
DENISE R. EBLEN, KRISTINA E. BARLOW,* AND ALECIA LAREW NAUGLE


ABSTRACT

The U.S. Food Safety and Inspection Service (FSIS) pathogen reduction—hazard analysis critical control point systems (HACCP) systems; final rule, published in 1996, established Salmonella performance standards for broiler chicken, cow and bull, market hog, and steer and heifer carcasses and for ground beef, chicken, and turkey meat. In 1998, the FSIS began testing to verify that establishments are meeting performance standards. Samples are collected in sets in which the number of samples is defined but varies according to product class. A sample set fails when the number of positive Salmonella samples exceeds the maximum number of positive samples allowed under the performance standard. Salmonella sample sets collected at 1,584 establishments from 1998 through 2003 were examined to identify factors associated with failure of one or more sets. Overall, 1,282 (80.9%) of establishments never had failed sets. In establishments that did experience set failure(s), generally the failed sets were collected early in the establishment testing history, with the exception of broiler establishments where failure(s) occurred both early and late in the course of testing. Small establishments were more likely to have experienced a set failure than were large or very small establishments, and broiler establishments were more likely to have failed than were ground beef, market hog, or steer-heifer establishments. Agency response to failed Salmonella sample sets in the form of in-depth verification reviews and related establishment-initiated corrective actions have likely contributed to declines in the number of establishments that failed sets. A focus on food safety measures in small establishments and broiler processing establishments should further reduce the number of sample sets that fail to meet the Salmonella performance standard.

The publication, “Pathogen reduction; hazard analysis and critical control point (HACCP) systems; final rule,” by the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) in 1996 (14), marked a new direction for the inspection of meat and poultry in the United States. Previously, federally inspected meat and poultry establishments were required to follow certain processing measures prescribed by the FSIS to ensure food safety under a “command-and-control” system. This approach left little leeway for an establishment to develop measures applicable to its unique situation. Under the pathogen reduction (PR)—HACCP final rule, FSIS inspection personnel verify the adequacy of the food safety systems adopted by individual establishments. The PR-HACCP final rule has four components: formulation of standard operating procedures for sanitation, development of establishment-specific HACCP plans, testing by establishments for Escherichia coli, and testing by the FSIS for Salmonella in meat and poultry products.

The FSIS chose Salmonella as the target pathogen for a number of reasons: (i) Salmonella is among the most common bacterial causes of foodborne illness; (ii) it is commonly present in many mammal and bird species, including all of the meat and poultry product classes produced under federal inspection, at frequencies that permit changes to be detected and monitored; (iii) there are methodologies available to recover Salmonella from a variety of meat and poultry products; and (iv) intervention strategies aimed at reducing contamination of raw products with feces and other sources of Salmonella will likely be effective against other foodborne pathogens (14). In the PR-HACCP final rule, Salmonella performance standards were defined for selected meat and poultry product classes, including carcasses of broiler chickens, cows and bulls, market hogs, and steers and heifers and ground beef, chicken, and turkey meat based on prevalence as determined in nationwide microbiological baseline studies (15). Mandatory testing for Salmonella was phased in from 1998 through 2000, based on establishment size, in federally inspected establishments that produce one or more of the selected product classes. In the FSIS Salmonella testing program, product samples are collected each day of production in a series of sets. The sets differ in size according to product class (Table 1). A sample set fails when the maximum number of positive samples allowable to meet the performance standard for each particular product class is exceeded.

According to the PR-HACCP final rule, the repeated failure of Salmonella sample sets from an establishment is indicative of sanitation or processing issues that could compromise the safety of the meat and poultry produced. Therefore, the FSIS uses the results of the Salmonella testing program to direct additional testing and investigation resources toward establishments with failed sets (14). If mul-
multiple set failures occur, the FSIS performs an assessment of the food safety systems at the establishment; this process was formalized as in-depth verification reviews (IDVs) in 2001 (18). IDVs were replaced by incident investigation team reviews (IITs) in 2005 (19). Analyzing Salmonella testing data from establishments where IDVs have been held can provide valuable information regarding the effectiveness of the FSIS and related establishment responses to Salmonella sample set failures.

The FSIS has reported that most PR-HACCP Salmonella sample sets are passed (13, 16); however, the present report is the first in which the performances of individual establishments are evaluated. Examination of the factors affecting how well establishments control Salmonella can provide valuable information on where to direct food safety resources, how to develop new testing programs, and how best to target efforts to protect public health. The objectives of this study were to characterize establishments tested as part the FSIS Salmonella testing program from 1998 through 2003, identify establishment-related factors associated with sample set failure, describe changes in establishment performance over time, and examine the effectiveness of IDVs. In a companion article (11), the factors affecting set performance over the same period are described.

**MATERIALS AND METHODS**

**PR-HACCP sample sets.** Product samples in the Salmonella testing program were collected in sets. Set sequence code A sets were initiated at randomly selected federally inspected establishments that produced one or more of the selected product classes. If the A set passed (i.e., did not exceed the maximum number of positive samples allowable in a set), the establishment was subjected to randomly scheduled collection of Salmonella A sets. Failure of a C set was required to perform further corrective actions by the establishment, and scheduling of collection of a D set.

**Sample collection.** Once an establishment was selected to provide a PR-HACCP Salmonella sample set, samples were collected by FSIS in-plant personnel on consecutive days of production, excluding weekends and nonproduction days, until the set was completed (14). For steer, heifer, cow, and bull carcasses, samples were collected after 12 h of chilling from three 100-cm² areas using sponges moistened with 30 ml of buffered peptone water (BPW). For broiler chickens, whole bird rinses with 400 ml of BPW were performed following immersion of the carcass in the chill tank or equivalent for air chilling. For ground product (beef, chicken, and turkey), 25-g samples were collected before final packaging, when possible before the addition of spices or seasonings. All samples were shipped under refrigeration via overnight delivery to an FSIS laboratory for analysis.

**Microbiological analyses.** A combination of enrichment, plating, and biochemical testing was performed to select for and confirm the presence of Salmonella. The FSIS Microbiology Laboratory Guidebook describes laboratory procedures for Salmonella analysis (17). Samples from carcass swabs representing 300 cm² of surface area, 30 ml of whole bird rinse fluid, or 25 g of raw ground product were enriched in BPW. After this initial nonselective enrichment, samples were subjected to a screening test. In October 2003, this immunoassay screening system was replaced with a BAX System PCR assay (DuPont Qualicon, Wilmington, Del.). Samples with presumptive positive results on the screening test were streaked on brilliant green sulfa agar and double modified lysine agar or xylose lysine tergitol 4 agar. As many as three presumptive colonies per sample were subjected to additional biochemical and serological testing until Salmonella was confirmed for one of the selected isolates. One confirmed Salmonella isolate, representing the predominant colony morphology of the positive sample, was serotyped.

**Statistical methods.** Sample results from 4,607 PR-HACCP Salmonella sample sets collected from 1998 through 2003 (11) were grouped by establishment based on their FSIS-assigned establishment number. A single unique identification number was assigned to establishments with more than one inspection number (i.e., with both meat and poultry inspection numbers).

The number of establishments was determined for each of the following variables: set sequence (A, B, C, or D), establishment size (large, ≥500 employees; small, ≥10 but <500 employees; or very small, <10 employees or less than $2.5 million in annual sales), year of set completion (1998 through 2003), and region. Regions were defined as northcentral (Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, and Wisconsin), northeast (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, D.C.), southeast (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Puerto Rico, and the U.S. Virgin Islands), southwest (Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas), and west (Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, and the Northern Marianas Islands) (10). Establishments with PR-HACCP Salmonella sample

**TABLE 1.** Salmonella performance standards as defined by the pathogen reduction hazard analysis critical control points final rule (14)

<table>
<thead>
<tr>
<th>Product class</th>
<th>Performance standard (% samples positive for Salmonella)</th>
<th>No. of samples tested per set</th>
<th>Maximum no. of positive samples to achieve standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broiler chickens</td>
<td>20.0</td>
<td>51</td>
<td>12</td>
</tr>
<tr>
<td>Cows and bulls</td>
<td>2.7</td>
<td>58</td>
<td>2</td>
</tr>
<tr>
<td>Ground beef</td>
<td>7.5</td>
<td>53</td>
<td>5</td>
</tr>
<tr>
<td>Ground chicken</td>
<td>44.6</td>
<td>53</td>
<td>26</td>
</tr>
<tr>
<td>Ground turkey</td>
<td>49.9</td>
<td>53</td>
<td>29</td>
</tr>
<tr>
<td>Market hogs</td>
<td>8.7</td>
<td>55</td>
<td>6</td>
</tr>
<tr>
<td>Steers and heifers</td>
<td>1.0</td>
<td>82</td>
<td>1</td>
</tr>
</tbody>
</table>

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sets from more than one product class were counted separately for each product class represented in the analysis.

Establishments that never had a set failure were referred to as control establishments, and establishments for which one or more sets failed were referred to as case establishments. For establishments that produced more than one product class, a set failure in any product class resulted in classification as a case establishment.

Once sets were grouped by establishment, a chronological PR-HACCP Salmonella testing history for each establishment was created by ordering sets by completion date. For establishments with PR-HACCP Salmonella sets from more than one product class, a separate testing history was created for each product class. Within each testing history, the number of sets contributing to the series was counted, and the time(s) of set failure determined. The timing of set failure(s) within an establishment’s testing history was described with six categories. Early failures occurred during the first half of the establishment’s testing history (e.g., fail, pass, pass, pass, pass). Middle failures occurred midway in the establishment’s testing history for those with an odd number of sets (e.g., pass, pass, fail, pass, pass). Late failures occurred during the second half (e.g., pass, pass, pass, pass, fail). Results reported as “both” indicated establishments with failures occurring in both the first and second halves (e.g., fail, pass, pass, pass, fail). Categories were also defined for testing histories that contained only failed sets (only failed) and for control establishments that contained only passed sets (only passed).

Logistic regression models were used to compare case and control establishments (PROC GENMOD, SAS version 9.1, SAS Institute, Inc., Cary, N.C.). Variables representing product class, establishment size, region, and the production of multiple product classes (yes or no) were evaluated for an association with the failure status of establishments. All variables with type 3 score statistics \( P \leq 0.15 \) in univariable models were included in a multivariable model. Insignificant variables were removed in a stepwise fashion until all variables retained in the final model had type 3 score statistics \( P \leq 0.05 \). Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated to compare the odds of establishment failure between the levels of categorical variables while controlling for other variables included in the final model.

**IDVs.** IDVs were performed by multidisciplinary FSIS teams consisting of HACCP and regulatory specialists, food technologists, microbiologists, and other experts as needed. During IDVs, all aspects of the establishment’s food safety systems were assessed, including HACCP plans, sanitation standard operating procedures, microbiological sampling methods and results, the establishment’s scientific basis for decision making, validation and verification procedures, and associated documentation. A report was written based on the review, which formed the basis for FSIS regulatory action and establishment-initiated corrective actions. To determine whether the IDV process led to improvements in establishment performance in the PR-HACCP Salmonella testing program, set results were compared before and after IDVs were held. Performance was measured as a percentage of the maximum number of positive results to meet the performance standard for each set by calculating a standardized percent-positive (SPP) value using the following formula:

\[
\text{Standardized percent-positive value} = \frac{\text{(no. of Salmonella-positive samples in the set)}}{\text{(maximum no. of positive samples to meet the performance standard)}} \times 100
\]

This value was calculated for each product class and was used for comparison of performance across all establishments where IDVs were held.

**RESULTS**

**Description of establishments.** A total of 1,584 federally inspected establishments met the criteria for analysis, i.e., produced the selected products and were included in the *Salmonella* testing program during the time period examined (1998 through 2003). The majority of establishments in the sampling program were defined as small \((n = 703)\) or very small \((n = 658)\); 223 large establishments also were included. Establishments included in the analysis were located throughout the United States: 404 in the northeast, 322 in the west, 320 in the southeast, 272 in the southwest, and 266 in the northcentral region. Broiler chicken establishments were concentrated in the southeast (50% of all broiler establishments). Ground beef establishments were primarily located in the northeast (29%) and west (23%).

The PR-HACCP sampling program expanded from 110 establishments where completed sets were collected in 1998 to 983 such establishments in 2003: not every establishment was sampled every year, although some establishments were sampled more than once in a year. One or more A sets were collected at each of the 1,584 federally inspected establishments, B sets were collected at 251 establishments, C sets were collected at 63 establishments, and D sets were collected at 8 establishments.

Most establishments \((n = 1,457)\) produced a single product class; however, 115 establishments produced two product classes and 12 establishments produced three product classes. Therefore, when analyses were performed by product class, 1,723 observations were considered: \((1,457 \times 1) + (115 \times 2) + (12 \times 3)\). Ground beef was the most commonly produced product class \((n = 1,021)\), 64.5% of establishments included in the analysis), followed by market hogs \((n = 258, 16.3%)\), broiler chickens \((n = 206, 13%)\), cows and bulls \((n = 107, 6.8%)\), steers and heifers \((n = 83, 5.2%)\), ground turkey \((n = 33, 2.1%)\), and ground chicken \((n = 15, 0.9%)\) (Table 2).

The number of consecutive *Salmonella* sets collected within a testing history (separate testing histories for each product class produced at an establishment) was examined. Over the course of the study period, large establishments had a median of five *Salmonella* sets collected (range, one to nine sets); small establishments had a median of three sets collected (range, one to seven sets), and very small establishments had a median of one *Salmonella* set collected (range, one to five sets). The majority of establishments passed all of their *Salmonella* sets \((n = 1,282)\) and were classified as control establishments. Of the 302 case establishments (those that failed one or more sets), 192 failed only one set, 87 failed two sets, 17 failed three sets, 5 failed four sets, and one establishment failed five sets.

**Timing of set failures in the testing history.** Generally, more establishments reported testing histories with early failures \((n = 151, 50\% \text{ of all case establishments})\) than reported histories with late failures \((n = 62, 20.5\% \text{ of all establishments})\).
case establishments) (Fig. 1); this observation was consistent across all three establishment sizes (data not shown). However, an exception was the broiler product class, where a similar number of testing histories with early and late failures was found, i.e., 25 (12.1%) of all broiler establishments had failed early sets and 24 (11.7%) had failed late sets. Additionally, 15 broiler establishments (7.3%) had set failures both early and late in their testing histories.

Factors associated with establishment performance. Product class and establishment size were associated with an establishment set failure status (type 3 score statistic chi-square \( P < 0.001 \)). After controlling for these variables, the production of multiple product classes and the region where the establishment was located were not associated with an establishment’s failure of one or more sets over time (\( P < 0.85 \); data not shown). Table 3 presents the ORs and 95% CIs that describe the relationship between these variables and an establishment’s failure status as estimated by this model:

The final logistic regression model estimated greater odds of experiencing one or more set failures in establishments producing broiler carcasses relative to those producing ground beef, market hogs, and steers and heifers (Table 3). The odds of failure of one or more sets were greater for large establishments relative to very small establishments and for small establishments relative to very small establishments. When large establishments were used as the referent, small establishments were 1.7 times more likely to experience one or more set failures than were large establishments (95% CI, 1.2 to 2.6).

IDVs. Of the 302 establishments with failed A sets during the examined period (1998 through 2003), 82 establishments also had failed B sets. The IDV process was initiated by the FSIS in 2000 to address Salmonella contamination issues at establishments with failed B sets. IDVs for PR-HACCP Salmonella set failure were held in 60 of these establishments (3.8% of all establishments in the sampling program). The remaining 22 establishments with failed B sets before implementation of IDVs in 2000 were not included in this analysis.

IDVs were held in all regions of the country: 15 each in the southeast, southwest, and west, 8 in the northcentral region, and 7 in the northeast. The greatest number of IDVs were held in establishments producing ground beef (\( n = 19 \)), market hogs (\( n = 17 \)), and broiler chickens (\( n = 11 \)) (1.9, 6.6, and 5.3% of establishments producing each product class, respectively).

Set performance was measured by comparing the number of positive samples to the maximum number of positive samples allowed in a set (SPP value). Examination of the set performance of establishments where IDVs were held revealed that for A and B sets, SPP values were above 100%, meaning that the maximum number of positive samples allowed in a set was exceeded (i.e., the sets were failed) (Fig. 2). SPP values were highest for cow and bull establishments and lowest for ground turkey establishments. Establishments tended to pass C sets after an IDV, as indicated by SPP values near or less than 100% (Fig. 2).

**DISCUSSION**

Examination of establishment performance in the PR-HACCP Salmonella testing program provides an opportunity to consider the scope of the program and its successes and to identify areas where adjustments may be made by both the FSIS and the meat and poultry industry to further reduce the occurrence of Salmonella sample set failures. This testing program was not statistically designed to reflect the nationwide prevalence of Salmonella, and production volume is not considered in the random choice of establishments to be sampled. However, the design of the program does provide impetus for all establishments to strive to maintain control of Salmonella in their products, if only to avoid being targeted for additional nonrandom testing.

Ground beef, market hogs, and broiler chickens were produced by the greatest number of establishments included in the PR-HACCP Salmonella sampling program. Although there were fewer large establishments than small or very small establishments, a greater number of consecutive sets

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**TABLE 2. Number of establishments at which Salmonella sample sets were collected, 1998 through 2003, by product class and establishment size**

<table>
<thead>
<tr>
<th>Product class</th>
<th>Large</th>
<th>Small</th>
<th>Small</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broiler chickens</td>
<td>128</td>
<td>67</td>
<td>11</td>
<td>206</td>
</tr>
<tr>
<td>Cows and bulls</td>
<td>8</td>
<td>62</td>
<td>37</td>
<td>107</td>
</tr>
<tr>
<td>Ground beef</td>
<td>31</td>
<td>514</td>
<td>476</td>
<td>1,021</td>
</tr>
<tr>
<td>Ground chicken</td>
<td>5</td>
<td>9</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Ground turkey</td>
<td>21</td>
<td>10</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>Market hogs</td>
<td>31</td>
<td>65</td>
<td>162</td>
<td>258</td>
</tr>
<tr>
<td>Steers and heifers</td>
<td>27</td>
<td>21</td>
<td>35</td>
<td>83</td>
</tr>
<tr>
<td>Total</td>
<td>251</td>
<td>748</td>
<td>724</td>
<td>1,723</td>
</tr>
</tbody>
</table>

* Although only 1,584 establishments were included in the study, totals reflect establishments that produced more than one product class and thus were counted multiple times (once for each product class).

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**FIGURE 1. Testing history of establishments where PR-HACCP Salmonella sample sets were collected (1998 through 2003), by product class. Note: passed sets are not included here.**
TABLE 3. Odds ratios estimated using a logistic regression model to identify associations between product class and establishment size and an establishment’s failure status

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of observations from case establishments</th>
<th>No. of observations from control establishments</th>
<th>Univariable odds ratio (95% CI)</th>
<th>Multivariable odds ratio (95% CI)</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishment size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>69</td>
<td>182</td>
<td>3.7 (2.6, 5.4)</td>
<td>2.0 (1.3, 3.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Small</td>
<td>197</td>
<td>551</td>
<td>3.5 (2.6, 4.7)</td>
<td>3.5 (2.6, 4.8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Very small</td>
<td>67</td>
<td>657</td>
<td></td>
<td>1.0 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Product class</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cows and bulls</td>
<td>41</td>
<td>66</td>
<td>1.0 (0.6, 1.6)</td>
<td>1.1 (0.6, 1.8)</td>
<td>0.83</td>
</tr>
<tr>
<td>Ground beef</td>
<td>136</td>
<td>885</td>
<td>0.3 (0.2, 0.4)</td>
<td>0.3 (0.2, 0.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Ground chicken</td>
<td>2</td>
<td>13</td>
<td>0.3 (0.1, 1.1)</td>
<td>0.2 (0.05, 1.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>Ground turkey</td>
<td>9</td>
<td>24</td>
<td>0.6 (0.3, 1.4)</td>
<td>0.6 (0.4, 0.9)</td>
<td>0.25</td>
</tr>
<tr>
<td>Market hogs</td>
<td>52</td>
<td>206</td>
<td>0.4 (0.3, 0.6)</td>
<td>0.4 (0.2, 0.9)</td>
<td>0.04</td>
</tr>
<tr>
<td>Steers and heifers</td>
<td>15</td>
<td>68</td>
<td>0.4 (0.2, 0.7)</td>
<td>0.5 (0.2, 0.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>Broiler chickens</td>
<td>78</td>
<td>128</td>
<td></td>
<td>1.0 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Referent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\( a \) Values from 302 unique establishments.

\( b \) Values from 1,282 establishments.

per testing history were collected at large establishments. This finding is partially the result of staggered implementation of the PR-HACCP program, wherein large establishments were tested earlier than were small and very small establishments. Set collection usually takes much longer to complete at small and very small establishments, possibly because of intermittent production and other factors, thus reducing the potential number of sets that could have been completed during the observation period (11).

The size of an establishment was associated with the

FIGURE 2. Performance of establishments where in-depth verification reviews (IDVs) were performed (2000 through 2003). Note: only completed C/D sets are included.
odds of an establishment experiencing set failure, with small establishments most likely to have experienced at least one failure in their testing history. Although small establishments produced more than one product class more frequently than did large establishments, increasing the opportunity to be classified as a case establishment, the production of more than one product class was not associated with an establishment’s failure status in the logistic regression model. Although small establishments completed fewer sets in their testing history than did large establishments and, thus, had fewer opportunities to experience a set failure, small establishments were still more likely to be classified as a case establishment in this study.

Reasons for the relatively poor performance of small establishments remain unclear. Presently, the FSIS does not systematically collect data about specific pathogen reduction interventions implemented by establishments; thus, we were unable to evaluate the adoption of these interventions or other characteristics that could influence microbiological quality relative to establishment size. One possible explanation could be that employees in very small establishments are highly skilled in all aspects of their relatively small production operation and they manage to control their food safety systems better than large establishments, where there are huge volumes of product to control and typically high employee turnover, and small establishments, where employees may be unable to appropriately monitor PR-HACCP activities. In a Swedish study, the authors suggested that the wide variation in bacterial counts observed in lower capacity establishments may have been attributable to the variation in evisceration techniques used in these smaller establishments (9). Smaller establishments also may have limited resources in terms of personnel with PR-HACCP expertise. These findings highlight the importance of the Small and Very Small Plant Outreach program overseen by the FSIS, which links establishments with PR-HACCP experts who can provide technical advice, assistance, and resources and can conduct activities to support PR-HACCP implementation in small and very small establishments.

The region in which the establishment was located was not significantly associated with establishment set failure. Animals are commonly shipped between regions for slaughter, so the results assigned by region are not necessarily representative of animals raised in that region. Regions were assigned based on preexisting USDA administrative considerations and included such large areas that considerable intraregional climate variation was likely.

Foodborne diseases appear to peak seasonally (4, 5), and Salmonella shedding by animals appears to increase in the summer months (2, 6–8) in part because of the higher temperatures, which facilitate pathogen proliferation. Therefore, an association between season and set failure in establishments was possible. However, set collection periods often spanned one or more seasons (11), preventing us from controlling for possible seasonal effects associated with set failure, and so season was not examined.

Product class was associated with establishment performance. Broiler chicken establishments were more likely than ground beef or market hog establishments to fail one or more Salmonella sets. Although this result might seem intuitive given the well-known association of chickens with Salmonella contamination (3, 21), this factor was accounted for when setting the performance standard for this product class. Food safety measures applied in the establishment cannot control the prevalence or concentrations of Salmonella on incoming animals or birds, and on-farm preharvest interventions may be necessary to address this problem (1, 12). More focused investigation of broiler chicken establishments by the FSIS is necessary to determine the reasons behind the consistently high number of set failures for broiler establishments and to develop mitigation strategies to reduce that number.

Examination of the testing histories of establishments revealed that failures at broiler chicken establishments were distributed throughout the testing histories, whereas establishments producing other product classes tended to have set failures earlier rather than later in their testing histories. This finding suggests that the introduction of requirements for food safety plans based on PR-HACCP principles has resulted in establishments progressively becoming more attuned to their own specific food safety requirements and thereby more readily addressing potential Salmonella contamination problems, at least for nonbroiler producers.

A comparison of the SPP values of establishments before and after IDVs revealed that establishments were more likely to pass Salmonella sets after an IDV was held. Unfortunately, more detailed analysis of the effect of IDVs is not possible because of the lack of a contemporaneous control group. Because of changes in the underlying rate of set failures over time, the C set results from the 20 establishments that qualified for an IDV before the program was initiated in 2000 were deemed inappropriate for a control group. In general, establishments that had failed A sets also had failed B sets, with similar mean SPP values. There were some apparent differences in the relative performance of establishments for A and B sets, but because the number of IDVs held per product class was so small it is impossible to draw general conclusions from these results. However, the decline in SPP values after an IDV, regardless of product class, suggests that FSIS intervention in the form of IDVs and subsequent establishment-initiated corrective actions may contribute to improvements in establishment performance in the PR-HACCP Salmonella testing program.

In this study, small establishments were more likely than very small and large establishments to experience one or more set failures during the observation period. In a companion article (11), set failures were more likely to have occurred in small and very small establishments. This apparent contradiction in findings can be attributed to different analytical approaches used in these two studies. In the current study, Salmonella testing histories were collected from individual establishments and analyzed over time to determine how certain characteristics affected the failure of one or more sets in an establishment. In the companion study, set results were examined individually irrespective of establishment. However, the findings from both studies emphasize the need to continue to focus resources on small
establishments and to continue the development of product class–specific interventions, especially for broiler chicken establishments.

It is encouraging that the overall rate of establishment Salmonella sample set failure is low; failed sets were distributed among 19.1% of the federally inspected establishments included in this study, and many of these establishments reported just one set failure. These findings expand upon those of an earlier FSIS report, in which the majority of sets were passed for all product classes after 3 years of the PR-HACCP Salmonella program (13). Recently the FSIS announced plans to implement risk-based sampling in establishments with Salmonella sample set failures (20). Continued efforts to focus food safety resources on establishments for which one or more sample sets have failed to meet the Salmonella performance standard will likely lead to decreases in Salmonella rates and better protection of public health.

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