Redesign of FSIS Sampling Methodologies To Improve Detection of *E. coli* O157:H7

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SUMMARY

The objective of this report is to evaluate the Food Safety and Inspection Service's (FSIS) *E. coli* O157:H7 sampling designs for testing beef trim, bench trim, and raw ground beef components other than trim to determine options for increasing the degree of confidence for detecting *E. coli* O157:H7 positives during FSIS verification testing. Ten options for focusing *E. coli* testing primarily on establishments with the highest probability of producing beef trim or components contaminated with *E. coli* O157:H7 were evaluated. They are to increase *E. coli* O157:H7 sampling frequency in

- Establishments with *E. coli* O157:H7 positives
- Volume classes with higher production volumes
- Volume classes with higher *E. coli* O157:H7 percent positive
- Volume classes with higher volume-weighted *E. coli* O157:H7 percent positive
- Beef trim and other component supplier establishments associated with *E. coli* O157:H7 positives in raw ground beef
- Establishments with higher HACCP noncompliances
- Establishments with higher sanitary dressing noncompliances
- Seasons of the year with higher *E. coli* O157:H7 positives
- Geographic regions with higher *E. coli* O157:H7 percent positive
- Product categories with higher *E. coli* O157:H7 percent positive

The impact of increasing the collection response rate is also evaluated.

The major observations were:

- Over the period 2007-June 2011, beef trim sampling produced 31 *E. coli* O157:H7 positives (0.60% positive rate), bench trim sampling produced 2 positives (0.19% positive), and raw ground beef components other than trim sampling produced 2 positives (0.28% positive). Within each of these three sampling programs, there is no statistically significant difference in the *E. coli* O157:H7 percent positives between years.

- The *E. coli* O157:H7 percent positive in beef trim (0.60%), bench trim (0.19%) and raw ground beef components other than trim (0.28%) are not statistically significantly different.

- The *E. coli* O157:H7 percent positive in beef trim (0.60%) is statistically significantly higher than that found in raw ground beef (0.27%). The probability of detecting an *E. coli* O157:H7 positive in beef trim is 2.2 times higher than in raw ground beef (two sided Exact Fisher, $p < 0.0002$). The *E. coli* percent positives in bench trim (0.19%) and raw ground beef components other than trim (0.28%) are not statistically significantly different than that found in raw ground beef (0.27%).

- The probability of detecting an *E. coli* O157:H7 positive during follow-up sampling after an *E. coli* O157:H7 positive in a beef trim establishment is 6.6 times higher than under routine beef trim *E. coli* sampling (two sided Exact Fisher $p < 0.00001$). No positives were detected during *E.*

coli O157:H7 follow-up sampling for bench trim or other ground beef components after an *E.* coli positive.

- Sampling beef trim establishments proportional to production volume and requiring that each establishment is sampled at least once per year is 1.01 times more likely to detect an *E. coli* O157:H7 positive than under the 2010 MT50 random sampling program. Establishments that supply beef trim to raw ground beef establishments that test positive for *E. coli* O157:H7 are termed beef trim suppliers. If it is the only supplier to the ground beef establishment, it is termed a sole beef trim supplier. The *E. coli* percent positives in beef trim suppliers (0.73%) and sole beef trim suppliers (0.69%) are not statistically different than that found in the MT50 beef trim sampling program (0.60%). The *E. coli* percent positives in other ground beef component suppliers (0.62%) and sole ground beef component suppliers (0.61%), while higher, are not statistically different than that found in the MT54 sampling of other ground beef components (0.28%).

- In 2007 FSIS categorized its regulations according to potential public health significance and designated those regulations most strongly related to public health as "health-related" noncompliances. No predictive relationship was found between health-related regulatory noncompliances and the probability of *E. coli* O157:H7 positive sample results.

- No predictive relationship was found between higher sanitary dressing noncompliances and the probability of *E. coli* O157:H7 positive sample results. In its response to OIG, FSIS proposed to revise the sanitary dressing verification Directive 6410.1 with an aim to improve and clarify verification of sanitary dressing by FSIS inspectors. This may improve the correlation between sanitary dressing noncompliances and *E. coli* positives in beef trim. There is a definite seasonality in *E. coli* O157:H7 rate in beef trim and beef trim suppliers. The probability of detecting an *E. coli* O157:H7 positive in a beef trim establishment during May-Oct is 3.8 times higher than in the rest of the year (two sided Exact Fisher $p < 0.002$). The probability of a beef trim supplier having an *E. coli* O157:H7 in May-Oct is 1.9 times higher (but not statistically significantly so; two sided Exact Fisher $p = 0.175$) than in the rest of the year. Due to the low number of positives, no seasonality is apparent in the number of *E. coli* positives in bench trim and ground beef components other than trim.

- The probability of detecting an *E. coli* O157:H7 positive in raw ground veal is 19.2 times higher than in raw ground beef (this conclusion is based on limited samples in raw ground veal). The *E. coli* percent positive rates in veal trim and beef trim are not statistically significantly different, possibly due to the low number of samples in veal trim.

Of the options reviewed, the ones that appear most promising for increasing the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing are to increase *E. coli* O157:H7 sampling in

- Volume classes with the highest *E. coli* O157:H7 percent positive
- Volume class with the highest volume-weighted *E. coli* O157:H7 percent positive
- The six month summer season when *E. coli* O157:H7 percent positive is highest

Sampling beef trim volume classes in proportion to the *E. coli* O157:H7 percent positive, ensuring that each establishment is sampled at least once per year, and increasing samples during summer months by 20% increases the probability of detecting an *E. coli* positive to 2.0 times greater than under the 2010 MT50 random sampling program.

Sampling proportional to beef trim volume-weighted percent positive, ensuring that each establishment is sampled at least once per year, and increasing samples during summer months by 20% increases the probability of detecting an *E. coli* positive to 1.4 times greater than under the 2010 MT50 random sampling program.

In addition to the above analysis, FSIS assessed over 30 discrete sampling designs and their related probabilities to detect *E. coli* O157:H7 in beef manufacturing trimmings. The design the agency chose to implement is weighted, random sampling with replacement that accounts for both the production volume and percent positive of volume classes. The agency also chose to over-schedule seasonally during the high prevalence season, over-schedule to adjust for non-response, implement an annual scheduling floor, and implement monthly scheduling ceilings. The chosen design gives FSIS an increased likelihood of 2.5 to detect *E. coli* O157:H7 as compared to the current design of simple random sampling without replacement.

1.0 INTRODUCTION

In February 2011 the U.S. Department of Agriculture's (USDA) Office of Inspector General (OIG) published an audit report on the Food Safety Inspection Service (FSIS) sampling protocol for testing beef trim for *E. coli* O157:H7 (OIG 2011). The OIG expressed concerns about the efficacy of the sampling the FSIS performs to detect *Escherichia coli* (*E. coli*) O157:H7 in U.S. beef trim. OIG recommended that FSIS redesign its sampling program to provide a higher degree of confidence that its beef trim tests are accurately identifying contaminated product.

The objective of this report is to evaluate FSIS *E. coli* O157:H7 sampling designs for testing beef trim, bench trim, and raw ground beef components other than trim to evaluate options for increasing the degree of confidence for detecting *E. coli* O157:H7 positives during FSIS verification testing, and to document the scientific support and rationale for each of the possible designs.

E. coli O157:H7 is a bacterium that can cause illness in humans, especially children and older adults. Approximately 62,000 cases of symptomatic *E. coli* O157:H7 infections occur annually in the United States due to foodborne exposures, resulting in approximately 1,800 hospitalizations and 52 deaths. Surveillance data indicate that the highest incidence of illness from *E. coli* O157:H7 occurs in children under 5 years of age. Ground beef is considered a primary source of human exposure to *E. coli* O157:H7 (FSIS 2001).

Beef trim consists of pieces of meat and fat that remain after cattle carcasses are cut into various intact cuts of meat (e.g., loin, ribs, roasts, and steaks). Bench trim is beef trim that is produced during the fabrication of primals and sub-primals from cattle not slaughtered on site. Raw ground beef components include raw esophagus (weasand) meat, head meat, cheek meat, and other beef components used to make raw ground beef. Beef trim, bench trim, and other raw ground beef components are later ground to produce ground beef or other hamburger products.

E. coli O157:H7 can contaminate beef trim when fecal material from slaughtered cattle comes into contact with, and remains on, the carcass. To prevent beef trim from becoming contaminated, plants apply interventions—safety controls such as lactic acid sprays, carcass washes, or steam cabinets, which are intended to decontaminate carcasses before they are cut into pieces or the meat is shipped from the plant.

The codes for the different domestic products that FSIS currently samples for *E. coli* O157:H7 are:

- MT43 –Raw ground beef
- MT44 – Follow up testing to a raw ground beef positive
- MT50 –Beef trim
- MT52–Supplier of beef trim or other components to raw ground beef establishments with an MT43 or MT55 positive
- MT53 – Follow-up testing of positives from 1) Routine Testing of Beef Trim (MT50); 2) Routine Testing of Other Components (MT54); 3) Routine Testing of Bench Trim (MT55); or 4) Positive Follow-up Testing at Suppliers (Positive MT52 Samples)
- MT54 –Components other than trim
- MT55 – Bench trim (i.e., beef trim derived from cattle not slaughtered in the establishment)

The ground beef, beef trim, bench trim, and components other than trim programs were initiated on the following dates.

- In August 1994, FSIS declared that ground beef containing *E. coli* O157:H7 to be adulterated under the Federal Meat Inspection Act (FMIA) unless further processed in a manner that destroys this pathogen. In CY 2010 FSIS analyzed 11,292 raw ground beef samples for *E. coli* O157:H7 and found 26 positives for a percent positive of 0.23%.
- On October 17, 1994, FSIS initiated a microbiological sampling program for *E. coli* O157:H7 in raw ground beef in meat plants and retail stores.
- On March 19, 2007, FSIS began routine verification sampling of beef manufacturing trimmings (MT50) intended for use in raw ground beef or beef patty products at the slaughter establishments that produced those trimmings. Trimmings that the establishment intends for use in further processing into ready-to-eat products are not sampled. The N60 sample collection method used to test beef trim in the MT50 sampling program is described in Appendix A.
- On October 26, 2007, FSIS announced the intention to initiate routine verification of other raw ground beef components and sampling of those other components began in late December.
- On July 31, 2009 FSIS initiated a bench trim microbiological sampling program for *E. coli* O157:H7 in establishments that produce trim derived from cattle not slaughtered on site (MT55 Sampling). Establishments that produce beef trimmings from cattle slaughtered on site continue to be subjected to sampling under the Trim Verification program (MT50 sampling), and establishments that produce other raw ground beef or patty components from cattle slaughtered on site continue to be subjected to sampling under the Raw Ground Beef Components program (MT54 sampling).

2.0 OPTIONS FOR REDESIGN OF FSIS *E. COLI* O157:H7 SAMPLING PROGRAMS

The purpose of this section is to present options for the redesign of the FSIS *E. coli* O157:H7 sampling programs in beef trim, bench trim, and raw ground beef components other than trim. Each of the options will be evaluated in subsequent sections.

In its response to the OIG report, FSIS states it plans to revise the *E. coli* MT50 sampling program to focus *E. coli* testing and inspection resources primarily on establishments with the highest probability of producing beef trim contaminated with *E. coli* O157:H7 (FSIS 2011). This will allow FSIS to more effectively verify process controls at beef establishments across the nation. FSIS believes that effective verification of food safety systems must include inspection of an establishment's production process to ensure that controls are adequately designed and implemented to prevent, eliminate, or reduce contamination with *E. coli* O157:H7.

Ten options for focusing *E. coli* testing primarily on establishments with the highest probability of producing beef trim contaminated with *E. coli* O157:H7 were identified. They are to increase *E. coli* O157:H7 sampling frequency in

- Establishments with *E. coli* O157:H7 positives
- Volume classes with higher production volumes
- Volume classes with higher *E. coli* O157:H7 percent positive
- Volume classes with higher volume-weighted *E. coli* O157:H7 percent positive
- Beef trim and other component supplier establishments associated with *E. coli* O157:H7 positives in raw ground beef
- Establishments with higher HACCP noncompliances
- Establishments with higher sanitary dressing noncompliances
- Seasons of the year with higher *E. coli* O157:H7 positives
- Geographic regions with higher *E. coli* O157:H7 percent positive
- Product categories with higher *E. coli* O157:H7 percent positive

As a baseline for analysis, the average *E. coli* O157:H7 positive rates in ground beef, beef trim, bench trim, and components other than trim for the years 2007 – June 2011 are presented in the next section. In subsequent sections, each of the above options for increasing the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing will be evaluated in turn.

3.0 AVERAGE *E. coli* O157:H7 POSITIVE RATES

This section reviews the FSIS verification testing programs for *E. coli* O157:H7 in ground beef, beef trim, bench trim, and raw ground beef components other than trim and presents the average *E. coli* O157:H7 positive rates for the years 2007-June 2011.

The intended purpose of ground beef, beef trim, bench trim, and other ground beef component *E. coli* O157:H7 sampling is to verify an establishment's food safety process control under HACCP. Under each program, the establishments tested in any given month are selected at random. Details can be found in the *Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs* (FSIS December 2011).

3.1 Ground Beef Sampling

FSIS began routine verification sampling for *E. coli* O157:H7 in raw ground beef in October 1994. There are approximately 1,400 federally inspected establishments producing raw ground beef or raw ground beef products that are routinely sampled for *E. coli* O157:H7 as part of the Agency's HACCP verification program.

Table 3-1 presents the *E. coli* O157:H7 test results in raw ground beef establishments tested under the MT 43 testing program. In CY 2010 FSIS analyzed 11,290 raw ground beef samples for *E. coli* O157:H7 and found 26 positives (0.23%).

Table 3- 1 *E. coli* O157:H7 Test Results for Raw Ground Beef

Year	Positives	Negatives	% Positive
CY2007	27	11,948	0.23%
CY2008	48	10,735	0.45%
CY2009	35	11,537	0.30%
CY2010	26	11,264	0.23%
Jan-June 2011	3	5,673	0.05%
CY2006-June 2011	139	51,157	0.27%

3.2 Beef Trim

Currently FSIS collects beef trim samples from about 390 slaughter establishments annually for *E. coli* O157:H7 testing. Approximately 1,300 samples are collected per year, with an average of about seven *E. coli* O157:H7 positives per year resulting in an average *E. coli* O157:H7 positive rate of 0.60% over the period 2007 to June 2011. The average beef trim establishment is sampled about 3.5 times per year.

Table 3-2 presents the *E. coli* O157:H7 test results for beef trim establishments tested under the beef trim sampling program MT50. During CY 2010, FSIS analyzed 1,274 trim samples for *E. coli* O157:H7 from 386 slaughter establishments producing beef trim and found 4 positive samples (0.31 percent). There is no statistically significant difference in the *E. coli* O157:H7 percent positives between years (smallest two sided Exact Fisher $p = 0.077$). The overall *E. coli* O157:H7 positive rate for the period 2007-June 2011 is 0.60%. This percent positive is statistically significantly higher (two sided Exact Fisher, $p < 0.0002$) than that found in raw ground beef (0.27%). The probability of detecting an *E. coli* O157:H7 positive in beef trim is 2.2 times higher than in raw ground beef.

Table 3- 2 MT50 *E. coli* O157:H7 Test Results for Beef Trim

Year	Number Establishments Tested	Number Positives	Number Negatives	% Positive
2007	336	2	710	0.28%
2008	344	12	1,326	0.90%
2009	368	9	1,218	0.73%
2010	386	4	1,270	0.31%
Jan-June 2011	302	4	597	0.67%
2007-June 2011		31	5,121	0.60%

3.3 Bench Trim

Currently FSIS collects bench trim samples from about 440 processing establishments annually for *E. coli* O157:H7 testing. Approximately 550 samples are collected per year, with an average of about one *E. coli* O157:H7 positive per 2.5 years resulting in an average *E. coli* O157:H7 positive rate of 0.19% over the period 2007 to June 2011.

Table 3-3 presents the *E. coli* O157:H7 test results for bench trim establishments tested under the bench trim sampling program MT55. There is no statistically significant difference in the *E. coli* O157:H7 percent positives between years (smallest two sided Exact Fisher p = 0.214). The overall *E. coli* O157:H7 percent positive for the period 2009-June 2011 is 0.19%. This percent positive is not statistically significantly different (Two Tailed Fisher Exact p **>**0.999) than that found in raw ground beef (0.27%)

Table 3- 3 MT55 *E. coli* O157:H7 Test Results for Bench Trim

Year	Number Establishments Tested	Number Positives	Number Negatives	% Positive
2009	149	1	148	0.67%
2010	440	0	547	0.00%
Jan-June 2011	266	1	335	0.30%
2009-June 2011		2	1,030	0.19%

3.4 Raw Ground Beef Components Other Then Trim

Currently FSIS collects component samples from about 150 establishments annually from establishments producing raw ground beef components other than trim for *E. coli* O157:H7 testing. Approximately 170 samples are collected per year, with an average of about two *E. coli* O157:H7 positives per 3.5 years resulting in an average *E. coli* O157:H7 percent positive of 0.28% over the period 2007 to June 2011.

Table 3-4 presents the *E. coli* O157:H7 test results for establishments tested under the MT54 raw ground beef components other than trim sampling program. There is no statistically significant difference in the *E. coli* O157:H7 percent positives between years (smallest two sided Exact Fisher p = 1). The overall *E. coli* O157:H7 percent positive for the period 2009-June 2011 is 0.28%. This percent positive is not statistically significantly different (two sided Exact Fisher, p **>**0.723) than that found in raw ground beef (0.27%).

Table 3- 4 MT54 *E. coli* O157:H7 Test Results for Ground Beef Components

Year	Number Establishments Tested	Number Positives	Number Negatives	% Positive
2007	2	0	2	0.00%
2008	142	1	216	0.46%
2009	147	1	230	0.43%
2010	100	0	169	0.00%
Jan-June 2011	69	0	104	0.00%
2007-June 2011		2	721	0.28%

The *E. coli* O157:H7 percent positive in trim suppliers (0.73%) and sole beef trim suppliers (0.69%) are not statistically different than that found in the MT50 beef trim sampling program (0.60%). The *E. coli* percent positives in other ground beef component suppliers (0.62%) and sole ground beef component suppliers (0.61%), while higher, are not statistically different than that found in the MT54 sampling of other ground beef components (0.28%).

In summary, the *E. coli* O157:H7 percent positive in beef trim (0.60%), bench trim (0.19%) and raw ground beef components other than trim (0.28%) are not statistically significantly different (smallest two sided Exact Fisher, $p > 0.118$). The *E. coli* O157:H7 percent positive in beef trim (0.60%) is statistically significantly higher (two sided Exact Fisher, $p < 0.0002$) than that found in raw ground beef (0.27%). However, the *E. coli* O157:H7 percent positives in bench trim (0.19%) and raw ground beef components other than trim (0.28%) are not statistically significantly different (smallest two sided Exact Fisher, $p > 0.723$) than that found in raw ground beef (0.27%).

The following sections review the options for increasing the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing.

4.0 TARGET ESTABLISHMENTS WITH *E. COLI* O157:H7 POSITIVES

The purpose of this section is to determine whether increasing routine trim and components sampling in establishments that have an *E. coli* O157:H7 positive will increase the probability of detecting further *E. coli* positives.

4.1 *E. coli* Positive in Routine Testing of Beef Trim (MT50)

The purpose of this section is to determine if beef trim establishments with an *E. coli* positive during MT50 routine testing have an increased probability of another *E. coli* positive during routine testing over the next 120 days.

Table 4-1 compares the probability of an MT50 *E. coli* O157:H7 positive sample result over the 120 days following an MT50 *E. coli* O157:H7 positive test result with the probability of an MT50 *E. coli* O157:H7 positive test result over the 120 days following an MT50 *E. coli* O157:H7 negative test result for the years 2007 to June 2011. The difference in the two probabilities is not statistically significant (Two sided Fisher Exact, p **>** 0.138).

Table 4- 1 Probability of MT50 *E. coli* Positive in 120 days following an MT50 *E. coli* Positive

	MT50 *E. coli* Positive Test Result in Next 120 Days	No MT50 *E. coli* Positive Test Result in Next 120 Days	Probability of *E. coli* Positive Test Result in Next 120 Days
MT50 *E. coli* Test Result is Positive	1	28	3.45%
MT50 *E. coli* Test Result is Negative	27	5,440	0.49%

4.2 *E. coli* O157:H7 Positive Follow-Up Sampling

FSIS currently conducts follow-up *E. coli* sampling in establishments that have an *E. coli* positive. The follow-up sampling is conducted under the MT53 sampling program. MT53 sampling includes follow-up testing of positives from 1) routine testing of beef trim (MT50); 2) routine testing of other components (MT54); 3) Routine Testing of Bench Trim (MT55); or 4) positive follow-up testing at suppliers (positive MT52 samples). Sixteen follow-up samples are scheduled at an establishment with an *E. coli* positive unless the establishment is a low volume producer (less than 1,000 lbs. per day), when eight follow-up samples are scheduled.

Table 4-2 presents the test results for the MT53 *E. coli* O157:H7 follow-up sampling program for 2008 – June 2011. There is no statistically significant difference in the *E. coli* O157:H7 percent positives between years (smallest two sided Fisher Exact, p **=** 0.440).

The probability of detecting an E. *coli* O157:H7 positive during MT53 beef trim follow-up sampling are 6.6 times higher than under MT50 beef trim sampling. No positives were detected during MT53 *E. coli* O157:H7 follow-up sampling for bench trim or other components.

Table 4- 2 MT53 Follow-Up Test Results for Beef Trim

Year	# Plants	# Plants with Positives in follow-up	Positives	Negatives	% Positive
2008	12	1	3	122	2.40%
2009	12	3	7	158	4.24%
2010	12	1	5	120	4.00%
Jan-June 2011	8	2	4	79	4.82%
2008-June 2011	44	7	19	479	3.82%

Table 4-3 and Table 4-4 presents follow-up test results for bench trim and raw ground beef components other than trim.

Table 4- 3 MT53 Follow-Up Test Results for Bench Trim

Year	# Plants	# Plants with Positives in follow-up	Positives	Negatives	% Positive
2008	0	0	0	0	0.00%
2009	1	0	0	16	0.00%
2010	0	0	0	0	0.00%
Jan-June 2011	1	0	0	8	0.00%
2008-June 2011	2	0	0	24	0.00%

Table 4- 4 MT53 Follow-Up Test Results for Other Components

Year	# Plants	# Plants with Positives in follow-up	Positives	Negatives	% Positive
2008	1	0	0	16	0.00%
2009	0	0	0	0	0.00%
2010	0	0	0	0	0.00%
Jan-June 2011	0	0	0	0	0.00%
2008-June 2011	1	0	0	16	0.00%

Conclusion: These results demonstrate that increasing *E. coli* O157:H7 sampling after an *E. coli* positive in beef trim is an effective means of increasing the probability of detecting an *E. coli* positive in beef trim. However, FSIS under the MT53 sampling program already increases *E. coli* O157:H7 sampling after an *E. coli* positive in beef trim. Thus this option is already being implemented as a means of increasing the probability of detecting *E. coli* O157:H7 positives in beef trim.

Follow up testing in bench trim and raw ground beef components other than trim has not produced an increase in the probability of detecting an *E. coli* O157:H7 positive. Thus, while follow up testing for bench time and raw ground beef components other than trim should be continued, there does not seem to be evidence for increasing the number of samples taken.

5.0 TARGET VOLUME CLASSES WITH LARGER VOLUMES

The purpose of this section is to determine whether allocating the number of samples in each volume class in proportion to the volume of that volume class will increase the probability of detecting *E. coli* positives. Under this option, the volume classes with the largest volume would be tested more frequently.

5.1 *E. coli* O157:H7 Percent Positive for Different Volume Classes

Table 5-1 presents the *E. coli* test results as a function of beef trim volume class for the years CY2007 through June 2011 combined (See Appendix B for more detail on the relationship between beef trim volumes and *E. coli* positives). The data were combined since no statistically significant difference was found in the *E. coli* O157:H7 positive rates in the years CY2007 through June 2011 (see Section 3.1). In addition, combining the data produces a larger number of samples for each trim volume class and thus produces more accurate estimates of the percent positive for the volume classes. A total of 509 unique beef trim establishments were tested during the period 2007-June 2011. However, because some establishments change volume class from year to year, the total number of unique establishments in Table 5-1 is 582.

Table 5- 1 Volume Classes for Beef Trim MT50 *E. coli* O157:H7 Sampling for 2007-June 2011

Volume Class	**# of unique plants**	Total volume CY2007-June 2011 (pounds)	% of Total Volume	***E. coli* Positives**	**Total Tests**	**% Positive**
Very Small	408	95,025,000	0.49%	15	3,558	0.42%
Small	93	1,268,625,000	6.48%	9	612	1.47%
Medium	41	4,725,000,000	24.12%	5	452	1.11%
Large	40	13,500,000,000	68.92%	2	530	0.38%
Total	582	19,588,650,000	100.00%	31	5,152	0.60%

The large volume class has the smallest *E. coli* percent positive, while the small volume class has the highest *E. coli* percent positive. There is no statistically significant difference in the *E. coli* O157:H7 percent positive for any of the volume classes (Smallest Two sided Fisher Exact $p > 0.066$) except for very small class, where the *E. coli* O157:H7 is statistically significantly less than that of the small beef trim volume classes (Two sided Fisher Exact $p = 0.005$) .

Sampling beef trim establishments proportional to production volume and requiring that each establishment is sampled at least once per year is only slightly more likely (1.01) to detect an *E. coli* O157:H7 positive; however, it does make sampling more representative of national production (See Appendix C).

Table 5-2 and Table 5-3 present the *E. coli* test results as a function of bench trim and other raw ground beef components production volume respectively for the years CY2007 through June 2011 combined. Again, the smaller volume classes have the highest *E. coli* percent positives, while the larger volume classes have zero percent positive.

Table 5- 2 Volume Classes for Bench Trim MT55 *E. coli* O157:H7 Sampling for 2009- June 2011

Volume Class	# of unique plants	*E. coli* Positives	Total Tests	% Positive
Very Small	353	1	552	0.18%
Small	77	1	124	0.81%
Medium	131	0	154	0.00%
Large	183	0	202	0.00%
Total	744	2	1,032	0.19%

Table 5- 3 Volume Classes for Other Ground Beef Components MT54 *E. coli* O157:H7 Sampling for 2008-June 2011

Volume Class	# of unique plants	*E. coli* Positives	Total Tests	% Positive
Very Small	206	1	462	0.22%
Small	67	1	156	0.64%
Medium	21	0	42	0.00%
Large	17	0	63	0.00%
Total	311	2	723	0.28%

Conclusion: These results demonstrate that beef trim, bench trim, and other ground beef component establishments have the lowest *E. coli* percent positive rates in the large volume class and the highest *E. coli* percent positive rates in the small production volume class. MT50 sampling in the small trim volume class has a 2 times higher probability of detecting an *E. coli* O157:H7 positive than MT50 sampling in large trim volume establishments.

These results demonstrate that increasing *E. coli* O157:H7 sampling in proportion to the relative volume of the volume class may not provide an effective means of increasing the probability of detecting an *E. coli* positive in beef trim, bench trim, and other ground beef component establishments. In fact, sampling proportional to production volume in beef trim establishments and requiring that each establishment is sampled at least once per year is only slightly more likely (1.01) to detect an *E. coli* O157:H7 positive than the 2010 random sampling program (See Appendix C).

6.0 TARGET VOLUME CLASSES WITH LARGER *E. coli* PERCENT POSITIVE

The purpose of this section is to determine whether allocating sampling for a volume class in proportion to the *E. coli* O157:H7 percent positive for that volume class will increase the probability of detecting *E. coli* positives. Under this option, the volume classes with the highest *E. coli* percent positive would receive the largest number of samples. The rationale for this option is that it targets volume classes that are most likely to have an *E. coli* O157:H7 positive.

Table 6-1 shows the average number of samples per beef trim plant if sampling were proportional to the percent positive in each volume class based on CY2010 data. Sampling volume classes proportional to percent positive in the volume class is 1.9 times more likely to detect an *E. coli* O157:H7 positive than under the current MT50 random sampling program (See Appendix C). Sampling volume classes proportional to percent positive in the volume class and requiring that each establishment is sampled at least once is 1.8 times more likely to detect an *E. coli* O157:H7 positive than under the current MT50 random sampling program (see Appendix C).

Table 6- 1 Distribution of Samples per Beef Trim Plant if Sampling Proportional to Percent Positive

Volume Class	2010 Unique Plants	2010 Total Tests	2010 Average Tests per Plant	Multi-Year % Positive	Number of Samples if proportional to % Positive	Average Tests per Plant if Proportional to % Positive
Very Small	291	915	3.1	0.42%	158	0.5
Small	42	136	3.2	1.47%	554	13.2
Medium	25	93	3.7	1.11%	418	16.7
Large	28	130	4.6	0.38%	143	5.1
Total	386	1,274	3.3	0.60%	1,274	3.3

Table 6-2 shows the average number of samples per bench trim plant if sampling were proportional to the percent positive in each volume class based on number of samples taken in CY2010. Sampling volume classes proportional to percent positive in the volume class is 3.6 times more likely to detect an *E. coli* O157:H7 positive than under the current MT55 random sampling program. However, under this sampling design, no samples would be taken in some volume classes. Sampling volume classes proportional to percent positive in the volume class and requiring that each establishment is sampled at least once is 2.5 times more likely to detect an *E. coli* O157:H7 positive than under the current MT55 random sampling program (Calculated similar to examples in Appendix C).

Table 6- 2 Distribution of Samples per Bench Trim Plant if Sampling Proportional to Percent Positive

Volume Class	2010 Unique Plants	2010 Total Tests	2010 Average Tests per Plant	Multi-Year % Positive	Number of Samples if proportional to % Positive	Average Tests per Plant if Proportional to % Positive
Very Small	222	274	1.2	0.18%	99	0.4
Small	52	69	1.3	0.81%	448	8.6
Medium	77	98	1.3	0.00%	0	0.0
Large	89	106	1.2	0.00%	0	0.0
Total	440	547	1.2	0.19%	547	1.2

Table 6-3 shows the average number of samples per other ground beef component plant if sampling were proportional to the percent positive in each volume class based on number of samples taken in CY2010. Sampling volume classes proportional to percent positive in the volume class is 2.0 times more likely to detect an *E. coli* O157:H7 positive than under the current MT54 random sampling program. However, under this sampling design, no samples would be taken in some volume classes. Sampling volume classes proportional to percent positive in the volume class and requiring that each establishment is sampled at least once is 1.9 times more likely to detect an *E. coli* O157:H7 positive than under the current MT54 random sampling program (Calculated similar to examples in Appendix C).

Table 6- 3 Distribution of Samples per Other Ground Beef Component Plant if Sampling Proportional to Percent Positive

Volume Class	2010 Unique Plants	2010 Total Tests	2010 Average Tests per Plant	Multi-Year % Positive	Number of Samples if proportional to % Positive	Average Tests per Plant if Proportional to % Positive
Very Small	67	101	1.5	0.22%	43	0.6
Small	24	37	1.5	0.64%	126	5.2
Medium	4	8	2.0	0.00%	0	0.0
Large	5	23	4.5	0.00%	0	0.0
Total	100	169	1.7	0.28%	169	1.7

Conclusion:
These results demonstrate that sampling volume classes in proportion to the percent positive of the volume class will increase the probability of detecting an *E. coli* O157:H7 percent positive.

7.0 TARGET VOLUME CLASSES WITH LARGER VOLUME-WEIGHTED PERCENT POSITIVE

One option for improving the MT50 sampling program is to make sampling in each volume class proportional to the volume-weighted percent positive of the volume class. The volume-weighted percent positive for a volume class is the product of its *E. coli* percent positive with the fraction of total production volume in that volume class (see Appendix B for more detail). Under such a program, production categories with higher volume-weighted percent positives would be tested more frequently. The rational for volume-weighted sampling is that it decreases the uncertainty in the *E. coli* percent positive estimate for the largest volume class and therefore provides the best approximation to the prevalence of *E. coli* O157:H7 in the beef trim supply. This option differs from the previous option (sampling proportional to percent positive) in that it targets volume classes that are most likely to cause the most number of illnesses as opposed to the previous option which targets volume classes most likely to have an *E. coli* O157:H7 positive.

Table 7-1 presents an estimate of the beef trim volume-weighted percent positive for *E. coli* O157:H7 based on cumulative data for the years CY2007 through June 2011. The volume-weighted percent positive over these years is 0.63%. Sampling volume classes proportional to volume-weighted percent positive in the volume class is 1.5 times more likely to detect an *E. coli* O157:H7 positive than under the current MT50 random sampling program.

Table 7- 1 *E. coli* O157:H7 Beef Trim Volume-Weighted Percent Positive

Volume Class	Number Estabs Tested	Total volume CY2007-June 2011 (pounds)	% of Total Volume	Number Samples	% of Total Samples	Unweighted % Positive	Volume Weighted % Positive
Very Small	1,267	95,025,000	0.49%	3,558	69.06%	0.42%	0.00%
Small	199	1,268,625,000	6.48%	612	11.88%	1.47%	0.10%
Medium	126	4,725,000,000	24.12%	452	8.77%	1.11%	0.27%
Large	144	13,500,000,000	68.92%	530	10.29%	0.38%	0.26%
Total	1,736	19,588,650,000	100.00%	5,152	100.00%	0.60%	0.63%

Table 7-2 shows the average number of samples per beef trim plant if sampling were proportional to the volume-weighted percent positive in each volume class based on CY2010 data. Sampling beef trim volume classes proportional to volume-weighted percent positive is 1.5 times more likely to detect an *E. coli* O157:H7 positive than under the current MT50 random sampling program (See Appendix C). Sampling beef trim volume classes proportional to volume-weighted percent positive and requiring that each establishment is sampled at least once is 1.3 times more likely to detect an *E. coli* O157:H7 positive than under the current MT50 random sampling program (See Appendix C).

Table 7- 2 Distribution of Samples per Beef Trim Plant if Sampling Proportional to Volume Weighted Percent Positive

Volume Class	# of unique plants	2010 # of Samples	2010 Average Tests per Plant	Volume Weighted % Positive	Distribution of Volume Weighted Percent Positives	Number of Samples if proportional to volume weighted % Positive	Average Tests per Plant if Proportional to volume weighted % Positive
Very Small	291	915	3.1	0.00%	0.38%	5	0.0
Small	42	136	3.2	0.10%	16.12%	205	4.9
Medium	25	93	3.7	0.27%	42.63%	543	21.7
Large	28	130	4.6	0.26%	40.87%	521	18.6
Total	386	1,274	3.3	0.63%	100.00%	1,274	3.3

Table 7-3 presents an estimate of the volume-weighted percent positive for *E. coli* O157:H7 in bench trim based on cumulative data for the years CY2009 through June 2011. The volume-weighted percent positive for bench trim over these years is 0.02%. Sampling bench trim volume classes proportional to volume-weighted percent positive in the volume class is 4.1 times more likely to detect an *E. coli* O157:H7 positive than under the current MT55 random sampling program.

Table 7- 3 *E. coli* O157:H7 Bench Trim Volume-Weighted Percent Positive

Volume Class	Number Estabs Tested	Total volume CY2007-June 2011 (pounds)	% of Total Volume	Number Samples	% of Total Samples	Unweighted % Positive	Weighted % Positive
Very Small	445	33,375,000	0.15%	552	53.49%	0.18%	0.00%
Small	93	592,875,000	2.59%	124	12.02%	0.81%	0.02%
Medium	132	4,950,000,000	21.60%	154	14.92%	0.00%	0.00%
Large	185	17,343,750,000	75.67%	202	19.57%	0.00%	0.00%
Total	855	22,920,000,000	100.00%	1,032	100.00%	0.19%	0.02%

Table 7-4 presents estimates of the volume-weighted percent positive for *E. coli* O157:H7 in ground beef components other than trim based on cumulative data for the years CY2009 through June 2011. The volume-weighted percent positive for ground beef components other than trim over these years is 0.1%. Sampling raw ground beef component volume classes proportional to volume-weighted percent positive in the volume class is 2.3 times more likely to detect an *E. coli* O157:H7 positive than under the 2010 MT54 random sampling program.

Table 7- 4 *E. coli* O157:H7 Other Component Volume-Weighted Percent Positive

Trim Volume Class	Number Estabs Tested	Trim volume CY2007-June 2011 (pounds)	% of Total Volume	Number Samples	% of Total Samples	Unweighted % Positive	Weighted % Positive
Very Small	310	23,250,000	0.60%	462	63.90%	0.22%	0.00%
Small	100	637,500,000	16.41%	156	21.58%	0.64%	0.10%
Medium	26	975,000,000	25.09%	42	5.81%	0.00%	0.00%
Large	24	2,250,000,000	57.90%	63	8.71%	0.00%	0.00%
Total	460	3,885,750,000	100.00%	723	100.00%	0.28%	0.11%

Conclusion: These results demonstrate that sampling volume classes in proportion to the volume-weighted percent positive of the volume class will increase the probability of detecting an *E. coli* O157:H7 percent positive.

8.0 TARGET ESTABLISHMENTS ASSOCIATED WITH *E. COLI* POSITIVES IN RAW GROUND BEEF

Slaughter establishments that supply beef trim, bench trim, or other components to raw ground beef establishments that test positive for *E. coli* O157:H7 are sampled under the MT52 sampling program. MT52 sampling is performed in supplier slaughter establishments following a raw ground beef (MT43 sampling) positive, a positive in follow-up sampling in response to a raw ground beef positive (MT44 sampling), or a positive sample from bench trim (MT55 sampling). MT52 samples are also taken for the Agricultural Marketing Service (AMS) School Lunch Program and of suppliers, when raw ground beef or bench trim are recalled. For the purposes of this report slaughter establishments tested under the MT 52 sampling program will be called supplier establishments or simply suppliers. A beef trim or other component supplier that is the only establishment that supplied beef trim or other components to a raw ground beef establishment that tested positive for *E. coli* O157:H7 will be called a sole supplier. Supplier establishments are identified by FSIS traceback to the originating slaughter establishments and are documented and tracked in the Supplier Traceback to *E. coli* Positive System (STEPS). Sixteen follow up samples are scheduled at a sole supplier establishment unless the establishment is a low volume producer (less than 1,000 lbs. per day), when eight follow up samples are collected. One follow up sample is collected at supplier establishments that are not sole suppliers unless they are identified in STEPS more than once in the past 120 days.

Table 8-1 shows the MT52 program *E. coli* O157:H7 test results for CY2007 through June CY2011. An average of 49 supplier establishments were identified and tested annually for the years CY2007-CY2010. Over the period CY2007-June 2011, 110 unique supplier establishments were identified and tested for *E. coli* O157:H7. There is no statistically significant difference in the *E. coli* O157:H7 percent positives for the years 2007 – 2010 (smallest two sided Exact Fisher $p > 0.579$).

Table 8- 1 MT52 *E. coli* O157:H7 Test Results for Suppliers

Year	Number Supplier Estabs	Number Positives	Total Tests	% Positive
2007	47	1	266	0.38%
2008	40	4	623	0.64%
2009	63	9	940	0.96%
2010	46	4	636	0.63%
Jan-June 2011	12	1	181	0.55%
2007-June 2011	208	19	2,646	0.72%

The *E. coli* percent positive in suppliers (0.72%) in Table 8-1 is not statistically different than that found in the MT50 beef trim sampling program (0.60%) in Table 3-1 (two-tailed corrected Chi Square p = 0.64, uncorrected Pearson Chi Square p = 0.54).

Table 8-2 separates suppliers into beef trim suppliers and other suppliers. The other supplier category consists almost entirely of suppliers of other ground beef components. The *E. coli* percent positive in beef trim suppliers (0.73%) in Table 8-2 is not statistically different than that found in the other suppliers (0.69%) (two sided Exact Fisher = 1).

Table 8- 2 MT52 *E. coli* O157:H7 Test Results for Beef Trim and Other Suppliers

	Beef Trim Suppliers			Other Suppliers		
Year	Positive	Total Tests	Rate	Positive	Total Tests	Rate
2007	1	242	0.41%	0	24	0.00%
2008	3	499	0.60%	1	124	0.81%
2009	8	708	1.13%	1	232	0.43%
2010	2	349	0.57%	2	287	0.70%
Jan-June 2011	0	125	0.00%	1	56	1.79%
2007-June 2011	14	1,923	0.73%	5	723	0.69%

Table 8-3 shows the MT52 program *E. coli* O157:H7 testing results for all sole supplier establishments for CY2007 through June CY2011. On average, 33 supplier establishments are identified as sole suppliers per year for the years CY2007-CY2010. There is no statistically significant difference in the *E. coli* O157:H7 percent positives for the years 2007 – June 2011 between the supplier *E. coli* percent positive rate in Table 8-1 (0.73%) and that for sole suppliers in Table 8-3 (0.62%) (Two sided Exact Fisher p = 0.703).

Table 8- 3 MT52 *E. coli* O157:H7 Test Results for Sole Suppliers

Year	Number Sole Suppliers	Number Positives	Total Tests	% Positive
2007	30	1	210	0.48%
2008	30	4	477	0.84%
2009	39	6	795	0.75%
2010	32	2	486	0.41%
Jan-June 2011	7	0	130	0.00%
2007-June 2011	138	13	2,098	0.62%

Table 8-4 separates sole suppliers into sole beef trim suppliers and other sole suppliers. The other sole supplier category consists almost entirely of sole suppliers of other ground beef components.

Table 8- 4 MT52 *E. coli* O157:H7 Test Results for Sole Beef Trim and Other Sole Suppliers

	Sole Beef Trim Suppliers			Other Sole Suppliers		
Year	Positive	Total Tests	Rate	Positive	Total Tests	Rate
2007	1	191	0.52%	0	19	0.00%
2008	3	415	0.72%	1	62	1.61%
2009	5	607	0.82%	1	188	0.53%
2010	1	319	0.31%	1	167	0.60%
Jan-June 2011	0	78	0.00%	0	52	0.00%
2007-June 2011	10	1,610	0.62%	3	488	0.61%

The *E. coli* percent positive in sole suppliers (0.62%) in Table 8-3 is not statistically different than that found in sole beef trim suppliers (0.62%) (Two sided Exact Fisher p = 1) or in other sole suppliers (0.61%) (Two sided Exact Fisher p = 1) from Table 8-4.

Volume estimates are not collected under the MT52 suppler sampling program. Therefore, *E. coli* percent positives for suppliers are not presented as a function of volume class.

Conclusion: There is no statistically significant difference between the *E. coli* O157:H7 positive rates in MT50 sampling of beef trim (0.60%), MT52 sampling of beef trim suppliers (0.72%), and MT52 sampling of sole beef trim suppliers (0.62%). There is also no statistically significant difference between the *E. coli* O157:H7 positive rates in MT54 sampling of other ground beef components (0.28%), MT52 sampling of other suppliers (0.69%), and MT52 sampling of other sole suppliers (0.61%).

FSIS under the MT52 sampling program already increases *E. coli* O157:H7 sampling in slaughter establishments associated with an *E. coli* positive in raw ground beef. Thus this option is already being implemented as a means of increasing the probability of detecting *E. coli* O157:H7 positives in slaughter establishments that are associated with an *E. coli* O157:H7 positive in raw ground beef.

9.0 TARGET ESTABLISHMENTS WITH HIGHER HACCP NON-COMPLIANCES

This section reviews the health-related regulatory noncompliance record (NR) for (1) slaughter establishments that produce beef trim and (2) supplier establishments that supplied beef trim to raw ground beef establishments that tested positive for *E. coli* O157:H7.

FSIS inspection program personnel perform inspection procedures in federally-inspected establishments each day to verify that the establishments are executing their SSOP and HACCP system under 9 CFR 416 and 417. In 2007 FSIS categorized its regulations according to potential public health significance and designated those regulations most strongly related to public health as "health-related" noncompliances. The rate at which an establishment fails to meet these health-related requirements and receives a health-related noncompliance is considered by FSIS to be an indication of the establishment's inability to control its production process and risk.

Ten inspection procedures are utilized by FSIS inspectors in all slaughter establishments. They are 01A01, 01B01, 01B02, 01C01, 01C02, 03A01, 03J01, 03J02, 05A01 and 06D01 (See Appendix D for definition of each procedure code). The number of inspection procedures performed and the number of health-related NRs issued were determined for each procedure code for each of the years CY2007 to June 2011 for each slaughter establishment producing beef trim. Noncompliances for the occurrence of fecal material on beef carcasses were also evaluated.

All ten inspection procedures were evaluated, but only 03J02 (03J02 consists of verifying all HACCP requirements at all critical control points in the HACCP slaughter establishment) was found to have statistically significantly higher health-related noncompliances for establishments with *E. coli* O157:H7 positives (Two sided Exact Fisher $p = 0.005$). The inspection procedure 03J01 (03J01 consists of verifying one or more HACCP requirements for monitoring, verification, and recordkeeping at a slaughter establishment) was not statistically significantly higher (Two sided exact fisher $p = 0.116$) for beef trim establishments with an *E. coli* positive. There was no difference in the rate of fecal noncompliances.

9.1 Beef Trim Establishments

Table 9-1 presents the 03J01 and 03J02 health-related noncompliance rates for beef trim establishments with and without *E. coli* O157:H7 positives during beef trim MT50 sampling.

Table 9- 1 Health-Related Noncompliance Rates for Beef Trim Establishments With and Without *E. coli* O157:H7 Positives during MT50 Sampling

	03J01		03J02	
Year	With *E. coli* Positive	Without *E. coli* Positive	With *E. coli* Positive	Without *E. coli* Positive
CY2007	0.00%	0.76%	0.64%	0.53%
CY2008	0.00%	0.69%	0.09%	0.48%
CY2009	0.55%	0.40%	0.13%	0.41%
CY2010	2.18%*	0.38%	5.74%*	0.62%
Jan-June 2011	1.4%	0.47%	0.00%	0.63%
CY2007-June 2011	0.77%	0.53%	0.97%*	0.52%

*Indicates statistically significant difference (two sided Exact Fisher $p < 0.01$ for both 03J01 and 03J02). . All other entries are not statistically significantly different.

The results in Table 9-1 are annual health-related noncompliances. It is expected that beef trim establishment 03J01 and 03J02 health-related noncompliances in the 3 or 6 months preceding an *E. coli* positive in beef trim may be higher than those 9 to 12 months before the *E. coli* positive. Table 9-2 presents 03J01 and 03J02 health-related noncompliance rates in 3 month increments for the months preceding an *E. coli* positive in beef trim based on 2007-June 2011 cumulative data.

Table 9- 2 Beef Trim Establishment 03J01 and 03J02 Health-Related Non-compliances in the Months Preceding an *E. coli* Positive in Beef Trim

	During the 3 months before the *E. coli* positive	**Between 6 and 3 months before *E. coli* positive**	**Between 9 and 6 months before *E. coli* positive**	**Between 12 and 9 months before *E. coli* positive**
03J01	0.71%	0.17%	0.53%	0.84%
03J02	1.36%	0.45%	1.92%	0.15%

The 03J01health-related noncompliance rate of 0.71% in the 3 months before an *E. coli* positive (in trim establishments with an *E. coli* positive between 2007 and June 2011) is not statistically different than the average *E. coli* noncompliance rate of 0.53% for trim establishments without an *E. coli* positive in Table 9-1 (Two sided Exact Fisher p = 1).

The 03J02 health-related noncompliance rate of 1.36% in the 3 months before an *E. coli* positive (in trim establishments with an *E. coli* positive between 2007 and June 2011) is statistically greater (Two sided Exact Fisher = 0.0058) than the average *E. coli* noncompliance rate of 0.52% for trim establishments without an *E. coli* positive in Table 9-1. This suggests that there is a correlation between 03J02 non-compliance and *E. coli* positives, but further investigation is necessary to show that a 03J02 non-compliance is likely to predict a future *E. coli* positive.

Table 9-3 shows that in the 3 months following a 03J02 non-compliance, beef trim establishments are more likely, but not statistically significantly so, (two sided Exact Fisher p = 0.0846) to have an *E. coli* positive than in the 3 months following a compliant 03J02. This demonstrates that a noncompliant 03J02 is not predictive of an *E. coli* positive in the following 3 months.

Table 9- 3 Probability Beef Trim Establishment Has an *E. coli* Positive in 3 Months Following an 03J02 Inspection

	Number of samples that were *E. coli* Positive	Number of samples that were not *E. coli* Positive	*E. coli* percent positive
MT50 Samples Taken up to 3 Months after a noncompliant 03J02	5	357	1.38%
MT50 Samples Taken up to 3 months after a compliant 03J02	724	112,890	0.64%

9.2 Beef Trim Suppliers

Table 9-4 presents 03J01 and 03J02 health-related noncompliance rates for beef trim suppliers. For the period 2007-June 2011, the 03J01 and 03J02 health-related noncompliance rates for beef trim suppliers are statistically significantly higher (Two sided Exact Fisher p < 0.0001) than 03J01 or 03J02 rates for beef trim establishments without *E. coli* positives from Table 9-1. For the period 2007-June 2011, the odds ratio associated with the 03J01 non-compliance rates is 2.2 with a confidence interval of 1.9 to 2.5. The odds ratio associated with the 03J02 non-compliance rates is 2.1 with a confidence interval of 1.8 to 2.4. This means

that a beef trim suppler is about 2 times more likely to have a 03J01 or 03J02 health-related noncompliance than a beef trim establishment without an *E. coli* positive.

Table 9- 4 03J01 and 03J02 Health-Related Noncompliance Rates for Beef Trim Suppliers

	03J01			03J02		
Year	Noncompliant	Compliant	Rate	Noncompliant	Compliant	Rate
CY2007	51	4,120	1.22%*	33	4,319	0.76%
CY2008	118	5,141	2.24%*	69	4,715	1.44%*
CY2009	34	6,893	0.49%	47	6,479	0.72%*
CY2010	34	6,893	0.49%	83	5,592	1.46%*
Jan-June 2011	4	747	0.53%	0	581	0.00%
CY2007-June 2011	262	22,569	1.15%*	232	21,686	1.06%*

*Indicates statistically significantly higher than 03J01 or 03J02 rates for beef trim establishments without *E. coli* positives from Table 9-1. All other entries are not statistically significantly different

Table 9-5 shows that in the 3 months following a 03J01 non-compliance, beef trim supplier establishments are less likely but not statistically significantly so (two sided Exact Fisher p = 0.380), to have an *E. coli* positive than in the 3 months following a compliant 03J01 inspection. The lack of statistical significance supports the conclusion that a 03J01 noncompliance is not predictive of an *E. coli* O157:H7 positive in the near future.

Table 9- 5 Probability Beef Trim Supplier Has an *E. coli* Positive in 3 Months Following an 03J01 Inspection

	Number of Samples that were *E. coli* Positive	Number of Samples that were not *E. coli* Positive	*E. coli* Percent Positive Rate
MT50 Samples in Beef Trim Suppliers Taken within 3 Months following a noncompliant 03J01	1	275	0.36%
MT50 Samples in Beef Trim Suppliers Taken within 3 Months following a compliant 03J01	427	38,657	1.09%

Table 9-6 shows that in the 3 months following a 03J02 non-compliance, beef trim supplier establishments are more likely but not statistically significantly so (two sided Exact Fisher p = 0.348), to have an *E. coli* positive than in the 3 months following a compliant 03J02 inspection. The lack of statistical significance supports the conclusion that a 03J02 noncompliance is not predictive of an *E. coli* O157:H7 positive in the near future.

Table 9- 6 Probability Beef Trim Supplier Has an *E. coli* Positive in 3 Months Following an 03J02 Inspection

	Number of Samples that were *E. coli* Positive	Number of Samples that were not *E. coli* Positive	*E. coli* Percent Positive Rate
MT50 Samples in Beef Trim Suppliers Taken within 3 Months following a noncompliant 03J02	4	245	1.61%
MT50 Samples in Beef Trim Suppliers Taken within 3 Months following a compliant 03J02	410	36,873	1.10%

Table 9-7 presents the 03J01 and 03J02 health-related noncompliance rates for beef trim establishments that were not suppliers.

Table 9- 7 03J01 and 03J02 Health-Related Noncompliance Rates for Beef Trim Establishments That Are Not Suppliers

Beef Trim that are not Suppliers	03J01			03J02		
Year	Noncompliant	Compliant	Rate	Noncompliant	Compliant	Rate
CY2007	115	17,751	0.64%	84	17,884	0.47%
CY2008	81	23,403	0.34%	74	24,954	0.30%
CY2009	91	23,851	0.38%	82	25,459	0.32%
CY2010	82	27,786	0.29%	141	27,239	0.51%
Jan-June 2011	56	11,159	0.50%	72	10,938	0.65%
CY2007-June 2011	425	103,950	0.41%	453	106,474	0.42%

Table 9-8 presents a comparison between the 03J01 and 03J02 health-related noncompliance rates for beef trim suppliers and beef trim establishments that were not suppliers. Both the 03J01 and 03J02 health-related noncompliances are statistically significantly higher for beef trim suppliers than non-suppliers (two sided Exact Fisher $p < 0.0001$ for both 03J01 and 03J02).

For the period 2007-June 2011, the odds of a beef trim supplier having a 03J01 non-compliance is 1.3 times higher (confidence interval of 1.2 to 1.5) than a beef trim non-supplier having a 03J01 noncompliance. The odds ratio associated with the 03J02 non-compliance rates is 1.3 with a confidence interval of 1.1 to 1.4. Thus, beef trim suppliers are about 1.3 times more likely to have a 03J01 or 03J02 health-related noncompliance than a beef trim non-supplier.

Table 9- 8 03J01 and 03J02 Health-Related Noncompliance Rates for Beef Trim Suppliers and Non-Suppliers

	03J01		03J02	
Year	Supplier	Not Supplier	Supplier	Not Supplier
CY2007	1.22%	0.64%*	0.76%	0.47%*
CY2008	2.24%	0.34%*	1.44%	0.30%*
CY2009	0.49%	0.38%	0.72%	0.32%*
CY2010	0.96%	0.29%*	1.46%	0.51%*
Jan-June 2011	0.53%	0.50%	0.00%	0.65%
CY2007-June 2011	1.15%	0.41%*	1.06%	0.42%*

*Indicates statistically significant difference. All other entries are not statistically significantly different.

Conclusion: No predictive relationship was found between health-related regulatory noncompliances and the probability of *E. coli* O157:H7 positive sample results.

10.0 TARGET ESTABLISHMENTS WITH SANITARY DRESSING NON-COMPLIANCES

FSIS in its response to OIG suggested that sanitary dressing noncompliances (06D01) may be related to *E. coli* O157:H7 positives in beef trim since carcass contamination is the primary cause of ground beef component adulteration with *E. coli* O157:H7 (FSIS 2011). The review of regulatory noncompliances in Section 5 found no statistically significant differences in the 06D01 health-related noncompliance rates between beef trim establishments with and without *E. coli* positives. In fact, the 31 beef trim establishments with *E. coli* positives did not have any 06D01 noncompliances during the period 2007 – June 2011, while the 478 beef trim establishments without *E. coli* positives had 3 06D01 noncompliances.

There was also no statistically significant difference in the carcass fecal contamination NR rates (Regulation code 381.65(e)) between beef trim establishments with and without *E. coli* positives. The 31 beef trim establishments with *E. coli* positives had one carcass fecal noncompliance during the period 2007 – June 2011, while the 478 beef trim establishments without *E. coli* positives had 31.

Conclusion: It does not appear that the rate of sanitary dressing noncompliances can be used as a means to identify beef trim establishments with a higher probability of having an *E. coli* O157:H7 positive. In its response to OIG, FSIS proposed to revise the sanitary dressing verification Directive 6410.1 with an aim to improve and clarify verification of sanitary dressing by FSIS inspectors. This may improve the correlation between sanitary dressing noncompliances and *E. coli* positives in beef trim.

11.0 INCREASE SAMPLING DURING THE SUMMER MONTHS

E. coli O157:57 concentrations in ground beef and also human illnesses demonstrate seasonality, with higher levels occurring during summer months. Thus, one option for increasing the probability of detecting an *E. coli* O157:H7 during MT50 sampling is to increase the number of tests performed during the summer months.

11.1 Seasonality of *E. coli* O157:H7 Positives

Table 11-1 presents the number of *E. coli* positives as a function of month. 81% of *E. coli* positives in beef trim, 53% of *E. coli* positives in raw ground beef, and 63% of *E. coli* positives in beef trim suppliers occur in the 6 month period May through October. Due to the low number of positives, no seasonality is apparent in the number of *E. coli* positives in bench trim and ground beef components other than trim.

Table 11- 1 *E. coli* O157:H7 Positives by Month 2007-June 2011

2007-June 2011 Totals	Raw Ground Beef *E. coli* Positives	Beef Trim *E. coli* Positives	Beef Trim Supplier *E. coli* Positives	Bench Trim *E. coli* Positives	Other Components *E. coli* Positives
January	55	1	2	1	0
February	5	0	3	0	0
March	6	0	0	0	1
April	7	2	0	0	0
May	15	4	0	0	0
June	24	5	4	0	0
July	12	3	2	0	0
August	10	3	2	0	0
September	20	4	1	1	0
October	20	6	3	0	0
November	9	1	1	0	0
December	6	2	1	0	1

Table 11-2 presents *E. coli* O157:H7 percent positive in raw ground beef, beef trim, and beef trim suppliers as a function of season. The probability of a beef trim establishment having an *E. coli* O157:H7 positive in May-Oct is 3.8 times higher (two sided Exact Fisher $p < 0.002$) than in the rest of the year. The probability of a beef trim supplier having an *E. coli* O157:H7 in May-Oct is 1.9 times higher (but not statistically significantly so; two sided Exact Fisher $p = 0.175$) than in the rest of the year. There is no statistical difference between the May-Oct *E. coli* percent positive and the rest of the season in bench trim and other ground beef component establishments. The inability to detect a seasonal increase in *E. coli* positives in bench trim suppliers, bench trim and other ground beef component establishments is probably due to the small number of *E. coli* positives in these establishments.

Table 11- 2 *E. coli* O157:H7 Percent Positive Seasonality May-Oct 2007-June 2011

2007-June 2011	May - Oct	Rest of Year
Raw Ground Beef	0.41%	0.14%
Beef Trim	0.92%	0.25%
Beef Trim Supplier	0.96%	0.50%
Bench Trim	0.21%	0.18%
Other Components	0.00%	0.62%

Conclusion: Increasing MT50 sampling during the summer months May-Oct will increase the probability of detecting *E. coli* O157:H7 positives in beef trim.

11.2 Seasonality of 03J01 and 03J02 Health-Related Noncompliances

Table 11-3 presents beef trim establishment 03J01 and 03J02 health-related noncompliances as a function of seasonality. Contrary to expectations, 03J01 and 03J02 health-related noncompliance rates are not higher during the summer months May-Oct. For beef trim establishments, the 03J01 health-related noncompliance rate is statistically significantly lower (two sided Exact Fisher $p = 0.0017$) in the summer months May-Oct than in the rest of the year, and there is no statistical difference (two sided Exact Fisher $p = 0.477$) between seasons in the 03J02 noncompliance rate.

Table 11- 3 Beef Trim Establishment 03J01 and 03J02 Health-Related Noncompliance Rates

	03J01			03J02		
2007-2011	Noncompliant	Compliant	Rate	Noncompliant	Compliant	Rate
May-October	344	74,901	0.46%	363	76,152	0.47%
Rest of the Months	395	68,072	0.58%	354	70,321	0.50%

Table 11-4 presents beef trim supplier 03J01 and 03J02 health-related noncompliances as a function of seasonality. Again, contrary to expectations, 03J01 and 03J02 health-related noncompliance rates are not higher during the summer months May-Oct. In fact, both the 03J01 and 03J02 health-related noncompliance rates are statistically significantly lower (two sided Exact Fisher $p < 0.0003$ and $p < 0.03$, respectively) in the summer months May-Oct than in the rest of the year.

Table 11- 4 Supplier Establishment 03J01 and 03J02 Health-Related Noncompliance Rates

	03J01			03J02		
2007-2011	Noncompliant	Compliant	Rate	Noncompliant	Compliant	Rate
May-October	234	22,349	1.04%	220	21,228	1.07%
Rest of the Months	302	20,902	1.42%	255	20,054	1.26%

Conclusion: 03J01 and 03J02 health-related noncompliance rates are not higher during the summer months May-Oct in either beef trim establishments or beef trim suppliers.

12.0 INCREASE THE COLLECTION RESPONSE RATE

The MT50 beef trim sampling program is intended to include all active, federally inspected beef and veal slaughter establishments that produce trim for use in raw ground beef and identified sister establishments. There are about 480 slaughter establishments in the MT50 sampling frame at any given time, of which about 390 are sampled per year. FSIS selects between 200 and 250 establishments from the frame every month, depending upon the number of weeks in a month. Annually, this amounts to sending 2600 sample forms per year. However, in CY2010 only 1274 samples were successfully collected at beef trim establishments. This is a response rate of about 49%. There are several reasons that sample forms mailed out may not result in successful sample collection, including that a sample is taken but discarded for various reasons (e.g., sample delivered to laboratory late, laboratory closed, container leaking, etc.), that due to conflicts the inspector could not collect a sample, or that the establishment was not producing trim during the sampling period.

The purpose of this section is to determine the probability of *E. coli* O157:H7 detection if FSIS could increase the response rate to 60 or 70 percent.

Table 12-1 presents the number of samples in each volume class if the collection response rate is increased from the current 50 percent to 60% or 70%. For a collection response rate of 60%, the expected number of *E. coli* positives is increased by a factor of 1.2 = 9.0/7.3. For a collection response rate of 60%, the expected number of *E. coli* positives is increased by a factor of 1.4 = 10.5/7.3.

Table 12- 1 Expected Number of *E. coli* Positives if Collection Response Rate Increased to 60 or 70 Percent

(A) Volume Class	(B) Number of Samples in 2010 Random Sampling Program	(C) Number of Samples in 2010 Random Sampling if Response Rate is Increased to 60%	(D) Number of Samples in 2010 Random Sampling if Response Rate is Increased to 70%
Very Small	915	1114	1300
Small	136	176	206
Medium	93	100	117
Large	130	169	197
Total	1,274	1559	1821
Expected Number of *E. coli* Positives	7.3	9.0	10.5

Table 12-2 presents the number of samples in each volume class and the expected number of *E. coli* positives if the collection response rate is increased from the current 50 percent to 60% or 70% for a sampling design where sampling is proportional to percent positive in the volume class and each establishment is sampled at least once. For a collection response rate of 60%, the expected number of *E. coli* positives is increased by a factor of 2.2 = 15.6/7.3. For a collection response rate of 70%, the expected number of *E. coli* positives is increased by a factor of 2.5 = 18.5/7.3.

Table 12- 2 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to *E. coli* Percent Positive with at Least One Sample per Establishment and Increased Collection Response Rates

(A) Volume Class	(B) Number of Samples in 2010 Random Sampling Program	(C) Number of Samples Based on Sampling Proportional to *E. coli* Percent Positive & at Least 1 Sample per Plant	(D) Number of Samples Based on Sampling Proportional to *E. coli* Percent Positive & at Least 1 Sample per Plant & 60% Response Rate	(E) Number of Samples Based on Sampling Proportional to *E. coli* Percent Positive & at Least 1 Sample per Plant & 70% Response Rate
Very Small	915	292	357	417
Small	136	488	597	697
Medium	93	368	451	526
Large	130	126	154	180
Total	1,274	1,274	1559	1821
Expected Number of *E. coli* Positives	7.3	12.96	15.58	18.52

Conclusion: These results demonstrate that increasing *E. coli* O157:H7 collection response rate provides an effective means of increasing the probability of detecting an *E. coli* positive in beef trim establishments.

An additional means of increasing the number of samples successfully obtained is to increase the number of sample forms mailed each year, called over-scheduling to adjust for non-response. Increasing the number of sample forms sent out by 20% will increase the number of successful samples collected by 20%, even if the collection response rate remains at 49%. This would result in an effective collection rate of 70% and would not increase the workload of the laboratories above its currently acceptable load of 2600 analyzed samples per year.

13.0 MISCELLANEOUS

The purpose of this section is to evaluate two miscellaneous issues.

13.1 Geographical Distribution of Beef Trim *E. coli* O157:H7 Positives

Table 13-1presents the *E. coli* O157:H7 test results by FSIS district for beef trim establishments tested under the beef trim sampling program MT50 during the years 2008-June 2011. The *E. coli* percent positives in district 5 and district 35 are not statistically significantly different (two sided Exact Fisher p = 0.675). The *E. coli* percent positive in district 5 is statistically significantly higher than the remaining districts except for districts 40, 45, 25, and 30.

Table 13- 1 Geographical Distribution of Beef Trim *E. coli* O157:H7 Positives

District Number	District Name	Number Establishments in District	Positives	Total Tests	Rate
5	Alameda	19	5	203	2.46%
35	Springdale	11	1	84	1.19%
90	Ridgeland	17	1	105	0.95%
80	Raleigh	27	2	216	0.93%
20	Minneapolis	43	4	436	0.92%
50	Lombard	22	2	275	0.73%
65	Albany	46	3	426	0.70%
85	Atlanta	21	1	145	0.69%
60	Philadelphia	49	3	559	0.54%
15	Denver	79	4	887	0.45%
75	Beltsville	31	1	249	0.40%
40	Dallas	31	1	364	0.27%
45	Madison	35	1	380	0.26%
25	Des Moines	30	1	411	0.24%
30	Lawrence	48	1	413	0.24%

13.2 Beef Trim Versus Veal

The purpose of this section is to determine if there is a difference in the *E. coli* O157:H7 percent positive for trim and ground beef produced from younger cattle (veal) versus older cattle.

Table 13-2 presents the *E. coli* percent positive for ground beef versus ground veal. The probability of detecting an *E. coli* O157:H7 percent positive in ground veal is 19.2 times higher than in ground beef. This difference is statistically significant (Two-Sided Fisher Exact p = 0.008). This conclusion is based on limited samples in raw ground veal. If this conclusion is confirmed as more samples accumulate, it is proposed that sampling rates in establishments producing ground veal be increased.

Table 13- 2 *E. coli* O157:H7 Percent Positive in Ground Beef and Ground Veal

	E. coli Positives	Number Samples	Percent Positive
Ground Beef	6	9605	0.06%
Ground Veal	2	174	1.15%

Table 13-3 presents the *E. coli* percent positive for beef trim and veal trim. The difference is not statistically significantly different (Two-Sided Fisher Exact p = 0.168).

Table 13- 3 *E. coli* O157:H7 Percent Positive in Beef Trim and Veal Trim

	E. coli Positives	Number Samples	Percent Positive
Beef Trim	4	986	0.41%
Veal Trim	1	36	2.78%

It is proposed that the issue of whether the *E. coli* O157:H7 percent positive rate in veal trim establishments is higher than that of beef trim establishments be reevaluated after additional data is gathered in veal trim establishments.

14.0 DISCUSSION AND RECOMMENDATIONS

This report reviews eight options for redesign of the FSIS *E. coli* O157:H7 beef trim, bench trim, and other ground beef component sampling programs. The major observations are

- Over the period 2007-June 2011, beef trim sampling produced 31 *E. coli* O157:H7 positives (0.60% positive rate), bench trim sampling produced 2 positives (0.19% positive), and raw ground beef components other than trim sampling produced 2 positives (0.28% positive). Within each of these three sampling programs, there is no statistically significant difference in the *E. coli* O157:H7 percent positives between years.

- The probability of detecting an *E. coli* O157:H7 positive in beef trim is 2.2 times higher than in raw ground beef (two sided Exact Fisher, $p < 0.0002$). The *E. coli* percent positives in bench trim and raw ground beef components other than trim are statistically significantly lower than that of beef trim and are not statistically significantly different than that found in raw ground beef.

- The probability of detecting an *E. coli* O157:H7 positive during follow-up sampling after an *E. coli* O157:H7 positive in a beef trim establishment are 6.6 times higher than under routine beef trim *E. coli* sampling (two sided Exact Fisher $p < 0.00001$). No positives were detected during *E. coli* O157:H7 follow-up sampling for bench trim or other ground beef components after an *E. coli* positive.

- Sampling beef trim establishments proportional to production volume and requiring that each establishment is sampled at least once per year is 1.01 times more likely to detect an *E. coli* O157:H7 positive than the 2010 MT50 random sampling program.

- Establishments that supply beef trim to raw ground beef establishments that test positive for *E. coli* O157:H7 are termed beef trim suppliers. If it is the only supplier to the ground beef establishment, it is termed a sole beef trim supplier. These establishments are tested under the MT52 program. The *E. coli* percent positives in beef trim suppliers (0.73%) and sole beef trim suppliers (0.69%) are not statistically different than that found in the MT50 beef trim sampling program (0.60%). The *E. coli* percent positives in other ground beef component suppliers (0.62%) and sole ground beef component suppliers (0.61%), while higher, are not statistically different than that found in the MT54 sampling of other ground beef components (0.28%).

- No association was found between health-related regulatory noncompliances and the probability of *E. coli* O157:H7 positive sample results.

- No association was found between higher sanitary dressing noncompliances and the probability of *E. coli* O157:H7 positive sample results.

- There is a definite seasonality in *E. coli* O157:H7 rate in beef trim and beef trim suppliers. The probability of detecting an *E. coli* O157:H7 positive in a beef trim establishment during May-Oct is 3.8 times higher than in the rest of the year (two sided Exact Fisher $p < 0.002$). The probability of a beef trim supplier having an *E. coli* O157:H7 in May-Oct is 1.9 times higher (but not statistically significantly so, two sided Exact Fisher $p = 0.175$) than in the rest of the year. Due to the low number of positives, no seasonality is apparent in the number of *E. coli* positives in bench trim and ground beef components other than trim.

- The probability of detecting an *E. coli* O157:H7 positive in raw ground veal is 19.2 times higher than in raw ground beef and the difference is statistically significant.

Of the options reviewed, the ones that appear most promising for increasing the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing are to increase *E. coli* O157:H7 sampling in

- The volume class with the highest *E. coli* O157:H7 percent positive.
- The volume class with the highest volume-weighted percent positives.
- The six month warm weather period when *E. coli* O157:H7 positives are the highest.

Conclusion:
Either of the following two designs for testing beef trim, bench trim, and raw ground beef components other than trim increases the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing.

- Sampling volume classes in proportion to the *E. coli* O157:H7 percent positive, insuring that each establishment is sampled at least once per year, and increasing samples during summer months by 20% increases the probability of detecting an *E. coli* positive by a factor of 2.0.
- Sampling proportional to volume-weighted percent positive, insuring that each establishment is sampled at least once per year, and increasing samples during summer months by 20% increases the probability of detecting an *E. coli* positive by a factor of 1.4.

Of the two sampling designs, sampling volume classes in proportion to the *E. coli* O157:H7 percent positive provides the largest increase in the probability of identifying establishments that may not be effectively controlling *E. coli* O157:H7.

FSIS will redesign *E. coli* verification testing in establishments producing beef manufacturing trimmings so that sampling is weighted by production volume and volume class-specific risk factor, ensures that each establishment is sampled at least once per year, and increases samples during summer months by 20%. This will increase the probability of detecting *E. coli* O157:H7 positives during FSIS verification testing in beef trim establishments by about a factor of 2 and increase the degree of confidence of identifying establishments that may not be effectively controlling *E. coli* O157:H7. FSIS will also increase the number of samples successfully collected (through a combination of allocating more resources in establishments more likely to collect and overscheduling to adjust for non-response) with the goal eventually of collecting 100% of the budgeted agency resources. This will increase the overall probability of detecting beef trim *E. coli* O157:H7 positives during FSIS verification testing by a factor of about 2.5. Additionally,

FSIS is considering revising the sampling programs for bench trim and other ground beef components similar to that discussed for beef manufacturing trimmings.

FSIS will continue to conduct follow up *E. coli* sampling in establishments with an *E. coli* O157:H7 positive in beef trim, bench trim, other components, and in supplier establishments. Under these programs, sixteen follow-up samples are scheduled at establishments with an *E. coli* positive unless the establishment is a low volume producer (less than 1,000 lbs. per day), where eight follow-up samples are scheduled. These follow up programs provide for repeated testing over a relatively short time period and increase confidence in the Agency's judgment as to whether tested establishments are effectively controlling *E. coli* O157:H7.

The conclusions of this report may need to be reassessed for non-O157 Shiga toxin-producing serotypes of *Escherichia coli* (STEC) once FSIS STEC testing has been in place for at least a year. FSIS will likely start STEC testing in June 2012.

15.0 STATISTICAL SAMPLING DESIGN

FSIS assessed over 30 discrete sampling designs and their related probabilities to detect *E. coli* O157:H7 in beef manufacturing trimmings. The design the agency chose to implement is weighted, random sampling with replacement that accounts for both the production volume and percent positive of volume classes. The agency also chose to over-schedule seasonally during the high prevalence season, over-schedule to adjust for non-response, implement an annual scheduling floor, and implement monthly scheduling ceilings. The chosen design gives FSIS an increased likelihood of 2.46 to detect *E. coli* O157:H7 as compared to the current design of simple random sampling without replacement.

FSIS plans to implement this new sampling design starting in April 2012, with some aspects, like scheduling floors, seasonal adjustment, and over-scheduling, being phased in gradually. Additionally, FSIS plans to re-evaluate risk factors using FSIS and available published, scientific data every few years to ensure the riskiest groups are being targeted correctly.

15.1 Sampling Frame

The sampling frame is the list of all establishments eligible for the sampling program. This includes all establishments whose Public Health Information System (PHIS) establishment profiles indicate they make beef manufacturing trimmings.

15.2 Sample Size

This is the number of sampling requests scheduled on a monthly basis. The sample size is 217 requests per month, which is 2604 requests per year. FSIS intends to begin adjusting the number per month for seasonality of prevalence. Under seasonality, 60% of the annual sampling resources would be allocated in high prevalence season (May – October) and 40% would be allocated in low prevalence season. FSIS also intends to begin gradually over-scheduling to adjust for non-response so that FSIS collects and analyzes 2600 samples in a 12-month period.

15.3 Annual Sampling Floor

This is the minimum number of analyses FSIS will allow at each establishment in the sampling frame in a 12-month period. The proposed annual sampling floor is one. FSIS intends to gradually implement this sampling floor starting with the largest producers. This floor is listed in table 15-1.

15.4 Monthly Sampling Ceiling

This is the maximum number of requests a given establishment could receive in any one month. FSIS intends to impose monthly sampling ceilings by production volume group. These ceilings are listed in table 15-1.

Table 15- 1 Monthly Sampling Ceilings and Annual Sampling Floor by Production Volume Group

PHIS Volume Group			
	Estimated Production Volume	**Monthly Sampling Ceiling**	**Annual Sampling Floor**
Group 1	< 1001 lbs/day	1	1
Group 2	1001 – 3000 lbs/day	2	1
Group 3	3001 – 6000 lbs/day	2	1
Group 4	6001 – 50,000 lbs/day	2	1
Group 5	50,001 – 250,000 lbs/day	3	1
Group 6	250,001 – 600,000 lbs/day	4	1
Group 7	>600,000 lbs/day	4	1
Group 99	Unknown	1	1

15.5 Sampling Weights

The sampling weights are the product of the volume score and the risk factor. Based upon the research presented in the previous chapters of this paper, FSIS chose to implement the risk factors shown in Table 15-2. FSIS may choose to incorporate more risk factors or to adjust those chosen below based upon new scientific data available to the Agency or from regular re-assessment of FSIS's own data.

Table 15- 2 Calculation of Sampling Weights by Production Volume Group

PBIS Volume Groups	PHIS Volume Groups	Multi-Year Percent Positive	Risk Factor (A)	Daily Volume Estimate	Volume Score (B)	Sampling Weight (A * B)
Very Small < 1001 lbs/day	Group 1 < 1001 lbs/day	0.42%	0.7	500	1	0.7
Small 1001 – 50,000 lbs/day	Group 2 1001 – 3000 lbs/day	1.47%*	2.45	2000	4	9.8
	Group 3 3001 – 6000 lbs/day			4500	9	22.05
	Group 4 6001 – 50,000 lbs/day			28,000	56	137.2
Medium 50,001 – 250,000 lbs/day	Group 5 50,001 – 250,000 lbs/day	1.11%	1.85	150,000	300	555
Large >250,000 lbs/day	Group 6 250,001 – 600,000 lbs/day	0.38%	0.63	425,000	850	535.5
	Group 7 >600,000 lbs/day			800,000 (assumed)	1600	1008
Unknown volume	Group 99 Unknown volume	NA	1	NA	1600	1600
Total		0.60%				

* The small group's percent positive is statistically significantly higher than in the large and very small.

The multi-year (overall) percent positive is that reported in chapter 6 of this paper. The risk factor is calculated as follows:

$$\text{risk factor} = \frac{\text{Percent positive in a given volume group}}{\text{Overal percent positive}}, \qquad \text{i.e. very small risk factor} = \frac{0.42\%}{0.60\%} = 0.7$$

The daily volume estimate is the midpoint of the volume range. The volume score is the normalized daily volume estimate, so that the volume score = daily volume estimate / the smallest daily volume estimate.

The sampling weight is the product of the risk factor and the volume score.

So, using the medium group as an example and the values from table 15-2, above, the sampling weight is calculated as follows:

$$\begin{matrix}\text{Medium}\\ \text{sampling weight}\end{matrix} = \begin{matrix}\text{risk}\\ \text{factor}\end{matrix} \times \begin{matrix}\text{volume}\\ \text{score}\end{matrix} = \frac{0.42\%}{0.60\%} \times \frac{150{,}000}{500} = 1.85 \times 300 = 555$$

15.5.1 Scaling Factors on Volume Scores

At this time, FSIS does not intend to apply scaling factors to the volume score. However, it may decide to do so in the future. The following formula would be used to scale down the volume scores to a chosen interval.

$$vs_i = S_L + \frac{(V_i - V_1)(S_H - S_L)}{V_7 - V_1}$$

V_i = Daily volume production for establishment in category *i*
V_7 = Maximum daily production volume
V_1 = Minimum daily production volume
S_H = High scaling factor
S_L = Low scaling factor

15.5.2 Calculating Probability of Selection

The probability of selection for establishment *j* is its weight divided by the sum of all *n* weights. The following formula is used, where *vs* is the volume score and *rf* is the risk factor.

$$p_j = \frac{vs_j \cdot rf_j}{\sum_{j=1}^{n} vs_j \cdot rf_j}$$

15.6 Historical Collection Rates

Historically, one of the leading causes of FSIS's low response rate was due to the sampling design. These rates are consistent year to year as well as across seasons. Increasing the number of scheduled samples can be used to adjust for the low response rates. Historical collection rates are given in Table 15-3.

Table 15- 3 Historical Collection Rates by Production Volume Group

PHIS Volume Group	Estimated Production Volume	Collection Rate[1]	Establishment Count[2]
Group 1	< 1001 lbs/day	58%	278
Group 2	1001 – 3000 lbs/day	76%	36
Group 3	3001 – 6000 lbs/day	75%	19
Group 4	6001 – 50,000 lbs/day	75%	30
Group 5	50,001 – 250,000 lbs/day	82%	19
Group 6	250,001 – 600,000 lbs/day	89%	19
Group 7	>600,000 lbs/day	82%	19
Group 99	Unknown volume	55%	4

15.7 Theoretical Sampling Distribution

Below is a theoretical distribution of FSIS sampling resources for this sampling design. It also presents an estimate of the number of analyses FSIS could expect to perform annually based upon the design and historical collection rates. This distribution reflects all aspects of the design—some of these aspects will be phased in gradually by the Agency.

Table 15- 4 Theoretical Monthly and Annual Sampling Distribution with Estimated Annual Collection

Increased ability to detect *E. coli* O157:H7 = 2.46	Volume Group								Grand Total
	Unknown	Large		Medium	Small			Very Small	
	99	7	6	5	4	3	2	1	
Number of establishments	4	19	19	19	30	19	37	277	424
Monthly sampling ceiling	1	4	4	3	2	2	2	1	NA
Historical Collection Rate	55%	82%	89%	82%	75%	75%	76%	58%	
Number of Samples Requested (HIGH prevalence season month)	4	76	76	57	60	24	19	9	325
Number of requests per establishment (HIGH prevalence season month)	1	4	4	3	2	1.26	0.51	0.03	
Estimated Analyses per month (HIGH prevalence season month)	2	62	68	47	45	18	14	5	261
Number of Samples Requested (LOW prevalence season month)	4	71	51	53	28	6	1	1	215
Number of requests per establishment (LOW prevalence season month)	1	3.74	2.68	2.79	0.93	0.32	0.03	0.00	
Estimated Analyses (LOW prevalence season month)	2	58	45	43	21	5	1	1	176
Number of samples requested per establishment (YEAR)	12	46.42	40.11	34.74	17.6	9.47	3.24	0.22	
Estimated Analyses	26	723	678	541	396	135	91	35	2622

15.8 Increased ability to detect *E. coli* O157:H7

This new design was compared to the current design to calculate the ability of the new design to detect *E. coli* O157:H7 as compared to the current design. The new design has an increased ability of 2.46 to

[1] Results based on 2007 – 2011 collection rates. Collection rates were consistent over the analysis years.
[2] Sampling frame distribution extracted from the FSIS PHIS database on February 7, 2012.

detect O157:H7. No predictions can be made for non-O157 STEC because FSIS has not yet begun testing for these pathogens, and the previous design will never have been implemented with additional STEC testing.

Table 15- 5 Computation of Increased Ability Compared to Previous Current Design Table

	Annual			High Season			Low Season		
PHIS Volume Group	Current Design Estimated Analyses	2007 – 2011 Percent Positive	Current Design Expected Positives	2007-2011 Percent Positive	New Design Estimated Analyses	New Design Expected Positives	2007-2011 Percent Positive	New Design Estimated Analyses	New Design Expected Positives
99	26	2.17%	0.57	4.76%	12	0.57	0.00%	12	0.00
7	108	0.00%	0.00	0.00%	372	0.00	0.00%	348	0.00
6	75	0.30%	0.23	0.52%	408	2.12	0.00%	270	0.00
5	69	1.99%	1.37	2.96%	282	8.35	0.75%	258	1.94
4	126	0.39%	0.49	0.75%	270	2.03	0.00%	126	0.00
3	90	3.10%	2.79	4.76%	108	5.14	1.52%	30	0.46
2	155	1.40%	2.17	1.27%	84	1.07	1.56%	6	0.09
1	1023	0.12%	1.24	0.11%	30	0.03	0.13%	6	0.01
TOTAL	1,672		8.85		1,566	19.31		1,056	2.49

$$\text{Ability to Detect } E.coli \text{ Positives} = \frac{\text{New Design High Season Expected Positives} + \text{New Design Low Season Expected Positives}}{\text{Previous Design Expected Positives}} = \frac{19.31 + 2.49}{8.85} = 2.46$$

15.9 Prevalence estimation

The current agency resources may not support prevalence estimation. If the annual sample size were increased, then this design could be used to calculate prevalence in beef manufacturing trimmings.

16.0 REFERENCES

1. Office of Inspector General (OIG) 2011, FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7
2. Food Safety and Inspection Service (FSIS) 2011, Food Safety and Inspection Service Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7 – Phase I
3. Food Safety and Inspection Service (FSIS) December 2011, Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs
4. Food Safety and Inspection Service (FSIS) November 3, 2011, FSIS Directive 6410.1, Rev. 1: Verifying sanitary dressing and process control procedures by off-line inspection program personnel (IPP) in slaughter operations of cattle of any age
5. Food Safety and Inspection Service (FSIS) March 31, 2010, FSIS Directive 10,010.1, Rev. 3: Verification activities for *Escherichia coli* O157:H7 in raw beef products
6. Food Safety and Inspection Service (FSIS) June 24, 2011, FSIS Directive 5000.1, Rev. 3: Verifying an establishment's food safety system
7. Food Safety and Inspection Service (FSIS) 2001, Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef
8. International Commission on Microbiological Specifications for Foods (ICMSF) http://www.icmsf.org/

17.0 APPENDECIES

Appendix A - N60 Sample Collection Method

FSIS uses a sample collection method called N60 to test for *E. coli* O157:H7 in beef trim. Under the N60 collection method, the inspector collects 60 pieces of beef trim from a production lot of beef cuts or trimmings that will be used for the making of ground beef. Each of the 60 pieces is a slice cut off of the surface of trimmings that is approximately 3 inches long by 1 inch wide and 1/8 inch thick. The priority is to collect samples from pieces of product taken from the original external surface of the beef carcass (this is the outside surface of the carcass after the hide is removed). Sixty pieces that are 3 inches long by 1 inch wide and 1/8 inch thick should weigh approximately ¾ lb. The sixty pieces are placed in a bag. An additional 1 1/4 pounds (approximately) of available smaller pieces of beef manufacturing trimmings from the same specific production lot are selected and placed in a second bag. The total weight of the 2 bags of samples is approximately 2 pounds. The N60 method is resource intensive, often taking inspection program personnel over an hour to collect a sample. The sample is shipped to a designated FSIS laboratory where it is composited for testing to determine the presence of *E. coli* O157:H7. The N60 method of sample collection is recommended by the International Commission on Microbiological Specifications for Foods (ICMSF).

Appendix B - Volume-Weighted *E. coli* Percent Positive in Beef Trim

FSIS inspectors record a daily volume estimate when taking a beef trim sample. The volume weights are recorded as one of four daily production volume groups which translate into the annual beef trim volumes given in Table B-1.

Table B- 1 Volume Groups for Beef Trim Sampling

Volume Group	Daily trim volume in lbs/day	Assumed Production Days	Estimated annual trim volume in lbs/yr
Very Small	< 1,000	250	75,000
Small	1,000 – 50,000	250	6,375,000
Medium	50,001 – 250,000	250	37,500,000
Large	> 250,000	150	93,750,000

Table B-2 presents the estimated annual beef trim volume for beef trim establishments tested for *E. coli* O157:H7 in each of the years. Since not all beef trim establishments are tested every year, the actual annual volume of beef trim produced in the U.S. should be slightly larger than these estimates. The establishments tested under the MT50 beef trim sampling program produce about 4 billion pounds of beef trim annually.

Table B- 2 Beef Trim Volume of Establishments Tested for *E. coli* O157:H7

Year	Number Establishments Tested	Annual Beef Trim Volume in Billion Pounds/yr
2007	336	4.3
2008	344	3.9
2009	368	3.8
2010	386	3.9

Table B-3 presents the *E. coli* test results as a function of beef trim volume produced for the years CY2007 through June 2011 combined. The data were combined since no statistically significant difference was found in the *E. coli* O157:H7 positive rates in the years CY2007 through June 2011. In addition, combining the data produces a larger number of samples from each trim volume class and thus produces more accurate estimates of the percent positive for each volume class. The large volume class has the smallest *E. coli* percent positive, while the small volume class has the highest *E. coli* percent positive and these rates are marginally statistically different (one-sided Fisher exact $p = 0.053$). However, there is no statistically significant difference in the *E. coli* O157:H7 percent positives for the medium and large beef trim volume classes. The *E. coli* O157 percent positives for very small establishments are statistically significantly less than that of the small and medium beef trim volume classes.

Sampling in the small volume class has a 3.9 times greater odds of detecting an *E. coli* O157:H7 positive than sampling in the large volume class (confidence interval 0.84 to 18.1).

Table B- 3 *E. coli* O157:H7 Percent Positive for Beef Trim as a Function of Beef Trim Volume Produced for the Years CY2007 - June 2011

CY07-CY11	Beef Manufacturing Trim			
Beef Trim	**# of unique plants**	Number Positives	Number Total Tests	% Positive
Very Small	408	15	3,558	0.42%
Small	93	9	612	1.47%
Medium	41	5	452	1.11%
Large	40	2	530	0.38%
Total	582	31	5,152	0.60%

Weighting the individual *E. coli* O157:H7 percent positives in Table B-3 by the corresponding fraction of total beef trim volume in each volume class provides an alternative estimate of the "average" *E. coli* O157:H7 percent positive in beef trim. Such an estimate is called a volume-weighted percent positive. Table C-4 presents an estimate of the volume-weighted percent positive for *E. coli* O157:H7 in beef trim based on cumulative data for the years CY2007 through June 2011. The volume-weighted percent positive over these years is 0.63%.

As an example of computing the weighted percent positives entries in the last column of Table B-4, consider the 0.27% in the medium volume class. This number is computed as 0.27% = 1.11% (from table B-3) *(volume of the medium volume class/total volume of all volume classes) = 1.11% *(4,762,500,000/19,545,000,000) = 0.27%. The 0.63% is the sum of the weighted percent positives for all volume classes.

Table B- 4 *E. coli* O157:H7 Beef Trim Volume Weighted Percent Positive for Years CY2007 - June 2011

Trim Volume Class	# of unique plants	**Trim volume CY2007-June 2011 (pounds)**	**% of Total Volume**	**Number Samples**	**% of Total Samples**	**Unweighted % Positive**	**Weighted % Positive**
Very Small	408	95,025,000	0.49%	3,558	69.06%	0.42%	0.00%
Small	93	1,268,625,000	6.48%	612	11.88%	1.47%	0.10%
Medium	41	4,725,000,000	24.12%	452	8.77%	1.11%	0.27%
Large	40	13,500,000,000	68.92%	530	10.29%	0.38%	0.26%
Total	582	18,588,650,000	100.00%	5,152	100.00%	0.60%	0.63%

Table B-5 summarizes estimates of the *E. coli* O157:H7 volume-weighted percent positive for beef trim by year.

Table B- 5 *E. coli* O157:H7 Volume Weighted Percent Positives for Beef Trim by Year

Year	Un-weighted Percent Positive	Volume-Weighted Percent Positive
2007	0.28%	0.67%
2008	0.90%	0.80%
2009	0.73%	0.28%
2010	0.31%	0.15%
Jan-June 2011	0.67%	1.52%
2007-June 2011	0.60%	0.62%

Appendix C - Probability of Detection of Beef Trim *E. coli* O157:H7 Positives

The purpose of this appendix is to demonstrate how the probability of detecting an *E. coli* O157:H7 positive is calculated under various beef trim sampling approaches.

C-1 Probability of Detection of *E. coli* O157:H7 Positives under Sampling Proportional to Volume

Table C-1 presents the expected number of *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program where the number of samples in each volume class is proportional to the volume of the volume class. As expected under a random sampling program, the fraction of samples in each volume class for the 2010 random sampling program (column D) is approximately equal to the fraction of beef trim establishments in each volume class. The expected number of samples under the 2010 random sampling program (column G) is computed as the product of the number of samples in each volume class for the 2010 sampling program (column D) times the average *E. coli* percent positive in each volume class (column F). The expected number of samples under a sampling program based on the percent volume in each volume class (column H) is computed as the product of the number of samples in each volume class for the percent volume sampling program (column E) times the average *E. coli* percent positive in each volume class (column F). The odds of detecting an *E. coli* positive under the percent volume sampling program are 1.08 higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of positives under each sampling program (1.08 = 7.99/7.37).

Table C- 1 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to Volume

(A) Volume Class	(B) Total Volume CY2007-June 2011 (pounds)	(C) Percent of Total Volume	(D) Number of Samples Based on 2010 Random Sampling Program	(E) Number of Samples Based on Sampling Proportional to Volume in Volume Class	(F) Average CY2007-June 2011 Percent Positive	(G) Expected Positives Based on 2010 Sampling Program	(H) Expected Positives Based on Sampling Proportional to Volume
Very Small	0.09 Billion	0.49%	915	6	0.42%	3.84	0.03
Small	1.3 Billion	6.48%	136	83	1.47%	2.00	1.21
Medium	4.8 Billion	24.12%	93	307	1.11%	1.03	3.41
Large	13.4 Billion	68.92%	130	878	0.38%	0.49	3.34
Total	19.5 Billion	100.00%	1,274	1,274	0.60%	7.37	7.99

Table C-2 presents the expected number of beef trim *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program in which the number of samples in each volume class is proportional to the volume of the volume class and each establishment is sampled at least once per year.

The odds of detecting an *E. coli* positive under the percent volume sampling program with at least one sample per establishment are 1.01 times higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of positives under each sampling program (1.01 = 7.42/7.37).

Table C- 2 Expected Number of Beef Trim *E. coli* Positives under Percent Volume Sampling Program with at Least One Sample per Establishment.

(A) Volume Class	(B) Total Volume CY2007-June 2011 (pounds)	(C) Percent of Total Volume	(D) Number of Samples Based on 2010 Random Sampling Program	(E) Number of Samples Based on Sampling Proportional to Volume & at Least 1 Sample per Plant	(F) Average CY2007-June 2011 Percent Positive	(G) Expected Positives Based on 2010 Sampling Program	(H) Expected Positives Based on Percent Volume Sampling Program
Very Small	0.09 Billion	0.49%	915	292	0.42%	3.84	1.23
Small	1.3 Billion	6.48%	136	65	1.47%	2.00	0.95
Medium	4.8 Billion	24.12%	93	240	1.11%	1.03	2.67
Large	13.4 Billion	68.92%	130	677	0.38%	0.49	2.57
Total	19.5 Billion	100.00%	1,274	1,274	0.60%	7.37	7.42

C-2 Probability of Detection of *E. coli* O157:H7 Positives under Sampling Proportional to *E. coli* Percent Positive

Table C-3 presents the expected number of *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program where the number of samples in each volume class is proportional to the *E. coli* percent positive of the volume class. The expected number of samples under the 2010 random sampling program (column F) is computed as the product of the number of samples in each volume class for the 2010 sampling program (column B) times the average *E. coli* percent positive in each volume class (column D). The expected number of samples under a sampling program based on the *E. coli* percent positive in each volume class (column G) is computed as the product of the number of samples in each volume class for the *E. coli* percent positive sampling program (column C) times the average *E. coli* percent positive in each volume class (column D). The odds of detecting an *E. coli* positive under the sampling program where the number of samples in each volume class is proportional to the *E. coli* percent positive of the volume class are 1.9 times higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of *E. coli* positives under each sampling program (1.9 = 14.00/7.37)

Table C- 3 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to *E. coli* Percent Positive.

.(A) Volume Class	(B) Number of Samples Based on 2010 Random Sampling Program	(C) Number of Samples Based on Sampling Proportional to *E. coli* Percent Positive in Volume Class	(D) Average CY2007-June 2011 Percent Positive	(E) Fractional Percent Positive	(F) Expected Positives Based on 2010 Sampling Program	(G) Expected Positives Based on Sampling Proportional to *E. coil* Percent Positive in Volume Class
Very Small	915	158	0.42%	12.4%	3.84	0.66
Small	136	554	1.47%	43.5%	2.00	8.14
Medium	93	418	1.11%	32.8%	1.03	4.64
Large	130	143	0.38%	11.2%	0.49	0.54
Total	1,274	1274	0.60%	100.0%	7.37	14.00

Table C-4 presents the expected number of beef trim *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program in which the number of samples in each volume class is proportional to the percent positive of the volume class and each establishment is sampled at least once per year. The odds of detecting an *E. coli* positive under the percent positive sampling program with at least one sample per establishment are 1.8 times higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of positives under each sampling program (1.8 = 12.96/7.37).

Table C- 4 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to *E. coli* Percent Positive with at Least One Sample per Establishment

(A) Volume Class	(B) Number of Samples Based on 2010 Random Sampling Program	(C) Number of Samples Based on Sampling Proportional to *E. coli* Percent Positive in Volume Class & at Least 1 Sample per Plant	(D) Average CY2007-June 2011 Percent Positive	(E) Fractional Percent Positive	(F) Expected Positives Based on 2010 Sampling Program	(G) Expected Positives Based on Sampling Proportional to *E. coil* Percent Positive in Volume Class
Very Small	915	292	0.42%	12.4%	3.84	1.23
Small	136	488	1.47%	43.5%	2.00	7.17
Medium	93	368	1.11%	32.8%	1.03	4.09
Large	130	126	0.38%	11.2%	0.49	0.48
Total	1,274	1,274	0.60%	100.0%	7.37	12.96

C-3 Probability of Detection of *E. coli* O157:H7 Positives under Sampling Proportional to Volume Weighted Percent Positive

Table C-5 presents the expected number of *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program which the number of samples in each volume class is proportional to the volume weighted percent positive of the volume class. The expected number of samples under the 2010 random sampling program (column F) is computed as the product of the number of samples in each volume class for the 2010 sampling program (column B) times the average *E. coli* percent positive in each volume class (column C). The expected number of samples under a sampling program based on the volume weighted percent positive in each volume class (column F) is computed as the product of the number of samples in each volume class for the *E. coli* volume weighted percent positive sampling program (column E) times the average *E. coli* percent positive in each volume class (column C). The odds of detecting an *E. coli* positive under the sampling program where the number of samples in each volume class is proportional to the volume weighted percent positive of the volume class are 1.5 times higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of *E. coli* positives under each sampling program (1.5 = 10.91/7.37).

Table C- 5 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to Volume Weighted Percent Positive

(A) Volume Class	(B) Percent of Total Volume	(C) Average CY2007 -June 2011 Percent Positive	(D) Volume Weighted Percent Positive (VWPP)	(E) Number of Samples Based on 2010 Random Sampling Program	(F) Number of Samples Based on Sampling Proportional to VWPP & at Least 1 Sample per Plant	(G) Expected Positives Based on 2010 Sampling Program	(H) Expected Positives Based on Sampling Proportional to VWPP in Volume Class
Very Small	0.49%	0.42%	0.00%	915	4	3.84	0.02
Small	6.48%	1.47%	0.10%	136	191	2.00	2.81
Medium	24.12%	1.11%	0.27%	93	545	1.03	6.05
Large	68.92%	0.38%	0.26%	130	533	0.49	2.03
Total	100.00%	0.60%	0.60%	1,274	1274	7.37	10.91

Table C-6 presents the expected number of beef trim *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program in which the number of samples in each volume class is proportional to the volume weighted percent positive of the volume class and each establishment is sampled at least once per year. The odds of detecting an *E. coli* positive under the volume weighted percent positive sampling program with at least one sample per establishment are 1.3 times higher than

under the current 2010 random sampling program. This is computed as the ratio of the expected number of positives under each sampling program (1.3 = 9.66/7.37).

Table C- 6 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to Volume Weighted Percent Positive with at Least One Sample per Establishment

(A) Volume Class	(B) Percent of Total Volume	(C) Average CY2007-June 2011 Percent Positive	(D) Volume Weighted Percent Positive (VWPP)	(E) Number of Samples Based on 2010 Random Sampling Program	(F) Number of Samples Based on Sampling Proportional to VWPP in Volume Class	(G) Expected Positives Based on 2010 Sampling Program	(H) Expected Positives Based on Sampling Proportional to VWPP in Volume Class
Very Small	0.49%	0.42%	0.00%	915	292	3.84	1.23
Small	6.48%	1.47%	0.10%	136	150	2.00	2.20
Medium	24.12%	1.11%	0.27%	93	421	1.03	4.67
Large	68.92%	0.38%	0.26%	130	412	0.49	1.56
Total	100.00%	0.60%	0.60%	1,274	1274	7.37	9.66

C-4 Probability of Detection of *E. coli* O157:H7 Positives under Increased Sampling Based on Seasonality

Table C-7 presents the beef trim *E. coli* O157:H7 percent positive as a function of volume class for May-Oct and the rest of the year for CY2006 to June 2011.

Table C- 7 Seasonality of Beef Trim *E. coli* Percent Positive

Volume Class	May-Oct *E. coli* Positives	May-Oct Total Tests	May-Oct Percent Positive	Rest of Year *E. coli* Positives	Rest of Year Total Tests	Rest of Year Percent Positive
Very Small	11	1,864	0.59%	4	1,687	0.24%
Small	9	305	2.95%	0	315	0.00%
Medium	3	242	1.24%	2	210	0.95%
Large	2	298	0.67%	0	231	0.00%
Total	25	2,709	0.92%	6	2,443	0.25%

Table C-8 presents the expected number of beef trim *E. coli* O157:H7 positives resulting from sampling programs based on (1) the current (2010) sampling program which selects beef trim establishments at random and (2) a sampling program in which the number of samples in each volume class is proportional to the percent positive of the volume class and each establishment is sampled at least once per year and 60% of total samples are taken during May-Oct. The odds of detecting an *E. coli* positive under the percent positive sampling program with at least one sample per establishment and increased sampling during May-Oct are 2.0 times higher than under the current 2010 random sampling program. This is computed as the ratio of the expected number of positives under each sampling program (2.0 = 14.57/7.37).

Table C- 8 Expected Number of Beef Trim *E. coli* Positives under Sampling Proportional to *E. coli* Percent Positive with at Least One Sample per Establishment and 60% of Total Samples are Taken During May - Oct

A) Volume Class	(B) Number of Samples Based on 2010 Random Sampling Program	(C) Number of Samples Based on *E. coli* Percent Positive Sampling & at Least 1 Sample per Plant	(D) Number of Samples If 60% Taken During May-Oct	(E) Number of Samples If 40% Taken During Rest of Year	(F) Expected Positives Based on 2010 Sampling Program	(G) Expected Positives Based on Sampling Proportional to *E. coli* Percent Positive & at least 1 Sample per Plant & Increase Sampling 20% during May-Oct
Very Small	915	292	175	117	3.84	1.31
Small	136	488	293	195	2.00	8.64
Medium	93	368	221	147	1.03	4.14
Large	130	126	76	50	0.49	0.51
Total	1,274	1,274	764	510	7.37	14.59

Appendix D - Procedures Codes

FSIS inspectors perform inspection verification procedures to verify that establishments are executing their sanitation standard operating procedures (SSOP) and hazard analysis and critical control point (HACCP) system as specified under federal regulations 9 CFR 416 and 9 CFR 417. Table D-1 presents a summary of the 11 procedure codes considered in this study along with the associated health-related (W3NR) federal regulation numbers.

Table D- 1 Procedure Code Description

Procedure Code	Description	Associated Regulation Numbers
01A01	Verify that establishment has met regulations for development or maintenance of sanitation standard operating procedures (SSOP)	416.15(a), 416.15(b)
01B01	Pre-operational review of establishment's SSOP records to verify daily documentation of implementation and monitoring of SSOP procedures and required corrective actions.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3)
01B02	Pre-operational review and observation of SSOP including implementation and monitoring, maintenance, corrective actions, and recordkeeping. Observe sanitation conditions; check one or more areas to ensure establishment is clean.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 416.4(d), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3)
01C01	Review establishment's operational SSOP records to verify that the regulatory requirements for operational sanitation are met. Ensure monitoring activities are conducted at required frequency that the corrective actions are initiated to prevent direct contamination, and that records are being authenticated.	
01C02	The 01C02 procedure is for operational SSOP verification. It is the same as the 01B02 procedure except that it is conducted during operations. It inspects one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product, observes the establishment perform the monitoring procedures, and compares finding to what the establishment has documented.	310.22(b), 310.22(d)(2), 416.15(a), 416.15(b), 416.4(d), 430.4(a), 430.4(b)(1), 430.4(b)(2), 430.4(b)(3),
03A01	Determine establishment met regulation requirements for development and implementation of hazard analysis critical control point (HACCP) Plan(s)	381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1), 417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a), 417.6
03J01	Verify one or more HACCP requirements for monitoring, verification, and recordkeeping at a slaughter establishment. The 03J01 procedure is designed to provide a "snapshot" of the HACCP system. A 03J01 noncompliance necessitates performing a 03J02 procedure. FSIS Directive 5000.1	301.2(1)_Adulterated, 301.2(1)_E.coli_O157:H7, 301.2(1)_L.monocytogenes, 301.2(1)_Salmonella, 301.2(2)_Adulterated, 301.2(3)_Adulterated, 301.2(4)_Adulterated, 301.2(4)_Foreign_Material,

Procedure Code	Description	Associated Regulation Numbers
		301.2(6)_Adulterated, 301.2(9)_Adulterated, 309.3, 309.4, 309.9, 310.22(b), 310.22(d)(2), 310.25(a), 310.25(b), 311.16, 311.17, 318.14(a), 381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.144(a), 381.151(a), 381.65(e), 381.83, 381.91(a), 381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1), 417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a), 417.6
03J02	Verify all HACCP requirements at all critical control points in the HACCP establishment for a specific production. Verify that the pre-shipment review requirements for that specific production have been met. FSIS Directive 5000.1	301.2(1)_Adulterated, 301.2(1)_E.coli_O157:H7, 301.2(1)_L.monocytogenes, 301.2(1)_Salmonella, 301.2(2)_Adulterated, 301.2(3)_Adulterated, 301.2(4)_Adulterated, 301.2(4)_Foreign_Material, 301.2(6)_Adulterated, 301.2(9)_Adulterated, 309.3, 309.4, 309.9, 310.22(b), 310.22(d)(2), 310.25(b), 311.16, 311.17, 318.14(a), 381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.144(a), 381.151(a), 381.65(e), 381.83, 381.91(a), 381.94(b)(3)(ii), 417.3(a)(1), 417.3(a)(2), 417.3(a)(3), 417.3(a)(4), 417.3(b)(1), 417.3(b)(2), 417.3(b)(3), 417.3(b)(4), 417.3(c), 417.4(a),

Procedure Code	Description	Associated Regulation Numbers
		417.6
04C04	Verify that poultry slaughter establishments comply with the relevant regulations for poultry finished product standards and good commercial practices for poultry slaughter	381.1(i)_Adulterated, 381.1(i)_E.coli_0157:H7, 381.1(i)_L.monocytogenes, 381.1(i)_Salmonella, 381.1(ii)_Adulterated, 381.1(iii)_Adulterated, 381.1(iv)_Adulterated, 381.1(iv)_Foreign_Material, 381.1(vi)_Adulterated, 381.78, 381.91(a)
05A01	Review establishment *E. coli* records to determine maintained accuracy in accord with regulation—verifies compliance with the basic regulatory requirements for *E. coli* testing in slaughter establishments.	310.25(a), 310.25(b), 381.91(a)
06D01	Verify compliance with Sanitation Performance Standards requirements -- addresses the manner in which establishments must be operated and maintained to prevent the creation of insanitary conditions, thereby ensuring that insanitary conditions are not created, and that product is not adulterated.	310.22(b), 310.22(d)(2), 416.1, 416.4(d)