

**Potential Public Health Impact
of *Salmonella* and *Campylobacter*
Performance Guidance for Young
Chickens and Turkeys**

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Potential Public Health Impact of *Salmonella* and *Campylobacter* Performance Guidance

Purpose

This document outlines methods and results to estimate the potential public health impact of revised performance guidance for *Salmonella* and new performance guidance for *Campylobacter* for young chickens and turkeys¹. The Food Safety and Inspection Service (FSIS) also examined the countervailing effect of these approaches by estimating the number of slaughter establishments that will initially pass (not pass) the guidance.

This document is not a risk assessment; it is an illustrative example of potential human illnesses that might be avoided given implementation of new performance guidance for *Salmonella* and *Campylobacter*. At this time, FSIS is proposing guidance that does not require a risk assessment to implement. Although the estimates developed in this document represent part of a risk assessment, there are important elements that are not included here that are necessary to complete a risk assessment. In particular, this document does not consider uncertainty about the estimates nor does it complete a sensitivity analysis of the underlying model. Therefore, the estimates provided should be considered illustrative.

Background

A number of guidance options were considered by FSIS. In general, all guidance options involved sampling finished poultry (young chickens and turkeys) carcasses in federally-regulated poultry slaughter establishments for the presence of *Salmonella* and *Campylobacter*. These options describe different approaches to determining whether a tested establishment passes the guidance or not.

The principal effect of any guidance option is to encourage industry to produce a safer product. Under FSIS' current *Salmonella* policy, the names of poultry carcass establishments in either Category 2 or Category 3 are posted monthly on the FSIS website (FSIS, 2006). Past experience has demonstrated that the disincentives of FSIS guidance have persuaded the industry to expend the resources necessary to improve performance.

In general, public health improves as slaughter establishments reduce the occurrence of pathogens on their products, and so we assume a stricter guidance option will generate more public health benefits. The stricter the guidance (*i.e.*, the fewer positive samples allowed in a set of samples) the more slaughter establishments will initially not pass the guidance. A stricter guidance equates to a lower allowable prevalence of contaminated carcasses, so the overall prevalence of contaminated carcasses will decline as more establishments pass the guidance.

Among *Salmonella*-contaminated poultry carcasses, the number of *Salmonella* organisms (*i.e.*, "level") is generally low. However, human salmonellosis is often attributable to small numbers of *Salmonella* growing to infectious doses between production and consumption, due to abusive storage and handling conditions. Therefore, because the occurrence of any *Salmonella* on a carcass poses a potential risk to consumers, guidance relates to prevalence *i.e.*, presence or absence of pathogens among samples tested.

Among *Campylobacter*-contaminated poultry carcasses, there is substantial variability in numbers of *Campylobacter* organisms. Large counts, or "high levels," of *Campylobacter* may be more important than its prevalence on carcasses, because *Campylobacter* are not expected to grow between production and consumption

¹ This document is a supporting report. It does not review the proposed policy and must be read in the context of the Federal Register Notice to which these polices refer.

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and, therefore, larger initial counts increase the chance that some viable organisms can survive cooking effects or cross-contaminate other food products. For this reason, FSIS' *Campylobacter* guidance is based, in part, on higher levels of *Campylobacter* demonstrated on samples tested.

Methods

If a policy is expected to change the prevalence of contaminated carcasses at the end of production (as determined by a qualitative microbiological test), but is not expected to significantly change the levels of a pathogen on these contaminated carcasses, then estimates about public health gains from the policy are relatively straightforward. This scenario seems particularly apt in the case of *Salmonella* and poultry. The levels of *Salmonella* observed on contaminated carcasses are generally low already, so a policy that intends to reduce the prevalence of *Salmonella* among poultry carcasses is unlikely to substantially reduce the already low levels on those *Salmonella*-positive carcasses.

To estimate the annual average number of illnesses avoided (λ_{Avoided}) by a policy that reduces the prevalence of contaminated units, the following equation can be solved (Williams *et al.* 2011, Section 3.1)

$$\lambda_{\text{Avoided}} = \left[\left(1 - \frac{P_{\text{new}}(\text{exp})}{P_{\text{initial}}(\text{exp})} \right) \lambda_{\text{ill}} \right]$$

In this equation, λ_{ill} represents the annual average number of illnesses (*i.e.*, cases of salmonellosis or campylobacteriosis) occurring before the policy was implemented (*i.e.*, the current “baseline” for the number of poultry illnesses). This input to the calculation is estimated from available public health surveillance evidence. In this formula, the prevalence of contaminated poultry carcasses prior to implementing the policy is $P_{\text{initial}}(\text{exp})$ and the prevalence following successful implementation of a prevalence-reducing policy is $P_{\text{new}}(\text{exp})$.

This approach suggests that illnesses avoided by a prevalence-reducing policy are a simple proportion of the number of illnesses that occurred prior to implementing the policy. Such an approach is reasonable for estimating changes in sporadic illnesses within populations when prevalence of contamination changes (Vose, 2008; Bartholomew *et al.*, 2005).

FSIS also used the same approach to estimate the public health benefit of the proposed *Campylobacter* guidance, with the caveat that the proposed guidance for *Campylobacter* on young chickens requires a reduction in the prevalence of carcasses contaminated with higher levels of *Campylobacter* (*i.e.*, detectable in one ml of rinsate).

For guidance that determines whether an establishment passes or does not pass (based on a set of samples collected from the establishment), this analytic approach considers some fraction of establishments (or fraction of production volume) that initially pass (ω). Before the guidance is implemented,

$P_{\text{initial}}(\text{exp}) = \omega P_{\text{pass}}(\text{exp}) + (1 - \omega) P_{\text{fail}}(\text{exp})$, where $P_{\text{pass}}(\text{exp})$ and $P_{\text{fail}}(\text{exp})$ are the prevalence of contaminated carcasses among all slaughter establishments (or production volume) that would pass or fail the guidance, respectively. In other words, if the prevalence of contaminated carcasses within each of the U.S. poultry slaughter establishments was known, then it could be determined whether or not each establishment would pass the guidance. Furthermore, if we knew each establishment's share of total U.S. poultry production (*e.g.*, the

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fraction of total young chickens produced per year by each young chicken establishment), then facilities could be pooled based on their classification of passing (or not) and the overall prevalence within each pool could be determined (*e.g.*, ω is the sum of the fractions of total young chickens produced per year across all passing young chicken establishments).

Once the guidance was implemented and establishments that did not pass were listed on the FSIS website, it is likely that some fraction, α , of those establishments not passing the guidance would change their production practices in order to pass the guidance. Over time, it is likely that these establishments would ultimately attain a prevalence of contaminated carcasses equal to those that pass FSIS' guidance ($P_{pass}(exp)$). Given this expected change, the estimated national prevalence of contaminated carcasses can be calculated based on the following equation;

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

In other words, a new weighted average of the prevalence among passing and not passing establishments is calculated after some fraction of those establishments not passing have changed their practices so that they pass FSIS' guidance (*i.e.*, they are "passing").

This approach to estimating potential public health benefits (*i.e.*, average number of human illnesses avoided per year by the guidance) requires data regarding the occurrence of pathogens across the poultry industry. These data can be analyzed to determine the inputs to this model. Nevertheless, the public health benefits of the guidance essentially depend on the perceived magnitude of the disincentive of being listed on the FSIS website to an establishment that currently does not pass the guidance. Although FSIS has some historic evidence regarding industry behavior in response to previous guidance measures (*i.e.*, *Salmonella* HACCP verification program data and categorization of establishments in that program (FSIS, 2006)), the true behavior of the industry to new guidance is unknowable. Therefore, the value of the α parameter in the model is uncertain. Estimates of the number of illnesses ultimately avoided for both the *Salmonella* and *Campylobacter* guidance are provided across a range of possible levels of effectiveness (*i.e.*, α values).

Data sources

Input values for ω , $P_{pass}(exp)$ and $P_{fail}(exp)$ were determined from FSIS' Nationwide Microbiological Baseline Data Collection Programs: the Young Chicken Survey, which is here referred to here as the Young Chicken Baseline Survey, 2007-2008, (YCBS) (FSIS, 2007), the Young Turkey Survey, referred to here as the Young Turkey Baseline Survey, 2008-2009, (YTBS) (FSIS, 2008), and/or *Salmonella* HACCP verification program data from 2008-2009. As with past performance standards developed for commodity groups, these guidances are based on analyses of FSIS microbiological baseline survey data. For the *Campylobacter* guidance, only the baseline data were available. For the *Salmonella* guidance, the YCBS and the YTBS data were used to establish criteria for passing the guidance, but final estimates were based on the more current *Salmonella* HACCP verification program data. Estimates are based on the HACCP verification dataset because average *Salmonella* prevalence among young chicken carcasses has decreased since the collection of the baseline data in 2007-2008. Using the HACCP data as the starting point for examining the effect of the policy should help prevent overestimation of the potential public health benefit.

The parameter ω was defined as the proportion of total poultry carcasses produced per year that originated from passing establishments. Because production data were available for each establishment in the YCBS and YTBS data

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and *Salmonella* HACCP verification program databases, calculation of ω was relatively straightforward once all establishments were classified as passing or not. Nevertheless, there is interest among decision-makers regarding the proportion of establishments (regardless of production volume) that would immediately be classified as passing under the new guidance because of their superior performance. This latter proportion is reported and denoted as ω' .

A default value for α is derived from FSIS' *Salmonella* HACCP verification program data collected from 2006 through the third quarter of 2009 (Figure 1). In 2006, FSIS augmented its *Salmonella* performance standard by establishing a system that categorized slaughter establishments into three broad categories based on the sampling results of two successive sample sets for each establishment (FSIS, 2006). Category 1 establishments had sample results that suggested their carcass prevalence levels were $\leq 50\%$ of the performance standard (12 or fewer positive samples among a 51 sample set for young chickens). Category 1 establishments had 6 or fewer positive samples across each of two successive 51 sample sets. Category 3 establishments had more than 12 positive samples among its last 51 sample set. Category 2 establishments were those that did not meet the Category 1 or 3 definitions. Establishments are given a Category 2T status after achieving a single sample set with less than or equal to 6 positives.

This classification system encouraged establishments to improve their performance by the posting of names of Category 2 or 3 establishments on the FSIS website. Over time, the change in the fraction of establishments in Category 3 (or in Categories 2 and 3) provides an estimate of the value of α .

Based on the past performance of the program (Figure 1) it was estimated that approximately 55-60% of young chicken establishments that initially did not pass the guidance modified their production practices to become compliant (*i.e.*, fewer than 12 positive samples out of a 51 sample set). Nevertheless, it is possible that as prevalence approaches zero, it will become more difficult for establishments to improve their production practices. Given this reasoning, the default assumption for the effectiveness of the guidance will be $\alpha = 0.5$.

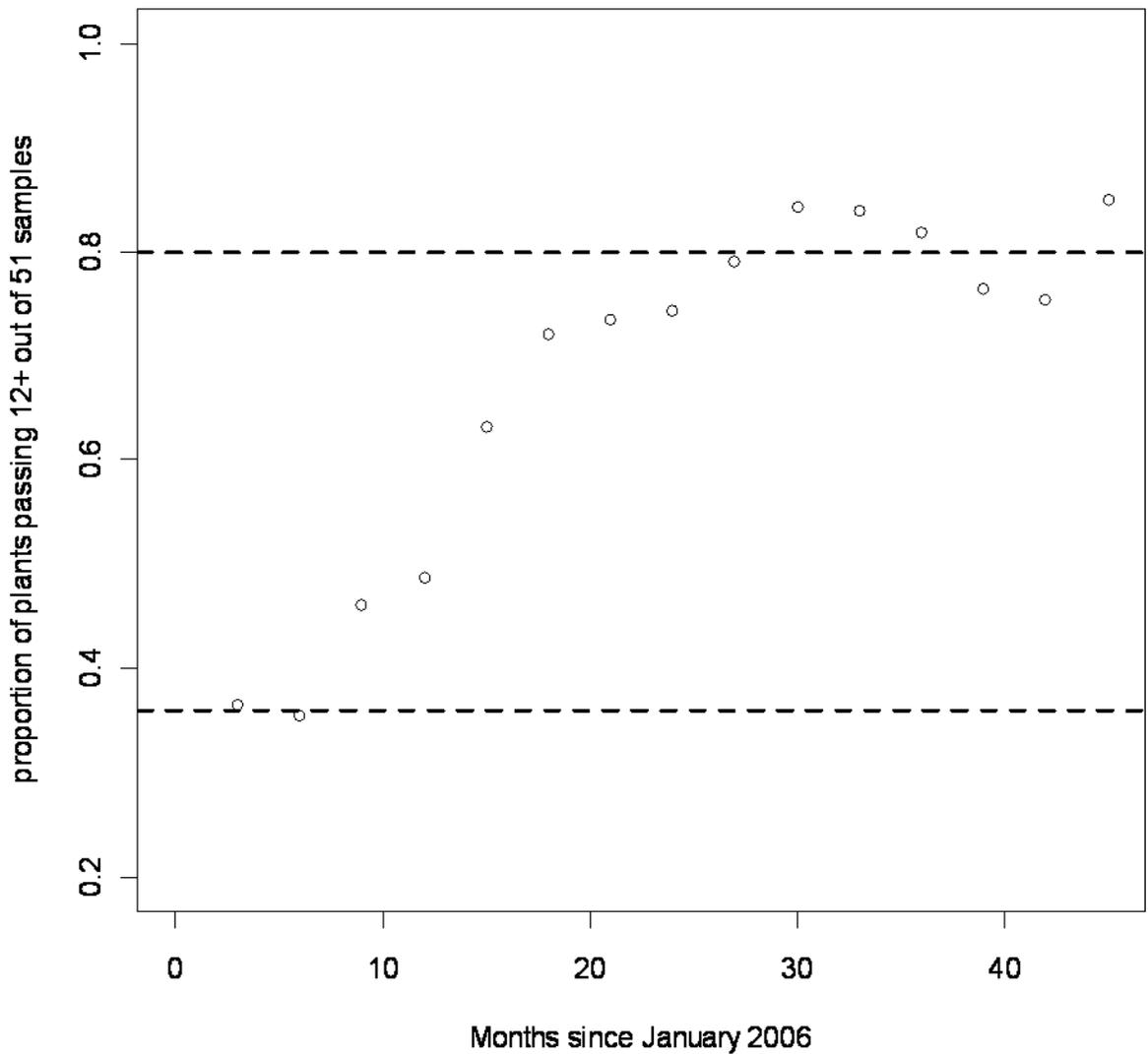


Figure 1. Change in the proportion of young chicken establishments that pass the existing *Salmonella* standard of 12 or fewer positive samples out of a 51-sample set.

The lower horizontal line in Figure 1 represents the initial level of compliance of roughly 36% of establishments passing the standard. The upper horizontal line represents an approximate upper bound for the proportion of establishments passing the standard. The level of compliance demonstrates a rapid improvement over the first 24 months followed by a stable period where between 80 and 85% of establishments are passing the standard.

Finally, the model requires input values for λ_{ill} for *Salmonella* and *Campylobacter*. These values for the current “baseline” number of illnesses per year attributed to poultry were derived using data sources and methodology given in Table 1.

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Table 1. Data source and methods used for estimating illnesses from *Campylobacter* and *Salmonella* attributed to young chickens and turkeys in the U.S. population. Minor discrepancies in final estimates are due to rounding of intermediate values.

Step	Input	<i>Campylobacter</i>	<i>Salmonella</i>	Data Source & Time Period / Estimation
1	Foodborne illnesses	845,024	1,027,561	Scallan <i>et al.</i> , 2011
2	Poultry attribution fraction	0.20	0.17	CDC outbreak data, 2001-2007 and Pires <i>et al.</i> , 2009 ²
3	Young chicken volume adjusted proportion positive	0.467	0.075	FSIS Young Chicken Baseline Study (2007-2008)
4	Turkey volume adjusted percent positive	0.011	0.017	FSIS Young Turkey Baseline Study (2008-2009)
5	Young chicken production fraction	0.838	0.838	ERS (2003-2008)
6	Young turkey production fraction	0.151	0.151	ERS (2003-2008)
7	Contaminated young chicken fraction	0.996	0.961	Step = (3 x 5) / ((3 x 5) + (4 x 6))
8	Contaminated young turkey fraction	0.004	0.039	Step = (4 x 6) / ((3 x 5) + (4 x 6))
9	Young chicken attribution fraction	0.199	0.163	Step = 2 x 7
10	Young turkey attribution fraction	0.001	0.007	Step = 2 x 8
11	Total foodborne illnesses from young chickens	168,291	167,831	Step = 1 x 9
12	Total foodborne illnesses from young turkeys	714	6,855	Step = 1 x 10

² An assessment of publically available Centers for Disease Control and Prevention (CDC) outbreak cases, 2001 – 2007 for *Salmonella* gave poultry attribution estimates of 16.9%. This estimate was rounded up to 17%. For *Campylobacter* poultry attribution, a CDC case-control study suggested the “population attributable fraction (PAF) of 24% was related to consumption of chicken prepared at a restaurant” (Friedman *et al.*, 2004). This estimate was rounded down to 20%.

Results

Salmonella

Alternative guidance options were considered based on the prevalence of contaminated young chicken carcasses among a sample set of 51 samples per slaughter establishment (Figure 2). This analysis proceeded by assuming the YCBS (*i.e.*, sampling results pooled by establishment) represented the current state of the industry. It was determined whether each establishment had passed or did not pass the various guidance options, and then the number of illnesses avoided per year was determined as described under Methods. For example, if the guidance was that a maximum of 5 positive samples was allowed, then ~80% of establishments were estimated to pass the guidance and ~25,000 illnesses were estimated to be avoided within a year or so following implementation of the guidance.

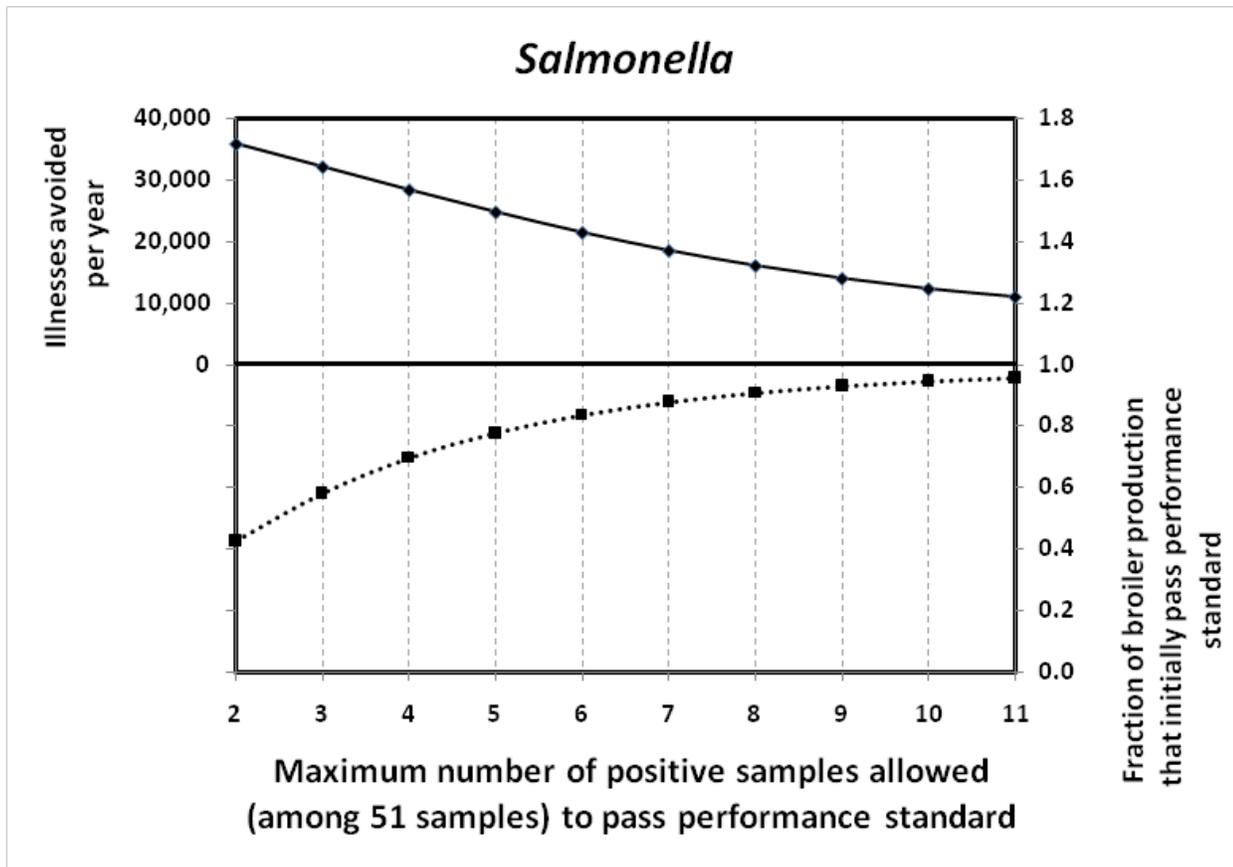


Figure 2. Estimates of the annual number of *Salmonella* illnesses avoided (top) and the proportion of production establishments that would pass the new guidance based on the YCBS. Estimated illnesses avoided per year are lower when based on FSIS HACCP verification data.

Figure 2 shows estimates of the annual number of *Salmonella* illnesses avoided and the proportion of establishments that would pass the new guidance based on data from the YCBS. Both values are given as a function of the number of allowable positive samples. As the number of allowable positives decrease in a 51-sample set, the number of illnesses avoided increases.

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Analysis of Figure 2 demonstrates the trade-off between improved public health (*i.e.*, decrease in the number of salmonellosis cases per year) and greater industry compliance required as the guidance becomes stricter. As the maximum allowable positive samples decreases from 11 to 2 (*i.e.*, moving right to left), the number of *Salmonella* illnesses avoided per year increases while the fraction of establishments that can initially pass the guidance decreases. Because fewer establishments initially pass a strict guidance, more establishments (initially noncompliant) will have to change their operations so that they can eventually pass the guidance.

Salmonella on young chickens

After examining the information in Figure 2 and the results of the most recent two years of *Salmonella* HACCP verification program data, FSIS decided to propose *Salmonella* guidance that required 5 or fewer *Salmonella*-positive samples among a 51 sample set to consider a young chicken slaughter establishment as passing. This guidance was then applied to the *Salmonella* HACCP verification program data collected from 2008 to the present. This analysis determined what fraction of establishments and young chicken production would pass (or not pass) this guidance. In addition, the values for $P_{pass}(exp)$ and $P_{fail}(exp)$ were estimated from these data.

Table 2. Data used to estimate the number of illnesses avoided due to the implementation of the proposed *Salmonella* guidance for young chickens. Minor discrepancies are due to rounding error.

Proportion of total volume initially compliant	$\omega =$	0.907	$P_{pass}(exp) =$	0.035	
Proportion of total volume initially noncompliant	$1 - \omega =$	0.093	$P_{fail}(exp) =$	0.153	
Proportion of compliant establishments	$\omega' =$	0.85			
Proportion of noncompliant establishments	$1 - \omega' =$	0.15			
Proportion of establishments that improve	$\alpha = 0.5$	$\lambda_{ill} =$	167,831	$\lambda_{avoided} =$	20,157

The proposed *Salmonella* guidance is expected to avoid ~20,000 human cases that otherwise would occur each year (Table 2). Introduction of this guidance will initially result in about 15% of establishments not passing, but we anticipate that 50% of these establishments will pass the guidance within one or two years and generate the potential public health benefits.

To examine the effect that different values for α might have on the human illnesses avoided, we considered a range of α values from 0% to 100% (Figure 3). For the guidance (*i.e.*, 5 positives out of 51 samples), the maximum number of illnesses that could be avoided is approximately 40,000 if all initially noncompliant establishments were to become compliant with the guidance.

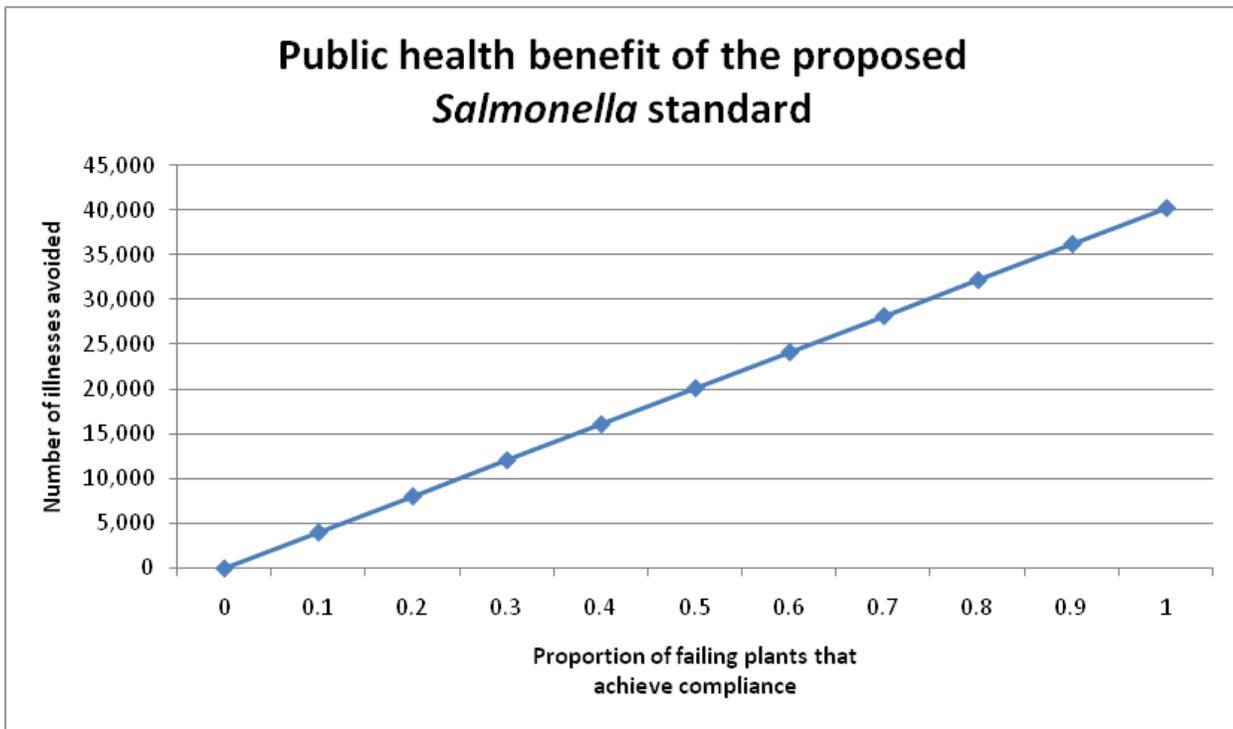


Figure 3. The number of *Salmonella* illnesses avoided increases linearly with the value of α in the young chicken model.

Salmonella on young turkeys

The guidance for young turkey carcasses reflects the very low prevalence of positive samples observed in the YTBS. Ultimately, the guidance was set such that a sample set of 56 samples was classified as passing if 4 or fewer samples were *Salmonella*-positive. The analysis estimates that 100 young turkey-associated *Salmonella* illnesses per year (assuming $\alpha = 0.5$) can be avoided (Table 3).

Table 3. Data used to estimate the number of illnesses avoided due to the implementation of the proposed *Salmonella* guidance for young turkeys.

Proportion of total volume initially compliant	$\omega =$	0.997	$P_{pass}(exp) =$	0.017	
Proportion of total volume initially noncompliant	$1 - \omega =$	0.003	$P_{fail}(exp) =$	0.188	
Proportion of compliant establishments	$\omega' =$	0.82			
Proportion of noncompliant establishments	$1 - \omega' =$	0.18			
Proportion of establishments that improve	$\alpha = 0.5$	$\lambda_{ill} =$	6,855	$\lambda_{avoided} =$	100

Campylobacter

In the past, FSIS has not regulated *Campylobacter*, and two primary factors influenced the decision about the proposed guidance:

- A desire to prevent raw poultry products with high levels of *Campylobacter* from reaching consumers.
- The need to integrate sample collection with the *Salmonella* testing in order to control costs and minimize the sample collection burden on field staff and establishments.

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Campylobacter on young chickens

For young chicken carcasses, the proposed guidance requires a reduction in the prevalence of contaminated carcasses with higher levels of *Campylobacter* organisms. The same 51 young chicken carcass samples collected for *Salmonella* are tested for *Campylobacter*, with the proposed *Campylobacter* guidance allowing a maximum of 8 positives carcasses.

This analysis of the public health effects of the guidance proceeded by assuming the YCBS represented the current state of the young chicken industry. The testing data from each establishment in the baseline study was used to determine if the establishment would pass or not pass the proposed guidance, then the illnesses avoided per year was determined as described in the Methods section.

The 51-sample set for *Campylobacter* on young chicken carcasses has an estimated public health benefit of ~5,000 illnesses avoided if the policy is 50% effective (similar to that considered for *Salmonella*). Pertinent values used in the calculations are provided in Table 4.

Table 4. Data used to estimate the number of illnesses avoided due to the implementation of the proposed *Campylobacter* guidance for young chickens. Minor discrepancies are due to rounding error.

Proportion of total volume initially compliant	$\omega =$	0.87	$P_{pass}(exp) =$	0.430	
Proportion of total volume initially noncompliant	$1 - \omega =$	0.13	$P_{fail}(exp) =$	0.655	
Proportion of compliant establishments	$\omega' =$	0.78			
Proportion of noncompliant establishments	$1 - \omega' =$	0.22			
Proportion of establishments that improve	$\alpha = 0.5$	$\lambda_{ill} =$	168,291	$\lambda_{avoided} =$	5,359

The proposed *Campylobacter* guidance is a semi-quantitative standard that is designed to detect highly contaminated carcasses. The method used to estimate the number of *Campylobacter* illnesses avoided does not account for any reduction in *Campylobacter* levels per contaminated carcass, and is only prevalence-related. As a result, the prevalence-related estimator likely underestimates the actual public health benefits of establishments meeting the guidance.

FSIS has not previously regulated *Campylobacter* so no data exist to determine the effectiveness of the policy. Figure 4 demonstrates the potential number of illnesses avoided across the range of possible levels of effectiveness (α) and shows that the public health benefit increases linearly with the effectiveness of the guidance.

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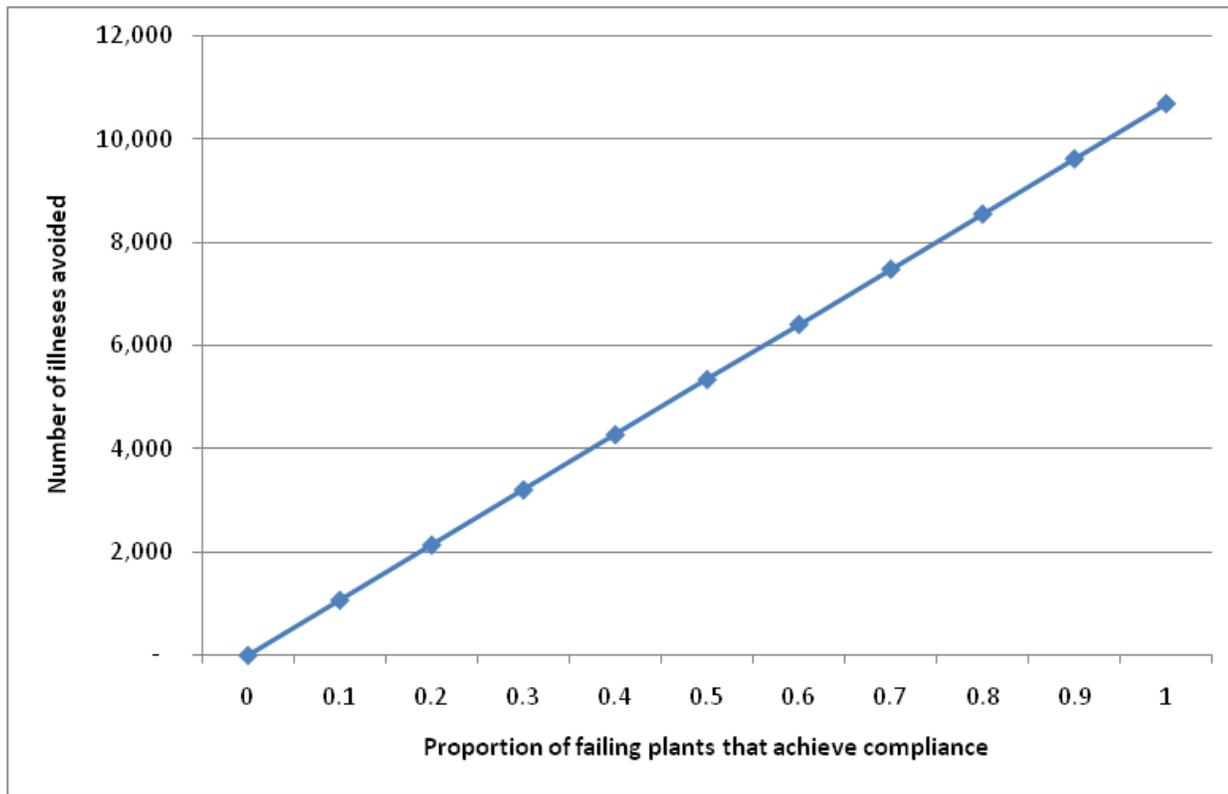


Figure 4. The number of *Campylobacter* illnesses avoided increases linearly with the value of α in the young chicken model.

Campylobacter on young turkeys

The *Campylobacter* guidance for young turkey carcasses took account of the very low prevalence of positive samples observed in the YTBS. Ultimately, the guidance was set such that a sample set of 56 samples was classified as passing if 3 or fewer samples were *Campylobacter*-positive. FSIS estimates this guidance will ultimately avoid an estimated 20 young turkey-associated *Campylobacter* illnesses per year (if $\alpha = 0.5$) (Table 5).

Table 5. Data used to estimate the number of illnesses avoided due to the implementation of the proposed *Campylobacter* guidance for young turkeys.

Proportion of total volume initially compliant	$\omega =$	0.99	$P_{pass}(exp) =$	0.010	
Proportion of total volume initially noncompliant	$1 - \omega =$	0.02	$P_{fail}(exp) =$	0.068	
Proportion of compliant establishments	$\omega' =$	0.88			
Proportion of noncompliant establishments	$1 - \omega' =$	0.12			
Proportion of establishments that improve	$\alpha = 0.5$	$\lambda_{ill} =$	714	$\lambda_{avoided} =$	20

Discussion

Based on the data and information available, several reasonable assumptions were made in this analysis. It was assumed that testing data from the YCBS, YTBS, and *Salmonella* HACCP verification program data are representative of current and future industry performance. Given the ongoing improvement in the performance

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of the industry as a whole with regard to *Salmonella*, it is possible that some additional reduction in *Campylobacter* levels has occurred since the baseline data were collected.

An area of considerable uncertainty is the determination of the number of attributed illnesses to these product-pathogen pairs. The estimates of illnesses avoided do not account for this source of uncertainty, so it is possible that actual benefit from the guidance differs significantly from the point estimates provided here. Regardless of these assumptions, however, it would be difficult to argue that a lower prevalence of contaminated products would not translate into safer products and less human illness.

Past experience has demonstrated that the disincentives of FSIS guidance have motivated industries to improve performance. Nevertheless, past reductions in *Salmonella* prevalence do not necessarily imply that the industry has the resources and technical ability to further reduce pathogen levels. There is likely a lower limit to pathogen levels that can be achieved with current technologies.

This analysis assumes the *Campylobacter* and *Salmonella* guidance have independent effects on public health. Nevertheless, it is likely that modifications to production practices that reduce levels of one pathogen would also reduce levels of the other.

The estimated number of illnesses avoided represents roughly 7% of the illnesses attributed to both pathogens. These are improvements, representing a small fraction of all illness cases. Year-to-year fluctuations in total cases might swamp these effects, and the success of these guidances may not be immediately reflected in public health surveillance statistics. However, with more precise attribution data, the effects of regulatory changes for these FSIS-regulated products should be demonstrable in the illness incidence data provided by the Centers for Disease Control and Prevention.

The trends in *Salmonella* prevalence since 2006 demonstrate that a substantial number of establishments have achieved a Category 1 ranking (*i.e.*, prevalence that is less than or equal to 50% of the current performance standard). The willingness and apparent ability of the industry to control pathogen levels is encouraging and suggests an opportunity to successfully further increase the stringency of guidance in the future.

The estimation of potential public health benefits associated with *Campylobacter* guidance is less certain because this pathogen has not been previously the subject of FSIS regulation. By implementing this guidance, FSIS has the opportunity to learn more about *Campylobacter* occurrence. Monitoring pathogen prevalence across time and assessing relationships between the occurrences of both pathogens will likely lead to improved knowledge and future guidance development.

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