Journal of Food Protection, Vol. 69, No. 11, 2006, Pages 2607–2614

U.S. Food Safety and Inspection Service Testing for *Salmonella* in Selected Raw Meat and Poultry Products in the United States, 1998 through 2003: Analysis of Set Results

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MS 06-119: Received 1 March 2006/Accepted 4 June 2006

ABSTRACT

The U.S. Food Safety and Inspection Service (FSIS) tests sets of samples of selected raw meat and poultry products for *Salmonella* to ensure that federally inspected establishments meet performance standards defined in the pathogen reduction–hazard analysis and critical control point system (PR-HACCP) final rule. In the present report, sample set results are described and associations between set failure and set and establishment characteristics are identified for 4,607 sample sets collected from 1998 through 2003. Sample sets were obtained from seven product classes: broiler chicken carcasses ($n = 1{,}010$), cow and bull carcasses ($n = 240$), market hog carcasses ($n = 560$), steer and heifer carcasses ($n = 123$), ground beef ($n = 2{,}527$), ground chicken ($n = 31$), and ground turkey ($n = 116$). Of these 4,607 sample sets, 92% (4,255) were collected as part of random testing efforts (A sets), and 93% (4,166) passed. However, the percentage of positive samples relative to the maximum number of positive results allowable in a set increased over time for broilers but decreased or stayed the same for the other product classes. Three factors associated with set failure were identified: establishment size, product class, and year. Set failures were more likely early in the testing program (relative to 2003). Small and very small establishments were more likely to fail than large ones. Set failure was less likely in ground beef than in other product classes. Despite an overall decline in set failures through 2003, these results highlight the need for continued vigilance to reduce *Salmonella* contamination in broiler chicken and continued implementation of programs designed to assist small and very small establishments with PR-HACCP compliance issues.

The U.S. Food Safety and Inspection Service (FSIS) is the regulatory agency within the U.S. Department of Agriculture that is tasked with ensuring the safety of meat, poultry, and egg products. In 1996, the FSIS published the ''Pathogen reduction; hazard analysis and critical control point (HACCP) systems; final rule'' *(9)* with the goal of preventing human foodborne infections by reducing the prevalence of *Salmonella* and other pathogens on meat and poultry products.

The pathogen reduction (PR)–HACCP final rule requires that all meat and poultry establishments implement science-based process controls designed to prevent or reduce significant food safety hazards, including microbiological hazards. There are four components to the PR-HACCP final rule that regulated establishments must address: standard operating procedures for sanitation, HACCP plans, *Escherichia coli* testing, and *Salmonella* performance standards *(9)*.

As one means of verifying that an establishment's HACCP plan is effective for controlling the microbiological contamination of raw meat and poultry products, the PR-HACCP final rule defines microbial performance standards for seven classes of raw meat and poultry products. *Salmonella* was selected as the target bacteria for these performance standards because these bacteria are a leading cause of foodborne illnesses in humans, are commonly found in the enteric tracts of livestock and poultry, can be recovered from a variety of meat and poultry products using available methodologies, and require interventions that would concomitantly be effective against other pathogens. The number of samples to be analyzed for *Salmonella* (collectively constituting a set) and the maximum number of *Salmonella*-positive samples allowable per set were established for each product class (Table 1). These testing requirements were defined so that contamination of product at the national baseline *Salmonella* prevalence would translate to an 80% probability that the establishment would meet the performance standard *(9)*.

In 1998, the FSIS began staggered implementation of the PR-HACCP final rule, including *Salmonella* testing, based on establishment size. As of 2000, all federally inspected meat and poultry establishments became subject to testing by FSIS to ensure that *Salmonella* performance standards are being met. Both random and targeted testing of establishments is conducted.

The FSIS publishes annual reports describing these PR-HACCP *Salmonella* testing results both on its Web site

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TABLE 1. Salmonella *performance standards as defined by the pathogen reduction hazard analysis critical control points final rule (9)*

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

and in periodic publications in the peer-reviewed literature *(7, 8).* However, only the results of random testing, stratified by product class and establishment size, have been reported since the inception of the testing program. This is the first detailed report of the results from targeted testing (i.e., B, C, and D *Salmonella* sample sets). Here, a complete description of sample set results obtained by the FSIS from both random and targeted testing is presented. The objectives of this study were twofold: (i) to describe the results of sample sets collected as part of random and targeted FSIS PR-HACCP *Salmonella* testing from 1998 through 2003 and (ii) to identify associations between sample set failure and certain set and establishment characteristics. In a companion article *(2),* these results are described in a longitudinal manner, focusing on the results obtained for establishments when multiple sets are collected over time.

MATERIALS AND METHODS

PR-HACCP sample sets. Federally inspected establishments that produce one or more of the seven product classes with defined performance standards (i.e., broiler chicken, cow and bull, market hog, and steer and heifer carcasses and ground beef, ground chicken, and ground turkey) are subject to *Salmonella* testing by the FSIS. Within each product class, eligible establishments were randomly selected to submit a sample set. Sample sets collected as part of this random testing program were designated A sets. When the number of *Salmonella*-positive samples identified within this A set was equal to or less than the maximum number allowed to achieve the performance standard, the sample set passed and the establishment became eligible for selection to complete subsequent A sets (random testing program).

However, when the number of *Salmonella*-positive samples in a sample set was higher than the maximum number allowed to meet the performance standard, the A set failed. Following implementation of establishment-initiated corrective actions to reduce microbiological contamination of the product as required by the FSIS, an establishment-specific targeted testing program began with collection of a B sample set. If the B set passed, the establishment again became eligible for the random testing program.

Following a B set failure, the FSIS evaluates an establishment's HACCP system to identify nonconformance with regulatory, technical, and scientific standards. In 2000, these activities were formalized as in-depth verification reviews *(12),* which were later replaced by incident investigation team reviews *(13).* Following these actions by the FSIS, the establishment was encouraged to implement further corrective actions, and a second establishment-specific targeted sample set, a C set, was collected. If the C set passed, the establishment again became eligible for random selection to submit an A set. Failure of a C set led to intensified scrutiny by the FSIS and further corrective actions by the establishment. In rare circumstances, a D sample set was collected.

Sample collection. Once an establishment was selected to submit a sample set, computer-generated sample requests, collection and shipping supplies, and instructions for collection and shipping of samples were forwarded to the FSIS inspector-in-charge at that establishment. The inspector was instructed to collect a sample from one randomly selected carcass or batch of ground product on each day of production until the set was completed *(10, 11).*

FSIS personnel aseptically collected samples following procedures outlined in Appendix E of the PR-HACCP final rule *(9).* Following 12 h of carcass chilling, three 100-cm^2 areas were sponged: the flank, rump, and brisket on carcasses of steers and heifers and of cows and bulls and on the ham, belly, and jowls of market hog carcasses. For broiler chickens, whole bird rinses with 400 ml of buffered peptone water (BPW) were collected at the end of the drip line after immersion in a chilling tank. For raw ground product (beef, chicken, and turkey), approximately 25-g samples of product were collected immediately before final packaging (after final grinding but before spices or seasonings were added). On the day of collection, samples were shipped in an insulated shipping container with a frozen gel pack via overnight courier to one of three preassigned FSIS laboratories for analysis.

Microbiological analyses. The FSIS *Microbiology Laboratory Guidebook* describes laboratory procedures for *Salmonella* analysis *(14, 15).* Carcass swab diluent representing 300 cm^2 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 step, samples were subjected to a screening test. Before October 2003, a commercially available automated immunoassay system (Assurance polyclonal enzyme immunoassay, BioControl, Bellevue, Wash.) was used to screen sample enrichment cultures for *Salmonella.* After October 2003, a commercially available PCR assay (BAX System, DuPont Qualicon, Wilmington, Del.) was used to screen samples.

Enrichment cultures with positive screening test results were considered presumptively positive for *Salmonella* and were subjected to bacteriologic culture. Enrichment cultures of presumptive positive samples were transferred into selective tetrathionate (Hajna formulation) broth and modified Rappaport-Vassiliadis broth and incubated overnight. Samples were then streaked on brilliant green sulfa agar and double modified lysine agar or xylose lysine tergitol 4 agar *(14, 15).* As many as three presumptive colonies per sample were selected for confirmation via serologic (polyvalent H and O group antigens) and biochemical tests until one of the selected isolates was confirmed to be *Salmonella.* One confirmed *Salmonella* isolate, representing the most dominant colony type observed in the culture medium, was serotyped.

Statistical methods. Results of the FSIS PR-HACCP *Salmonella* tests performed from 1998 through 2003 were available. Our analysis was restricted to (i) completed sets for which all required samples had been submitted and tested and results reported or (ii) sets for which testing was in progress but the outcome could be determined (either because the maximum number of positive samples allowed to meet the performance standard had

already been exceeded or because the maximum number could not be exceeded given the number of untested samples remaining in the set).

The number of sets was determined for each level of the following categorical variables: product class, sequence code, establishment size, establishment region, and year. Sequence code refers to A, B, C, or D set designation. The FSIS defines establishments as large (500 or more employees), small (from 10 to 500 employees), and very small (less than 10 employees or annual sales of <$2.5 million) *(9).* The establishment region was determined by the geographic location of an establishment as follows: 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.), southwest (Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas), southeast (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Puerto Rico, and the U.S. Virgin Islands), and west (Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, North Dakota, Nevada, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, and the Northern Marianas Islands) *(6).* Year was defined as the calendar year in which the final sample necessary to complete the set was collected. For incomplete sets, the sample year was that of the sample most recently collected.

Set results were determined by the number of *Salmonella*-positive samples in a sample set relative to the maximum number of positive samples allowed to achieve the performance standard established for each product class. Sets passed when the number of *Salmonella*-positive samples in the set was equal to or lower than this defined number and failed when the number of *Salmonella*-positive samples was higher than this number.

The standardized percent-positive (SPP) value for a set, interpreted as the percentage of the maximum number of positive samples allowed in a set, was calculated as

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

This value accounted for the different performance standards for each product class and facilitated a direct comparison of the number of positive samples in a set among product classes. Calculation of SPP values was limited to completed A and B sets obtained from broiler chickens, market hogs, and ground beef because these product classes have performance standards of five or more positive samples per set and had an adequate number of sets distributed across all product classes and sequence codes. The Kruskal-Wallis test was used to identify significant differences in the median set performance values between levels of the categorical variables.

Generalized estimating equations (GEEs) were used to estimate logistic regression models that examined associations between set failure and product class, year, establishment size, and region (SAS version 9.1, SAS Institute, Inc., Cary, N.C.). This modeling approach provides robust standard errors that accounted for the correlation between results for multiple sets within establishments over time by using the exchangeable correlation structure. A and B set failures were modeled separately. Because few sets were available for the ground chicken product class, this class was excluded from the GEE analysis.

Initially, univariable GEE logistic regression models were used to evaluate associations between set failure and product class, year, establishment size, and region, respectively. All variables with generalized (type 3) score statistics $P \leq 0.15$ in these univariable models were included in a multivariable model. Insignificant variables were removed in a stepwise fashion until all variables in the model had type 3 score statistics $P \leq 0.05$. Odds ratios and 95% confidence intervals (CIs) were calculated for comparison of the odds of set failure between levels of these retained categorical variables.

RESULTS

Description of sets. From 1998 through 2003, a total of 5,254 PR-HACCP *Salmonella* sample sets were collected at federally inspected establishments. Of these, 4,607 sets collected from 1,584 federally inspected establishments met the inclusion criteria for this analysis: 4,455 sets contained the requisite number of samples, and the remaining 152 sets were incomplete but were included in our analysis because the set result could be determined.

The majority of sets included in further analysis (4,255 sets, 92.0%) were collected as part of random testing efforts (A sets). The remaining sets were collected during establishment-specific targeted testing: 281 B sets, 63 C sets, and 8 D sets. Of the 4,607 sets analyzed, 441 sets (9.6%) failed.

Sample sets were collected for the seven product classes: broiler chickens (1,010 sets), cows and bulls (240 sets), ground beef (2,527 sets), ground chicken (31 sets), ground turkey (116 sets), market hogs (560 sets), and steers and heifers (123 sets). During the 6-year observation period, the number of sets increased as the PR-HACCP final rule was implemented: 118 sets in 1998, 552 sets in 1999, 849 sets in 2000, 851 sets in 2001, 1,197 sets in 2002, and 1,040 sets in 2003. An additional 402 sets had been collected in 2003 but were excluded from our analysis because the set result had not yet been determined. Table 2 provides a summary of the set results stratified by year, sequence code, and product class.

An examination of the results from the 647 sets that were excluded from further analysis revealed that they differed from the 4,607 sets included in our analysis with respect to both year and establishment size. The majority of excluded sets (402) were initiated in 2003, and testing was still in progress at the time data were obtained for this analysis. The same number of excluded sets (402) were collected from very small establishments. After stratifying by establishment size, consistent differences were no longer identified between excluded and included sets with respect to region or sequence code.

SPP values. SPP values were calculated for 3,686 total A sets from broiler carcasses (894 sets), market hog carcasses (482 sets), and raw ground beef (2,310 sets). SPP values ranged from 0.0 to 533.3% of the maximum number of positive samples permitted in a set. The median SPP value across all of these A sets was 20.0% of the maximum number, and 93% of the sets had SPP values less than or equal to the maximum number. The median SPP value was highest in the broiler product class (33.3%) relative to the market hog (16.7%) and ground beef (20.0%) product classes ($P < 0.0001$). After stratifying by product class, median

TABLE 2. *PR-HACCP* Salmonella *testing program set results by set sequence code and product class, 1998 through 2003*[a]

Product class by year of set completion	No. of sets by sequence code[b]								Year total		% sets that failed
	A		B		C		D				
	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	
1998											
Broiler chicken carcasses	69	7	2	4	0	0	0	0	71	11	13.4
Cow and bull carcasses	1	0	0	0	0	0	0	0	1	0	0.0
Ground beef	8	1	0	0	0	0	0	0	8	1	11.1
Ground chicken	0	0	0	0	0	0	0	0	0	0	
Ground turkey	6	1	1	0	0	0	0	0	7	1	12.5
Market hog carcasses	11	5	0	1	0	0	0	0	11	6	35.3
Steer and heifer carcasses	1	0	0	0	0	0	0	0	1	0	0.0
Subtotal	96	14	3	5	0	0	0	0	99	19	16.1
1999											
Broiler chicken carcasses	135	16	9	1	4	0	0	0	148	17	10.3
Cow and bull carcasses	15	4	0	1	0	1	0	0	15	6	28.6
Ground beef	239	35	5	6	0	2	0	0	244	43	15.0
Ground chicken	5	0	0	0	0	0	0	0	5	0	0.0
Ground turkey	21	2	0	1	0	0	0	0	21	3	12.5
Market hog carcasses	32	6	3	1	2	0	0	0	37	7	15.9
Steer and heifer carcasses	6	0	0	0	0	0	0	0	6	0	0.0
Subtotal	453	63	17	10	6	3	0	0	476	76	13.8
2000											
Broiler chicken carcasses	175	16	12	1	1	0	0	0	188	17	8.3
Cow and bull carcasses	29	5	3	2	0	0	1	0	33	7	17.5
Ground beef	413	40	22	7	3	0	1	1	439	48	9.9
Ground chicken	5	0	0	0	0	0	0	0	5	0	0.0
Ground turkey	16	2	2	1	0	0	0	0	18	3	14.3
Market hog carcasses	54	13	8	5	0	0	0	0	62	18	22.5
Steer and heifer carcasses	10	1	0	0	0	0	0	0	10	1	9.1
Subtotal	702	77	47	16	4	0	2	1	755	94	11.1
2001											
Broiler chicken carcasses	156	16	12	5	0	0	0	0	168	21	11.1
Cow and bull carcasses	29	6	2	3	1	0	0	0	32	9	21.9
Ground beef	413	20	28	6	4	1	0	0	445	27	5.7
Ground chicken	6	0	0	0	0	0	0	0	6	0	0.0
Ground turkey	17	1	0	1	1	0	0	0	18	2	10.0
Market hog carcasses	84	15	2	3	3	2	0	0	89	20	18.3
Steer and heifer carcasses	13	0	0	1	0	0	0	0	13	1	7.1
Subtotal	718	58	44	19	9	3	0	0	771	80	9.4
2002											
Broiler chicken carcasses	164	23	9	6	3	2	0	0	176	31	15.0
Cow and bull carcasses	57	11	1	2	2	0	0	0	60	13	17.8
Ground beef	601	36	16	5	5	1	1	0	623	42	6.3
Ground chicken	8	1	1	0	0	0	0	0	9	1	10.0
Ground turkey	21	0	0	0	2	0	0	0	23	0	0.0
Market hog carcasses	153	7	2	8	3	0	1	0	159	15	8.6
Steer and heifer carcasses	39	4	1	0	1	0	0	0	41	4	8.9
Subtotal	1,043	82	30	21	16	3	2	0	1,091	106	8.9
2003											
Broiler chicken carcasses	117	20	13	4	5	1	1	1	136	26	16.1
Cow and bull carcasses	40	7	10	4	3	0	0	0	53	11	17.2
Ground beef	563	14	26	1	2	1	0	0	591	16	2.6
Ground chicken	3	1	0	0	0	1	0	0	3	2	40.0
Ground turkey	19	1	0	0	0	0	0	0	19	1	5.0
Market hog carcasses	116	5	6	2	6	0	1	0	129	7	5.2
Steer and heifer carcasses	40	3	3	0	0	0	0	0	43	3	6.5
Subtotal	898	51	58	11	16	3	2	1	974	66	6.3
Total	3,910	345	199	82	51	12	6	2	4,166	441	9.6

[a] PR-HACCP, ''Pathogen reduction; hazard analysis and critical control points systems; final rule.''

[b] Sets represent a defined series of product samples collected on consecutive days of production. Set size varies according to product class. A sets are collected at randomly selected federally inspected establishments. B, C, and D sets represent targeted testing in establishments that failed to achieve performance standards with previous sets.

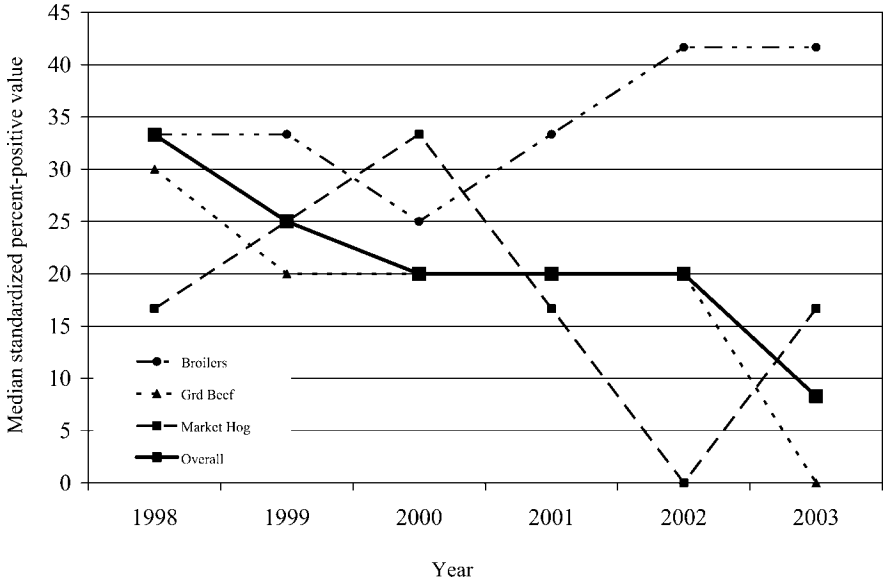

FIGURE 1. *Median standardized percent* Salmonella*-positive values for completed A sets for broiler chicken, ground beef, and market hog product classes by year, 1998 through 2003. These sample sets were collected as outlined by the FSIS pathogen reduction–hazard analysis and critical control point system final rule (9).*

SPP values for A sets differed among the levels of establishment size ($P < 0.001$), region ($P = 0.004$), and year of set completion ($P < 0.001$).

Results among different levels of establishment size varied according to product class. In the broiler and market hog product classes, the median SPP value for A sets was higher for small establishments (41.7 and 33.3%, respectively) relative to large establishments (33.3 and 16.7%, respectively). For establishments producing ground beef, A sets collected from small and large establishments had similar median SPP values (20.0% of the performance standard). Median SPP values for sets from very small establishments were the highest in the broiler product class (median = 104.2%) but the lowest (median = 0.0%) in both the ground beef and market hog product classes. However, these median SPP values were based on a small number of sets within the broiler product class (12 sets) relative to the ground beef (813 sets) and market hog (200 sets) product classes.

The A sets completed in the southeast region had a median SPP value of 25.0% relative to a median value of 20.0% in each of the remaining regions. Although SPP values remained significantly different among regions after stratifying by product class, SPP values for sets from the southeast region were not consistently higher than those for sets from the other regions.

Although median SPP values for A sets decreased over time, each product class had a unique temporal pattern (Fig. 1). The decrease in median SPP values for ground beef sets, which represented 62% of the sets for which SPP values were calculated, appeared to be the primary determinant of the crude decrease that was observed. Although highly variable from year to year, set performance in the market hog product class did not appear to change over time, whereas the percentage of the maximum number of positive samples permitted increased for sets in the broiler product class.

SPP values were also calculated for 232 total B sets from broiler chicken carcasses (75 sets), market hog carcasses (37 sets), and raw ground beef (120 sets). SPP values ranged from 0.0 to 616.7% of the performance standard, with a median of 66.7% of the performance standard. The median SPP value was highest in the market hog product class (133.3%) relative to the broiler chicken (66.7%) and ground beef (50.0%) product classes. After stratifying by product class, differences in median SPP values for B sets were not identified with respect to establishment size or region. All three product classes exhibited a decrease in median SPP values in B sets over time.

Factors associated with set failure. The results for 4,226 A sets from 1,573 establishments were analyzed. Establishment size ($P < 0.0001$), product class ($P < 0.0001$), and year ($P = 0.0002$) were associated with the failure of an A set. The multivariable odds ratios (mORs) calculated using the final GEE model controlled for establishment size, product class, and year, and their standard errors accounted for the correlation between multiple A sets within establishments.

A sets from both small and very small establishments had greater odds of failure than did large establishments. The odds of an A set failure were greater for the broiler, cow and bull, and market hog product classes relative to the ground beef product class. Relative to 2003, the odds of an A set failure were higher in 1998, 1999, and 2000 (Table 3).

Results for 280 targeted B sets from 251 establishments were analyzed. Product class ($P = 0.007$) and year ($P = 0.003$) were associated with the failure of a B set. The mORs calculated using the final model controlled for product class and year, and their standard errors accounted for the correlation between multiple B sets within establishments.

The odds of a B set failure were greater for the cow and bull and the market hog product classes relative to both the ground beef and broiler chicken product classes. Relative to broiler chicken sets, the odds of B set failure were greater for sets from the cow and bull (mOR, 3.5; 95% CI, 1.2 to 10.0) and market hog (mOR, 3.2; 95% CI, 1.3 to

TABLE 3. *Odds ratios estimated using generalized estimating equations to identify associations between A and B PR-HACCP sample set failures and establishment size, product class, and year*[a]

Variables included in final GEE model	No. of passed sets	No. of failed sets	Univariable odds ratio (95% CI)	Multivariable odds ratio (95% CI)	*P* value
A set results					
Establishment size					
Very small	1,090	70	0.8 (0.6, 1.1)	1.9 (1.1, 3.1)	<0.0001
Small	1,799	193	1.3 (1.0, 1.8)	2.5 (1.7, 3.7)	0.01
Large	994	80		1.0 Referent	
Product class					
Broiler chickens	816	98	1.9 (1.4, 2.6)	3.0 (1.8, 4.0)	<0.0001
Cows and bulls	171	33	2.9 (1.9, 4.5)	3.1 (2.0, 4.8)	<0.0001
Ground turkey	100	7	1.0 (0.5, 2.2)	1.6 (0.7, 3.5)	0.27
Market hogs	450	51	1.8 (1.3, 2.6)	2.4 (1.6, 3.4)	<0.0001
Steers and heifers	109	8	1.2 (0.6, 2.4)	1.6 (0.7, 3.4)	0.24
Ground beef	2,237	146		1.0 Referent	
Year					
1998	96	14	2.6 (1.4, 4.8)	3.0 (1.5, 5.6)	0.001
1999	448	63	2.5 (1.7, 3.5)	2.4 (1.6, 3.6)	<0.0001
2000	697	77	1.9 (1.4, 2.8)	1.9 (1.3, 2.7)	0.001
2001	712	58	1.4 (1.0, 2.1)	1.4 (0.9, 2.0)	0.09
2002	1,035	81	1.4 (1.0, 2.0)	1.3 (0.9, 2.0)	0.14
2003	895	50		1.0 Referent	
B set results					
Product class					
Broiler chickens	57	21	1.4 (0.7, 2.8)	1.2 (0.6, 2.6)	0.59
Cows and bulls	16	12	2.9 (1.2, 6.8)	4.3 (1.7, 10.8)	0.002
Ground turkey	3	3	3.9 (0.7, 22.2)	3.3 (0.5, 22.5)	0.23
Market hogs	21	20	3.7 (1.8, 7.6)	3.8 (1.8, 8.4)	0.001
Steers and heifers	4	1	1.0 (0.1, 9.0)	1.3 (0.1, 12.5)	0.83
Ground beef	97	25		1.0 Referent	
Year					
1998	3	5	9.0 (1.8, 44.4)	11.2 (1.8, 68.9)	0.009
1999	17	10	3.1 (1.1, 8.2)	3.9 (1.3, 12.2)	0.02
2000	47	16	0.8 (1.8, 4.1)	1.9 (0.8, 4.8)	0.17
2001	44	19	2.3 (1.0, 5.1)	3.1 (1.3, 7.6)	0.01
2002	29	21	3.8 (1.7, 8.7)	4.7 (1.9, 11.4)	0.001
2003	58	11		1.0 Referent	

[a] PR-HACCP, ''Pathogen reduction; hazard analysis and critical control points systems; final rule.''

7.5) product classes. When compared with 2003, the odds of a B set failure were higher for all other years except 2000 (Table 3).

DISCUSSION

The FSIS microbiological testing results described here are one component of a regulatory program designed to reduce the occurrence of foodborne pathogens in raw meat and poultry products. The FSIS PR-HACCP *Salmonella* testing program is not designed to estimate the prevalence of *Salmonella* in raw meat and poultry products in the United States. However, the testing conducted during this six-year period (1998 through 2003) provides the most comprehensive publicly available information regarding *Salmonella* contamination of specific classes of raw meat and poultry products in the United States. This report is the first to systematically present the results of establishment-specific targeted testing (i.e., B, C, and D sets) conducted by the FSIS and is the first to present a formal evaluation of set and establishment characteristics associated with set failure. In this analysis, three factors associated with PR-HACCP *Salmonella* set failure were identified: establishment size, product class, and year. The geographic location (region) of an establishment was not associated with set failure.

In this analysis, we considered only set-level results rather than results from individual samples. This approach prevented us from evaluating the association between season of the year and set results and from controlling for seasonal effects in our logistic regression model. Because only 25% of the analyzed sets were completed in 90 days or less (data not shown), it was not possible to assign a set to a particular season (most sets were collected through at least two seasons). Evaluation of results for individual samples to account for seasonal variation in *Salmonella* contamination of meat and poultry products *(1, 3, 5)* was beyond the scope of this analysis.

Our decision to exclude certain incomplete sets may have introduced bias into our analysis. Sets collected from very small establishments were overrepresented among the excluded sets, most likely because very small establishments took longer to complete sets than did either small or large establishments (data not shown). However, exclusion of these sets should not have impacted our results or subsequent conclusions. Approximately one third of the sets considered in our analysis were collected from very small establishments. After controlling for establishment size, excluded and included sets did not differ with respect to region or sequence code.

Evaluation of set performance on a continuous scale yielded some findings that were not apparent when sets were scored as either passing or failing. For example, the finding that approximately 90% of A and B sets completed in the broiler chicken, market hog, and ground beef product classes passed was refined to indicate that 75% of these passed sets had SPP values that were 40% or less of the performance standard. Thus, in most sets, the number of positive samples was well below the maximum permitted.

In this analysis, an interaction between year and product class was identified for A sets. Overall, SPP values decreased over time, primarily because of a decrease in values for ground beef. However, values for market hogs remained unchanged. Importantly, an increase in the median SPP values for the broiler chicken product classes over the study period also was observed. The FSIS currently is exploring different strategies for addressing the lack of progress with respect to *Salmonella* contamination in the broiler chicken product class.

Several findings reflect an overall decline in the occurrence of set failures since the FSIS initiated the PR-HACCP *Salmonella* testing program in 1998. The crude rate of set failures decreased from 16.1% in 1998 to 6.4% in 2003. However, this apparent decrease may be confounded by the relatively small number of sets collected from small and very small establishments in 1998 and 1999, before full implementation of the PR-HACCP *Salmonella* testing program. After controlling for the potential confounding effects of both establishment size and product class, year was associated with both A set failures (i.e., random testing) and B set failures (i.e., targeted testing). Although significant reductions were not detected from year to year, A set failures were more likely to have occurred early in the testing program (from 1998 through 2000) relative to 2003. From 2000 to 2003, the A set failure rates appear to have plateaued. When compared with results from 2003, B set failures were more likely to occur in all years examined, with the exception of 2000. These results suggest that the PR-HACCP *Salmonella* testing program has been an effective tool over this time period for encouraging establishments to implement corrective actions, leading to reductions in set failure rates.

Product class also was associated with both A and B set failures after controlling for year and establishment size. Even though the performance standards were designed to vary by product class to account for differences in the underlying prevalence of *Salmonella* contamination, failed sets were more likely in certain product classes than in others. Specifically, A set failures were more likely to occur in the broiler chicken, cow and bull, and market hog product classes relative to ground beef, whereas B set failure was more likely in the cow and bull and the market hog product classes relative to both broiler chickens and ground beef. However, the limited numbers of sets, especially B sets, within certain product classes compromised our ability to detect other differences in set failure between product classes. Continued FSIS and industry efforts to direct resources and food safety programs toward product classes with greater odds of set failure will likely lead to improved performance in future test results.

Small and very small establishments were more likely than large establishments to have a failed A set. Small establishments also tended to have higher median SPP values than did large establishments when controlling for product class. Establishment size was not associated with B set failure in this analysis. However, we may have simply lacked the statistical power necessary to detect a difference.

The increased odds reported here of A set failure in small and very small establishments relative to large estab-

lishments appear to contradict the results obtained when these data are analyzed at the establishment level, where the odds of failure are greater for small establishments relative to large ones *(2).* However, this apparent contradiction can be attributed to the different outcome of interest defined for each of the two analyses. The present analysis was focused on the failure of individual sets across establishments, whereas the establishment-level analysis considered whether an establishment had one or more failed sets during the observation period. Because large establishments were included earlier in the PR-HACCP sampling program and completed sample sets in a shorter period of time than did small or very small establishments, large establishments completed more sets during the observation period. Thus, large establishments had more opportunities to be classified as having had one or more failed sets than did smaller plants. In the present set-level analysis, the opportunity for a single set to fail was consistent between the various sizes of establishments. In both analyses, establishment size was consistently associated with set failure, and small establishments had the highest odds of experiencing such failures.

The role of establishment size in set failure may be related to the ability of large establishments to implement certain pathogen reduction strategies that are cost prohibitive for smaller establishments or their ability to assign specific personnel to ensure PR-HACCP compliance. Other explanations may include factors such as variability in evisceration techniques, limited space between clean and unclean areas, and multiple cuts on the same carcasses by individual workers in low-capacity establishments *(4).* The need to address these variables should drive the continued development and implementation of FSIS programs designed to assist small and very small establishments with PR-HACCP compliance issues.

Our analysis identified certain factors associated with failure of a PR-HACCP *Salmonella* set. This information refines our understanding of risk factors for PR-HACCP set failures and, indirectly, risk factors for *Salmonella* contamination of raw meat and poultry products. Presently, the FSIS does not systematically collect data about specific pathogen reduction interventions implemented by establishments; however, incorporation of such information into future analyses will likely lead to an even greater understanding of factors affecting sample set performance.

ACKNOWLEDGMENTS

We gratefully acknowledge the contributions of the FSIS inspection personnel who collected the samples, laboratory personnel who analyzed the samples, and the data management personnel who provided the data for this report. We also thank the FSIS staff, who provided constructive criticism during the preparation of this manuscript.

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