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**Research Paper**

# Changes in *Salmonella* Contamination in Meat and Poultry Since the Introduction of the Pathogen Reduction and Hazard Analysis and Critical Control Point Rule

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## ABSTRACT

In 1996, the Food Safety and Inspection Service (FSIS) published its pathogen reduction and hazard analysis and critical control point (PR-HACCP) rule. The intention of this program was to reduce microbial contamination on meat, poultry, and egg products. The program was implemented in stages between January 1998 and January 2000, with sampling for *Escherichia coli* O157:H7 and/or *Salmonella* in large production establishments beginning in 1998. As the PR-HACCP program begins its third decade, it is reasonable to question whether there have been reductions in the frequency of pathogen-contaminated meat and poultry products reaching consumers. This study summarizes the results for over 650,000 samples collected by FSIS between 2000 and 2018 in slaughter and processing establishments across the United States and compares these results to the roughly 100,000 retail samples collected by the U.S. Food and Drug Administration between 2002 and 2017. The data demonstrate that there has been an overall reduction in the occurrence of *Salmonella* on meat and poultry products, but the direction and magnitude of change has not been consistent over time or across commodities. Although the available data do not support the identification of causal factors for the observed changes, a historical review of the timing of various factors and policy decisions generates potential hypotheses for the observed changes.

## HIGHLIGHTS

- FSIS HACCP program for meat and poultry was announced in 1998.
- Federal, state, and private agencies tested >750,000 samples for *Salmonella*.
- Samples have been collected at retail, slaughter, and processing establishments.
- Trends in *Salmonella* contamination of meat and poultry were compared.
- Overall reductions in *Salmonella* occurred, but anomalies were observed.

Key words: Beef; Foodborne illness; Hazard analysis and critical control point; Pork, Poultry; *Salmonella*

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The pathogen reduction and hazard analysis and critical control point (PR-HACCP) regulation program was implemented by the Food Safety and Inspection Service (FSIS) in 1996 *(31)*. The intention of this rule was to reduce pathogenic microorganisms on meat and poultry products, thereby reducing the incidence of foodborne illness associated with the consumption of these products. The pathogen product pairs of primary interest were *Salmonella* and *Escherichia coli* O157:H7 in meat and poultry products. To a lesser extent, the rule also focused on *Campylobacter* and *Listeria monocytogenes*. The rule was implemented in stages, beginning in 1998, with a focus on *E. coli* O157:H7 in beef establishments and *Salmonella* for all large production establishments across beef, chicken, pork, and turkey commodities.

Changes in *Salmonella* contamination for various meat and poultry products can be tracked across time because a key component of the PR-HACCP regulation was sampling of establishments for the presence of this pathogen. Establishments were subjected to performance standards, which are two-class attribute sampling plans that specify a maximum number of *Salmonella*-positive samples within a set of samples collected at each establishment. The size of sets varied from 51 to 82 samples, depending on the commodity.

Each of the performance standards was developed from baseline survey data. The duration of these baseline surveys was between 3 and 12 months, depending on the commodity. Many of the baseline surveys collected information for additional pathogens and indicator organ-

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isms, as well as sometimes performing sampling at multiple locations in the slaughter process. Nevertheless, the cross-sectional nature of the baseline surveys did not support trend analyses.

In addition to the PR-HACCP data collected by FSIS, the U.S. Food and Drug Administration (FDA) has been collecting retail meat and poultry samples since 2002 as part of the National Antimicrobial Resistance Monitoring System (NARMS) *(45)*. Relative to the FSIS data, the NARMS data consist of fewer annual samples that are collected from a more limited geographic area. Nevertheless, the NARMS samples are more likely to be representative of consumer exposure than FSIS samples collected in establishments, because retail sampling results include the effects of further processing, as well as microbial growth and attenuation that can occur during transport and storage of food products between production and retail.

Although the PR-HACCP regulation imposed mandatory adoption of HACCP principles across all meat and poultry slaughter and processing establishments, HACCP plans varied by the individual establishment and evolved across time. Furthermore, the implementation and interpretation of the original rule by FSIS has also evolved over time. For example, FSIS intended to make compliance with performance standards a precondition for marketing products. The authority to mandate adherence to the performance standards was rescinded in 2001 as a result of the Supreme Beef lawsuit *(18)*. Following this lawsuit, FSIS explored several options to promote performance standards, many of which relied upon market-based incentives to encourage establishments to reduce *Salmonella* contamination *(14, 23, 41, 47)*. These incentives began in 2006 when FSIS announced that they intended public dissemination of each poultry establishment's *Salmonella* status *(38)*. More recently, large retail corporations have begun to impose additional food safety requirements on their suppliers *(48)*. Changes in the observed trends in pathogen contamination can provide insight into the possible effect of these changes on food safety.

Nearly 30% of foodborne salmonellosis cases are currently attributed to meat and poultry *(17),* so there is interest in understanding how changes in the contamination of these commodities could affect the overall burden of disease. As regulation of the meat and poultry industries under the PR-HACCP rule begins its third decade, it is useful to assess if, and by how much, pathogen occurence has changed, as well as gaining a better understanding of factors that may have led to any observed changes. This study combines multiple FSIS data sources to assess changes in pathogen occurence from prior to the implementation of the PR-HACCP to the end of 2018. The trends and patterns in FSIS sampling results are compared with those observed in retail samples collected as part of the NARMS progam. Estimates from a series of nongovernmental surveys of poultry are included to further investigate discrepancies between FSIS and NARMS data sources.

## MATERIALS AND METHODS

A brief description of each data source is provided. Additional details regarding sampling rates, sample type, and laboratory methods can be found in the referenced materials. The data sets used to assess trends are provided in the Supplemental Material.

**FSIS data.** FSIS has operated two separate data collection programs. One program constituted the baseline surveys that were intended to support the agency's "War on Pathogens" *(28)*. The baseline surveys represented some of the first nationwide assessments of the frequency and levels of microbial contamination on various meat and poultry products in the United States. Prior to the baseline surveys, there were only limited attempts to characterize *Salmonella* contamination at the national level, with one FSIS study collecting chicken carcass samples from 15 establishments in 1967 and 1979 *(15)*. The laboratory methods and the theoretical limits of detection for the assay used for this study differed from those used during the baseline surveys (the 200-mL aliquot volume for the rinse samples provided a theoretical limit of detection for the assay of 1/200 = 0.005 CFU/mL). Nevertheless, this study found *Salmonella* present on 28.6 and 36.9% of carcasses in 1967 and 1979, respectively. This study also found substantial differences in the percentage of positive samples at the 15 establishments, with the range for the 1967 study being 7.5 to 73.7 and the range for the 1979 study being 2.5 to 87.5. This study also investigated regional patterns and concluded that most of the observed differences were likely associated with disparities in establishment performance rather than being indicative of large regional differences.

The other FSIS sampling program is the continuous sampling of meat and poultry products at the end point of the respective production processes as part of the PR-HACCP verification testing program *(31)*. These samples will be referred to as the "verification" data, and they are collected for the application of performance standards to each slaughter and processing establishment. There were 650,395 verification samples included in this study, and the sample collection efforts for the baseline and verification programs were independent (i.e., there were no samples shared between the two programs).

Chicken carcasses were sampled at the end of the slaughter process from all broiler chicken slaughter facilities. At each slaughter establishment, one chicken carcass was selected randomly for 51 consecutive days of production, although technical issues sometimes extended the sampling period (e.g., a new sample had to be collected if a submitted sample exceeded a temperature threshold when received at the laboratory).

For poultry carcass sampling, FSIS personnel collected a 400-mL carcass rinse sample immediately following the chilling process (postchilled), and a 30-mL aliquot was used for *Salmonella* testing. Ground beef and turkey samples were collected immediately following the grinding process in each establishment. A 25-g aliquot was used for testing, and this was later increased to 325 g. Pork carcass samples were collected after chilling of the finished carcass by using a sponge to remove surface bacteria from areas (100 cm$^2$) on the belly, ham, and jowl of a carcass. FSIS also collected beef carcass samples up until the suspension of the sampling program in 2011. These data are not included in this analysis because the ground beef data was considered an adequate representation of this commodity. The date of sample collection was recorded, and the samples were shipped to the FSIS laboratory to be tested for the presence *Salmonella* by using methods described in the FSIS laboratory guide *(35, 43)*.

**NARMS data.** NARMS is a retail meat and poultry surveillance program whose primary goal is to monitor the prevalence and trends of antimicrobial resistance among foodborne isolates of *Salmonella, Campylobacter, Enterococcus,* and *E. coli (46)*. NARMS began as a collaboration among the FDA's Center for Veterinary Medicine, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention, and state public health laboratories that participate in the Foodborne Diseases Active Surveillance Network (FoodNet) surveillance system led by the Centers for Disease Control and Prevention *(26)*. At each of the FoodNet sites, a randomized list of large retail establishments is used for sample selection. The four commodities that have been monitored across time are chicken breasts, ground turkey, ground beef, and pork chops, with 101,828 samples used in this study. Samples for each commodity were collected at a single retail establishment on the same day. In the rare instance that one of the commodities was not available, the sample for that commodity was collected from a different retail establishment on the same day. The sampled establishments vary across time.

At the 2002 inception of the NARMS retail sample collection program, 10 samples were collected monthly from retail establishments within an established geographic area surrounding each FoodNet site. The month code was assigned on the basis of when each sample arrived at the laboratory. The program began with the original 5 FoodNet sites (50 samples per month) and expanded to all 10 FoodNet sites by 2004 (100 samples per month). Additional sites outside of those associated with FoodNet were added in 2008 and 2012 (up to 140 samples per month). Sampling was further intensified in 2015 when the program was expanded to cover 18 states. By 2017, the total number of samples per month was more than 700. Beginning in 2011, samples of chicken thighs or wings were taken in the rare instance that no chicken breast samples were available. If no alternative part was available, a whole chicken was purchased for sampling, but only the chicken breast was sampled. Data were available for 2002 through 2017 at the time of this study.

Meat and poultry samples were shipped to a laboratory where rinse sampling was conducted on intact chicken and pork samples by adding 250 mL of buffered peptone water to a sterile bag containing the sample and shaking the contents vigorously. For ground meat, samples were stomached at low speed (230 rpm) and then hand massaged until clumps were dispersed. For bone-in samples, a mechanical shaker set to 200 rpm was used following hand massage. The 50-mL aliquot volume for the rinse samples provides a theoretical limit of detection for the assay of 0.02 CFU/mL. The samples were then speciated and tested for resistance to a number of different antimicrobial agents *(20, 46)*.

**CR data.** A series of five privately funded surveys were conducted by the Consumers Union and are referred to as the *Consumer Reports* (CR) data. These studies assess microbial contamination of retail chicken breasts *(1–4, 6)*. Although the details of the sample collection and laboratory methods are not published in peer-reviewed literature, the results of these surveys are of interest in this analysis because the sample collection was from more than 20 different states in the United States for each survey and the locations of sample collection differed on each occasion. The results of these surveys can be used in the comparison of the NARMS and FSIS chicken trends and to assess if trends observed in the NARMS data are biased because inferences drawn from these surveys were not limited to the geographical boundaries of the NARMS catchment area.

**Modeling framework.** The data for the FSIS baselines and privately funded surveys were treated as simple random samples. The percentages of positive samples and confidence intervals were derived by using standard survey methods for proportions *(9)*.

The temporal change in the percentage of positive samples was modeled by using the monthly percentage of pathogen-positive samples. This analysis fitted a penalized B-spline regression model to the data by using a second-order difference penalty *(24, 51)*. This model consists of a monthly component that predicts the percentage of positive samples and the associated 95% confidence intervals. A zero-one indicator variable was added to the model to indicate a change in laboratory or sampling methods that would fundamentally change the probability of a sample testing positive, such as the increase in sample aliquot volume from 25 to 325 g for some of the FSIS ground product sampling programs (where applicable, as explained in the following).

For the penalized B-spline model, a period in which the 95% confidence band about the estimated curve completely contains a line with a slope equal to zero (i.e., a flat line) that indicates no significant change across the period. This visual test, referred to as the horizontal line test, can be used to identify significant trends that are monotonic (increasing or decreasing), nonmonotonic (e.g., cyclic, U-shaped), or nonlinear (e.g., a step function). The model also provides test statistics for significant temporal trends. The analysis was performed by using the mgcv package in R software *(25, 51)*.

We were interested in assessing the agreement between the observed trends in the FSIS verification data and the NARMS data collected at retail. A sign test statistic is used to establish concordance or discordance in the monthly trends in the percentage of positive samples between the FSIS and NARMS data sets. For example, a strong degree of concordance between the FSIS chicken carcass and NARMS retail chicken trends would imply that a monthly increase (or decrease) in carcass contamination corresponds to an increase (or decrease) in contamination of retail chicken breasts purchased by the general population. The statistic is referred to as the concordance index *(16)*, and it is used to measure the fraction of time that the two time series are concurrently increasing or decreasing. Time series models with concordant directions of change are referred to as comoving *(8)*. For this application, let $S_{\mathrm{FSIS},t} = 1$ if the predicted percentage of positive samples from the penalized B-spline model for the FSIS slaughter data increases from month $t - 1$ to $t$, and 0, if there is a decrease. Define $S_{\mathrm{NARMS},t}$ similarly. The concordance index is given by

$$\hat{I}_{\mathrm{FSIS,NARMS}} = \frac{1}{T}\left[\sum_{t=1}^{T} S_{\mathrm{FSIS},t} S_{\mathrm{NARMS},t} + \sum_{t=1}^{T} (1 - S_{\mathrm{FSIS},t})(1 - S_{\mathrm{NARMS},t})\right]$$

The value of $\hat{I}$ is 1 for perfect concordance, 0 for perfect discordance, and 0.5 when the monthly change in the percentage of positive samples are unrelated.

Additional insights into the overall change in the percentage of *Salmonella*-positive samples are possible by considering the FSIS and NARMS trends separately. An overall percentage change was determined by comparing the monthly estimated percent positive value to a standardized value. For the FSIS data, the standardized value was the percent positive value from the first baseline study for the commodity. For example, the FSIS chicken carcass data percent reduction is expressed as

$$R_{\mathrm{FSIS},j} = 100\,\frac{\hat{P}_{\mathrm{FSIS},j} - \hat{P}_{\mathrm{baseline}}}{\hat{P}_{\mathrm{baseline}}}$$

where $\hat{P}_{\mathrm{baseline}} = 20$ is the percentage of *Salmonella*-positive

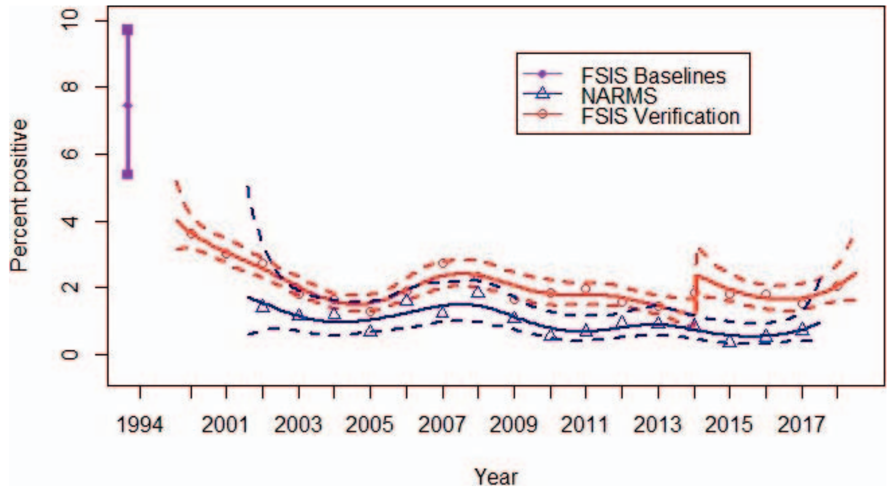



FIGURE 1. *Trends in* Salmonella-*positive ground beef samples from FSIS verification sampling results are depicted for comparison with similar data collected by the NARMS program. In addition, the results from the 1994 FSIS baseline survey of this product are included. Confidence limits (95%) for the FSIS verification and NARMS trends are estimated by using a penalized B-spline regression model. The discontinuity in the FSIS verification data trend in 2014 corresponds to an increase in the sample aliquot size from 25 to 325 g.*

chicken carcass samples from the 1994 to 1995 chicken carcass baseline survey *(29)* and $\hat{P}_{\mathrm{FSIS},j}$ is the percentage of positive samples in month *j*. For the NARMS analysis, there was no obvious standardized value, so the mean of the monthly percent positive across the entire study period was used. Therefore, the $R_{\mathrm{NARMS},j}$ for a particular sampling program is

$$R_{\mathrm{NARMS},j} = 100\frac{\hat{P}_{\mathrm{NARMS},j} - \bar{P}_{\mathrm{NARMS}}}{\bar{P}_{\mathrm{NARMS}}}$$

where $m = 192$ is the number of months of data collection between 2002 and 2017 and $\hat{P}_{\mathrm{NARMS},j}$ is the monthly percent positive such that $\bar{P}_{\mathrm{NARMS}} = \frac{1}{m}\sum_{j=1}^{m}\hat{P}_{\mathrm{NARMS},j}$.

## RESULTS

Comparisons of the data sets for ground beef, chicken, turkey, and pork are presented.

**Ground beef.** FSIS completed an 8-month baseline study for ground beef between August 1993 and March 1994. This study consisted of 563 ground beef samples (25 g each), and the percentage that tested positive for *Salmonella* was 7.5, with a 95% confidence interval (5.4, 9.7).

Beginning in 2000, all slaughter and processing establishments that produced more than 454 kg (1,000 lb) of ground beef per day were assessed under the PR-HACCP verification testing program. As depicted in Figure 1, the percentage of *Salmonella*-positive samples starts at approximately 4%, and the trend decreases monotonically through 2004, at which point the estimated percentage of positive samples had dropped to 1.5%. The horizontal line test for the penalized B-spline model indicates the reduction in the percentage of *Salmonella*-positive samples was statistically significant. Following this 5-year period of constant decline, the percentage of positive samples begins to monotonically increase for nearly 3 years. The horizontal line test indicates a statistically significant increase, with the percentage of positive samples increasing to 2.4% at the end of 2007. After a peak in the early 2007 to 2008 time frame, the estimated percentage of positive samples begins a nearly 6-year period that is either generally decreasing or roughly constant. The overall reduction during this period is statistically significant. At the end of this period, the percentage of positive samples had fallen to less than 1.2%. The estimated percentage of positive samples had a discontinuity in mid-2014 when FSIS increased the aliquot volume from 25 to 325 g. This 13-fold increase in the aliquot volume reduced the limit of detection from 0.04 to 0.003 CFU/g. This change to the assay roughly doubled the observed percentage of positive samples to 2.4%. Following the change, the estimated percentage of positive samples decreases for roughly 2 years before increasing again, but the changes during this period are not statically significant.

The trend in the NARMS retail ground beef samples appears to track well with the estimated trend model on the basis of the FSIS data (Fig. 1). This general agreement is confirmed by a concordance index of 0.78.

The smaller monthly number of samples collected by the NARMS program (a mean of 111, with only 50 per month in the first year) limits our ability to identify any statistically significant trends between 2002 and 2008, but there is a significant overall reduction between 2008 and 2017, with the estimated percentage positive dropping from greater than 1% to between 0.5 and 0.6% during 2015 and 2016. There is a slight, but nonsignificant increase in 2017 (Fig. 1).

An interesting comparison between the FSIS and NARMS data is that the monthly percentage of positive samples is always higher for the FSIS data, with the ratio being $\hat{P}_{\mathrm{FSIS}}/\hat{P}_{\mathrm{NARMS}} = 1.8$ when comparing only the periods across which both programs used a 25-g aliquot volume. There are several possible explanations for this difference, such as a difference in the sensitivity of the laboratory methods, a reduction in viable *Salmonella* for the NARMS data because of possible freezing during transportation or storage, or additional mixing of ground beef from different sources that might occur during handling of the product at retail. This additional mixing step may dilute contamination at retail and result in a reduced recovery of positive samples for NARMS samples.

**Chicken.** The time series of pathogen contamination for chicken is the most complex of the commodities studied. FSIS has conducted three baselines surveys for chicken

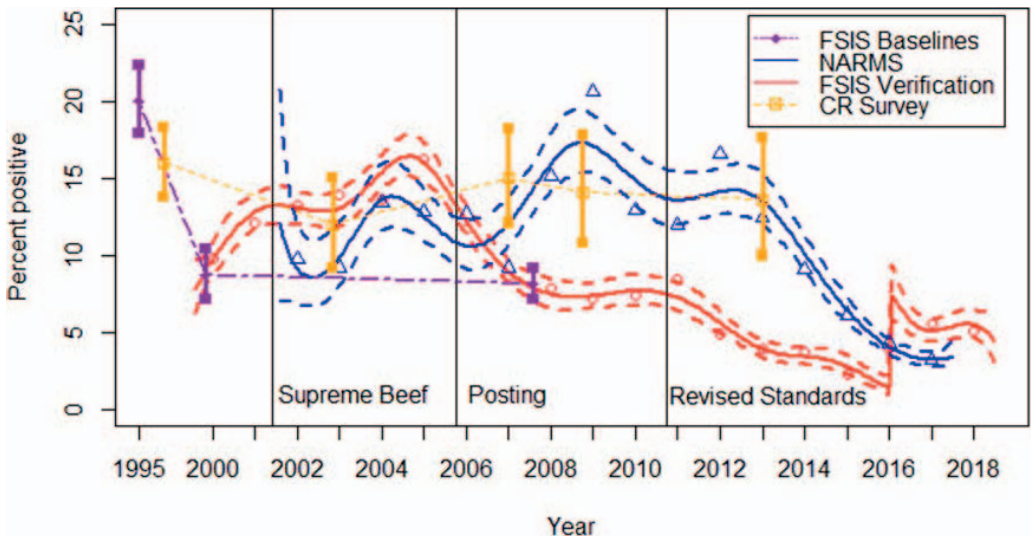



FIGURE 2. *Trends in* Salmonella*-positive chicken carcass rinse samples from FSIS verification sampling results are depicted for comparison with retail chicken breast data collected by the NARMS program. In addition, the results from 1995, 2000, and 2008 FSIS baseline surveys, and privately funded surveys conducted in 1997, 2003, 2007, 2009, and 2013, are included. Confidence limits (95%) for the FSIS verification and NARMS trends are estimated by using a penalized B-spline regression model. The discontinuity in the FSIS verification data trend in 2016 corresponds to a change in the buffered rinse solution. Significant programmatic changes are indicated by vertical lines.*

carcasses across roughly the first decade of the PR-HACCP program. The first nationwide baseline survey *(29)* was conducted during July 1994 to June 1995 and consisted of 1,297 postchill samples, with 20% being *Salmonella* positive *(36)*. The second FSIS baseline collected 1,225 postchill carcass samples *(39)* between November 1999 and October of 2000; 8.7% of the samples tested positive for *Salmonella*. The third baseline study collected 3,275 samples at postchill between July 2007 and June 2008 *(39),* with 8.15% of the samples testing positive for *Salmonella*. The difference in the percentage of *Salmonella*-positive samples between the second and third baselines (2000 versus 2007) was not significant $(P = 0.57)$, while the 56% reduction between the first and second baselines was significant $\left(P < 2 \times 10^{-15}\right)$.

Overlaying the baseline estimates of the percentage of *Salmonella*-positive samples with the penalized B-spline regression model derived from the FSIS verification data demonstrates that although the estimates for the 2000 and 2007 baseline surveys are very similar, *Salmonella* contamination of this commodity changed dramatically between these two periods (Fig. 2). From 2000 through late 2001, the penalized B-spline regression model shows a significant increasing trend. Between late 2001 and late 2003, no trend is evident, but this period is followed by a roughly 2-year period in which the percentage of positive samples increases to an estimated maximum of slightly more than 16% by June 2005. This increase was noted by FSIS previously *(38)*.

From mid-2005 through 2008, the FSIS verification data imply a significant downward trend in *Salmonella* occurrence such that those results nearly match the results of the second baseline study (mid-2007 to 2008). From 2007 through 2011, the percentage of *Salmonella*-positive verification samples is unchanged. There is a significant reduction from 2012 through mid-2016 that follows the introduction of revised chicken carcass performance standards *(41),* with the estimated mean dropping to as low as 1.5%.

The FSIS verification data show a sharp increase in July of 2016 to nearly 8% *Salmonella*-positive when FSIS introduced a neutralizing buffered peptone water rinse to its sampling procedure. This revised rinsate was formulated to address concerns regarding the effects of antimicrobial carryover into rinsates that could reduce the laboratory's ability to recover organisms from samples *(12, 13)*. FSIS has previously reported the increase in *Salmonella* contamination rates on chicken carcasses following the introduction of neutralizing buffered peptone water and suggested that there may have been little to no actual reduction in *Salmonella* contamination of carcasses between roughly 2011 and 2017. A detailed analysis of the effect of the change in rinsate for corporations that operated multiple slaughter establishments found that some corporations saw little to no change in *Salmonella* occurrence, while other corporations saw substantial increases across all their establishments *(50)*. This substantial corporate effect suggests that factors, such as geographically driven environmental differences, may play a lesser role in *Salmonella* contamination on finished carcasses.

Overall the trend in the NARMS retail chicken breast samples is poorly related to the FSIS verification data, with a concordance index of only 0.62 (0.5 is no more agreement than random chance). On closer examination, there are three distinct periods over which the trends are either concordant or discordant. For the NARMS retail sampling data, there was a general increase (i.e., no periods of statistically significant decrease) that is not dissimilar to the trend observed in the FSIS data from the inception of the NARMS program until roughly 2005. Between 2005 and 2006, there is a similar decline in the percentage positive estimates, although the decline for the NARMS program is not statistically significant. The index of concordance for this period (2002 to 2005) is 0.83. In early 2006, there is a clear departure in the trends of the two data sources. For the FSIS verification data, there is a significant trend of reduced carcass contamination following the implementation of categorization in 2006. This coincides with the observed increase in the percentage of chicken slaughter establishments that were passing performance standard following the implementation of the public disclosure of category 3 establishments *(11)*. This trend, however, is not observed in the NARMS retail sampling data, when there was a general increase (i.e., no periods of statistically significant decrease) in the occurrence of *Salmonella*-positive retail samples up to the maximum positive rate for this data source of greater than 17% in early 2009. This disagreement between the FSIS and NARMS trends is highlighted by the low concordance index of 0.17 between 2006 and 2009. This indicates that as the occurrence of *Salmonella*-positive carcasses at slaughter appeared to decrease, and consumer exposure was increasing. This period of disagreement ends in roughly 2010, with the NARMS and FSIS trends demonstrating either a decline or no significant increase through the end of data collection. The 8-year period of general agreement between 2010 and 2017 results in a concordance index of $\hat{I}_{\mathrm{FSIS,NARMS}} = 0.74$.

Comparing the NARMS trend with the CR surveys demonstrates that both of these more direct measures of consumer exposure generate similar estimates, as demonstrated by the confidence intervals for the CR estimates generally overlapping with the estimated trend line for the NARMS data. Of the five CR surveys, the only statistically significant difference in the estimated percentage of positive samples *(22)* is the reduction from 16 to 12% between 1997 and 2003 ($P = 0.049$). The close agreement between the NARMS and CR retail chicken surveys also suggests that limiting the NARMS survey frame to the FoodNet catchment areas did not appear to bias the inferences drawn from those data.

The comparison of the NARMS and FSIS verification sampling data sets provides unique insight into the onset of problems with antimicrobial contamination in poultry rinse samples. Pathogens on poultry carcasses and parts are predominantly the result of contamination of the skin and outer surface or the internal cavity of the carcass. Only a modest portion of the microbial flora on these surfaces is removed during rinse sampling *(19)* and sent to the laboratory. The surface area of the NARMS breast sample is only a small fraction of the total surface area of the carcass, so if the sensitivities of the laboratory methods are similar, it is reasonable to expect the percentage of positive samples to be lower for the NARMS retail samples, which is the case during two time periods: from the inception of NARMS sampling in 2002 through roughly the end of 2006 and from the introduction of neutralizing buffered peptone water (2016) through the end of these data sets (2018). Otherwise, the percentage of positive samples for NARMS samples is greater than that for the FSIS verification samples. Reduced percentages of positive FSIS verification samples relative to NARMS results suggest that the problem of antimicrobial carryover into FSIS verification carcass samples was suppressing recovery of *Salmonella* that were rinsed off the carcasses *(50)*. Certain antimicrobials applied to carcasses during or immediately after the chiller are thought to remain active against *Salmonella* during transit to the laboratory, thus negatively affecting potential pathogen recovery. In contrast, chicken sampled at retail has not undergone recent antimicrobial treatment, and those rinsates are not likely to contain active compounds that could interfere with *Salmonella* recovery.

**Turkey.** The only FSIS baseline study for ground turkey was conducted between March 1995 and November 1995 *(32)*. A total of 296 samples were analyzed, and 49.9% were positive for *Salmonella,* with a 95% confidence interval (0.44, 0.56).

The penalized B-spline regression model derived from the FSIS verification data demonstrates a starting percent positive value of roughly 30%, with the horizontal line test indicating a statistically significant reduction between 2000 and 2002 before stabilizing with no significant change between roughly 2002 and 2006 (Fig. 3). There is another roughly 2-year period of significant reduction between 2006 and 2008, which is again followed by a 4- to 5-year period of no significant change. The effect of increasing the sample aliquot in mid-2013 from 25 to 325 g results in the observed discontinuity, after which there is a third 2-year period of significant decline, followed by no significant changes through the end of data collection.

The penalized B-spline regression model derived from the NARMS retail ground turkey data indicates a significant increasing trend between the start of sample collection and roughly 2008, at which point the trend is reversed. From the estimated peak of greater than 17% *Salmonella* positive in 2008, there is a roughly 6-year period in which the estimated percentage of positive samples is monotonically decreasing. The estimated *Salmonella* percent positive then stabilizes at slightly less than 6% for the remainder of the survey. The single CR survey *(5)* is in general agreement with the NARMS estimated trend.

The agreement between the penalized B-spline regression model derived for the FSIS and NARMS ground turkey data is poor, with an index of concordance of $\hat{I}_{\mathrm{FSIS,NARMS}} = 0.43$. The concordance index is 0 from 2002 through 2008 (i.e., perfect discordance). From 2009 through the end of sampling, both data sources indicate a general decline in *Salmonella* contamination, with the concordance index being $\hat{I}_{\mathrm{FSIS,NARMS}} = 0.69$.

Another interesting feature of the data set is that the relationship between $\hat{P}_{\mathrm{FSIS}}$ and $\hat{P}_{\mathrm{NARMS}}$ is not consistent across the study period, as was the case with ground beef. When the NARMS program was initiated in 2002, the ratio of the estimated percentage of *Salmonella*-positive samples was $\hat{P}_{\mathrm{FSIS}}/\hat{P}_{\mathrm{NARMS}} = 2.0$. By 2008, this relation was reversed, with a minimum value of $\hat{P}_{\mathrm{FSIS}}/\hat{P}_{\mathrm{NARMS}} = 0.74$.

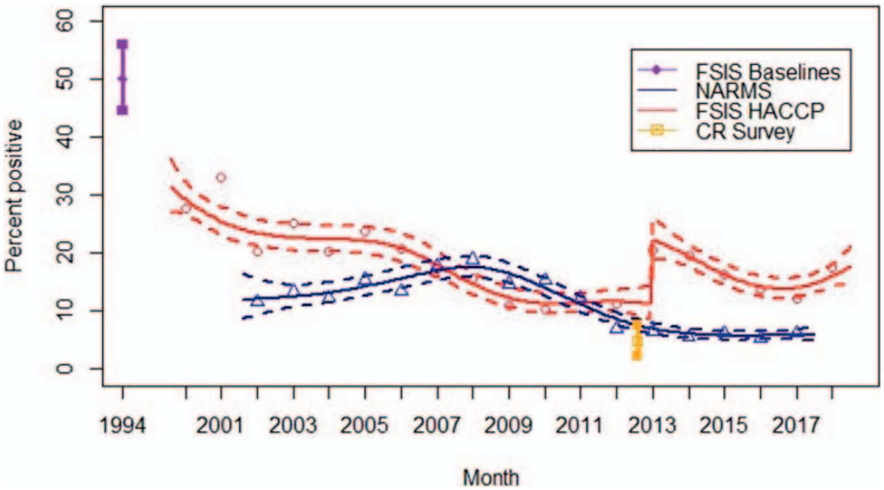



FIGURE 3. *Trends in* Salmonella*-positive ground turkey samples from FSIS verification sampling results are depicted for comparison with similar data collected by the NARMS program. In addition, the results from the 1994 FSIS baseline survey of this product are included, as are the results of a privately funded survey conducted in 2012. Confidence limits (95%) for the FSIS verification and NARMS trends are estimated by using a penalized B-spline regression model. The discontinuity in the FSIS verification data trend in 2013 corresponds to an increase in the sample aliquot size from 25 to 325 g.*

This relationship again reversed so that $\hat{P}_{\mathrm{FSIS}}/\hat{P}_{\mathrm{NARMS}} = 1.6$ just prior to the increase in the sample aliquot volume in 2013.

**Pork.** FSIS has completed three baseline surveys of pork carcasses. The first baseline survey collected 2,112 samples from market hogs between April 1995 and March 1996 *(30)*. The sample consisted of a total of 300 $cm^2$ of surface tissue (i.e., skin) removed from the carcass, with approximately 100-$cm^2$ tissue collected from the belly, ham, and jowl from carcasses that had been chilled for a minimum of 12 h. For this survey, 8.7% of samples, with a 95% confidence interval (7.5, 9.9), were *Salmonella* positive. The second baseline survey was conducted from June 1997 to May 1998 and included 2,127 sponge samples of swine carcasses *(34)*. A template (10 by 10 cm) was used to collect a sponge sample covering 300 $cm^2$ from the same three locations as sampled in the first baseline survey. Of the 2,127 samples collected, 147 were *Salmonella* positive: 6.9%, with 95% confidence interval (5.9, 8.0). The third FSIS baseline study was conducted from August 2010 through July 2011 and used the same sponge sampling protocol as the second survey. Of 1,960 samples collected, 53 were *Salmonella* positive: 2.7%, with 95% confidence interval (2.0, 3.3) *(42)*.

The penalized B-spline regression model derived from the FSIS verification data demonstrates statistically significant reductions in carcass contamination from the beginning of sampling through 2002 (Fig. 4). The line test indicates a period of no significant change from approximately 2003 through 2007. There is another 2-year period of significant reduction, followed by a final period of no significant change up to the time when this sampling program was discontinued in late 2011.

The trend model for the NARMS data is unique because it is the only commodity to demonstrate no statistically significant change in contamination over the entire sampling period (Fig. 4). This commodity had the lowest level of contamination of the commodities tested by NARMS, with roughly 1.2% testing positive.

The concordance index was $\hat{I}_{\mathrm{FSIS,NARMS}} = 0.51$, indicating that there is no association between changes in the estimated monthly percentage of positive samples for the two data sets.

**FSIS and NARMS summary.** The percent change in *Salmonella*-positive proportions relative to the initial FSIS

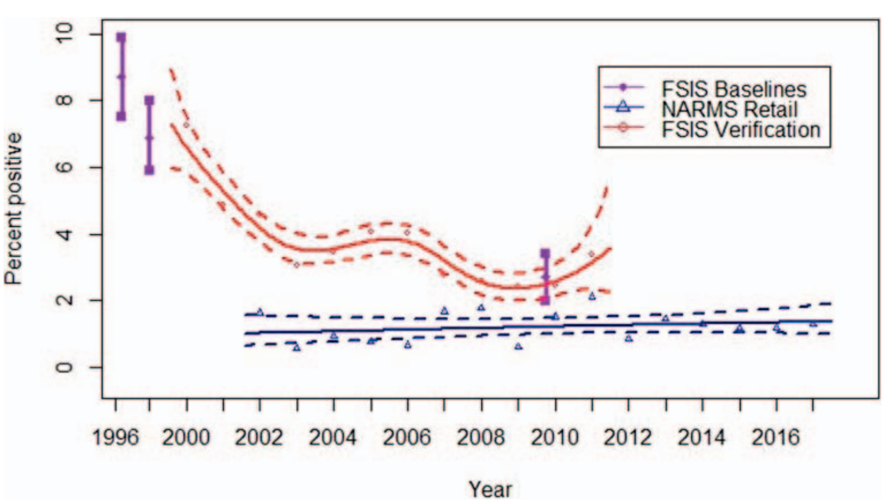
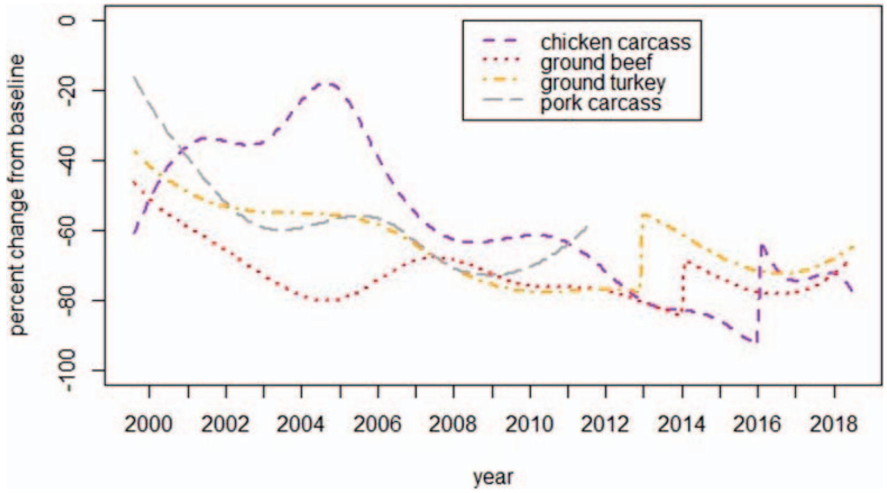



FIGURE 4. *Trends in* Salmonella*-positive pork samples from FSIS verification sampling results are depicted for comparison with similar data collected by the NARMS program. In addition, the results from 1996, 1998, and 2010 FSIS baseline surveys of this product are included. Confidence limits (95%) for the FSIS verification and NARMS trends are estimated by using a penalized B-spline regression model.*

FIGURE 5. *The percent change in* Salmonella*-positive proportions relative to initial FSIS baseline surveys* (R*FSIS*) *is shown for FSIS verification data of chicken, ground beef, turkey, and pork carcasses.*




baseline surveys ($R_{\mathrm{FSIS}}$) is consistently negative for all four FSIS commodities (Fig. 5). Additionally, apart from chicken carcasses, there is a general reduction from 2000 through the end of 2018 for the other commodities. The overall reduction exceeds 60% for the last 3 years (2016 to 2018) for chicken, ground beef, and turkey; this occurs despite the 13-fold increases in aliquot volume for ground beef and turkey.

The chicken carcass sampling data for the 2000 to 2005 time frame suggest that much of the improvement made since the introduction of the PR-HACCP rule was lost during this 6-year period. This increasing trend was reversed in 2005, and there were drastic reductions, but these reductions might have resulted from antimicrobial carryover into the rinsate. The overall reduction for this commodity was roughly 70%, assuming the introduction of neutralizing buffered peptone water adequately addressed the issue of antimicrobial carryover.

For the NARMS retail data, the percent change in *Salmonella*-positive proportions relative to the mean (calculated for the entire 2002 to 2018 period; $R_{\mathrm{NARMS}}$) demonstrates a more complicated pattern of *Salmonella* contamination for all four commodities (Fig. 6). The patterns suggest that monthly contamination was above the average from 2002 to 2007 for ground beef, ground turkey, and chicken, although there was a slight reduction initially for chicken. A period of peak contamination occurs between 2007 and 2009, and these peaks are roughly 50% above the overall mean for beef, chicken, and turkey. This suggests a period of peak consumer exposure, and the increase is coincident with the observed increases in the relative rates of laboratory-confirmed cases of salmonellosis, compared with the 1996 to 1998 rates reported by the Centers for Disease Control and Prevention's FoodNet system *(45)*.

Following the peak period, there are statistically significant reductions in *Salmonella* contamination for the three commodities. Although *Salmonella* contamination in ground beef appears to rapidly increase in the last 2 years, this increase is not statistically significant. Of the three

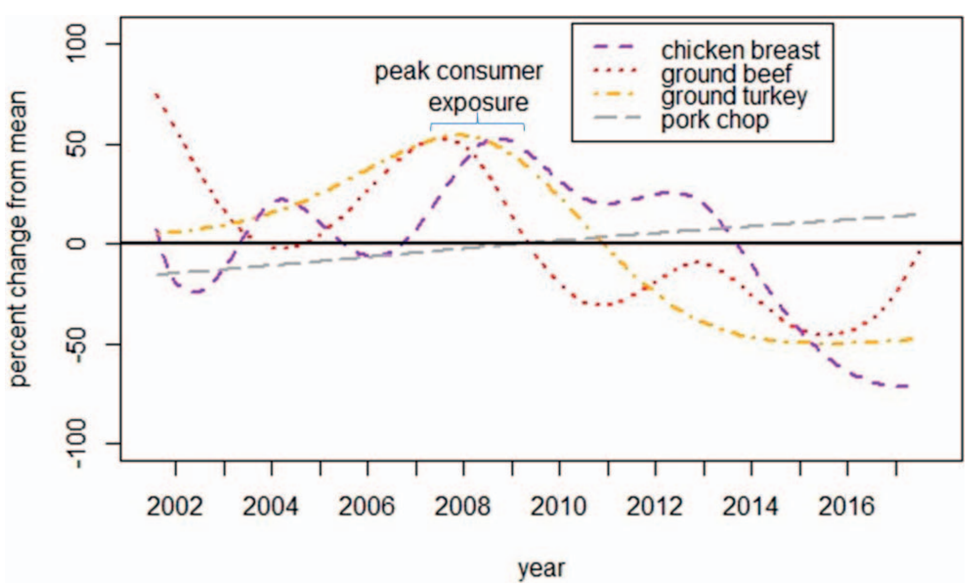



FIGURE 6. *The percent change in* Salmonella*-positive proportions relative to the overall mean (across 2002 to 2018;* R*NARMS*) *is shown for NARMS retail sampling data of chicken breast, ground beef, turkey, and pork chops.*

products, chicken shows the greatest overall maximum percent change from the mean (71%). Although pork appears to increase, this increase is not significant.

## DISCUSSION

This study cannot determine causality or attribute any portion of the changes in *Salmonella* contamination directly to the implementation of the PR-HACCP program. Specifically, the relationships between the timing of federal food safety policies and changes in the occurrence of *Salmonella* cannot be inferred and is likely too simplistic by not accounting for many other potential contributing factors. Nevertheless, the observed patterns can suggest possible hypotheses for the underlying factors that led to the changes.

The PR-HACCP legislation intended to improve the microbiological safety of regulated products in establishments inspected by FSIS. That legislation also supported baseline surveys and performance standards testing; these programs enabled systematic review of microbial contamination on meat and poultry in the United States. It would be difficult to argue that the substantial reductions in *Salmonella* contamination observed between the initial baseline studies conducted in the mid-1990s and the period following PR-HACCP implementation (through the early 2000s) did not result in reductions in exposure to foodborne pathogens for all product pathogen pairs that were actively regulated under the PR-HACCP. Public health surveillance data generally support this conclusion as well, with multiple studies reporting case rate reductions in the late 1990s *(21, 24, 44, 49)*. Further evidence of the reduction in *Salmonella* contamination is highlighted by the substantial reduction in *Salmonella* occurrence on chicken carcasses compared with the 1967 and 1979 studies (28.6 and 36.9%, respectively) *(15)*. However, the increases in *Salmonella*-positive samples observed in the FSIS and NARMS data after 2002 are of concern. One potential contributing factor, which occurred concurrently with this increase, was the Supreme Beef lawsuit in 2001 *(18)*. The lawsuit subsequently limited authority of FSIS to regulate *Salmonella*. The retail sampling suggests that for three of the four commodities studied, *Salmonella* exposures appear to consistently increase from 2002 to new peaks that occurred in the 2007 to 2009 time frame. This peak period of consumer exposure was coincident with an observed increase in the relative rates of laboratory-confirmed cases of salmonellosis, compared with the 1996 to 1998 rates reported by Centers for Disease Control and Prevention's FoodNet system *(45)*.

Following the Supreme Beef lawsuit, FSIS explored several nonregulatory options to encourage reductions in microbial contamination. FSIS considered a more market-based approach that included making the information on each establishment's *Salmonella* test results publicly available *(14, 23, 37, 38),* whereas FSIS only shared test results with the establishment prior to 2006. It was thought that the public disclosure of *Salmonella* testing results would allow consumers, processors, and retail outlets to base purchasing decisions on the relative safety of each establishment, which in essence, introduced competition on the basis of safety *(23, 47)*. FSIS increased the frequency at which it reported aggregated *Salmonella* test results *(38),* and in 2010, the posting of individual establishment test results was finalized and implemented *(40, 41)*.

Following the 2007 to 2009 peaks in *Salmonella* contamination, there was an extended period of general decline in *Salmonella* contamination for all commodities other than pork. For chicken in particular, there was a precipitous drop in *Salmonella* observed in the NARMS data that began in 2013 and continued through the end of the study period. This reduction in *Salmonella* contamination could potentially be attributed to multiple factors, such as the introduction of new performance standards for chicken parts, the public disclosure of establishment testing information, the assignment of establishments to categories that clearly indicated whether an establishment was passing or failing the performance standard, and new food safety requirements from major retailers *(48)* and food service providers *(10)*.

The concordance indices for beef indicate good agreement between the trends observed in the FSIS and NARMS data. There is a similarly good agreement between FSIS and NARMS data for chicken and turkey from roughly 2010 through 2017. The agreement between the two data sources for pork is no better than random chance. This may highlight the need to more closely match the sample unit collected at the two locations in the farm-to-table continuum. The FSIS pork carcass sample is a measure of exterior contamination prior to the fabrication of the carcass into marketable products. In contrast, the NARMS sample is a relatively small, individual piece of internal muscle tissue that is most likely to be contaminated through a cross-contamination event during the fabrication process. Neither of these sample types capture other routes through which *Salmonella* can contaminate pork products, such as lymphatic tissue that may be included in ground pork products *(7)*. Both the FSIS and NARMS sampling programs might be able to more accurately monitor pork contamination by sampling a similar product that is more likely to be contaminated, such as ground pork. For example, FSIS completed a baseline study for ground pork in 1998 and found 30% of all samples *Salmonella* positive *(33)*. A more recent survey of ground pork industry in the United States demonstrates a nearly identical percentage of positive samples, 28.9% with the confidence interval (24.1, 33.8), though the aliquot volume has increased *(27)*.

The likely driver of the observed initial reductions in contamination was the more draconian approach of mandated reductions in the occurrence of *Salmonella* immediately following the initial implementation of the rule. The attempt of FSIS to enforce mandatory reductions in *Salmonella* contamination ended with the Supreme Beef lawsuit in 2001 *(18)*. In the aftermath of the Supreme Beef lawsuit, there was a period in which there were only limited consequences for establishments failing to adhere to the performance standards. This period coincides with the increasing trend in the NARMS retail samples for chicken, beef, and turkey. A potential factor driving subsequent reductions in contamination was the public dissemination of testing results. The availability of these results to inform the purchasing decisions of distributors and food service corporations is thought to influence both price and the ability to market product. The lack of an observable reduction in *Salmonella* prevalence for pork may suggest that the absence of performance standards (and the incentives for improvement they provide) may have reduced the beneficial effects of implementing a HACCP program for this commodity.

There has been an expectation that over time, the presence of *Salmonella* would decrease as control measures were put in place, but the question remains: how low would one expect this to be with the current production practices? Although there is no definitive answer to this question, note that the FSIS performance standards have always been derived such that a substantial fraction of the establishments producing the commodity have a lower *Salmonella* occurrence than implied by the standard.

Although the intent of the NARMS sampling program was to study antimicrobial resistance, these analyses demonstrate the additional utility of the NARMS program for corroborating that improvements observed at slaughter and processing establishments are having the intended effects on public health. We highlight potential contributors that may have affected the observed changes in the occurrence of *Salmonella* in meat and poultry products between 2000 and 2017; however, it cannot be inferred that there is a causal relationship, given the many other potential contributing factors.

A formal framework for identifying and investigating discrepancies between FSIS and NARMS *Salmonella* sampling data would be beneficial, as would extending the monitoring of foodborne pathogens to preharvest activities, as well as cases of human illness.

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## SUPPLEMENTAL MATERIAL

Supplemental material associated with this article can be found online at: https://doi.org/10.4315/JFP-20-126.s1

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