to reflect the standard error of the mean of the most likely distribution. We propagate the most likely, 5th and 95th percentile distributions through the remaining calculations to evaluate the influence of this source of uncertainty on our results.

Once a *beta* distribution is estimated, it can be queried to determine the conditional expectations for the share of the industry above a threshold prevalence defined by a particular performance standard. For example, a performance standard of 5 maximum allowable positives in a set of 52 samples implies a threshold prevalence $p_{threshold}$ of 9.6% (5/52).

Conditional expected value calculations depend on a calculation for the limited expected value of a random variable x, $E\left[x \wedge t\right]$, such that $x = X$ for values less than t but $x = t$ for all values larger than t. Computer software packages provide simple commands to solve for $E\left[x \wedge t\right]$ when x is *beta* distributed. Therefore,

$$p_{passing} = \frac{E\left[p \wedge p_{threshold}\right] - p_{threshold}\left(1 - F(p_{threshold})\right)}{F(p_{threshold})} \tag{1.4}$$

$$p_{failing} = \frac{E\left[p\right] - \left(E\left[p \wedge p_{threshold}\right] - p_{threshold}\left(1 - F(p_{threshold})\right)\right)}{1 - F(p_{threshold})} \tag{1.5}$$

where $F\left(p_{threshold}\right)$ is the cumulative probability of the p distribution up to value $p_{threshold}$. Because the distribution of p is production volume weighted, the value for ω simply equals $F\left(p_{threshold}\right)$. 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 as falling above or below the threshold will also decrease, especially so if failing establishments take actions to reduce their prevalence such that their probability of passing increases.

Compliance fraction, α

Another input to the public health model is the fraction of initially failing production volume that eventually becomes compliant with the performance standard. This is the α parameter in the equation above and we call this the "compliance fraction".

The compliance fraction for any new performance standard is unknowable in advance. In previous analyses, it has been assumed to range from nearly 0% (none of the initially noncompliant establishments pursue becoming compliant) to nearly 100% (all initially noncompliant establishments become compliant eventually) (FSIS 2011). Evidence regarding a previous chicken carcass *Salmonella* performance standard suggested that industry improvements were associated with a 50% reduction in the share of industry that was noncompliant with that performance standard (Ebel, Williams et al. 2012). Previous research suggests that some improvement in food safety process control occurs via market incentives wherein establishment managers are encouraged by their customers to be more attentive to their process control (Ollinger and Moore 2009, NRC 2011). Other *Salmonella* evidence suggests that since FSIS implemented its HACCP rule in 1995, the prevalence of positive tests has been reduced by ≥50% across most species and products (Progress Report on *Salmonella* and *Campylobacter* Testing of Raw Meat and Poultry Products, 1998-2013[2]. Although this latter evidence is likely confounded by the effects of other activities, it does reflect, in part, the effect of *Salmonella* performance standards enacted for those products.

For the purposes of the assessments completed here, we treat the compliance fraction as a decision variable and assume α can equal 50%, 40% or 30%. A maximum of 50% reduction in non-compliance was chosen on the basis of the aforementioned evidence (FSIS 2011, Ebel, Williams et al. 2012). Results are presented assuming 40% and 30% reduction in non-compliance; these results represent more conservative estimates of the percentage of failing production volume that FSIS assumes will decrease its proportion of *Salmonella*-positive samples in response to FSIS' new performance standards.

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[2] http://www.fsis.usda.gov/wps/wcm/connect/885647f4-2568-48bf-ae5c-4a0d8279f435/Progress-Report-Salmonella-Campylobacter-CY2013.pdf?MOD=AJPERES)

Annual rate of illnesses before implementation, λ_{ill}

Each performance standard is designed for a specific commodity-pathogen pair. Therefore, a unique λ_{ill} must be estimated for each performance standard.

Table 1 outlines modal values and minimum-maximum values used for λ_{ill}. CDC provides estimates of the annual domestically-acquire foodborne *Salmonella* illnesses per year (Scallan, Hoekstra et al. 2011) and estimates of attribution fractions for poultry (Painter, Hoekstra et al. 2013). Based on a previous analysis, we assume that chicken and turkey represent 85% and 15% of poultry production, respectively (FSIS 2011). Chicken industry data enables us to estimate that chicken parts, whole chicken and comminuted chicken represent 81%, 13% and 6% of chicken consumed, respectively (NCC 2011). We assume that illnesses are proportional to the volume available for consumption. Similarly, we infer from turkey industry production volume data (National Turkey Federation, personal communication, 2014) that intact turkey (whole and parts) and comminuted turkey represent 75% and 25% of turkey illnesses, respectively.

We propagate uncertainty about the Scallan et al. (2011) and Painter et al. (2013) estimates by assuming these follow $Pert(\text{min}, \text{mode}, \text{max})$ distributions and simulate their product to generate 5th and 95th quantile values (rounded to nearest hundred). These results are multiplied by the predicted effects of the performance standards to generate mean (5th – 95th percentile) values for the annual number of illnesses avoided by the performance standard.

Table 1. Results for annual illness rates, λ_{ill}, based on CDC illness counts and attribution estimates, FSIS production volume data and industry information regarding relative production of intact and comminuted poultry products.

Illness measures	*Salmonella* mode (min - max)	*Campylobacter* mode (min - max)
Total annual illnesses (Scallan et al. 2011)	1,027,561 (644,786 - 1,679,667)	845,024 (337,031 - 1,611,083)
Poultry attribution fraction (Painter et al. 2013)	19% (10.1% - 29.2%)	7.6% (5.3% - 10.3%)
	mean (5th – 95th percentile)	**mean (5th – 95th percentile)**
Annual poultry illnesses by simulation	200,700 (126,700 - 303,600)	66,500 (37,700 - 103,900)
Annual whole chicken illnesses	20,600 (14,000 - 33,500)	7,100 (4,200 - 11,500)
Annual chicken parts illnesses	133,600 (87,200 - 209,000)	44,200 (25,900 - 71,600)
Annual comminuted chicken illnesses	10,300 (6,500 - 15,500)	3,400 (1,900 - 5,300)
Annual intact turkey illnesses	22,600 (14,700 - 34,200)	7,500 (4,400 - 11,700)
Annual comminuted turkey illnesses	7,500 (4,800 - 11,400)	2,500 (1,400 - 3,900)

Other issues

When estimating the potential public health benefits of new performance standards, it is necessary to consider how existing policies influence the ability to reap additional benefits. The issue of primary concern is that updated performance standards for chicken carcasses have been recently implemented. Taking the effect of the updated carcass standard into consideration implies that the incremental public health effect of a new parts performance standard is uncertain.

If the current carcass performance standard influences both whole chicken and chicken parts contamination (considered here to be a positive correlation), then the existing carcass performance standard prevents illnesses from both whole chicken and chicken parts. If a carcass performance standard only applies to whole chicken illnesses (deemed complete independence), then only a chicken parts standard can prevent illnesses from parts.

With respect to *Salmonella*, current evidence does not support determining the degree to which carcass and parts prevalence are correlated at the slaughter establishment level. Because poultry parts samples are not routinely collected, a comparison of carcass and parts results that are temporally matched is not feasible at this time. Nevertheless, such data may become available after the parts performance standard is implemented.

We are only concerned about this issue with respect to chicken parts and *Salmonella*. The updated chicken carcass performance standard for *Salmonella* (FSIS 2011) was predicted to achieve a 12% reduction in chicken-related illnesses[3]. Consequently, the effect of successful control of carcass contamination could be material to the illnesses avoided from reduced parts contamination in the future. This issue is not as important for chicken parts and *Campylobacter* because the expected effect of the chicken carcass performance standard on *Campylobacter* illnesses was much lower (i.e., ~3%) and consideration of such effects are not expected to matter in the development of a parts performance standard for *Campylobacter*.

The issue of correlation of carcass contamination with comminuted product contamination is considered negligible because FSIS sampling evidence suggests that – while a great majority of establishments that produce carcasses also fabricate those carcasses into parts – only 5% of establishments producing carcasses also produce comminuted product. Therefore, it is likely that comminuted product represents a mixture of products across establishments and this mixing would suggest independence between carcass contamination and comminuted product contamination at the establishment level at a particular point in time. Nevertheless, if the average prevalence of source materials declines across time, then the prevalence of comminuted product across establishments also may decline across time regardless of the correlation at the establishment level in cross section.

To account for our uncertainty about the magnitude of correlation of *Salmonella* prevalence between chicken carcasses and chicken parts, we considered two extreme possibilities:

- <u>Perfect positive correlation</u> between the proportion of positive carcass and positives parts samples at establishments
    - i.e., if an establishment's proportion of positive carcasses is high, then so is its proportion of positive parts samples (and vice versa)
- <u>Complete independence</u> between the proportion of positive carcass and parts samples at establishments.

[3] In the FSIS 2011 analysis, the proposed performance standard was expected to prevent 20,157 (12%) of 167,831 total *Salmonella* illnesses attributed to chicken. That analysis used a slightly different attribution calculation; therefore those numbers of illnesses differ from the numbers used here.

- i.e., an establishment's proportion of positive carcasses has no relationship to its the proportion of positive parts

Positive correlation may be true because carcasses, of course, generate parts and better control of carcasses translates to cleaner parts. Independence may be true if an establishment fabricates parts from carcasses slaughtered at another establishment or if the fabrication area is a reservoir. The truth almost certainly lies between these extremes.

In terms of choosing a chicken parts performance standard for *Salmonella*, the extreme of perfect positive correlation implies that fewer illnesses need to be avoided to achieve the 25% reduction objective. Because the chicken carcass performance standard is assumed to prevent some chicken parts illnesses, the perfect positive correlation case predicts fewer illnesses avoided for a given chicken parts performance standard. Furthermore, if FSIS wants to reduce all intact chicken illnesses (i.e., whole carcasses and parts) by 25%, then the parts performance standard must contribute to reducing exposures by >25% to make up for the existing carcass standard. In other words, a chicken parts *Salmonella* performance standard must be more stringent than the existing carcass standard, but will prevent fewer chicken parts-associated illnesses under the perfect positive correlation case than under the complete independence case. For this reason, our analysis focuses on the perfect positive correlation case as the more conservative option because it will generate performance standards that under-predict the public health effects relative to the complete independence case.

As stated above, if FSIS wants to achieve a 25% reduction in illnesses associated with intact chicken products, then the chicken parts performance standard must accomplish more than a 25% reduction in parts illnesses because the carcass performance standard was predicted to accomplish just a 12% reduction. We can solve for the needed effect of the chicken parts performance standard from;

$$0.25 = carcass_{effect} \times carcass_{share} + parts_{effect} \times parts_{share}$$

The carcass effect is 12%, the carcass share is the whole chicken share of intact product $(0.1336 = \frac{20,600}{20,600+133,600})$ and the parts share is the remaining share of intact product (0.8664). Solving for the parts effect results in a needed 27% reduction in parts illnesses.

The health benefits estimate for the 2011 performance standards accounted for the ~90% of volume that was already in compliance with the new standard prior to its initiation date of July 2011. The chicken parts baseline was conducted in Jan. – August 2012, so it may have been too early for the parts baseline prevalence to reflect the full impact of the 2011 carcass performance standards. Therefore the calculation of the illnesses avoided under the perfect correlation scenario avoids potential double counting benefits already claimed under the 2011 performance standards.

If carcass and parts *Salmonella* contamination are perfectly positively correlated, then an establishment with a high carcass prevalence would have a high parts prevalence. Consequently, for the perfect correlation scenario, we assume the illnesses avoided by the carcass performance standard must be subtracted from the illnesses avoided for the parts performance standard. This assumption amounts to crediting illnesses avoided to the parts performance standards equal to 15% (i.e., 27% - 12%) of parts associated illnesses, rather than the full 27% the parts standard is designed to achieve.

Sampling data used

Comminuted poultry sampling data

Data from an exploratory sampling program of not ready-to-eat comminuted poultry products – generated from June 2013 through January 2014 – were analyzed (FSIS 2012, FSIS 2014) . In that sampling program, 325g samples of comminuted poultry (chicken or turkey) were intended to be collected from establishments producing such products. Samples were tested for *Salmonella* and *Campylobacter*. Samples were identified as originating from ground, "other" or mechanically separated kind (MSK) comminuted materials. "Other" samples consisted of sausage, patties, meatloaf, or other non-breaded, non-battered comminuted products.

Although results from MSK samples were analyzed, only those samples categorized as ground or other were used in developing performance standards. Ground and other samples represent retail-ready comminuted products whose contamination relates directly to a public health hazard. In contrast, MSK material is not directly marketed for consumption but, instead, may be mixed into one of the other comminuted products. . Most mechanically separated poultry is destined for further processing into RTE products, and FSIS excludes such products from verification sampling when the establishment either processes all product in a product class (e.g., ground chicken) into RTE product or moves all product in a product class to another official Federally-inspected establishment for further processing into RTE product. (FSIS Directive 12,250.1, 9/20/13[4]). Therefore, most of the MSK is outside of the sample frame for the performance standard.

Table 2 summarizes the results of the survey of comminuted poultry products. Generally, these results show that;

- there are more *Salmonella*-positive samples than *Campylobacter*-positive samples

[4] http://www.fsis.usda.gov/wps/wcm/connect/ebf83112-4c3b-4650-8396-24cc8d38bf6c/10250.1.pdf?MOD=AJPERES

- there are more *Salmonella* and *Campylobacter*-positives in chicken than in turkey comminuted products
- mechanically separated products are much more contaminated than ground or other comminuted products
- ground and other comminuted products have similar frequencies of contamination
- the average number of samples per establishment is small

Table 2. Summary of results of a survey of comminuted poultry products conducted by FSIS (June, 2013 – January, 2014).

		Ground		Other comminuted		Mechanically separated		All comminuted	
	Results	*Salmonella*	*Campylobacter*	*Salmonella*	*Campylobacter*	*Salmonella*	*Campylobacter*	*Salmonella*	*Campylobacter*
Chicken	Number of establishments tested	45	45	41	42	41	41	105	105
	Total samples analyzed	617	625	337	344	780	794	1734	1763
	Total positive samples (%)	271 (44)	22 (4)	141 (42)	2 (1)	651 (83)	159 (20)	1063 (61)	183 (10)
	Average samples per tested estab.	14	14	8	8	19	19	17	17
Turkey	Number of establishments tested	36	36	26	26	11	11	49	49
	Total samples analyzed	623	632	253	253	58	58	934	943
	Total positive samples (%)	123 (20)	7 (1)	54 (21)	0 (0)	27 (47)	3 (5)	204 (22)	10 (1)
	Average samples per tested estab.	17	18	10	10	5	5	19	19

In this exploratory sampling, laboratory methods were designed to detect contamination concentrations of approximately one *Salmonella* colony forming unit (cfu) per 325 grams, or 6 *Campylobacter* cfu per gram of sampled material. We expect that these different limits of detection partly explain the lower frequency of detection for *Campylobacter* relative to *Salmonella* among the comminuted poultry samples. Nevertheless, such differences in methods are similar to those used currently to detect these pathogens on carcasses and chicken parts.

There were 73 chicken and 49 turkey establishments from which at least one ground or other sample was collected in this survey. These represent all U.S. establishments that are producing at least 1000 lbs. of not ready-to-eat comminuted poultry per month. An average of 13 samples per chicken establishment (range 1- 31) and 18 samples per turkey establishment were collected. For the purposes of weighting the establishment sampling data, the annual production volume (in pounds) for each sampled establishment was captured from FSIS' records.

Chicken parts sampling data

Data describing microbial contamination of chicken parts were generated by an FSIS baseline survey (FSIS 2013). Samples were collected from January through August of 2012. Although this survey collected samples from many different types of chicken parts, only the data related to breast, wing and leg sampling were used here (Table 3). We chose these parts because they had similar levels of *Salmonella* and *Campylobacter* contamination and constituted about 90% of the chicken parts produced (Table 4) in the United States (AMS 2014). In this baseline study, each sample consisted of 4 lbs. of a particular part. We assume testing for the parts performance standard will either consist of 4 lb. samples comprising a single part or a mixture of parts. In the latter case, it is desirable that pooling of different parts types should be among parts with similar pathogen occurrence. This is the case for wing, breast and leg samples as opposed to, for example, neck or giblets samples.

There were 384 establishments in the baseline survey with at least one breast, wing or leg sample. An average of 4.4 such samples per establishment (range 1 – 13) were collected. For the purposes of weighting the establishment sampling data, the annual production volume (in pounds) for each sampled establishment was captured from FSIS' records. The *Campylobacter* performance standards are based on the one ml. sample results from this survey.

Table 3. *Salmonella* and *Campylobacter* (1 ml). Percent Positive by Specific Chicken Part for Samples in the raw chicken parts baseline study (FSIS, 2013).

Chicken Part by Type	Number of Samples	Number of *Salmonella* Positives	Number of *Campylobacter* Positives	Percent *Salmonella* Positives	Percent *Campylobacter* Positives
A - Breast	776	210	68	27.06%	8.76%
B - Neck	22	12	10	54.55%	45.45%
C - Leg	584	141	72	24.14%	12.33%
D - Wing	321	107	52	33.33%	16.20%
E - Half Carcass	149	33	21	22.15%	14.09%
F - Quarter Carcass	330	68	58	20.61%	17.58%
G - Giblets	57	23	22	40.35%	38.60%
H - Other	248	59	31	23.79%	12.50%
NP*	9	4	1	44.44%	14.29%
Total	2496	657	335		

(*) Part type not provided

Table 4. United States chicken industry data demonstrate that breast, wing and leg parts represent 90% of all chicken parts production (AMS 2014).

Chicken Part	% of Reported Production
Breast - B/S	32.9%
Leg Quarters (Bulk)	16.7%
Wings (Whole)	10.2%
Tenderloins	9.1%
Leg Quarters (4/10)	7.1%
Drumsticks	4.5%
Legs	4.3%
Breast – Line Run	3.8%
B/S Thighs	3.6%
Thighs	2.3%
Breast – With Ribs	1.7%
Front Halves	1.5%
Wings (Cut)	1.0%
Gizzards & Hearts)	0.7%
Livers (5 Pound Tub)	0.3%
Back and Neck (Stripped)	0.2%

Results

This section is organized by commodity-pathogen pair (for example, comminuted chicken and *Salmonella*), and the results are presented in the same manner and order for all 6 combinations. A more detailed description of the estimated effects of the chicken parts-*Salmonella* standard is required to account for its relationship to the existing chicken carcass-*Salmonella* standard. Prior to presenting results, a brief summary of the standard outputs for each commodity-pathogen pair is provided.

The within-establishment distribution of the proportion of positive samples describes the frequency of establishments with different pathogen occurrences (i.e., proportions ranging from ~0.0 to 1.0) across the target industry. This distribution is crucial for determining the inputs to the model that predict the public health effects for a range of performance standard options. The first output, therefore, is a graph that illustrates the most likely industry distribution (i.e., within-establishment proportion positive) and overlays 5th and 95th percentile uncertainty distributions. This is the output of the statistical fitting described in the Methods. To examine how uncertainty about this distribution might influence the choice of a performance standard, we tabulate how the performance standard changes as we assume the most likely, 5th or 95th percentile instances of this distribution. These tables also report estimates for both the fraction of the industry's production volume that will initially fail the performance standard, and the number of establishments that will fail. This latter value is somewhat crudely determined from the actual sampling data because we only considered establishments with 4 or more samples collected (i.e., the evidence from establishments with fewer than 4 samples was deemed insufficient to determine the passing/failing status for a performance standard).

The second output is a graphical relationship between alternative performance standards and the predicted public health effect. In this case, the performance standards are shown as the maximum allowable number of positive samples among a set of 52 samples. The predicted public health effect on the y-axis of this graph is the expected percent reduction in human illnesses. Generally, this value is calculated as $\left(1-\frac{p_{new}}{p_{baseline}}\right)$ from equation 1.1. The maximum allowable number of positive samples on the x-axis provides the value for $p_{threshold}$ in Eqns. 1.4 and 1.5. Because a different curve is generated depending on whether the assumed compliance fraction (α) is 50%, 40% or 30%, all three curves are shown in this graph. A horizontal line illustrates the HP2020 goal while vertical lines highlight the maximum allowable positives to achieve this goal.

The effects of the 50%, 40% and 30% compliance fractions are further tabulated to communicate performance standard options in terms of the expected percent reduction in human illnesses, expected illnesses avoided, the percent of the industry's production that initially fails the performance standard and the percent of establishments that initially fail the performance standard.

The third output is a graphical relationship between alternative performance standards and the expected share of an industry's production volume that will initially fail the performance standard. The y-axis value in this graph is calculated as $1-F(p_{threshold})$ from Equation 1.5. Although this curve is not affected by different compliance fraction (α) values, it would be different if the 5th or 95th percentile distributions for the within-establishment proportion positive variable were used. For simplicity, we only display the curve associated with the most likely distribution of that variable.

Comminuted chicken *Salmonella*

The distribution of within-establishment *Salmonella*-positive samples across the comminuted chicken industry is substantially uncertain (Figure 1). The limited number of comminuted chicken establishments (n=73) is primarily responsible for the larger amount of statistical uncertainty about this distribution. This uncertainty implies that a performance standard – intended to reduce the industry's percent positive samples by 25% - would be different (range: 13 – 19 acceptable positives in 52 samples) depending on which distribution is considered (Table 5). Nevertheless, the share of production volume initially failing these performance standards is stable (range: 84% - 86%). The smaller share of establishments failing these performance standards – relative to share of production volume – suggests that larger establishments make up a disproportionate share of failing establishments.

If the most likely industry distribution is used, but alternative compliance fractions are considered, then the performance standard that accomplishes a 25% reduction in human illnesses is 16, 12 and 5 allowable positives (in 52 samples) for 50%, 40% and 30% compliance fractions, respectively (Figure 2 and Table 6). The modal value for annual illnesses avoided by each of these standards is approximately 2,600. Figure 2 illustrates that if a performance standard of 12 allowable positives was chosen, it could accomplish a reduction in human illnesses of 25% or ~32% depending on whether the true compliance fraction was 40% or 50%. Similarly, if a performance standard of 5 allowable positive was chosen, it could accomplish a reduction in human illnesses of 25%, 34% or 42% depending on whether the true compliance fraction was 30%, 40% or 50%. Assuming the performance standard is 16 allowable positives, the share (i.e., percentage) of production volume that initially fails the performance standard is 86% (Figure 3).

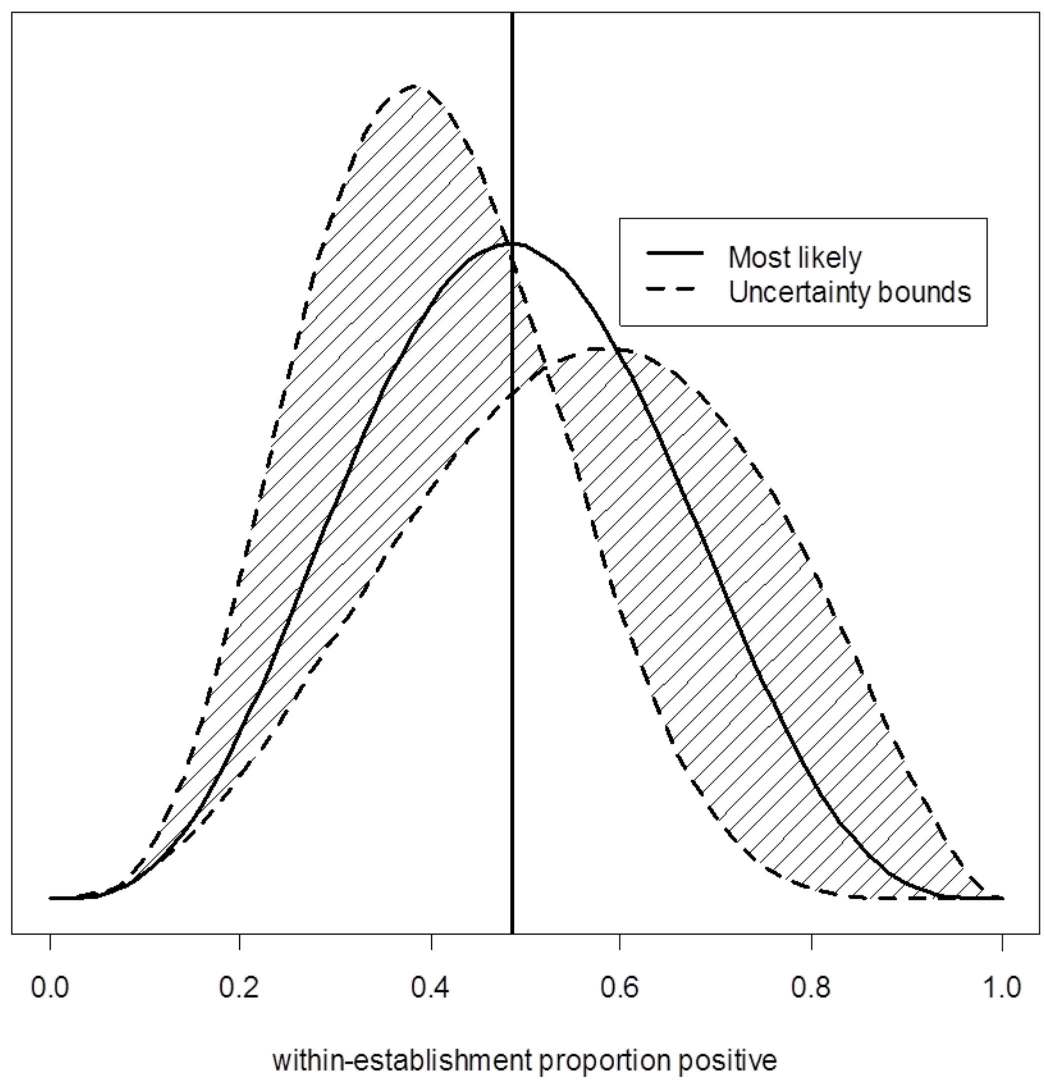

Figure 1. Fitted *beta* distributions for within-establishment *Salmonella* contamination for comminuted chicken. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Salmonella* contamination in comminuted chicken across establishments. The 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 expected value, 48.7%, of the most likely *beta*(a=4.302,b=4.533) distribution.

Table 5. Effect of the within-establishment distributions on performance standard options. The comminuted chicken *Salmonella* performance standards intended to accomplish a 25% reduction in illnesses are determined for the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a moderate difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	16 of 52 samples	26%	86%	53%
Lower bound	13 of 52 samples	25%	87%	63%
Upper bound	19 of 52 samples	26%	83%	53%

*Based on fitted distribution
**Based on number of establishments

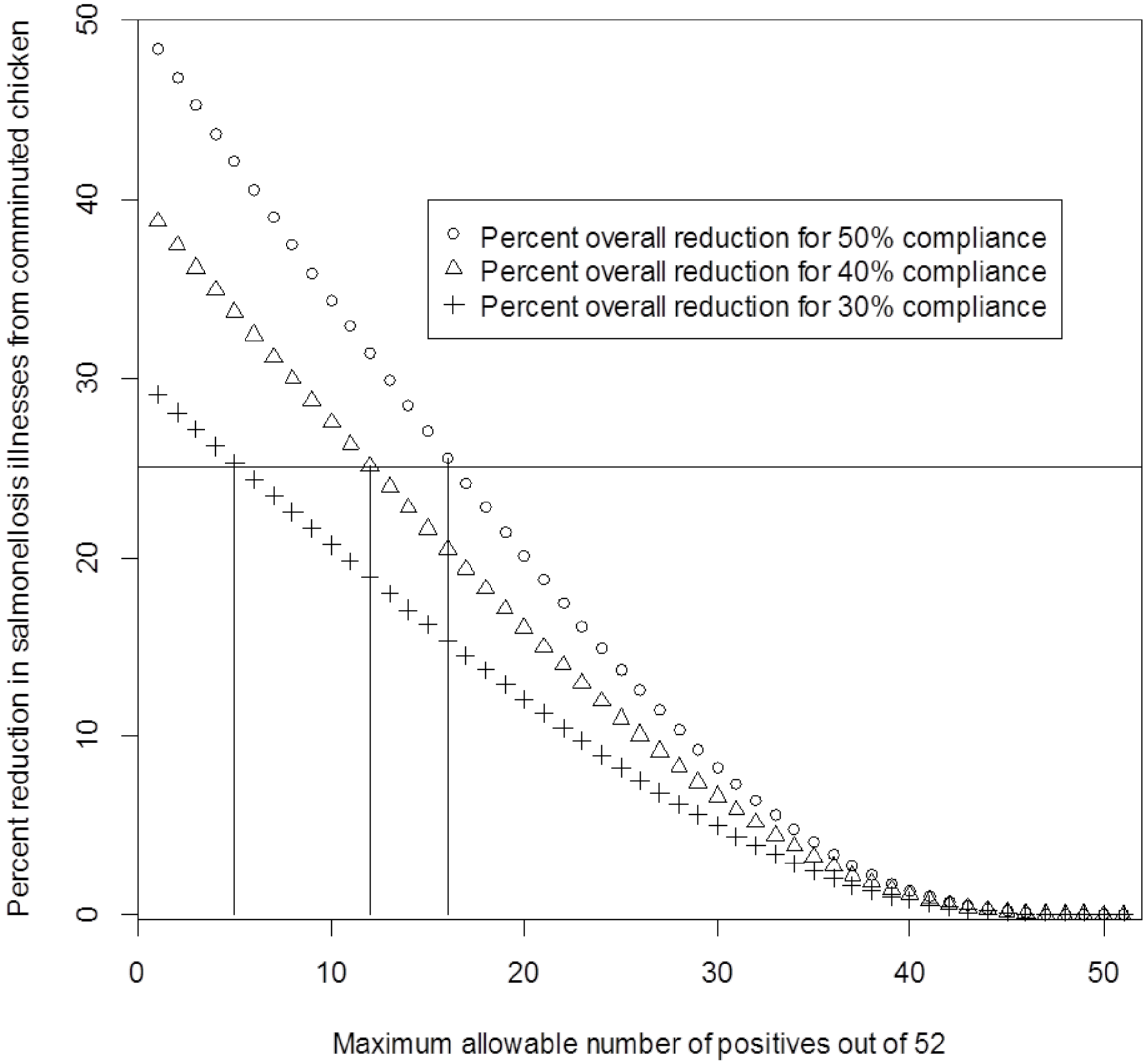

Figure 2. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives. Derivation of a comminuted chicken *Salmonella* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. To achieve a HP2020 goal of a 25% reduction in human illnesses, the standard should be 16, 12 or 5 for compliance fractions of 50%, 40% or 30%, respectively. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 6. The comminuted chicken *Salmonella* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The comminuted chicken *Salmonella* performance standard necessary to accomplish a 25% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses	Illnesses avoided mode (min – max)	Failing production volume share*	Failing establishment share**
50 percent compliance	16 of 52 samples	26%	2,700 (1,700 – 4000)	86%	53%
40 percent compliance	12 of 52 samples	25%	2,600 (1,600 – 3,900)	95%	70%
30 percent compliance	5 of 52 samples	25%	2,600 (1,600 – 3,900)	99%	79%

*Based on fitted distribution
**Based on number of establishments

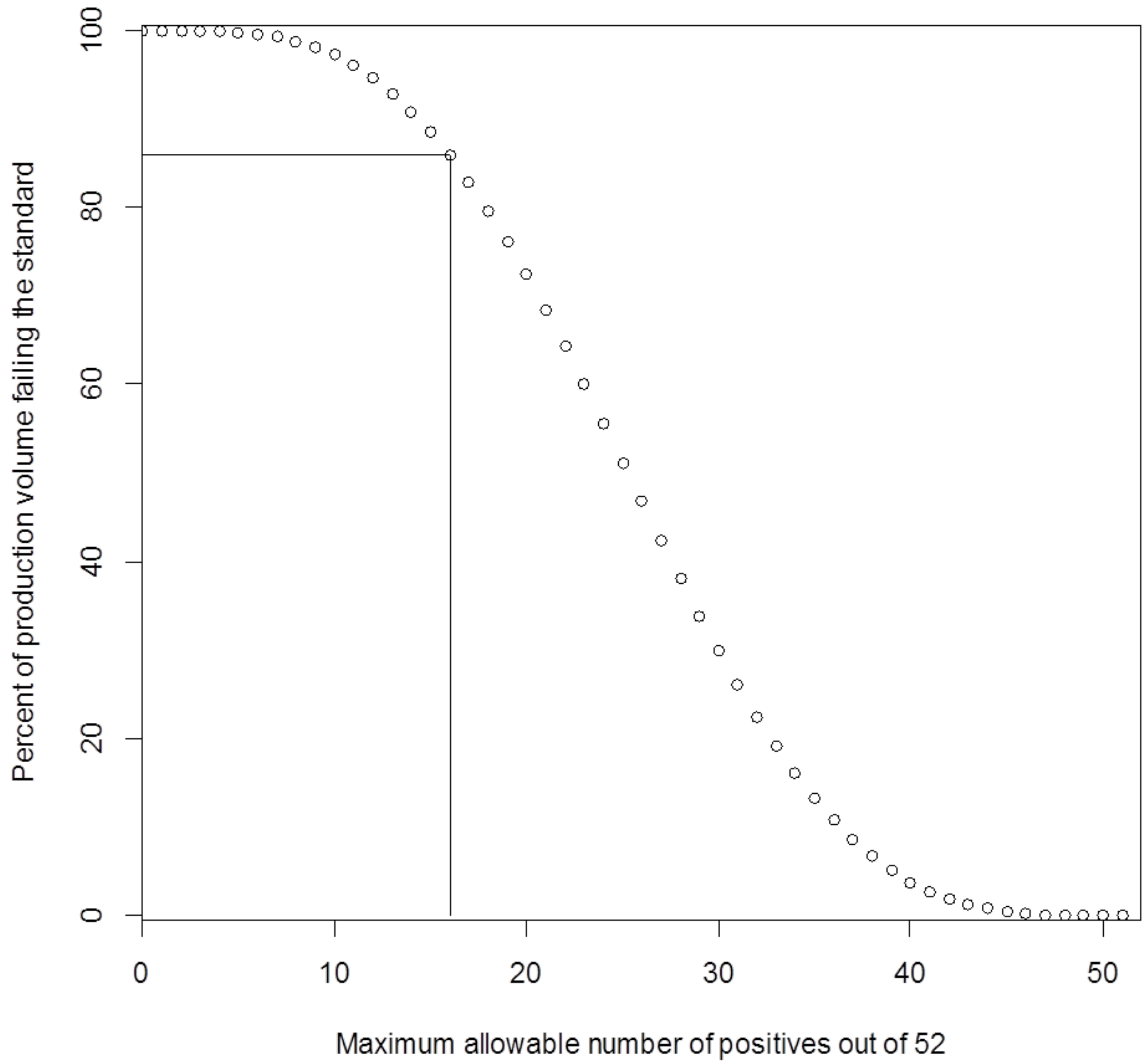

Figure 3. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard. The initial effect of a comminuted chicken *Salmonella* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 16 acceptable positives will result in 86% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Comminuted chicken *Campylobacter*

The distribution of percent *Campylobacter*-positive samples across the comminuted chicken industry is shifted substantially towards zero and moderately uncertain (Figure 4). The distribution of the within plant proportion positive is substantially different for *Campylobacter* as compared to *Salmonella.* This occurs because the percent positive rate for *Campylobacter* is much lower, at about 3.3% when volume weighted, as compared to nearly 50% for *Salmonella*. The distributions in Figure 4 indicate that the majority of the industry produces comminuted chicken with levels of *Campylobacter* that are below the limit of detection for the assay. This uncertainty implies that a performance standard – intended to reduce the industry's percent positive samples by 33% - would be adjusted up or down by one depending on which distribution is true (Table 7). Notably, the lower bound distribution results in a smaller reduction in human illnesses because zero positives for the performance standard – i.e. zero tolerance - is not an option. The fraction of the industry initially failing these performance standards is stable for the most likely and upper bound distributions (range: 55% - 56%). The smaller share of establishments failing these performance standards – relative to share of production volume – suggests that larger establishments make up a disproportionate share of failing establishments. Nevertheless, this pattern is reversed for the lower bound distribution.

If the most likely industry distribution is used, but alternative compliance fractions are considered, then the performance standard that achieves a 33% reduction in this industry's percent positive samples is defined as only one allowable positive (in 52 samples) for the 50% compliance fraction (Figure 5 and Table 8). The modal value for annual illnesses avoided by this standard is approximately 1,300. If the alternative compliance fractions are assumed, then a performance standard of 1 allowable positive accomplishes less than a 33% reduction in human illnesses. This amounts to modal annual illnesses avoided of 1,000 or 800 for the 40% or 30% compliance fractions respectively. For the performance standard of 1 allowable positive, the share of production volume that initially fails the performance standard is 56% (Figure 6).

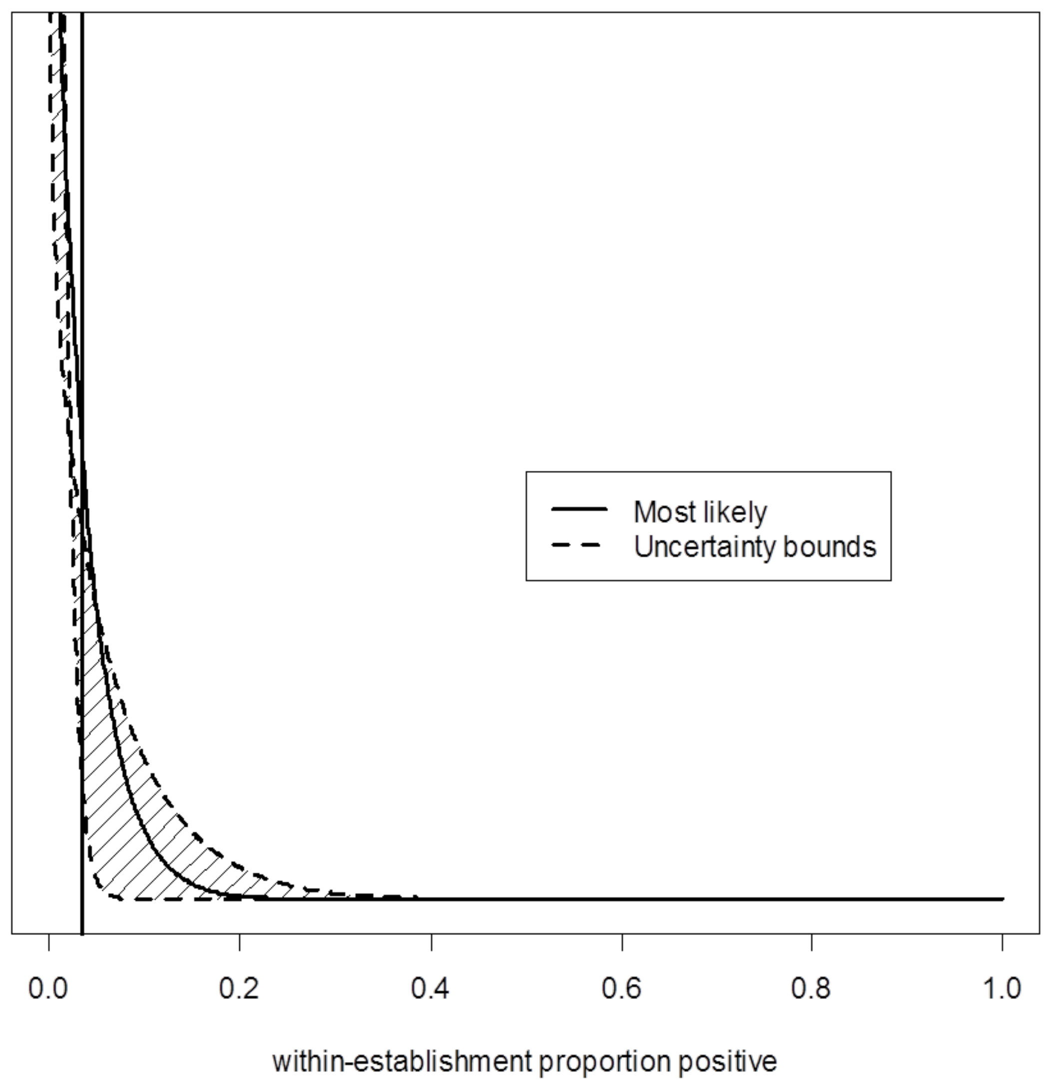

Figure 4. Fitted *beta* distributions for within-establishment *Campylobacter* contamination for comminuted chicken. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Campylobacter* contamination in comminuted chicken across establishments. The uncertainty about the true or actual distribution is illustrated by including bounding distributions—the 5^{th} and 95^{th} percentiles—determined using the statistical fitting algorithm. The vertical line indicates the expected value, 3.4%, of the most likely *beta*(a=0.923,b=26.509) distribution.

Table 7. Effect of the within-establishment distributions on performance standard options.
The comminuted chicken *Campylobacter* performance standards intended to accomplish a 33% reduction in illnesses are determined for the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a small difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	1 of 52 samples	37%	56%	24%
Lower bound	1 of 52 samples	14%	12%	24%
Upper bound	2 of 52 samples	37%	55%	14%

*Based on fitted distribution
**Based on number of establishments

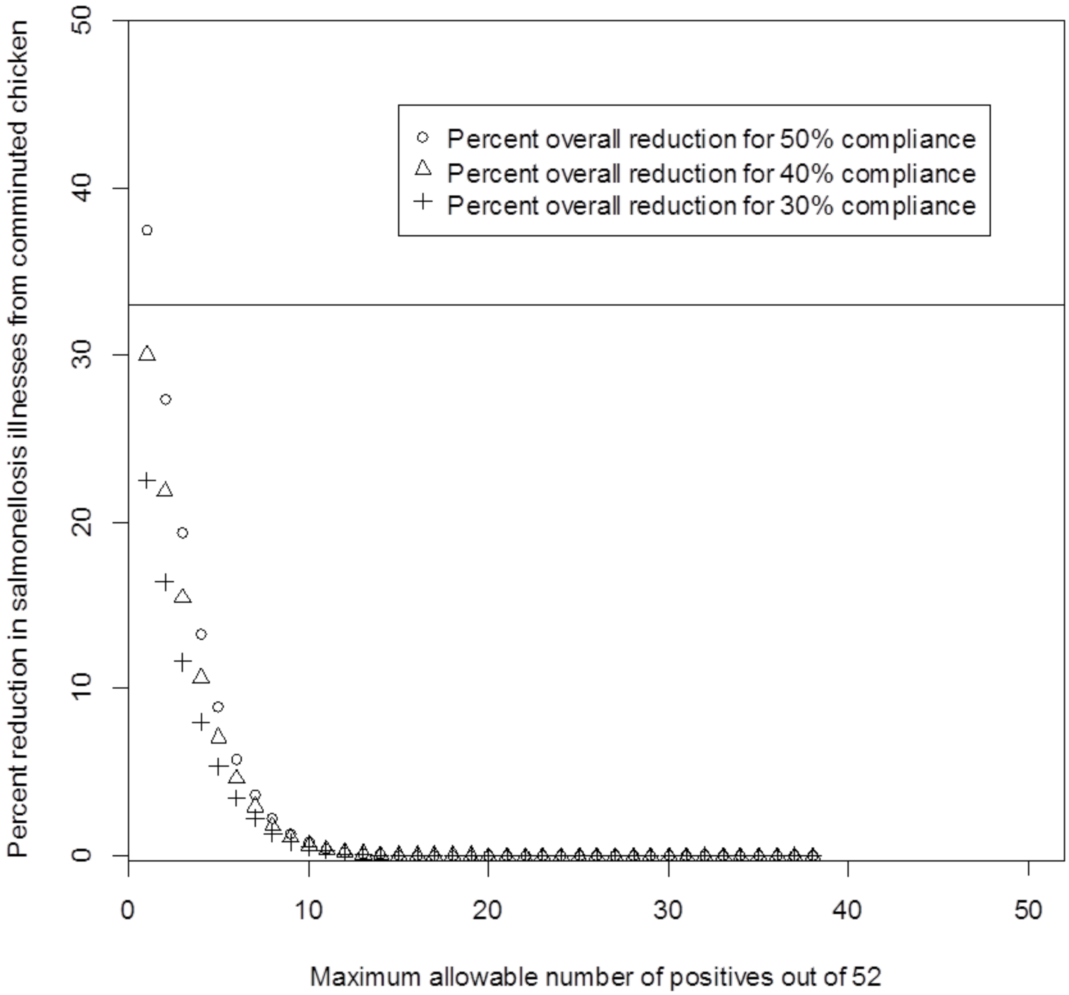

Figure 5. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives. Derivation of a comminuted chicken *Campylobacter* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. To approximate the HP2020 goal of a 33% reduction in human illnesses, the standard should be 1 positive sample for a compliance fraction of 50%. If the compliance fraction is 40% or 30%, no performance standard approximates the HP2020 goal. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 8. The comminuted chicken *Campylobacter* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The comminuted chicken *Campylobacter* performance standard necessary to accomplish a 33% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses	Illnesses avoided mode (min – max)	Failing production volume share*	Failing establishment share**
50 percent compliance	1 of 52 samples	37%	1,300 (700 – 2,000)	56%	24%
40 percent compliance	1 of 52 samples	30%	1,000 (600 – 1,600)	56%	24%
30 percent compliance	1 of 52 samples	22%	800 (400 – 1,200)	56%	24%

*Based on fitted distribution
**Based on number of establishments

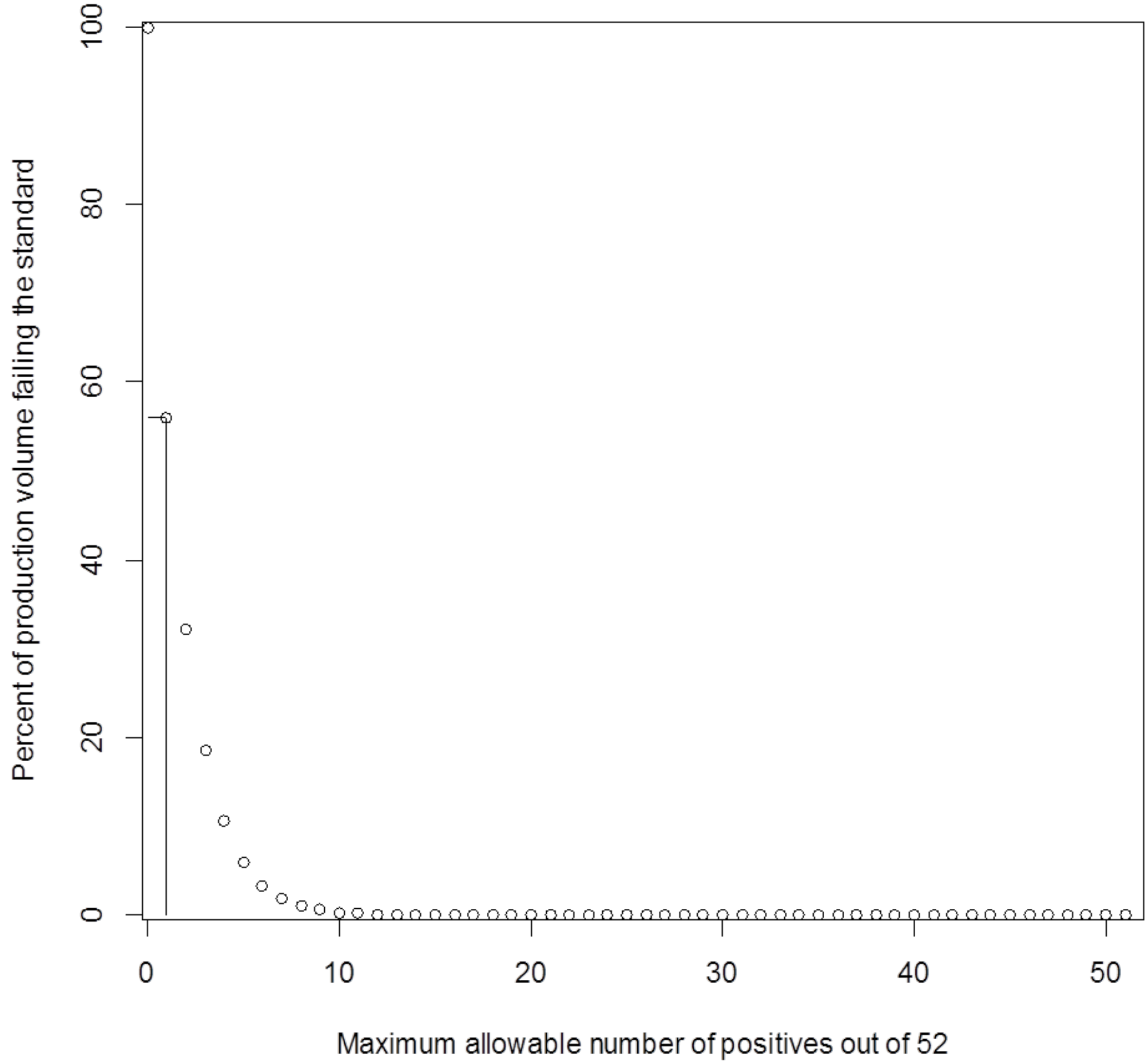

Figure 6. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard. The initial effect of a comminuted chicken *Campylobacter* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 1 allowable positives will result in 56% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Comminuted turkey *Salmonella*

The distribution of within-establishment *Salmonella*-positive samples across the comminuted turkey industry is substantially uncertain (Figure 7). The limited number of comminuted turkey establishments (n=49) is primarily responsible for the larger amount of statistical uncertainty about this distribution. This uncertainty implies that a performance standard – intended to reduce the industry's percent positive samples by 25% - would be different (range: 5 – 15 allowable positives in 52 samples) depending on which distribution is considered (Table 9). Nevertheless, the share of production volume initially failing these performance standards is stable (range: 49% - 55%). In this case the share of establishments failing these performance standards is similar to the share of production volume failing such that larger establishments are not over-represented among failing establishments.

If the most likely industry distribution is used, but alternative compliance fractions are considered, then the performance standard that accomplishes a 25% reduction in human illnesses is 9, 7 and 3 allowable positives (in 52 samples) for 50%, 40% and 30% compliance fractions, respectively (Figure 8 and Table 10). The modal value for annual illnesses avoided by each of these standards ranges between 1,900 and 2,000. Figure 8 illustrates that if a performance standard of 7 allowable positives was chosen, it could accomplish a reduction in human illnesses of 25% or 32% depending on whether the true compliance fraction was 40% or 50%. Similarly, if a performance standard of 3 allowable positives was chosen, it could accomplish a reduction in human illnesses of 25%, 34% or 42% depending on whether the true compliance fraction was 30%, 40% or 50%. Assuming the performance standard is 9 allowable positives, the share of production volume that initially fails the performance standard is 49% (Figure 9).

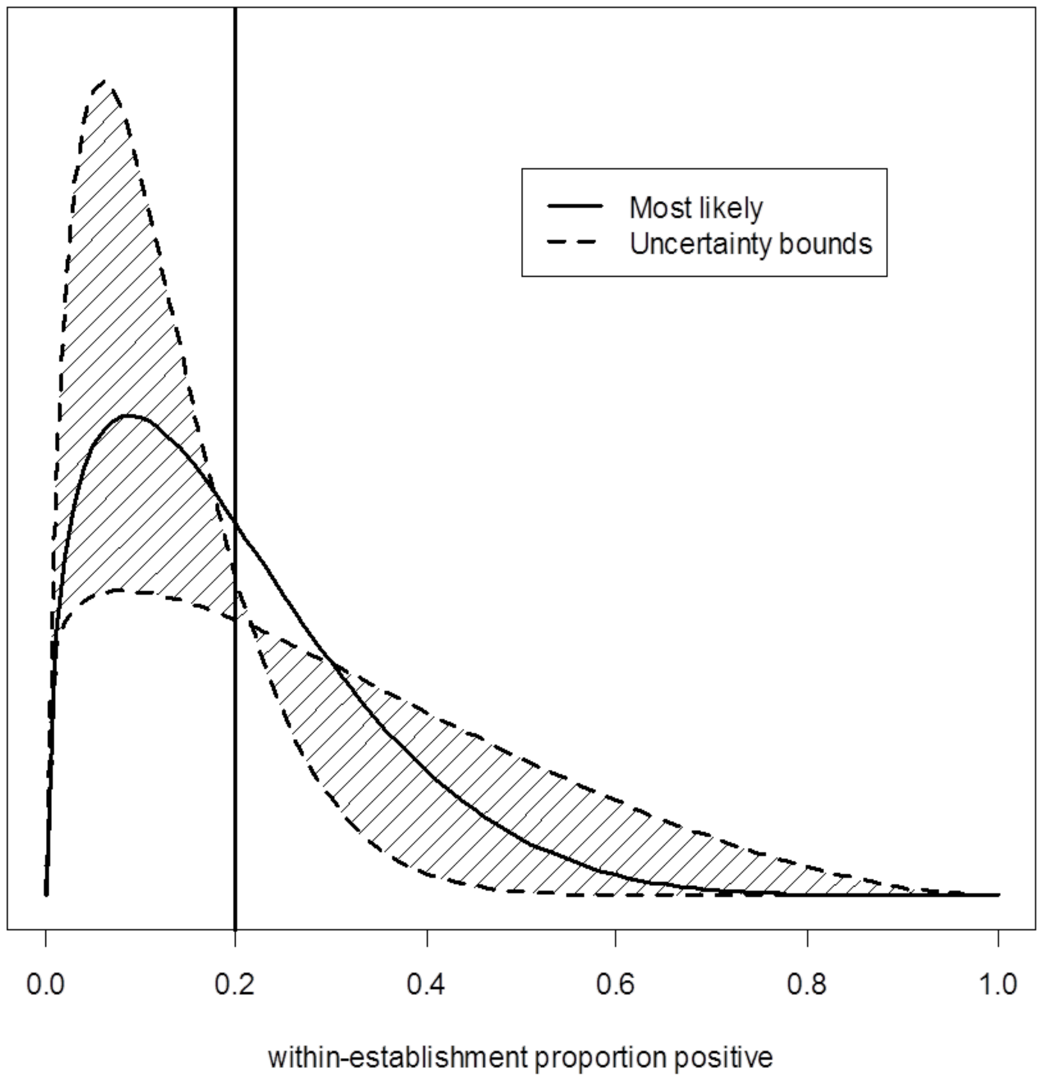

Figure 7. Fitted *beta* distributions for within-establishment *Salmonella* contamination for comminuted turkey. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Salmonella* contamination in comminuted turkey across establishments. The uncertainty about the true or actual distribution is illustrated by including bounding distributions—the 5^{th} and 95^{th} percentiles—determined using the statistical fitting algorithm. The vertical line indicates the expected value, 19.9%, of the most likely *beta*(a=1.477,b=5.954) distribution.

Table 9. Effect of the within-establishment distributions on performance standard options. The comminuted turkey *Salmonella* performance standards intended to accomplish a 25% reduction in illnesses are determined for the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a substantial difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	9 of 52 samples	27%	49%	51%
Lower bound	5 of 52 samples	28%	55%	63%
Upper bound	15 of 52 samples	26%	45%	32%

*Based on fitted distribution

**Based on number of establishments

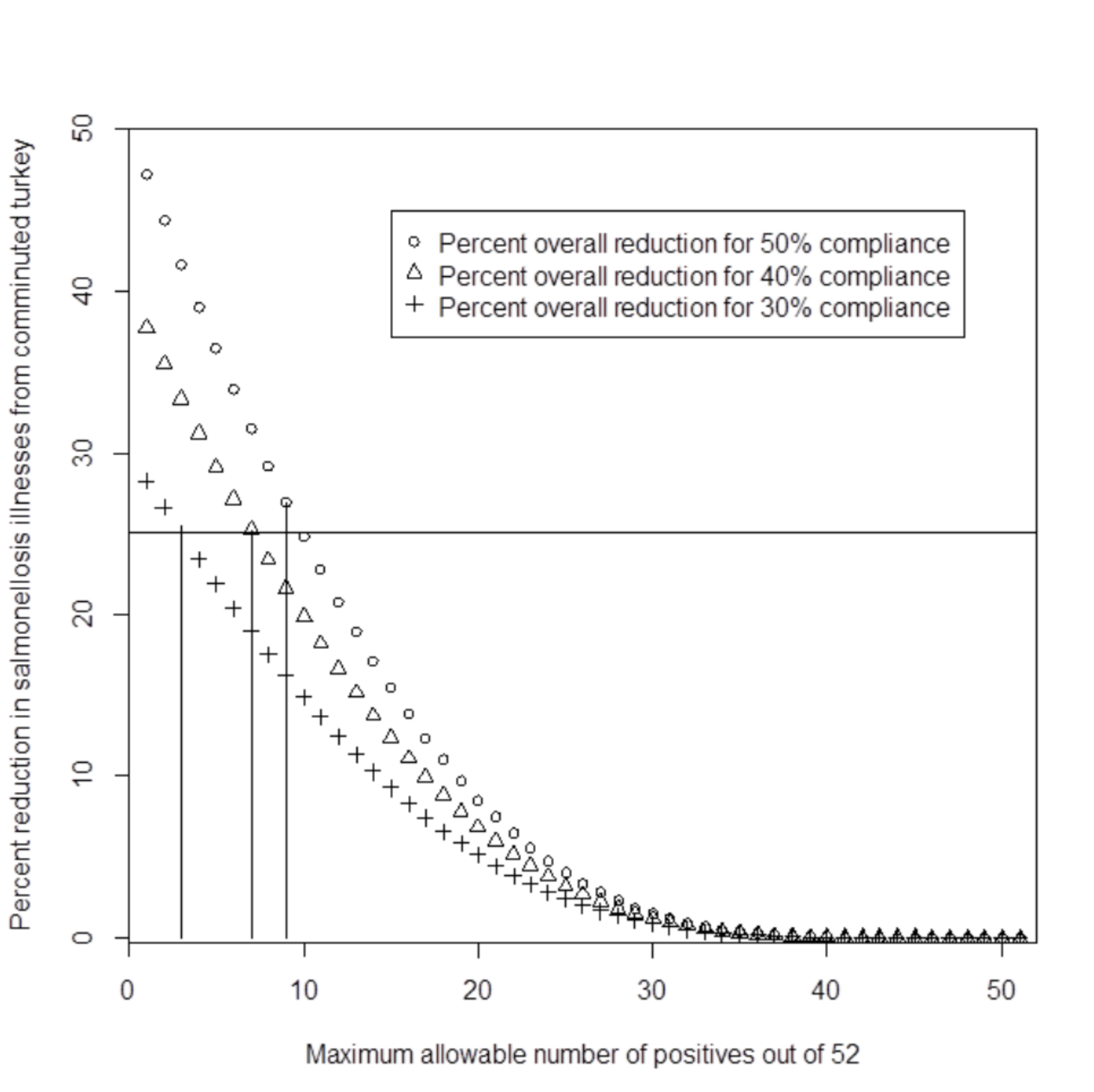

Figure 8. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives.

Derivation of a comminuted turkey *Salmonella* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. To accomplish the HP2020 goal of a 25% reduction in human illnesses, the standard should be 9, 7 or 3 positive samples for compliance fractions of 50%, 40% or 30%, respectively. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 10. The comminuted turkey *Salmonella* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The comminuted turkey *Salmonella* performance standard necessary to accomplish a 25% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses	Illnesses avoided mode (min – max)	Failing production volume share*	Failing establishment share**
50 percent compliance	9 of 52 samples	27%	2,000 (1,300 – 3,100)	49%	51%
40 percent compliance	7 of 52 samples	25%	1,900 (1,200 – 2,900)	61%	58%
30 percent compliance	3 of 52 samples	25%	1,900 (1,200 – 2,900)	86%	80%

*Based on fitted distribution
**Based on number of establishments

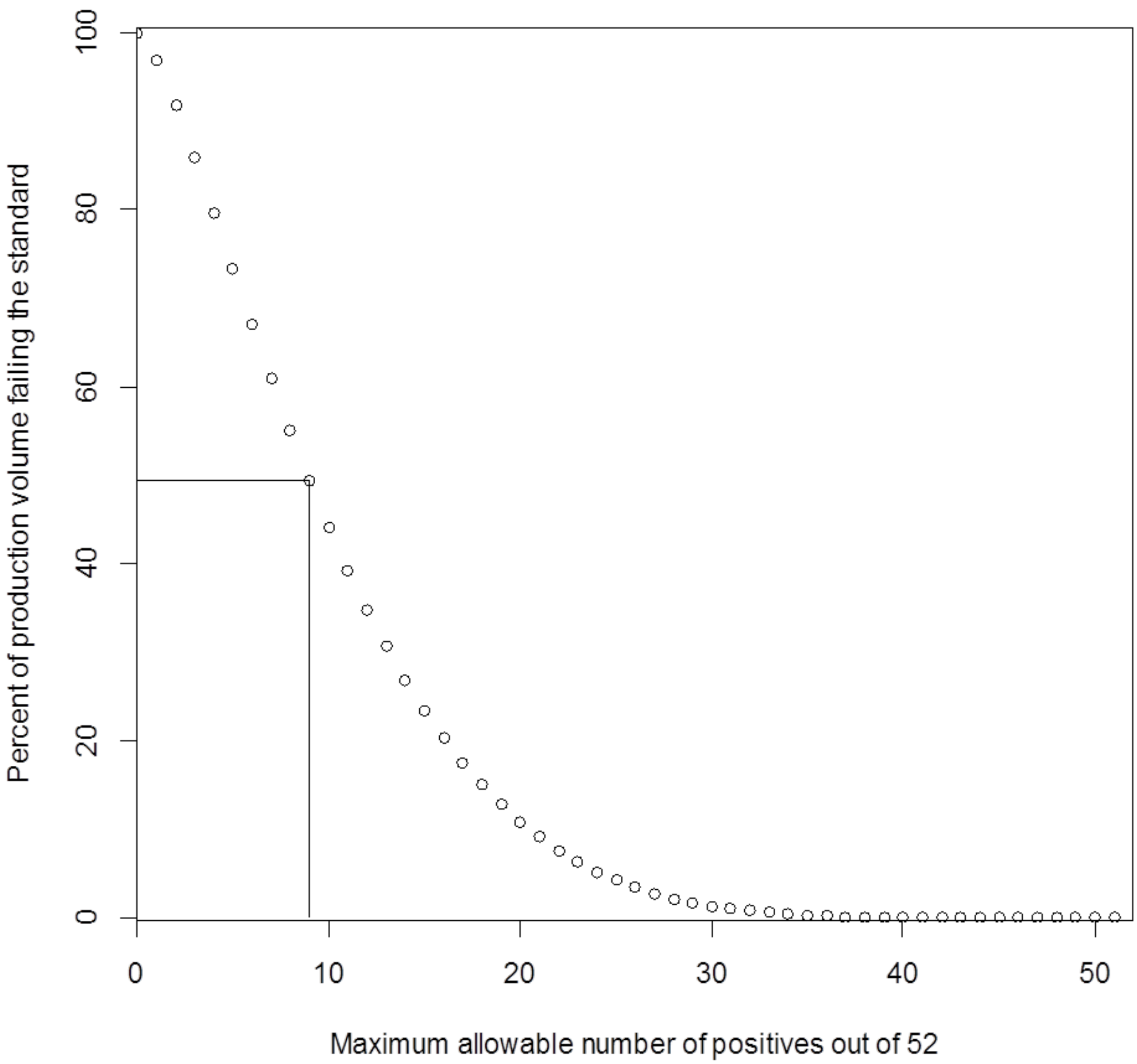

Figure 9. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard.
The initial effect of a comminuted turkey *Salmonella* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 9 allowable positives will result in 49% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Comminuted turkey *Campylobacter*

Campylobacter was detected in only about 1.2% of comminuted turkey samples. Because of this low proportion of positive samples at essentially all establishments, it is not possible to develop a performance standard that accomplishes a 33% reduction in illnesses. The distribution of percent *Campylobacter*-positive samples across the comminuted chicken industry is shifted substantially towards zero and moderately uncertain (Figure 10). The distributions in Figure 10 indicate that the majority of the industry produces comminuted chicken with levels of *Campylobacter* that are below the limit of detection for the assay. Table 11 reports the accomplishable reductions in human illnesses for a standard of one allowable positive (out of 52 samples) for the most likely and lower/upper bound distributions. The fraction of the industry initially failing these performance standards is ranges between 12% and 24%.

If the most likely industry distribution is used and a standard of one allowable positive is assumed, then human illnesses can be reduced by 19%, 15% or 11% depending on a compliance fraction of 50%, 40% or 30%, respectively (Figure 11 and Table 12). The modal value for annual illnesses avoided by this standard is 500, 400 or 300 for compliance fractions of 50%, 40% or 30%, respectively. For the performance standard of 1 allowable positive, the share of production volume that initially fails the performance standard is 20% (Figure 12).

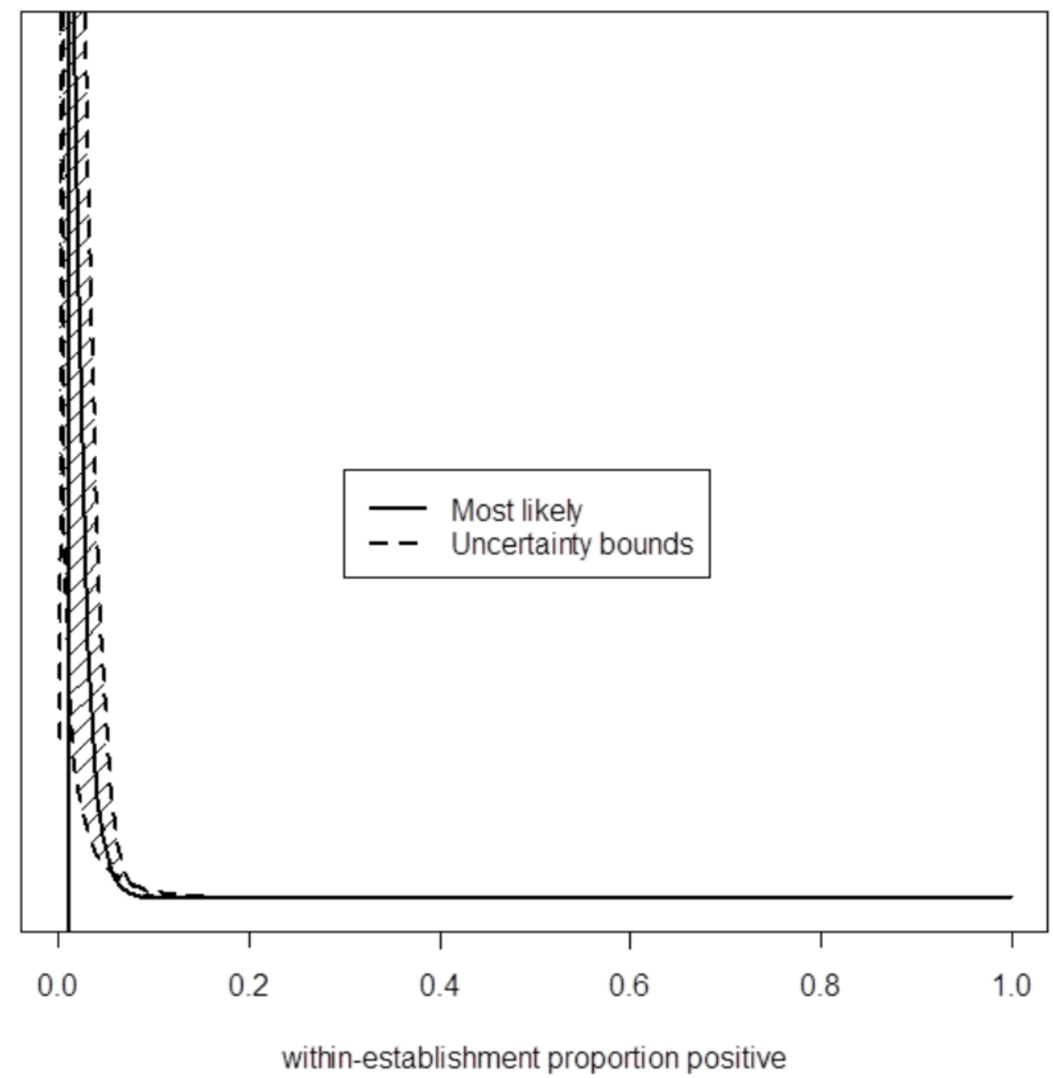

Figure 10. Fitted *beta* distributions for within-establishment *Campylobacter* contamination for comminuted turkey. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Campylobacter* contamination in comminuted turkey across establishments. 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 expected value, 1.2%, of the most likely *beta*(a=1.168,b=94.137) distribution.

Table 11. Effect of the within-establishment distributions on performance standard options. A comminuted turkey *Campylobacter* performance standard of 1 positive in 52 samples is assessed for its effectiveness given the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a small difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	1 of 52 samples	19%	20%	9%
Lower bound	1 of 52 samples	14%	12%	9%
Upper bound	1 of 52 samples	24%	24%	9%

*Based on fitted distribution

**Based on number of establishments (insufficient data for accurate estimation)

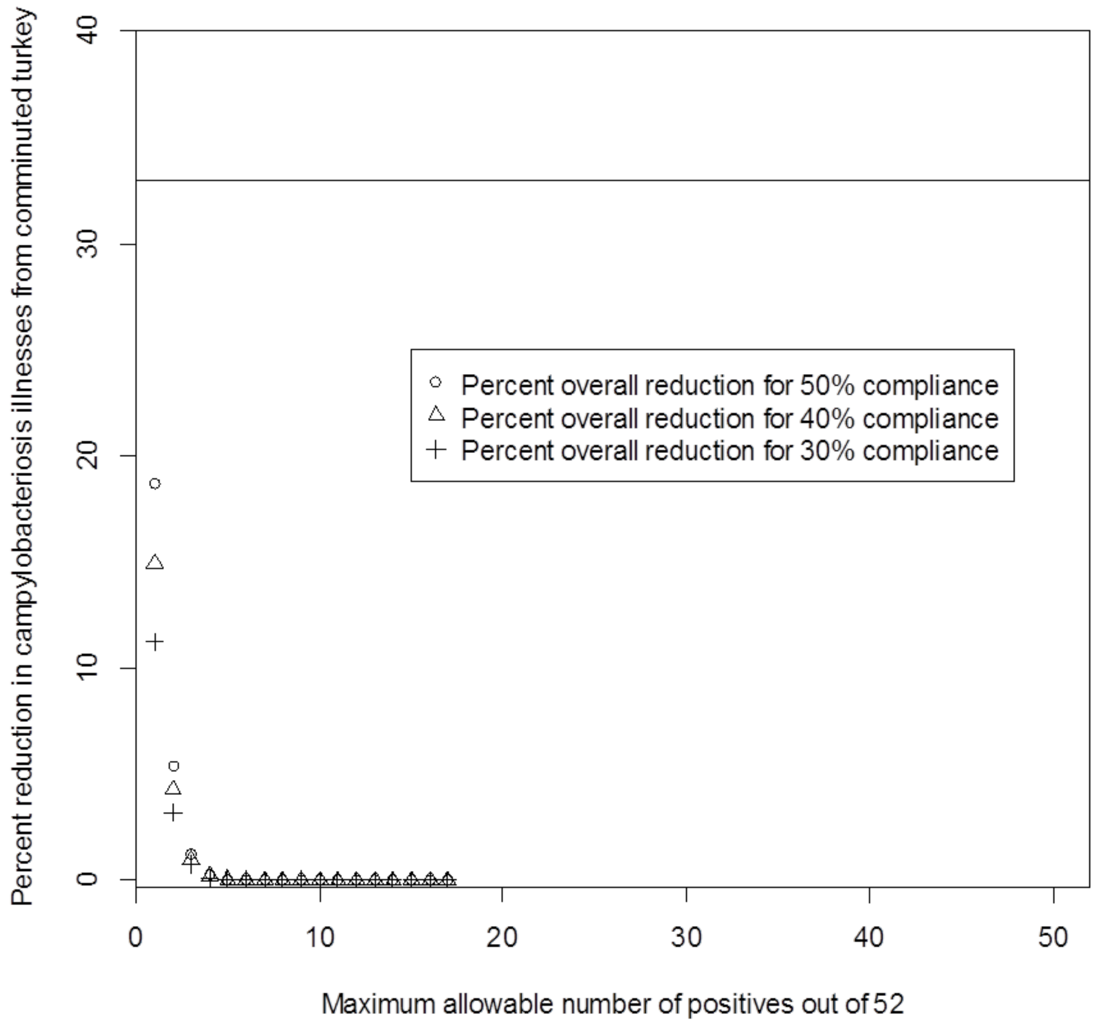

Figure 11. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives.
Derivation of a comminuted turkey *Campylobacter* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. Regardless of the assumed compliance fraction, no performance standard can accomplish the HP2020 goal of a 33% reduction in human illnesses. A performance standard of 1 positive sample should accomplish a 19%, 15% or 11% reduction in illnesses for 50%, 40% or 30% compliance fractions, respectively. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 12. The comminuted turkey *Campylobacter* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The comminuted turkey *Campylobacter* performance standard necessary to accomplish a 33% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses	Illnesses avoided mode (min – max)	Failing production volume share*	Failing establishment share**
50 percent compliance	1 of 52 samples	19%	500 (300 – 700)	20%	9%
40 percent compliance	1 of 52 samples	15%	400 (200 – 600)	20%	9%
30 percent compliance	1 of 52 samples	11%	300 (200 – 400)	20%	9%

*Based on fitted distribution
**Based on number of establishments (insufficient data for accurate estimation)

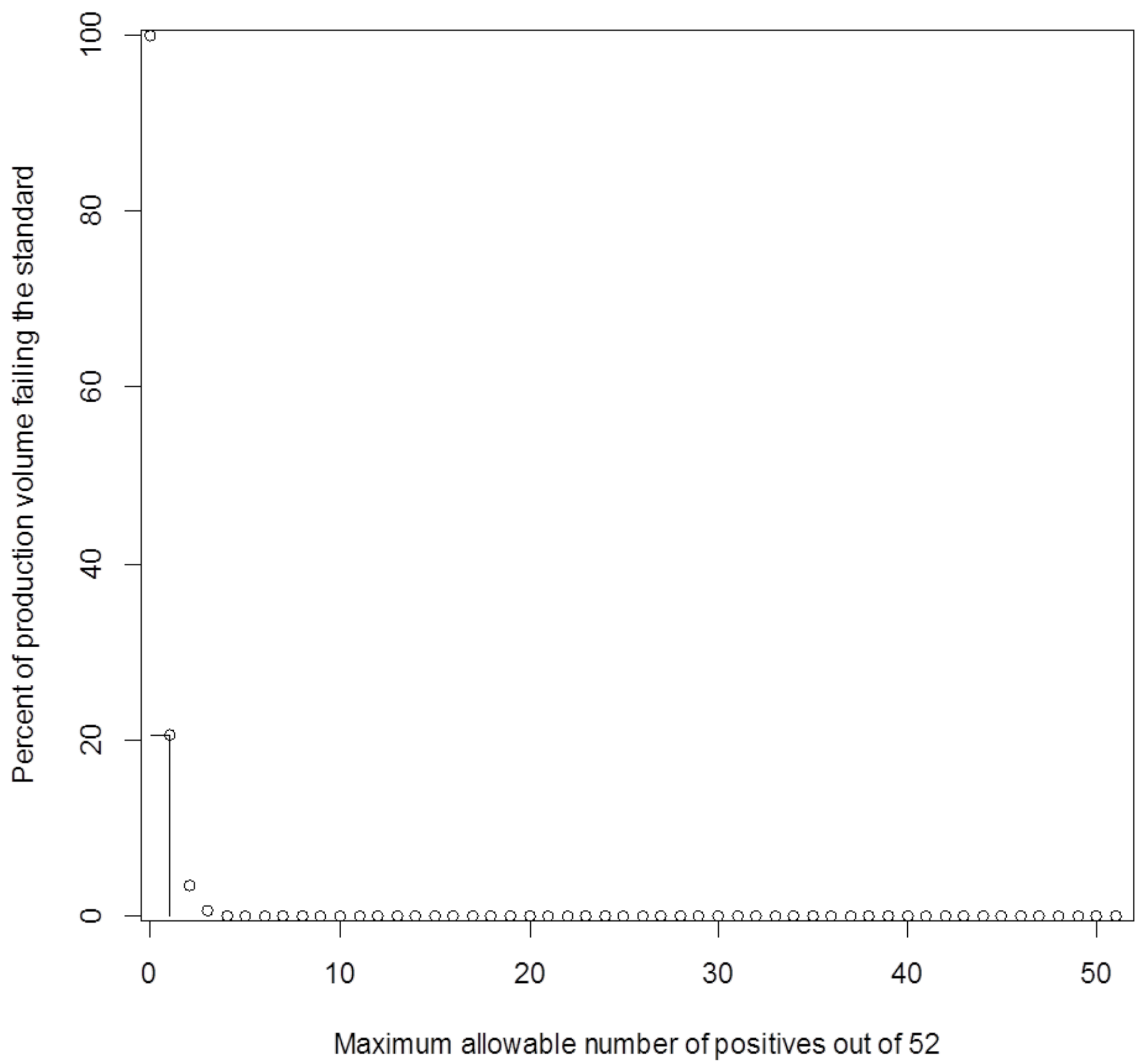

Figure 12. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard.
The initial effect of a comminuted turkey *Campylobacter* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 1 allowable positives will result in 20% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Chicken Parts *Salmonella*

The distribution of within-establishment *Salmonella*-positive samples across the chicken parts industry is slightly uncertain (Figure 13). This uncertainty implies that a performance standard – intended to reduce the industry's percent positive samples by 25% – would be essentially the same (11 or 12 allowable positives) regardless of which distribution is considered (Table 13). Similarly, the share of production volume initially failing these performance standards is stable (range: 55% - 60%). The smaller share of establishments failing these performance standards – relative to share of production volume – suggests that larger establishments make up a disproportionate share of failing establishments.

If the most likely industry distribution is used, but alternative compliance fractions are considered, then the performance standard that accomplishes a 25% reduction in human illnesses across the intact industry is 11, 8 and 2 allowable positives (in 52 samples) for 50%, 40% and 30% compliance fractions, respectively (Figure 14 and Table 14). Recall that the actual reduction for the chicken parts industry will be 27%, but this amounts to an overall reduction of 25% for intact chicken illnesses (i.e., those associated with whole carcasses and chicken parts). The modal value for annual illnesses avoided by each of these standards is between 20,000 and 21,600. Recall that these avoided illnesses are based on an assumption of perfect positive correlation between carcass and parts contamination (i.e., these are smaller values relative to an assumption of independence). Figure 14 illustrates that if a performance standard of 8 allowable positives was chosen, it could accomplish a reduction in human illnesses of 25% or 32% depending on whether the true compliance fraction was 40% or 50%. Similarly, if a performance standard of 2 allowable positives was chosen, it could accomplish a reduction in human illnesses of 25%, 34% or 44% depending on whether the true compliance fraction was 30%, 40% or 50%. Assuming the performance standard is 11 allowable positives, the share of production volume that initially fails the performance standard is 60% (Figure 15).

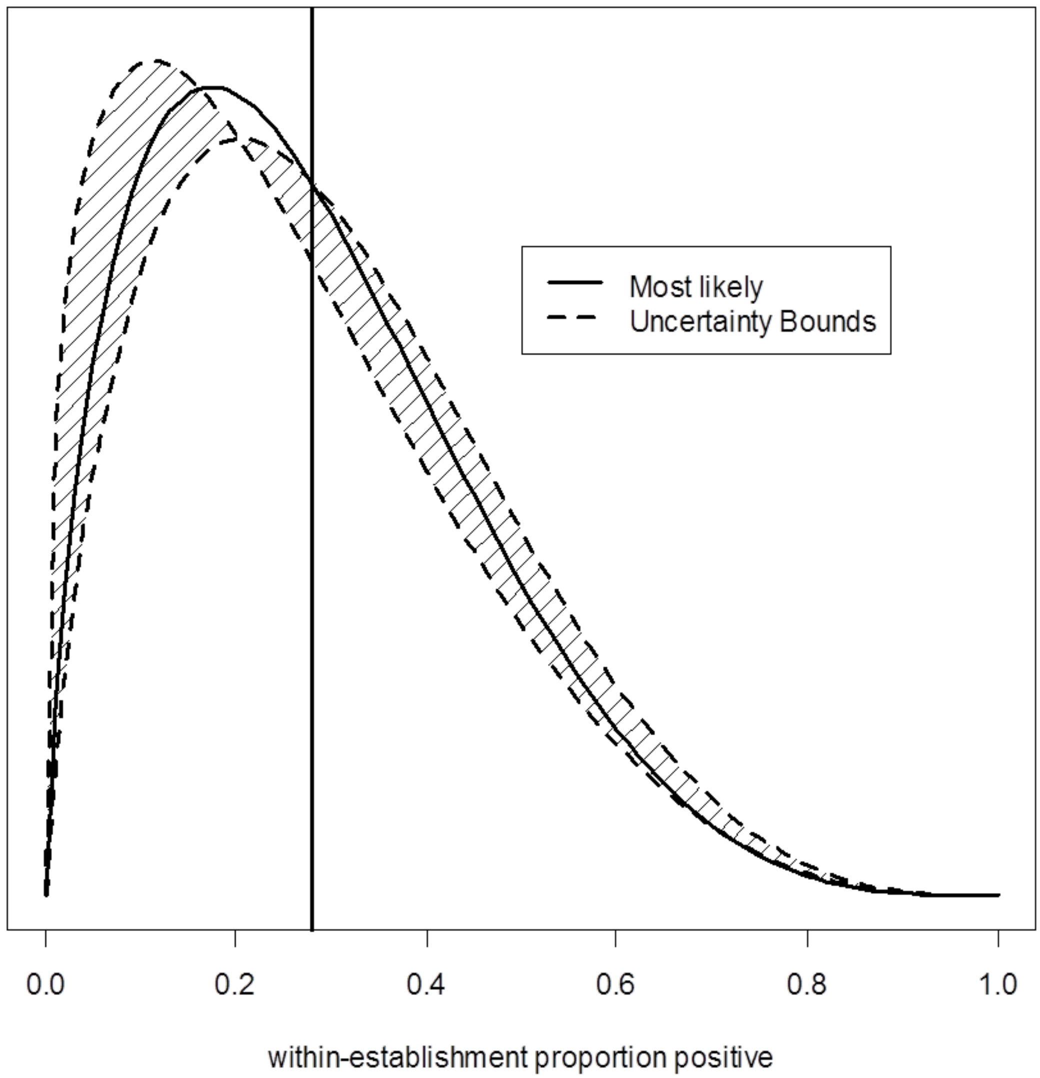

Figure 13. Fitted *beta* distributions for within-establishment *Salmonella* contamination for chicken parts. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Salmonella* contamination in comminuted chicken across establishments. The uncertainty 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 expected value, 28.0%, of the most likely *beta*(a=1.717,b=4.410) distribution.

Table 13. Effect of the within-establishment distributions on performance standard options. The chicken parts *Salmonella* performance standards intended to accomplish a 25% reduction in illnesses are determined for the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a small difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	11 of 52 samples	28%	60%	44%
Lower bound	11 of 52 samples	28%	60%	44%
Upper bound	12 of 52 samples	28%	55%	43%

*Based on fitted distribution

**Based on number of establishments (insufficient data for accurate estimation)

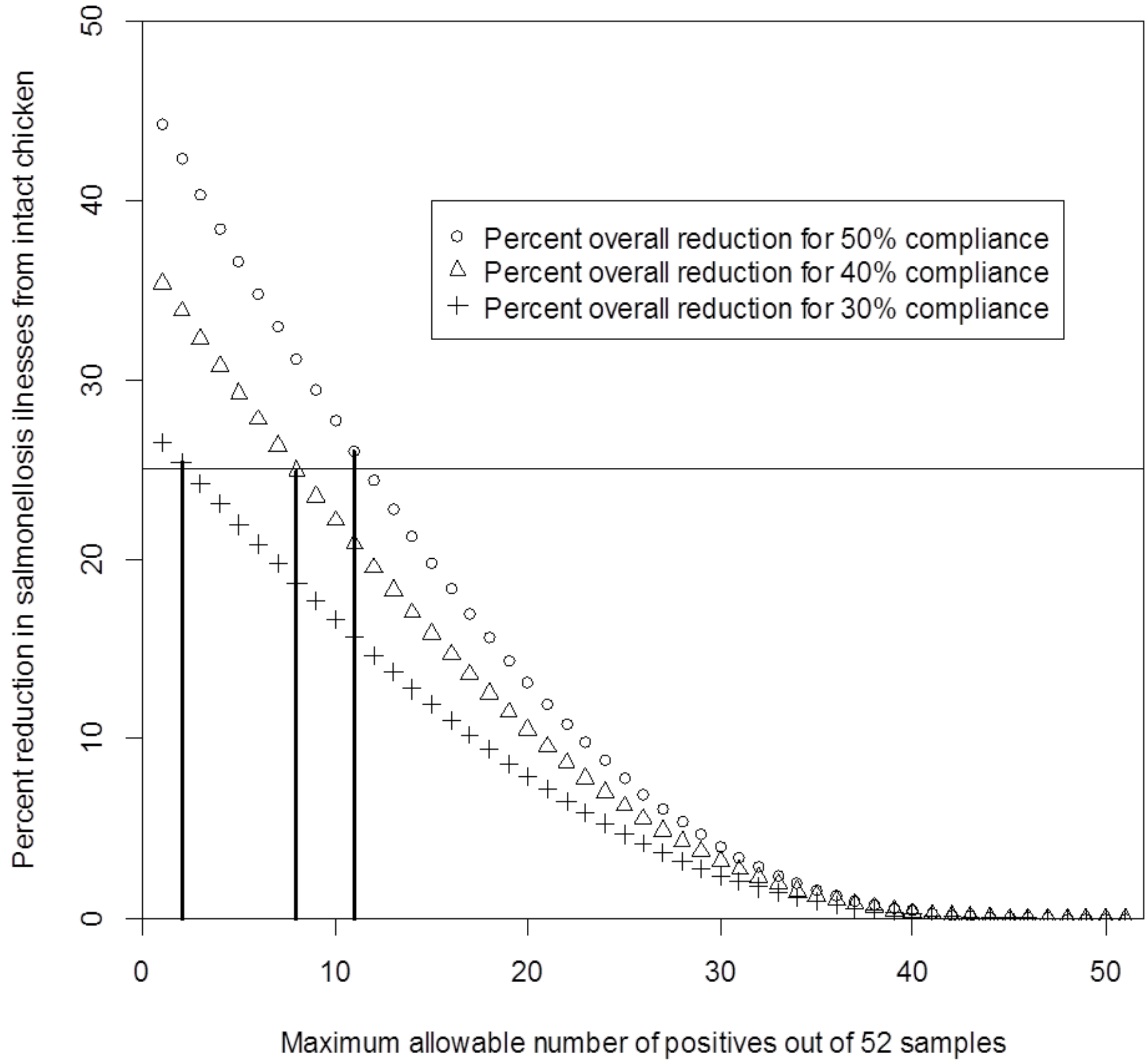

Figure 14. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives. Derivation of a chicken parts *Salmonella* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. To achieve a HP2020 goal of a 25% reduction in human illnesses, the standard should be 11, 8 or 2 for compliance fractions of 50%, 40% or 30%, respectively. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 14. The chicken parts *Salmonella* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The chicken parts *Salmonella* performance standard necessary to accomplish a 25% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses* intact/parts	Illnesses avoided mode (min – max)	Failing production volume share**	Failing establishment share***
50 percent compliance	11 of 52 samples	26%/28%	21,600 (14,100 – 33,800)	60%	44%
40 percent compliance	8 of 52 samples	25%/27%	19,900 (13,100 – 31,400)	73%	63%
30 percent compliance	2 of 52 samples	25%/27%	20,600 (13,400 – 32,200)	97%	75%

*Calculations assume perfect positive correlation between carcass and parts contamination. The overall effect on intact illnesses (whole chicken and parts) is designed to compensate for existing carcass performance standard (assumed to generate a 12% reduction in intact chicken illnesses). Therefore, a larger effect is necessary for the parts performance standard (e.g., 27% vs. 25%). Furthermore, the estimated illnesses avoided that are attributed to the parts performance standard are determined by subtracting the 12% carcass effectiveness from the parts effectiveness.
**Based on fitted distribution
***Based on number of establishments (insufficient data for accurate estimation)

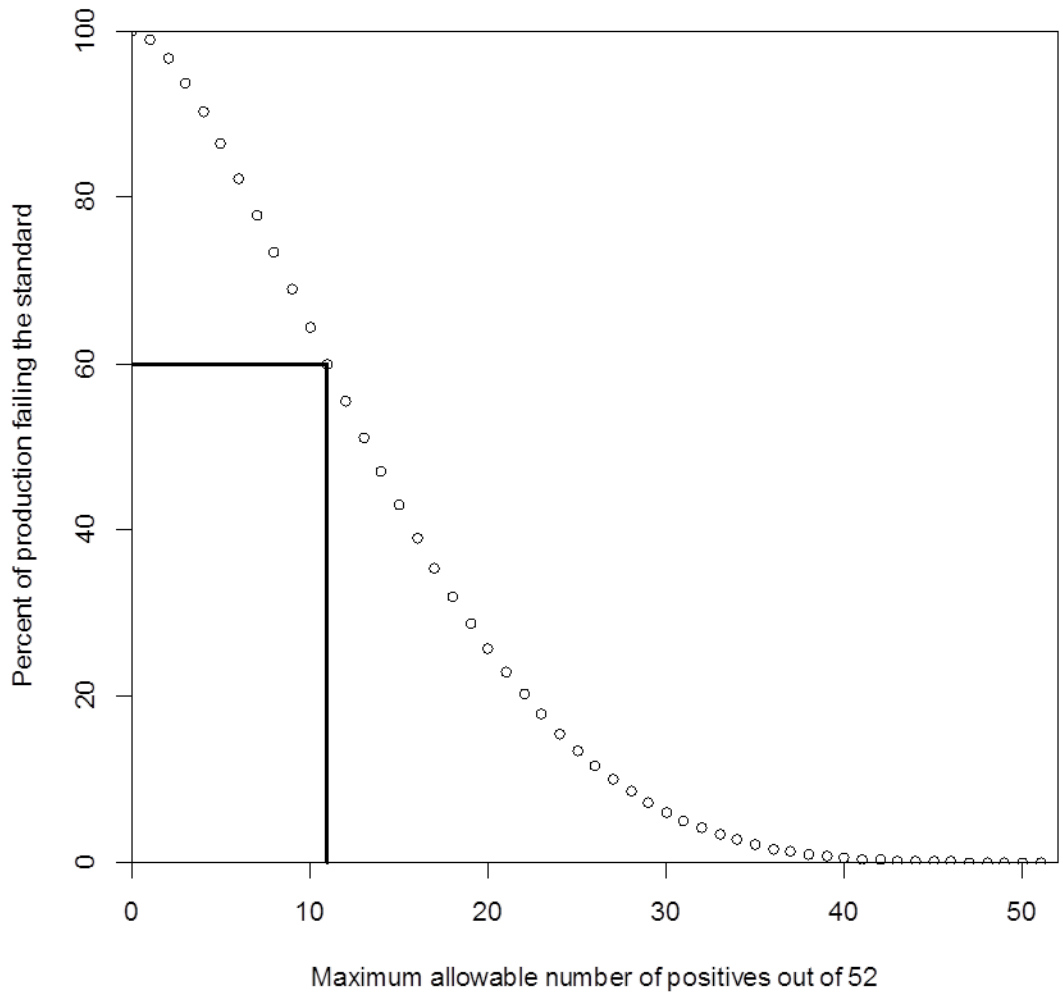

Figure 15. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard.
The initial effect of a chicken parts *Salmonella* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 11 acceptable positives will result in 60% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Chicken Parts *Campylobacter*

The distribution of percent *Campylobacter*-positive samples across the chicken parts industry is slightly uncertain (Figure 16). The distribution of the within-establishment proportion positive is similar for *Campylobacter* and *Salmonella.* This uncertainty implies that a performance standard – intended to reduce the industry's percent positive samples by 33% – ranges between 3 and 5 allowable positives depending on which distribution is applicable (Table 15). The fraction of the production volume initially failing these performance standards is stable for the most likely and upper bound distributions (range: 83% - 87%). The smaller share of establishments failing these performance standards – relative to share of production volume – suggests that larger establishments make up a disproportionate share of failing establishments.

If the most likely industry distribution is used, but alternative compliance fractions are considered, then the performance standard that achieves an approximate 33% reduction in human illnesses is defined as 4 or 2 allowable positives (in 52 samples) for the 50% or 40% compliance fractions (Figure 17 and Table 16). Note that the performance standard of 4 allowable positives (at 50% compliance) accomplishes slightly less than a 33% reduction. Nevertheless, this standard is preferred in this case because a standard of 3 allowable positives would exceed the target reduction by more than 10%. If the compliance fraction is 30%, then a performance standard of 1 allowable positive only accomplishes a 27% reduction in human illnesses.

The modal values for annual illnesses avoided for these standards range from 12,000 to 14,500. Figure 17 illustrates that if a performance standard of 2 allowable positives was chosen, it could accomplish a reduction in human illnesses of 34% or 42% depending on whether the true compliance fraction was 40% or 50%. For the performance standard of 4 allowable positives, the share of production volume that initially fails the performance standard is 85% (Figure 18).

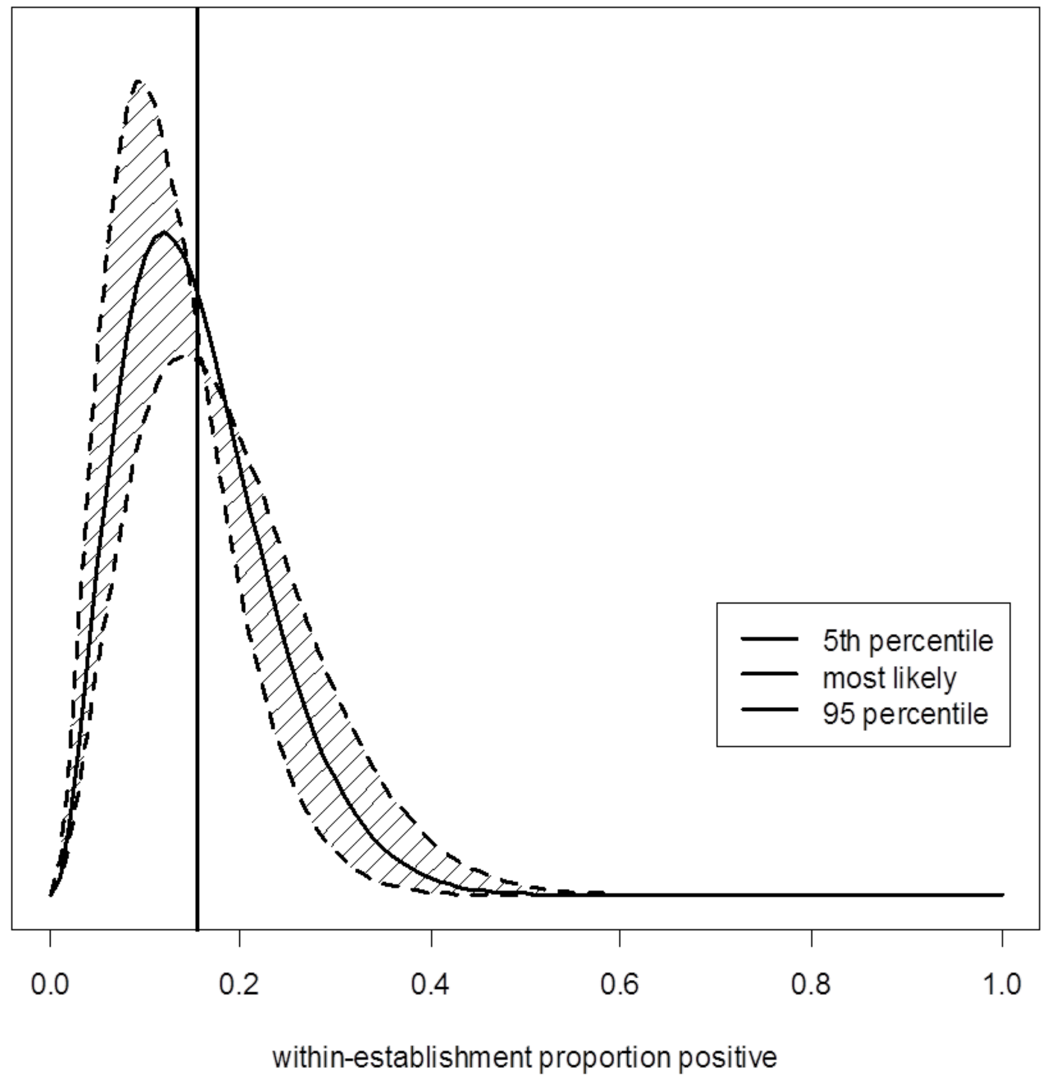

Figure 16. Fitted *beta* distributions for within-establishment *Campylobacter* contamination for chicken parts. The central distribution represents the most likely (that is, the Maximum Likelihood Estimate) distribution of *Campylobacter* contamination in chicken parts across establishments. The uncertainty about the true or actual distribution is illustrated by including bounding distributions—the 5^{th} and 95^{th} percentiles—determined using the statistical fitting algorithm. The vertical line indicates the expected value, 15.5%, of the most likely *beta*(a=3.255,b=17.70) distribution.

Table 15. Effect of the within-establishment distributions on performance standard options. The chicken parts *Campylobacter* performance standards intended to approximate a 33% reduction in illnesses are determined for the most likely and lower/upper bounds of the within-establishment proportion positive distribution. There is a small difference in the performance standard depending on which distribution is applicable. The calculated results assume the compliance fraction of establishments not meeting the standard (α) is 50%.

Fitted distribution	Performance criterion	Reduction in illnesses	Failing production volume share*	Failing establishment share**
Most likely	4 of 52 samples	32%	85%	46%
Lower bound	3 of 52 samples	34%	87%	46%
Upper bound	5 of 52 samples	32%	83%	46%

*Based on fitted distribution

**Based on number of establishments (insufficient data for accurate estimation)

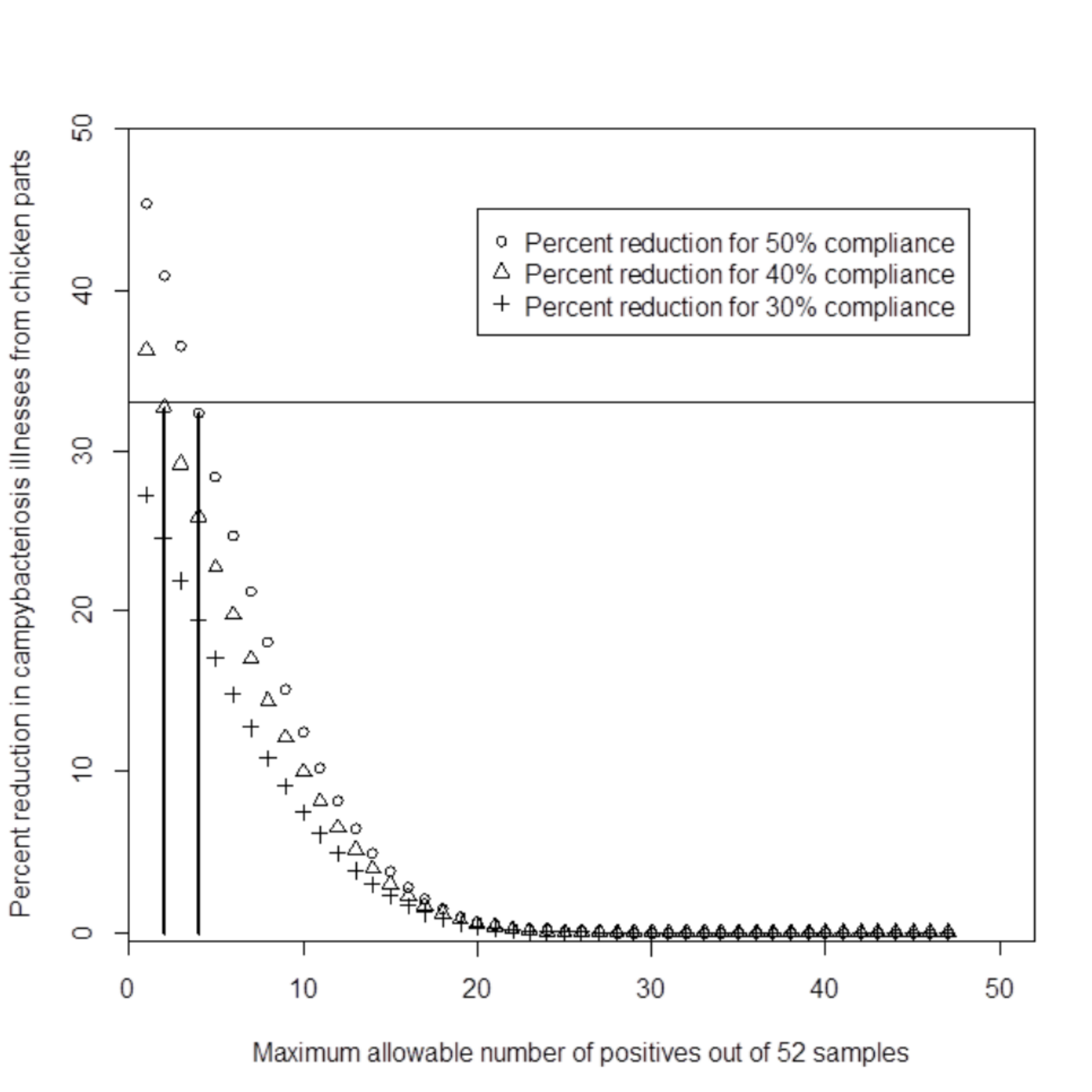

Figure 17. Graphical depiction of the effect of the compliance fraction on the illness reduction estimated from the maximum allowable number of positives.
Derivation of a chicken parts *Campylobacter* performance standard depends on the relationship shown here. The percent reduction in illnesses increases as the maximum allowable number of positives in 52 samples decreases (i.e., the performance standard option becomes more stringent). For any maximum allowable number of positives, the percent reduction in illnesses decreases as the compliance fraction (α) decreases from 50% to 30%. To approximate the HP2020 goal of a 33% reduction in human illnesses, the standard should be 4 or 2 for compliance fractions of 50% or 40%, respectively. If the compliance fraction is 30%, no performance standard approximates the HP2020 goal. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Table 16. The chicken parts *Campylobacter* performance criterion required to achieve a given percentage and number of illnesses avoided for different compliance fraction assumptions.
The chicken parts *Campylobacter* performance standard necessary to approximate a 33% reduction in human illnesses depends on the assumed compliance fraction of establishments not meeting the standard (α). More stringent (lower) performance standards are needed to achieve equivalent reductions in illnesses for decreased compliance fractions. These calculations assume the most likely industry distribution for within-establishment proportion positive.

Percent of failing establishments that become compliant	Performance criterion	Reduction in illnesses	Illnesses avoided mode (min – max)	Failing production volume share*	Failing establishment share**
50 percent compliance	4 of 52 samples	32%	14,300 (8,400 - 23,100)	85%	46%
40 percent compliance	2 of 52 samples	34%	14,500 (8,500 - 23,400)	97%	46%
30 percent compliance	1 of 52 samples	27%	12,000 (7,000 – 19,500)	99%	46%

*Based on fitted distribution
**Based on number of establishments (insufficient data for accurate estimation)

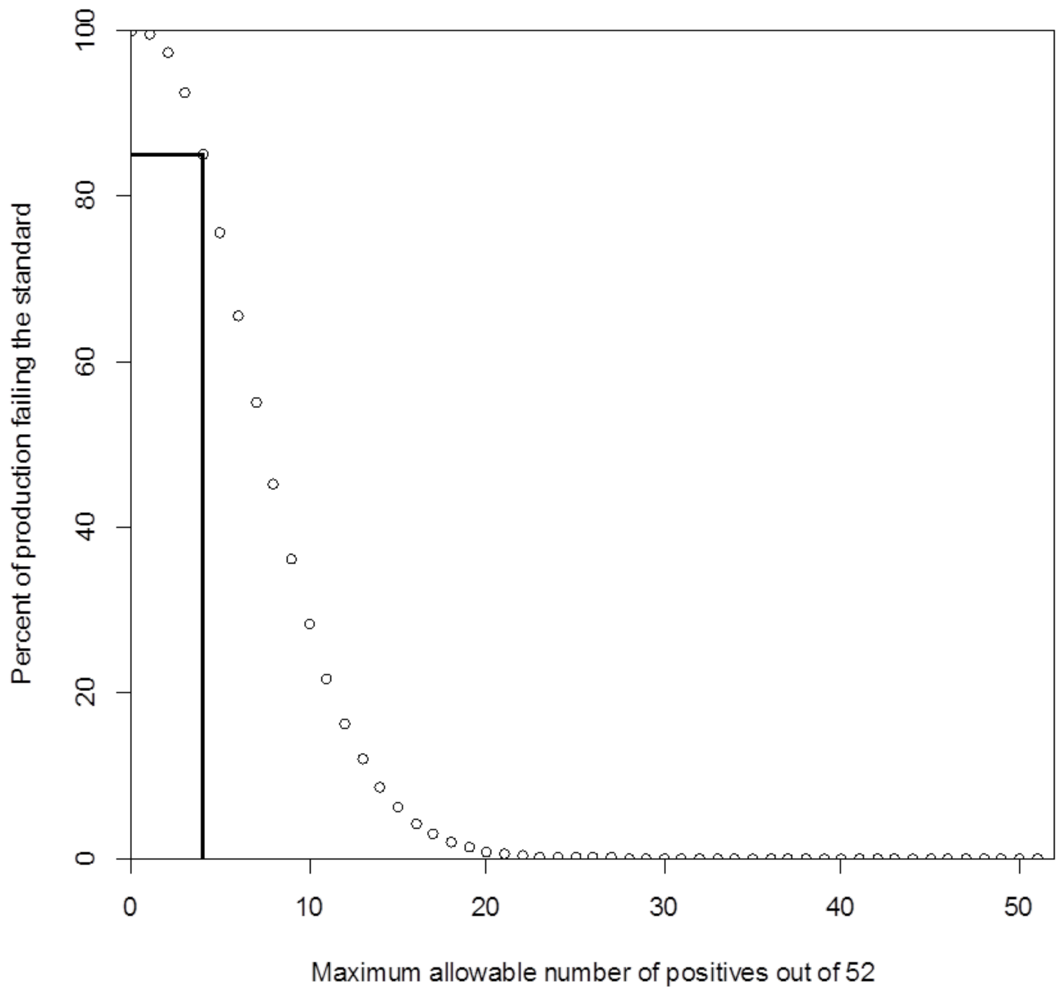

Figure 18. Effect of the maximum allowable number of positives on the percentage of production that would initially fail the standard. The initial effect of a chicken parts *Campylobacter* performance standard depends on the relationship shown here. This example illustrates that a performance standard of 4 acceptable positives will result in 85% of the industry failing initially. This graph assumes the most likely industry distribution for within-establishment proportion positive.

Discussion

These analyses estimate the benefits that could result from different performance standard options in six commodity-pathogen pairs. The effects are explored using different assumptions about different distribution curves (i.e., MLE, and 5th and 95th percentile), and the percentages of industry that initially are failing the standards but will eventually comply with the standards. The results of these analyses are conditioned on the assumptions outlined in this report. For example, sample sets of sufficient size will be available to categorize establishments accurately and industries will be incentivized to seek improvements in process control.

For all assumptions, the goal is to at least meet the agency's illness reduction goals outlined in HP2020. Nevertheless, this is not always feasible for all commodity-pathogen pairs. The outputs of these analyses provide FSIS management information they can use when deciding the most appropriate performance standard. 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 general, lower assumptions about the compliance fraction value seem appropriate. New standards will be implemented for chicken parts and we cannot be sure how industry will respond to these or revised comminuted poultry performance standards. It should be understood that assuming a lower compliance fraction generates more stringent performance standards (i.e., smaller maximum allowable positive samples). It is also true that compliance with performance standards is influenced by the degree to which such standards influence establishment managers to improve their food safety controls. In the past, effective measures to encourage compliance with performance standards have included public listing of the names of establishments that fail the performance standard and enhanced inspection/review of establishments.

Data limitations include the use of data for chicken parts and comminuted poultry representing a period less than one year. Therefore, it is possible that these data miss some seasonal effects in pathogen occurrence in these products. In addition, the chicken parts data were collected in 2012 and may not reflect current conditions in that industry. Past experience suggests that industries anticipate the imminent implementation of performance standards (or changes to existing standards) and begin to reduce pathogen occurrence in anticipation of such implementations.

Sources of model uncertainty include assumptions about proportional effects inherent in our model. Such assumptions relate to the mathematical model that predicts the change in illnesses as a linear function of the change in industry prevalence. Previously, we have explained somewhat more complicated models (e.g., assuming that failing establishments adopt a prevalence just low enough to pass the standard), but such models require more assumptions without data for support (Ebel, Williams et al. 2012). The estimates for current rates of illness for the commodity-pathogen pairs also hinge on the assumptions that risk of the various products is proportional to the production volume share. It might be argued that ground product should be considered more risky than its share of production volume implies. Nevertheless, there currently is insufficient data to make such adjustments to the calculations.

The high limit of detection for *Campylobacter* in comminuted poultry generated low proportions of positive samples. In the future, sampling using a lower limit of detection would detect more positive samples and allow the performance standard development more flexibility than it has currently. Flexibility includes larger numbers of allowable positives so that future performance standards could call for smaller numbers of allowable positives to achieve subsequent improvements in public health. At a minimum, a lower limit of detection for *Campylobacter* would likely generate a positive proportion of samples for this pathogen that more closely matched the positive proportion of samples for *Salmonella*. The differences between *Campylobacter* and *Salmonella* occurrence in comminuted poultry observed currently are likely artifacts of the different limits of detection for these pathogens.

In summary, FSIS risk managers considered the results of this analysis to select performance standards for these product-pathogen pairings (Table 17 and Table 18). The risk managers preferred the most likely within-establishment contamination distributions and a 50% compliance fraction among establishments that initially failed the performances standards. Furthermore, where considered feasible, risk managers preferred performance standards that were expected to accomplish a reduction in *Salmonella* and *Campylobacter* illnesses on a product-pathogen pair basis of approximately 30% and 33%, respectively.

Given these intended outcomes, Tables 17 and 18 examine performance standards that reduce illnesses for alternative assumptions about the compliance fraction. For example, the selected chicken-*Salmonella* standard for not-ready-to-eat comminuted product is 13 of 52 (Table 17). From Figure 2, we can observe that the percent reduction in human illnesses is approximately 30% for the 50% compliance fraction curve at a maximum allowable number of positives of 13 (one step to the right of the 12 of 52 vertical line associated with the 40% compliance fraction curve). Nevertheless, we can observe that a maximum number of allowable positives of 13 intersects the 40% compliance fraction curve just below an illness reduction of 25% and the 30% compliance fraction curve around an illness reduction of 18%.

With the exceptions of *Campylobacter* for comminuted turkey and chicken parts, the 50% compliance fraction assumption accomplishes the preferred reduction in illnesses targets. These exceptions have been explained previously; i.e., the 33% goal is not achievable for the *Campylobacter* in comminuted turkey standard and a more stringent *Campylobacter* in chicken parts standard would overshoot the illness reduction goal by too large an amount. For the other standards, if the 40% compliance fraction is assumed, then the expected reduction in illnesses closely approximates the HP2020 targets of 25% and 33% reductions in *Salmonella* and *Campylobacter* illnesses. For example, the 40% compliance fraction predicts 24%, 30% and 25% reductions in illnesses for the comminuted chicken-*Salmonella*, comminuted chicken-*Campylobacter* and comminuted turkey-*Salmonella* performance standards in Table 17, respectively. In these cases—as well as the chicken parts-*Salmonella* standard—these results suggest that FSIS could nearly accomplish the HP2020 goals if the compliance fraction should fall below the expected 50% mark. These intended and alternative predictions are used by FSIS economists in an analysis of the performance standards.

Table 17. Summary of information about Not Ready to Eat Comminuted Poultry performance standards selected by FSIS. Results are based on the most-likely within-establishment contamination distributions for each product-pathogen pair. For each performance standard, the fraction of initially failing establishments that eventually become compliant with the performance standard (i.e., the compliance fraction of establishments not meeting the standard) is evaluated at levels of 50%, 40% and 30%.

Compliance fraction	Metric	*Salmonella* chicken	*Campylobacter* chicken	*Salmonella* turkey	*Campylobacter* turkey
	Performance standard	13 of 52	1 of 52	7 of 52	1 of 52
50%	Reduction in illnesses	30%	37%	32%	19%
	Illnesses avoided mode	3,100	1,300	2,400	500
	(min – max)	(2,000 -- 4,700)	(700 -- 2,000)	(1,500 -- 3,600)	(300 -- 700)
40%	Reduction in illnesses	24%	30%	25%	15%
	Illnesses avoided mode	2,500	1,000	1,900	400
	(min – max)	(1,600 -- 3,700)	(600 -- 1,600)	(1,200 -- 2,900)	(200 -- 600)
30%	Reduction in illnesses	18%	22%	19%	11%
	Illnesses avoided mode	1,900	700	1,400	300
	(min – max)	(1,200 -- 2,800)	(400 -- 1,200)	(900 -- 2,200)	(200 -- 400)
	Failing production volume share	93%	56%	61%	20%
	Failing establishment share	62%	24%	58%	9%

Table 18. Summary of information about raw chicken parts performance standards selected by FSIS. Results are based on the most-likely within-establishment contamination distributions for each product-pathogen pair. For each performance standard, the fraction of initially failing establishments that eventually become compliant with the performance standard (i.e., the compliance fraction of establishments not meeting the standard) is evaluated at levels of 50%, 40% and 30%.

Compliance fraction	Metric	*Salmonella*	*Campylobacter*
	Performance standard	8 of 52	4 of 52
50%	Reduction in parts illnesses	34%	32%
	Illnesses avoided mode	29,000	14,300
	(min – max)	(18,900 – 45,400)	(8,400 - 23,100)
40%	Reduction in parts illnesses	27%	26%
	Illnesses avoided mode	19,900	11,400
	(min – max)	(13,100 – 31,400)	(6,700 – 18,500)
30%	Reduction in parts illnesses	20%	19%
	Illnesses avoided mode	11,000	8,600
	(min – max)	(7,200 – 17,100)	(5,000 – 13,900)
	Failing production volume share	73%	85%
	Failing establishment share	63%	46%

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