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Food Safety and Inspection Service Regulatory Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef

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ABSTRACT

We analyzed raw ground beef testing data to determine whether a decrease in the rate of *Escherichia coli* O157:H7–positive raw ground beef samples has occurred since the inception of Food Safety and Inspection Service (U.S. Department of Agriculture) regulatory actions and microbiological testing concerning this commodity and pathogen. A main effects log-linear Poisson regression model was constructed to evaluate the association between fiscal year and the rate of *E. coli* O157:H7–positive raw ground beef samples while controlling for the effect of season for the subset of test results obtained from fiscal year (FY)2000 through FY2003. Rate ratios were used to compare the rate of *E. coli* O157:H7–positive raw ground beef samples between sequential years to identify year-to-year differences. Of the 26,521 raw ground beef samples tested from FY2000 through FY2003, 189 (0.71%) tested positive for *E. coli* O157:H7. Year-to-year comparisons identified a 50% reduction in the rate of positive ground beef samples from FY2002 to FY2003 when controlling for season (95% CI, 10 to 72% decrease; $P = 0.02$). This decrease was the only significant year-to-year change in the rate of *E. coli* O157:H7–positive raw ground beef samples but was consistent in samples obtained from both federally inspected establishments and retail outlets. We believe this decrease is attributed to specific regulatory actions by Food Safety and Inspection Service and subsequent actions implemented by the industry, with the goal of reducing *E. coli* O157:H7 adulteration of raw ground beef. Continued monitoring is necessary to confirm that the decrease in the rate of *E. coli* O157:H7 in raw ground beef samples we observed here represents the beginning of a sustained trend.

Escherichia coli O157:H7 is recognized as an important foodborne pathogen. It is estimated that nearly 73,500 cases of illness and 60 deaths associated with *E. coli* O157:H7 occur annually in the United States *(14).* Although illnesses associated with this organism were reported throughout the 1980s, it was an outbreak during 1992 to 1993, involving more than 700 cases of human infection and four deaths in the western United States, that led to regulatory actions and food safety education efforts aimed at reducing public health risks associated with *E. coli* O157:H7 *(5–7, 10, 17, 31).*

Because these early illnesses implicated improperly cooked ground beef as the vehicle for *E. coli* O157:H7, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture initiated several regulatory and program policy changes addressing *E. coli* O157:H7 contamination of raw ground beef. In 1994, under the authority of the Federal Meat Inspection Act, FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef. FSIS promulgated regulations requiring the placement of a safe handling label on packages containing raw meat or poultry *(20).* FSIS also expanded its microbiological testing program to include *E. coli* O157:H7 in raw ground beef ''to stimulate industry actions to reduce the presence of *E. coli* O157:H7 in raw ground beef'' *(21).*

In 1996, FSIS promulgated Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems regulations, emphasizing the importance of the identification and control of microbiological hazards that can occur during food manufacture *(22).* In 1997, instructions to inspection program personnel for enforcing ''zero tolerance'' for visible fecal contamination on carcasses at slaughter were reemphasized, with the intent to reduce microbiological hazards, including *E. coli* O157:H7, associated with raw meat products *(24, 25).*

In 1998, FSIS published Directive 10,010.1 revising instructions for sample collection and microbiological testing requirements for *E. coli* O157:H7 in raw ground beef. At that time, in an effort to shift agency resources to establishments perceived to represent the greater risk, the directive revised sample collection criteria, which resulted in the possible exclusion of certain federally inspected establishments from FSIS testing. Specifically, those establishments that used validated pathogen reduction interventions on beef carcasses or those establishments that conducted their own routine testing for *E. coli* O157:H7 (or used suppliers that did) and had not identified a positive sample within the previous 6 months would not have their production sampled by FSIS personnel; however, the status of an establishment with respect to FSIS testing could change over time *(23).*

In October 2002, FSIS informed manufacturers of raw

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ground beef products that they must reassess their HACCP plans for *E. coli* O157:H7 with regard to new scientific data regarding the epidemiology of the pathogen in cattle and subsequent contamination of beef carcasses, as well as the relatively consistent incidence of human illnesses resulting from *E. coli* O157:H7 infections as reported by the Centers for Disease Control and Prevention *(8, 9, 19, 28)*. If establishments identified *E. coli* O157:H7 as a food safety hazard reasonably likely to occur as a result of these reassessments, existing FSIS HACCP regulations required the implementation of critical control points to prevent, eliminate, or reduce *E. coli* O157:H7 contamination *(28)*. All establishments were to complete these reassessments by April 2003. As of 18 April 2003, all federally inspected establishments producing raw ground beef became subject to *E. coli* O157:H7 microbiological testing conducted by FSIS personnel, eliminating the possibility that certain establishments could be excluded from testing *(30)*.

The actions instituted by FSIS are intended to reduce *E. coli* O157:H7 contamination of meat and meat products, especially raw ground beef, to ultimately reduce the incidence of human foodborne illness caused by this pathogen. The purpose of this study was to determine whether a decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples has occurred since the inception of FSIS regulatory actions and microbiological testing for this pathogen.

MATERIALS AND METHODS

Sampling and laboratory methods. FSIS microbiological regulatory testing for *E. coli* O157:H7 was designed to collect raw ground beef samples from both federally inspected establishments and retail outlets with the goal of analyzing a total of 5,000 samples per year *(21, 23, 30)*. Throughout the course of a year, computer-generated requests randomly identified federally inspected establishments for testing from the list of establishments identified by inspection program personnel as producing raw ground beef. Establishments in which *E. coli* O157:H7 had been previously identified, or establishments identified by FSIS program personnel on the basis of other program information, could also be targeted for testing (generally referred to as follow-up testing). Compliance program personnel would identify retail stores at which to collect raw ground beef samples on the basis of recent testing history, geographic location, and in-store beef trimming use. A limited number of raw ground beef samples were collected from state-inspected establishments and imported products.

FSIS personnel aseptically collected either one-half pound of product before October 1997 or one pound of product after October 1997 that represented a production lot of raw, comminuted beef from federally inspected establishments, or they purchased one pound of unfrozen, raw ground beef from retail outlets for testing *(23, 26)*. Samples were shipped cold ($<15^{\circ}C$) via overnight delivery to one of three FSIS laboratories, in which a subsample of the raw ground beef was stomached and incubated in an enrichment broth.

The *FSIS Microbiology Laboratory Guidebook* describes current laboratory procedures in detail *(29)*. A commercially available enzyme-linked immunosorbent assay was used to screen the enriched samples. Samples negative on the screening test were reported as negative for *E. coli* O157:H7 and discarded without additional testing. Samples positive on the screening test were subjected to bacteriologic isolation. Presumptive colonies were confirmed as *E. coli* O157:H7 by additional biochemical and serological testing *(23, 29)*.

Several important changes in laboratory methods have occurred since FSIS initiated microbiological regulatory testing for *E. coli* O157:H7. Before fiscal year (FY)1998, a 25-g subsample was analyzed. Since the beginning of FY1998, five individual 65-g subsamples (totaling 325 g) have been analyzed. At the beginning of FY2000, bacteria in aliquots of sample enrichment cultures positive on the screening enzyme-linked immunosorbent assay were concentrated by immunomagnetic separation before plating on Rainbow agar (Biolog, Inc., Hayward, Calif.). Latex agglutination assays for the O157 antigen were performed on suspect *E. coli* O157:H7 colonies. Latex-positive colonies were cultured on blood agar, and additional biochemical, serological, and molecular methods were used to confirm the isolation of *E. coli* O157:H7 *(29)*.

Statistical methods. Initially, chi-square tests were used to screen three variables for their association with the number of *E. coli* O157:H7–positive raw ground beef samples: fiscal year, laboratory method, and season. Because changes in *E. coli* O157:H7 microbiological testing requirements and methods within FSIS coincided with the beginning of certain fiscal years, fiscal year (October 1 through September 30) was used to define 12-month periods rather than a calendar year. Three different laboratory methods were used during the observation period: a 25-g sample (FY1995 to FY1997), 325-g sample (FY1998 to FY1999), and 325-g sample plus immunomagnetic separation (FY2000 to FY2003). Season has been associated with *E. coli* O157:H7 shedding in feedlot cattle and infections in humans *(3, 4, 11–13, 15)*. The high-prevalence season was defined in this study as 1 June through 30 September, and the low-prevalence season was 1 October through 31 May *(16, 27)*.

To control for the effect of laboratory method on the ability to detect *E. coli* O157:H7 in samples, we restricted further statistical analysis to the subset of test results obtained for the period with the most sensitive detection method—a 325-g sample and immunomagnetic separation (samples collected from FY2000 to FY2003). A main effects log-linear Poisson regression model was constructed to evaluate the association between fiscal year and the rate of *E. coli* O157:H7–positive raw ground beef samples (SAS version 8.2, SAS Institute, Inc., Cary, NC). A variable for season was forced into the model to control for potential confounding associated with seasonal effects. A scale parameter (defined as the square root of the Pearson chi-square statistic divided by the degrees of freedom) was included in the model to correct for overdispersion. The log of the total number of samples tested for *E. coli* O157:H7 within a month was defined as the offset value to standardize for differences in the number of samples tested in different time periods *(1, 18)*.

Rate ratios that compared the rate of *E. coli* O157:H7–positive samples between FY2000 and FY2001, FY2001 and FY2002, and FY2002 and FY2003 were computed with 95% confidence intervals (CIs). Chi-square $P \leq 0.05$ identified significant year-to-year differences in the rate of *E. coli* O157:H7–positive samples.

The data included test results for all raw ground beef samples analyzed in association with verification testing in federally inspected establishments, retail outlets, state-inspected establishments, and imported ground beef, as well as samples collected for follow-up testing. Because samples obtained from state-inspected establishments, imported ground beef, and follow-up testing could

TABLE 1. *FSIS microbiological regulatory testing for* Escherichia coli *O157:H7 in raw ground beef for all testing programs stratified by laboratory method, fiscal year, and season, FY1995 to FY2003*

Prevalence season	25-g sample						325-g sample			
	FY1995		HY1996		FY1997		FY1998		FY1999	
	Low	High	Low	High	Low	High	Low	High	Low	High
Positive samples (*n*)	1	2	2	2	0	2	7	7	8	21
Negative samples (*n*)	2,763	2,525	3,400	1,924	4,147	1,769	4,766	2,752	5,947	2,734
Seasonal total (*n*)	2,764	2,527	3,402	1,926	4,147	1,771	4,733	2,759	5,955	2,755
Seasonal rate (%)	0.04	0.08	0.06	0.10	0.00	0.11	0.15	0.25	0.13	0.76
Yearly total (*n*)	5,291		5,328		5,918		7,532		8,710	
Yearly rate (%)	0.06		0.08		0.03		0.19		0.33	

bias the number and temporal distribution of *E. coli* O157:H7–positive samples observed, we repeated the Poisson regression analysis described above for both the subset of HACCP verification samples obtained at federally inspected establishments and the subset of verification samples obtained at retail outlets from FY2000 through FY2003.

RESULTS

For the period 1 October 1994 through 30 September 2003 (including all three laboratory methods), 241 (0.41%) of 59,300 ground beef samples tested positive for *E. coli* O157:H7 (Table 1). Fiscal year ($P < 0.0001$), laboratory method ($P < 0.0001$), and season ($P < 0.0001$) were all associated with the number of ground beef samples identified as positive for *E. coli* O157:H7.

Subset of samples collected from all sources, FY2000 to FY2003. Of the 26,521 ground beef samples tested from FY2000 through FY2003 (325-g samples plus immunomagnetic separation), 189 (0.71%) samples tested positive (Table 1). When controlling for season in a Poisson regression model, year-to-year comparisons identified a 50% reduction in the rate of *E. coli* O157:H7–positive ground beef samples from FY2002 to FY2003 (95% CI, 10 to 72% decrease; $P = 0.02$). A 16% reduction in the rate of positive samples was observed from FY2000 to FY2001 (95% CI, 50% decrease to 40% increase; $P = 0.50$), and a 23% increase occurred from FY2001 to FY2002 (95% CI, 25% decrease to 100% increase; $P = 0.41$).

Subset of samples collected from federally inspected establishments, FY2000 to FY2003. From FY2000 through FY2003, 19,628 raw ground beef samples obtained from federally inspected establishments were tested, 106 (0.54%) of which tested positive for *E. coli* O157:H7 (Table 2). The 19,628 samples in this subset constituted nearly 75% of all raw ground beef samples tested by FSIS (and 56% of the samples identified as positive for *E. coli* O157:H7) during FY2000 through FY2003. When controlling for the effect of season, year-to-year comparisons specified in the Poisson regression model revealed a 46% reduction in the rate of *E. coli* O157:H7–positive raw ground beef samples from FY2002 to FY2003 (95% CI, 72% decrease to 6% increase; $P = 0.07$). An increase of approximately 20% was observed in the rate of *E. coli* O157:H7–positive results obtained from federally inspected establishments for the periods FY2000 to FY2001 and from FY2001 to FY2002 (95% CI, 42% decrease to 137% increase; $P = 0.65$ and 95% CI, 32% decrease to 127% increase; $P = 0.48$, respectively).

Subset of samples collected from retail outlets, FY2000 to FY2003. Of the 4,389 raw ground beef samples obtained from retail establishments during FY2000 through FY2003, 33 (0.75%) tested positive for *E. coli* O157:H7 (Table 3). A 65% reduction in the rate of *E. coli* O157:H7–positive raw ground beef samples was observed for FY2002 to FY2003 (95% CI, 88% decrease to 5% increase; $P = 0.06$). For raw ground beef samples obtained from retail establishments, a 26% reduction in the rate of positive samples was observed for FY2000 to FY2001 (95% CI, 67% decrease to 65% increase; $P = 0.47$), and a 60% increase observed for FY2001 to FY2002 (95% CI, 24% decrease to 237% increase; $P = 0.22$).

A seasonal trend was identified for the rate of *E. coli* O157:H7–positive raw ground beef samples (Fig. 1). Season was associated with the rate of *E. coli* O157:H7–positive raw ground beef samples collected from FY2000 to FY2003 in test results for all samples ($P = 0.0004$) and for the subset of results obtained through verification testing of federally inspected establishments ($P = 0.05$), but season was not associated with the rate of positive results obtained from retail outlets ($P = 0.30$).

DISCUSSION

The FSIS microbiological testing results described here represent one component of a public health regulatory program designed to reduce the occurrence of *E. coli* O157:H7 in raw ground beef. The testing of over 59,000 samples conducted during this 9-year period provides the most comprehensive, publicly available information regarding *E. coli* O157:H7 contamination of raw ground beef in the United States. However, because selection of federally inspected establishments was not weighted according to production volume and the selection of retail outlets was neither completely random nor weighted according to production or sales volume, FSIS microbiological testing does not provide an ideal estimate of the prevalence of *E. coli* O157:H7 in raw ground beef in the United States.

We identified a decrease in the rate of *E. coli* O157:H7–positive ground beef samples from FY2002 to FY2003.

TABLE 1. *Extended*

325-g sample and IMS								
FY2000		FY2001		FY2002		FY2003		
Low	High	Low	High	Low	High	Low	High	Subtotal
13	37	22	28	38	23	20	8	241
3,525	2,150	4,578	2,398	4,533	2,390	4,931	1,827	59,059
3,538	2,187	4,600	2,426	4,571	2,413	4,951	1,835	—
0.37	1.69	0.48	1.15	0.83	0.95	0.40	0.44	—
5,725		7,026		6,984		6,786		59,300
0.87		0.71		0.87		0.41		0.41

This represents the only statistically significant year-to-year change in the rate of *E. coli* O157:H7 identified during the period FY2000 through FY2003. This decline was consistent for both the subset of samples obtained through HACCP verification testing of federally inspected establishments and for those obtained through testing of samples collected at retail outlets, although these differences only approached statistical significance.

The Centers for Disease Control and Prevention has reported a 42% decline in the number of human *E. coli* O157:H7 illnesses from 1996 to 2003 *(8).* Furthermore, it is noted that this overall decline is primarily a result of a significant reduction in incidence from 2002 to 2003. This reduction in human illnesses from 2002 to 2003 coincides with the reduction of *E. coli* O157:H7 in raw ground beef we report here.

Several recent changes in FSIS policy and industry actions might explain the observed decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples. During FY2003, FSIS required industry reassessments of HACCP plans with respect to *E. coli* O157:H7 (October 2002) and eliminated criteria in effect since 1998 that permitted exclusions from the *E. coli* O157:H7 testing program (April 2003). Simultaneously, an industry summit in January 2003 created a unified, comprehensive platform with the goal of defining and documenting industry practices in order to ''reduce, and ultimately eliminate, the risk of *E. coli* O157:H7 in the beef supply'' *(2).*

Several factors make it challenging to assess the individual effects of these actions. There is no official system within FSIS to document the time at which actions such as pathogen reduction interventions or product testing were implemented by establishments. Without knowing specific implementation dates for establishments, it is difficult to refine this analysis further, given the staggered implementation of HACCP reassessments and resultant actions within industry and the variable inclusion or exclusion of an establishment in sample collection by FSIS personnel from February 1998 through April 2003. FSIS is also aware of increased product testing by establishments (or their suppliers), holding of product until negative test results are available, and diversion of contaminated product away from raw ground beef manufacture to cooking or rendering. Although these actions might have decreased the amount of *E. coli* O157:H7–contaminated raw ground beef that subsequently reached consumers, we are unable to quantify their potential contributions to the observed decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples.

If federally inspected establishments that were excluded, either intermittently or consistently, from sample collection by FSIS personnel from February 1998 through April 2003 had a lower rate of *E. coli* O157:H7 contamination than those establishments consistently eligible for sampling during that time, the inclusion of these establishments in FSIS testing after April 2003 might have contributed to the observed decrease in the rate of *E. coli* O157:H7–positive results from FY2002 to FY2003. However, we have no evidence to suggest that the resumption of testing at all establishments had any effect, either positive or negative, on this decrease. If the resumption of consistent sample collection at these establishments was an important determinant of this decrease, we would have expected a sudden rate reduction at the time of the high-prevalence season (1 June through 30 September), which roughly coincided

TABLE 2. *FSIS microbiological regulatory testing for* Escherichia coli *O157:H7 in raw ground beef for federally inspected establishments stratified by fiscal year and season, FY2000 to FY2003*

	FY2000		FY2001		FY2002		FY2003		
	Low	High	Low	High	Low	High	Low	High	Subtotals
Positive samples (*n*)	7	13	12	17	27	9	13	8	106
Negative samples (*n*)	2,586	1,435	3,379	1,647	3,295	1,689	3,912	1,579	19,522
Seasonal total (*n*)	2,593	1,448	3,391	1,664	3,322	1,698	3,925	1,587	19,628
Seasonal rate (%)	0.27	0.90	0.35	1.02	0.81	0.53	0.33	0.50	—
Yearly total (*n*)	4,041		5,055		5,020		5,512		—
Yearly rate (%)	0.49		0.57		0.72		0.38		—

TABLE 3. *FSIS microbiological regulatory testing for* Escherichia coli *O157:H7 in raw ground beef from retail outlets stratified by fiscal year and season, FY2000 to FY2003*

	FY2000		FY2001		FY2002		FY2003		
	Low	High	Low	High	Low	High	Low	High	Subtotals
Positive samples (*n*)	4	5	6	3	7	5	3	0	33
Negative samples (*n*)	659	346	944	429	759	373	662	184	4,356
Seasonal total (*n*)	663	351	950	432	766	378	665	184	4,389
Seasonal rate (%)	0.60	1.42	0.63	0.69	0.91	1.32	0.45	0.00	—
Yearly total (*n*)	1,014		1,382		1,144		849		—
Yearly rate (%)	0.89		0.65		1.05		0.35		—

with the period in FY2003 in which exemptions were no longer granted (19 April through 30 September). This was not observed. Instead, the rate observed for federally inspected establishments during the high-prevalence season in FY2003 was similar to the rate observed during the high-prevalence season in FY2002 (Fig. 1).

Seasonality has been an important component in the epidemiology of *E. coli* O157:H7 in both people and cattle *(3, 4, 11–13, 15).* Recently, seasonal differences in *E. coli* O157:H7 recovery from beef carcasses have been reported *(3).* In this study, we also identify a seasonal trend in the rate of *E. coli* O157:H7–positive raw ground beef samples from all sources, as well as those collected from federally inspected establishments (Fig. 1). We did not identify a significant seasonal effect in the subset of samples obtained from retail outlets.

When considering results from all sources, the rate of *E. coli* O157:H7–positive samples in the low-prevalence season was relatively stable throughout the observation period (Fig. 1). The exception to this generalization was the low-prevalence season of FY2002, in which the rate of positive samples appeared to be approximately twice that observed in the other low-prevalence seasons. This uncharacteristically high rate in the low-prevalence season of FY2002 was also observed in the subsets of samples collected from both federally inspected establishments and retail outlets. The rate of positive samples collected during the high-prevalence seasons from all sources appeared to decline throughout the observation period.

Seasonal rates of *E. coli* O157:H7–positive samples appeared to be highly variable for the subset of samples collected from federally inspected establishments, especially for those collected from retail outlets. For example, the observed seasonal variation between the low- and high-prevalence seasons was opposite of that expected for both samples collected from federally inspected establishments in FY2002 and from retail outlets in FY2003. This variability contributed to our inability to detect statistically significant decreases in the rates of *E. coli* O157:H7–positive samples from FY2002 to FY2003 when conducting separate analyses for samples collected from federally inspected establishments and retail outlets.

Our definitions of high-prevalence (1 June through 30 September) and low-prevalence (1 October through 31

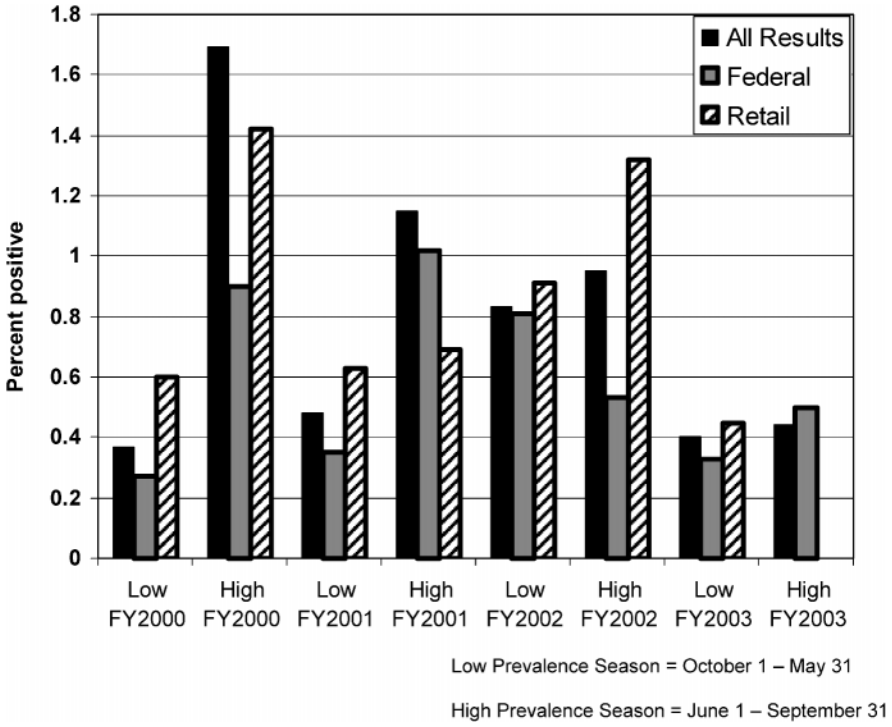

FIGURE 1. *Seasonal variation in FSIS microbiological regulatory testing for* Escherichia coli *O157:H7 in raw ground beef samples for all testing programs, verification testing in federally inspected establishments, and verification testing in retail outlets, FY2000 to FY2003.*

May) seasons were consistent with those previously used within FSIS *(16, 27).* However, evaluation of monthly rates of *E. coli* O157:H7–positive raw ground beef samples (data not shown) suggests that the month of October should be classified within the high-prevalence season. With the use of this alternative definition of season in the Poisson regression analyses described here, our findings did not change.

We compared the rates of *E. coli* O157:H7–positive raw ground beef samples between fiscal years rather than calendar years because changes in FSIS microbiological testing requirements and laboratory methods occurred near the beginning of certain fiscal years. When analyzed by calendar year (CY), a statistically significant decrease in the rate of *E. coli* O157:H7–positive ground beef samples collected from all testing programs (verification testing in federally inspected establishments, retail outlets, state-inspected establishments, imported ground beef, and samples collected for follow-up testing) from CY2002 to CY2003 was observed (data not shown). Although a decline was observed for the subset of samples obtained from federally inspected establishments during this period, it lacked statistical significance. It was not possible to model year-to-year changes for the subset of samples collected at retail outlets by this approach because there were no positive samples for this subset in CY2003.

Over 90% of samples collected from all sources during FY2000 to FY2003 were obtained from either federally inspected establishments (75%) or retail outlets (17%). As expected, nearly twice as many samples were collected in the low-prevalence seasons relative to the high-prevalence seasons from both federally inspected establishments and retail outlets. FSIS is currently reviewing verification strategies and priorities with respect to these observations. The Poisson regression model we describe here standardizes year-to-year comparisons to adjust for variable numbers of samples collected between fiscal years and prevalence seasons. By analyzing samples collected from federally inspected establishments and retail outlets separately, we also controlled for differences in the number of samples collected from different sources. These variations in sampling only influenced the statistical power of our analyses. They did not influence the point estimates for the year-to-year changes in the rate of *E. coli* O157:H7–positive samples.

The occurrence of an *E. coli* O157:H7–positive test result is a rare event in the FSIS regulatory microbiological testing program. Poisson regression models are often used when the outcome of interest is the count (or rate) of rare events occurring during a defined time period. It is because of the rarity of positive samples these models suffer from limited power. When conducting separate analyses for samples collected from federally inspected establishments and retail outlets, we did not observe statistically significant decreases in the rates of *E. coli* O157:H7–positive samples from FY2002 to FY2003. We believe this is a consequence of limited statistical power. Furthermore, limited power might have masked a seasonal effect in positive samples collected from retail outlets.

As for all time trend analyses, year-to-year variability in rates is to be expected. As additional data becomes available in the future, continued monitoring is necessary to confirm that the decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples we observed here represents the beginning of a sustained trend.

We identified a significant decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples from FY2002 to FY2003. This rate reduction is consistent in samples obtained from both federally inspected establishments and retail outlets that produce raw ground beef. This decrease occurred following specific regulatory changes by FSIS and actions by industry that were implemented with the goal of reducing *E. coli* O157:H7 adulteration of raw ground beef. The consistency between results from establishments producing raw ground beef and the simultaneous reduction in human illnesses resulting from *E. coli* O157:H7 infection suggests that the recent decrease in the rate of *E. coli* O157:H7–positive raw ground beef samples reflects a real change resulting in measurable public health improvements.

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