Cost-Benefit Analysis for FSIS’ Implementation of Its Non-O157 STEC Testing on Beef Manufacturing Trimmings and Expansion of Its Testing to Ground Beef and Ground Beef Components Other Than Beef Manufacturing Trimmings

Summary

FSIS has estimated the cost to the regulated industry and FSIS associated with the implementation of its non-O157 STEC testing on beef manufacturing trimmings, based on Agency testing data and information collected through the FSIS 2013 Pathogen Controls in Beef Operations Survey.1 We also assessed the benefits associated with the new testing. In addition, we estimated the cost and examined benefits of expanding its non-O157 STEC testing to ground beef and ground beef components other than beef manufacturing trimmings. The Agency concludes that the costs for sampling and testing are low and believes that the benefits justify the costs. However, FSIS was not able to quantify the benefits of expanding the testing.

1. Cost to the Industry

The FSIS testing does not require the industry to conduct its own testing for non-O157 STEC. Establishments may use

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interventions that have been validated to address STEC, and verify that they are employing their interventions using critical operating parameters necessary to address STEC. Similarly, they may verify that their suppliers are meeting their purchase specifications by obtaining necessary information from their suppliers. However, we understand that some establishments started testing (or will start testing) for non-O157 to verify that their food system addresses non-O157 STEC, even though FSIS does not require the testing. Therefore, we developed estimates for the testing cost for the industry.

To estimate the cost of establishment testing, we first estimated the additional tests that the industry conducts after FSIS starts testing, i.e. the difference between the numbers of tests industry conducts before FSIS starts testing (pre-FRN) and the number of tests after (post-FRN.) We also needed the average cost per test, which will be addressed later.

Data from the 2013 Pathogen Controls in Beef Operations Survey (conducted in May-July 2013) allowed us to estimate the numbers of non-O157 STEC testing for a 12-month period. For beef manufacturing trimmings, we use the numbers to represent the post-FRN number since FSIS announced in September 2011 that the Agency would start testing in March 2012, although the

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2The FRN refers to the 2012 Federal Register notice (77 FR 9889; Feb. 2012,) in which FSIS announced that it would implement a verification sampling and testing program for the six adulterant non-O157 STEC in raw beef manufacturing trimmings on June 4, 2012.
starting date was later changed to June 2012.\(^3\) For bench trim, other components, and raw ground beef, the numbers represent the pre-FRN baseline (see Table 1.) With these numbers, we still need to estimate the pre-FRN baseline number for beef manufacturing trimmings and the post-FRN numbers for bench trim, other components, and raw ground beef.

Table 1. Annual number of samples tested for non-O157 STEC by the industry

<table>
<thead>
<tr>
<th>Product</th>
<th># of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef manufacturing trimmings</td>
<td>107,370</td>
</tr>
<tr>
<td>Bench trim</td>
<td>296</td>
</tr>
<tr>
<td>Other components</td>
<td>2,102</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>3,928</td>
</tr>
</tbody>
</table>

Source: FSIS 2013 Pathogen Controls in Beef Operations Survey, details of data analyses are in the technical appendix.

We do not have data on the number of establishments that were testing beef manufacturing trimmings for non-O157 STEC or the number of samples tested before FSIS started testing. The Agency’s best estimate is that about 20% of the establishments that were testing beef manufacturing trimmings for \textit{E. coli} O157:H7 were also testing for non-O157 STEC.\(^4\) The 2013 Pathogen Controls in Beef Operations Survey data show that the percentage of establishments that test for both non-O157 STEC and \textit{E. coli}

\(^3\)Since some establishments may not have started testing until after the Agency started in June 2012, these numbers of April-July 2012 to April-July 2013 may represent less than a full-year for those establishments if they answered the Survey before June 2013.

\(^4\)FSIS experts’ opinion and we request public comments on this.
O157:H7 after the notice is about 33%, which suggest a 63% increase \([(33\%-20\%)/20\%\]. Applying this percentage change (of 63%) to Table 1, we obtain the number of beef manufacturing trimming samples tested for non-O157 pre-FRN, as well as the numbers of samples for bench trim, other components, and raw ground beef that would be tested after FSIS expands non-O157 STEC testing to these products (see Table 2).6

Table 2. Annual number of samples tested for non-O157 STEC by the industry pre-FRN, post-FRN, and the differences

<table>
<thead>
<tr>
<th>Product</th>
<th>Pre-FRN</th>
<th>Post-FRN</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef manufacturing trimmings</td>
<td>65,913</td>
<td>107,370</td>
<td>41,457</td>
</tr>
<tr>
<td>Bench trim</td>
<td>296</td>
<td>488</td>
<td>192</td>
</tr>
<tr>
<td>Other components</td>
<td>2,102</td>
<td>3,468</td>
<td>1,366</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>3,928</td>
<td>6,481</td>
<td>2,553</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>45,569</td>
</tr>
</tbody>
</table>

As for the cost of testing, the Agency cannot get actual cost for all the methodologies that the industry is using because both the establishments and the commercial labs treat this information as business confidential. Furthermore, some establishments use different methodologies for different time-periods (such as high-prevalence season7 and other time-periods.)

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5 See Technical Appendix.
6 We have to use the number of establishments to proxy the number of samples because of data limitations. That is, the survey data are anchored to establishments.
7 The high prevalence season in the period of time in which more contamination happens, usually in the warmer months.
We do know that for those who are already testing for *E. coli O157:H7*, adding non-O157 will, in most cases, involve switching to new test kits. Market information and Agency expert opinion indicate that the new test kits will only cost about $1 or $2 more per test, giving an average of $1.5. If an establishment has to contract out to a different lab, the test will be about $15 to $60 more per test.\(^8\)\(^9\) We do not have data on which establishments switched to new test kits and which ones switched to new labs or purchased new equipment. Therefore, we rely on data about whether the establishments use in-house lab or contract-lab from the FSIS 2013 Pathogen Controls in Beef Operations Survey. We used $1.5 as a proxy for the testing costs for the establishments using in-house labs as these are most likely to have switched testing kits. For the ones using contract labs, we used $30 for average cost per test based on the cost of FSIS testing methodology. We believe $30 per test for contracting labs is a reasonable assumption, as (1) the FSIS testing methodology is available to the industry, and (2) some establishments using contracting labs may only have to switch testing kits, not labs. The 2013 Pathogen Controls in Beef Operations Survey results indicated that among the

\(^8\) Besides the testing methodologies, another main price-driver is the number of samples sent to the labs.

\(^9\) If a small establishment wants to run one test per month at a contract lab, the cost of shipping and doing the one test could easily be $60. On the other side of the spectrum, if an establishment runs daily samples the cost per test could be as low as $15.
establishments that are testing for non-O157 STEC, between 73% to 78% use contract labs (see Table 3).\textsuperscript{10} Therefore, the annual cost to the industry to conduct non-O157 testing is about $0.99 million dollars, among which $0.89 million is attributed to increased manufacturing trim testing after FSIS started testing, and the other 0.10 million is from predicted increase of testing of bench trim, other components and raw ground beef after FSIS expands testing(see Table 4.)

Table 3. Percentage of establishments using contract lab and in-house lab for non-O157 STEC testing

<table>
<thead>
<tr>
<th>Product</th>
<th>Contract lab</th>
<th>In-house Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trim (beef manufacturing trimming and bench trim)\textsuperscript{11}</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Other components</td>
<td>77%</td>
<td>23%</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>77%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Source: FSIS 2013 Pathogen Controls in Beef Operations Survey. Details of data analysis are in the technical appendix.

\textsuperscript{10} For details of the data analyses, see Technical Appendix. Also note that since the percentages are very close across size categories, this table will not present the results by size for the sake of simplicity.

\textsuperscript{11} Data for this survey question cannot be separated by beef manufacturing trimmings and bench trim, so we have to assume the same ratio for both.
Table 4. Annual costs of industry testing

<table>
<thead>
<tr>
<th></th>
<th>Contract lab</th>
<th></th>
<th>In-house lab</th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># samples</td>
<td>Cost ($)</td>
<td># samples</td>
<td>Cost ($)</td>
<td># samples</td>
</tr>
<tr>
<td></td>
<td>30/test</td>
<td>1.5/test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beef manufacturing trimmings</td>
<td>29,020</td>
<td>870,603</td>
<td>12,437</td>
<td>18,656</td>
<td>41,457</td>
</tr>
<tr>
<td>Bench trim</td>
<td>135</td>
<td>4,040</td>
<td>58</td>
<td>87</td>
<td>192</td>
</tr>
<tr>
<td>Other components</td>
<td>1,052</td>
<td>31,562</td>
<td>314</td>
<td>471</td>
<td>1,366</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>1,966</td>
<td>58,979</td>
<td>587</td>
<td>881</td>
<td>2,552</td>
</tr>
<tr>
<td>Total</td>
<td>32,173</td>
<td>965,184</td>
<td>13,396</td>
<td>10,095</td>
<td>45,569</td>
</tr>
</tbody>
</table>

Note: Totals may not always add up due to rounding.

The 2013 Pathogen Controls in Beef Operations Survey shows that some establishments are conducting confirmation test after products screened positive for non-O157 STEC: 28 for trim, 12 for other components, and 22 for raw ground beef. After extrapolating the results by sampling weight, we estimated the number of establishments that proceed to confirmation on non-O157 STEC screening tests are about 59 for trim, which is about 5% of the ones that test, 15 (4%) for other components, and 74 (6%) for raw ground beef. We do no have the number of samples because the Survey did not ask for it. Nevertheless, the Survey results indicate that “proceeding-to-confirmation” is only one of the several actions the establishments take when products are screened positive. This information and the finding that only a

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12 The Survey did not collect data on this item separately for beef manufacturing trimmings and bench trim.
13 Details of data analysis are in the technical appendix.
small percentage of establishments do confirmation test make us believe that the total cost for industry of conducting confirmatory testing is not significant. We will discuss this more when we discuss the loss of value for products with screen-positive results in the next section.

For products that test positive for non-O157 STEC, either from FSIS testing or establishment testing, the establishments have to prevent the raw products from going into commerce. The common practices of disposing of products that test positive include cooking or other treatment that would render the product suitable for human food, destroying, or rendering into other products not for human food. Since many establishments do not do confirmation testing, there are concerns that the loss value from disposed beef products after screen positive may be significant. However, we found that it is very difficult to capture and monetize the loss value of such products. In examining the 2013 Pathogen Controls in Beef Operations Survey data, we found that 43% of the establishments that tested for non-O157 STEC took more than one of the four actions (proceeding to confirm, cooking, destroying, and selling14) with products that screened positive.15 The Agency believes that it is impossible to get the volume of the products disposed under any

14In the survey question, “selling” means “shipping to another official establishment for disposition (e.g., cooking) under appropriate controls.”

15For details of data analysis, see Technical Appendix.
of the actions, even if we asked that question in the survey. This is because the actions the establishments choose are often based on their particular circumstances. For example, if the establishment is very confident with its screening test methodology, it will probably cook the products subject to available cooking capacity at that time. If the establishment is not confident about its screening methodology, and there is not enough cooking capacity, it will probably proceed to confirmation or destroy the products, depending on the relative costs of conducting confirming tests versus destroying the products. Empirical literature on industry behavior shows that industry behaves strategically to maximize profits or minimize losses.\textsuperscript{16} Therefore, whatever action an establishment takes, the incentive is to avoid recalls and potential outbreaks. The expected benefit should outweigh the cost. If the false positive rate of the screening test is high, then some of the disposed products would have been diverted “unnecessarily.” However, the Agency test data show that the false positive rate of non-O157 STEC screening is low at about 13.2%.\textsuperscript{17} FSIS testing

\textsuperscript{16}For example, it was found that establishments behave strategically with regard to regulations of the National School Lunch Program in Ollinger, Michael, The Performance on Pathogen Test of Ground Beef Suppliers to the National School Lunch Program, for presentation at the Agricultural & Applied Economics Association’s 2013 AAEA&CARE Joint Annual Meeting.

\textsuperscript{17}Data are from the Executive Associate for Laboratory Services. Office of the Assistant Administrator, Office of Public Health Science, FSIS. The rate of confirmation of the non-O157 STEC testing from presumptive to confirmed-positive for the time period of June 2013 to June 2014 is 86.8%. For comparison, the rate of confirmation for the O157 STEC testing from
methodology is available to the industry. Given that the FSIS false positive rate is low, we do not think the lost value of the diverted products due to false positive results will be significant.

As for the cost of holding the products while awaiting FSIS test results, we expect an increase resulting from products being screen-positive for non-O157 STEC because FSIS data on beef manufacturing trimmings testing show very small overlap between non-O157 and O157 STEC positives.\textsuperscript{18} FSIS requires all official establishments to maintain control of their products that have been tested by FSIS for adulterants until acceptable results become available.\textsuperscript{19} If FSIS includes ground beef and ground beef components in its non-O157 STEC testing, it will analyze for non-O157 STEC samples collected for \textit{E. coli} O157:H7 analysis. Therefore, FSIS will not collect additional samples from additional lots of product. As mentioned above, Agency test data for FY 2013 showed that the screen positive sample rate for non-O157 STEC in beef manufacturing trimming is only 2 percent. Therefore, the additional costs of holding products presumptive to confirmed-positive is 86.5%. Both analyses are performing at a comparable rate.

\textsuperscript{18} Based on data from June 4, 2012 to June 1, 2014 only 2 out of 7,995 samples were positive for both O157 and non-O157 STEC. Data are from Science Staff, OPIS, FSIS.

\textsuperscript{19} Not Applying the Mark of Inspection Pending Certain Test Results, Federal Register Notice, 77, 73401 (2012).
because of additional tests and additional positive samples are likely to be minimal.

What corrective actions and preventative measures the industry will take is a business decision for the establishments to make. Each establishment will choose the approach that is the most cost-beneficial. Therefore, the Agency cannot estimate the cost for increased corrective actions and prevention for the industry.

As we have stated in this analysis, many establishments that produce raw non-intact beef products implement controls for E. coli O157:H7.20 There is reason to believe that these methods will be effective in controlling non-O157 STEC.21 If they are, the industry would incur minimal additional processing costs in controlling non-O157 STEC as a result of FSIS expanding its

20 One common measure that establishments use is purchase specifications in a prerequisite program. FSIS Directive 10,010.1 stipulates that FSIS expects the establishment to have: (1) a document from each supplier that provides assurance that the supplier employs CCPs (critical control points) that address E. coli O157:H7, (2) certificates of analysis and the sampling method used by the supplier, and (3) records that verify on an on-going basis that the receiving establishment is executing its program effectively. Other measures establishment can use include (a) treating or washing the product when removed from Cryovac bags and trimming the outer surface before processing non-intact product, and (2) using antimicrobials or other lethality treatments on raw beef product and verifying the effectiveness of those antimicrobials. (FSIS Directive 10,010.1.)

21 Research done by Colorado State University researchers found that decontamination treatments that reduce E. coli O157:H7 on beef trim also reduce non-O157 STEC. See Geornaras, Ifigenia, et al. (2011.) Evaluating of Chemical Decontamination Treatments for Beef Trimmings against Escherichia Coli O157:H7, non-O157 Shiga Toxin-Producing E. Coli and Antibiotic Resistant and Susceptible Salmonella Typhimurium and Salmonella Newport, Final Report submitted to American Meat Institute Foundation.
testing for non-O157 STEC. FSIS requests the public to comment on the above cost estimates with supporting data.

2. Budgetary Costs to the Agency

The Agency found that the annual cost of testing beef manufacturing trimmings for non-O157 STEC is about $475,800 in 2013 dollars. The cost for the Agency to expand testing to bench trim, other components, and raw ground beef will be another $903,900 ($201,600 + $702,300). Table 5 presents the estimates, and the following sections explain how we obtained these estimates.

Table 5. Annual Costs to the Agency for non-O157 STEC testing ($ thousand, 2013 dollars)

<table>
<thead>
<tr>
<th></th>
<th>Scheduled testing</th>
<th>Follow-up testing</th>
<th>For-cause FSA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef manufacturing trimmings</td>
<td>302</td>
<td>157</td>
<td>16.8</td>
<td>475.8</td>
</tr>
<tr>
<td>Bench trim &amp; other components</td>
<td>152</td>
<td>23</td>
<td>26.6</td>
<td>201.6</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>656</td>
<td>18.3</td>
<td>28</td>
<td>702.3</td>
</tr>
<tr>
<td>Total</td>
<td>1,110</td>
<td>198.3</td>
<td>71.4</td>
<td>1,379.7</td>
</tr>
</tbody>
</table>

a. Cost of testing beef manufacturing trimmings

We analyzed the costs for the Agency in three parts: (1) cost to FSIS laboratories for analyzing samples collected by FSIS for non-O157 STEC, (2) cost to conduct follow-up sampling and testing, and (3) cost to conduct for-cause-FSAs (food safety assessments). The Agency has estimated the total costs
for these three parts of testing beef manufacturing trimmings to be approximately $475,800 per year in 2013 dollars.\(^2\)

The direct immediate cost to FSIS laboratories for analyzing samples is about $302,000. This cost includes supplies and labor for screening, confirmation, most-probable-number (MPN) procedures, serogrouping, and pulsed-field gel electrophoresis (PFGE).\(^3\) Some key variables behind this cost estimate include:

- The annual number of samples tested in FY2013 was 2,973 (2,565 for domestic products and 408 for imported products, based on FY2013 data,)\(^4\) and
- Screen (potential) positive sample rate is 2 percent (based on FY2013 data).\(^5\)

FSIS conducts follow-up sampling and testing for all 7 STEC if FSIS finds a sample positive for \textit{E. coli} O157:H7 or non-O157 STEC. The Agency data show that the number of follow-up tests for beef manufacturing trimmings non-O157 STEC positive samples in FY 2013 was about 1,208. As a result, the cost for follow-up

\(^2\) Data for sampling and testing are from the Executive Associate for Laboratory Services, Office of the Assistant Administrator, Office of Public Health Science, FSIS. Data for for-cause-FSAs are from OFO.

\(^3\) Because the laboratory analysis of samples for non-O157 STEC is an extension of the program for \textit{E. coli} O157:H7, we only have to estimate the marginal cost. There is no additional cost for shipping or sample-collection.

\(^4\) Data are from the Data Analysis and Integration Staff, Office of Data Integration and Food Protection, FSIS.

\(^5\) Ibid.
testing, including sample collection, supplies, and analytical personnel was about $157,000.

In addition, FSIS conducts for-cause FSAs for every positive sample. The Agency estimated that the average cost to conduct an FSA is about $1,400.\textsuperscript{26} FSIS FSA data of FY 2013 showed 12 for-cause FSAs triggered by non-O157 STEC positives in beef manufacturing trimmings,\textsuperscript{27} so the total cost to conduct for-cause FSAs is about $16,800. Adding the cost to sample testing (scheduled and follow-up) costs of $459,000, we get the total cost of about $475,800.

b. Cost of expanding testing to ground beef components other than beef manufacturing trimmings

The method of estimating the cost for testing other components is the same as the one for beef manufacturing trimmings. The only caveat is that we have to use the numbers associated with \textit{E.coli} O157:H7 testing as proxies for numbers related to non-O157 testing.\textsuperscript{28} Assuming the annual sample of bench trim and other components collected and analyzed would be about 1,392 (which is the number of samples of bench trim and other components tested for \textit{E.coli} O157:H7 in FY 2013), we

\textsuperscript{26} Data is for 2013 from the Office of Field Operations, FSIS.
\textsuperscript{27} The numbers of for-cause FSAs are from the Issuance Staff, Office of Policy and Program Development, FSIS.
\textsuperscript{28} We believe this is a reasonable approximation given that all these samples will be tested for non-O157 STEC as well as 0157 when this policy is implemented.
estimated that the cost of scheduled testing would be about $152,000.

The Agency data show that the number of follow-up tests for positive samples of bench trim or other components in FY 2013 was about 179. Using this number, the cost for follow-up testing (including sample collection, personnel, and supplies) will be about $23,000.

The cost for conducting for-cause FSAs for other components is the same as the cost for conducting for-cause FSAs for beef manufacturing trimmings, which is about $1,400. Assuming 19 for-cause FSAs based on FY 2013 data, the total cost for conducting for-cause FSAs will be about $26,600. Adding the costs for scheduled testing, follow up testing, and FSAs, we estimated that the total annual additional cost to the Agency of expanding the program to testing bench trim and other components is about $201,600 per year in FY 2013 dollars.

c. Cost of expanding testing to raw ground beef

The method of estimating the cost for testing raw ground beef is the same as the one for ground beef components other than beef manufacturing trimmings. If the Agency expands the non-O157 STEC testing to raw ground beef, assuming that (1) 12,963 samples will be analyzed, and (2) the screen positive rate is 1.0 percent, the estimated costs for scheduled testing will be
approximately $656,000.29 30 This represents the marginal cost for supplies and personnel.

The Agency data show that the average number of follow-up tests for raw ground beef for E.coli O157:H7 in FY 2013 is about 258. Using this number, the Agency estimated that the cost for follow-up testing (including personnel, supplies, and shipping costs) will be about $18,300 per year.31

The average cost to conduct an FSA is still about $1,400. Multiplying it by the estimated annual number of for-cause FSAs (i.e. 20, based on FSIS FY2013 data), the cost of conducting for-cause FSAs is about $28,000. Adding the cost of scheduled sample testing, follow-up testing and for-cause FSAs, the total cost will be approximately $702,300.

d. Total cost to the Agency

Adding all the above costs together, we obtained the total cost to the Agency for the existing non-O157 STEC testing of manufacturing beef trimmings and for expanding the testing to other raw beef products to be approximately $1.38 million per year.

29 Data are from the Executive Associate for Laboratory Services, Office of the Assistant Administrator, OPHS/FSIS.
30 Again we use the number of raw ground beef samples tested for E.coli O157:H7 and the positive rates of FY 2013 as proxies. Data are from the Data Analysis and Integration Staff, Office of Data Integration and Food Protection, FSIS.
31 The per-test cost for raw ground beef is less than trim because the test of raw ground beef uses only one analytical portion of 325g, while the test of trim uses the N60 procedure which currently requires two 325g portions.
3. **Expected Benefits**

   a. **Reduced illnesses and deaths**

   One benefit from sampling and testing for non-O157 STEC is the reduction of illnesses and deaths caused by non-O157 STEC because we assume FSIS sampling and testing leads to keeping adulterated product out of commerce. In addition, we believe that, as establishments take corrective actions in response to positive test results, including appropriate changes to their HACCP systems\(^{32}\), overall control of STEC will improve, which will further reduce illness. The most recent CDC analysis estimated that there are about 112,752 (with a range of 11,467 to 287,321) domestically-acquired foodborne illnesses caused by non-O157 STEC annually, and the average annual number of hospitalization is 271 (with a range of 0 to 971.)\(^{33,34}\) FSIS economists used these case numbers and estimated the expected cost per illness to be about $450 in 2012 dollars.\(^{35,36}\) However, limited data

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\(^{32}\) Some other examples of actions establishments may take in response to positive test results are: conducting an investigation to determine the cause of the positive, developing a comprehensive sanitary dressing program, strengthening the requirements of a purchase specification program, adding additional interventions, increasing the effectiveness of existing interventions, beginning testing for all adulterant STEC, and increasing sampling to verify that the corrective actions are effective.


\(^{34}\) Note that Scallan et al. reports the median value for the distribution of deaths caused by STEC non-O157 because of extremely skewed data. See Ibid. Table 3.

\(^{35}\) Marks, H. M., Tohamy S., & Tsui, F. (2013). Modeling Uncertainty of Estimated Illnesses Attributed to Non-O157:H7 Shiga Toxin-Producing
creates uncertainty in the estimation of the illnesses prevented, so we could not quantify this benefit.

b. Benefits from reduced outbreak-related recalls and improved industry practices

Any recall may have a significant impact on the industry, the consumer, and the Government. The negative impacts of recalls on industry include the loss of sales revenue, the cost to dispose of recalled products, and the loss of consumer confidence and business reputation. Recalls negatively impact consumers by creating anxiety and time-consuming inconveniences (e.g., looking for recall information, checking the products purchased, returning or disposing of products identified by the recalls, and so on). For the Government, the Agency incurs costs for verifying that companies recalled and properly disposed of product.37

Through early detection of products contaminated with non-O157 STEC, testing for non-O157 STEC may prevent outbreak-related food recalls. From June 4, 2012 to June 1, 2014, FSIS testing alone has found 85 samples positive for non-O157 STEC.38

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37 The estimate represents a lower bound analyses for an average cost of illness because it only includes medical costs and loss-of-productivity costs. It does not include pain and suffering costs.

37 This includes inspectors’ activities at the establishments, FSAs and recall effectiveness checks, and dissemination of information about recalls through press releases.

38 Data are from Science Staff, OFHS, FSIS based on testing results of MT60, MT52, MT53, and MT51.
All these products could have potentially led to illnesses, outbreaks, and recalls if the products were sold into commerce. Some have argued that, while early detection of contaminated products could have prevented recalls, the additional testing may increase the total number of recalls as the new policy would require recalling all products that are adulterated with non-O157 STEC and have entered commerce, regardless of whether they are associated with an outbreak or not. However, these additional non-outbreak-related recalls normally cost the industry less than the outbreak-related recalls as the damage to business reputation is more limited. There was one recall before FSIS started testing, which occurred in August 2010, which was associated with a cluster of reported illnesses.\textsuperscript{39} Since FSIS started testing, there have been two Class-I recalls associated with raw beef products contaminated with non-O157 STEC, and in both cases products were recalled before any illnesses were reported.\textsuperscript{40} These early-stage recalls actually carry the benefit of preventing potential outbreaks and outbreak-associated recalls, which are more costly to the industry, the consumer, and the government.

\textsuperscript{39}This first FSIS non-O157 STEC recall took place in August 2010. Recall number 050-2010 involved 8,500 pounds of ground beef possibly contaminated with \textit{E. coli} O26.
\textsuperscript{40}The list of recalls is on \url{http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts/current-recalls-and-alerts}. The two recalls are recall number 045-2013 and recall number 010-2014.
In addition, investigation of these recalls generates other benefits. Through recall investigations, FSIS is able to determine process failures to help establishments take corrective actions to prevent future contamination, resulting in a reduction in future illnesses. Beyond establishment-level improvements, a better understanding of product adulteration through investigation can serve as the basis for education that will benefit the entire industry as well as regulatory organizations. For example, the identification of potentially hazardous practices can lead to improved guidance, and the linking of such practices to outbreaks and recalls motivates establishments to refrain from risky behavior. The Agency requests information that could help quantify the above benefits.

4. Net benefits

The cost for the current testing of beef manufacturing trimmings (including Agency and the industry testing) is about $1.37 million. If the Agency expands the testing to bench trim, other components, and raw ground beef, it will add another $1 million to the cost and bring the grand total up to about $2.37 million.
Table 6. Summary of Annual Costs and Benefits ($thousand, in 2013 dollars)

<table>
<thead>
<tr>
<th>Costs</th>
<th>Benefits from reduced illnesses and deaths, outbreak-associated recalls and improved business practices.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency</td>
<td>Industry</td>
</tr>
<tr>
<td>Beef manufacturing trimmings</td>
<td>475.8</td>
</tr>
<tr>
<td>Bench trim &amp; other components</td>
<td>194.6</td>
</tr>
<tr>
<td>Raw ground beef</td>
<td>709.3</td>
</tr>
<tr>
<td>Total</td>
<td>1,379.7</td>
</tr>
</tbody>
</table>

Benefits would accrue from reduced illnesses and deaths, reduced outbreak-related recalls, and improved business practices. FSIS asserts that the benefits accrued to industry, Government, and consumers from this new testing policy will results in net economic benefits.

5. Impact on Small Business

FSIS does not require establishments to test. Establishments are already required to identify hazards reasonably likely to occur and to take measures that will prevent, eliminate, or reduce those hazards under HACCP. Establishments can choose to conduct verification testing to verify the effectiveness of food safety system. The 2013 Pathogen Controls in Beef Operations Survey showed that only 14% of the small establishments and 6% of the very small establishments that produced trim were testing for non-O157 STEC

41 Based on FSIS’ HACCP (Hazard Analysis and Critical Control Points) size definition: very small establishments have fewer than 10 employees or generate less than $2.5 million in annual sales; and small establishments have 10 or more but fewer than 500 employees and generate more than $2.5 million in annual sales.
after the Agency started testing\textsuperscript{42}. Therefore, testing does not impose significant negative impact on a substantial number of small and very small businesses.

\textsuperscript{42}For details of data analysis, see technical appendix.
Technical Appendix on Analysis of FSIS 2013 Pathogen Controls in Beef Operations Survey for the Cost to the Industry

In April-July 2013, FSIS conducted a Pathogen Controls in Beef Operations Survey. The purpose of the survey was to gather information on the controls that beef slaughtering and processing establishments have in place to reduce STEC and salmonella contamination. The survey questions covered a wide range of topics, including pre-harvest management controls, sanitary dressing, carcass sampling and testing, high event period, various beef products, and non-O157 STEC. FSIS sent surveys to inspectors in over 500 establishments out of a total of approximately 2300 beef slaughter or beef processing operations. For the survey design, sampling frame, implementation, and summary of survey results, please see FSIS Report on 2013 Pathogen Controls in Beef Operations Survey (space holder for link to where the report is published). This technical appendix documents how we obtained the numbers we used in the cost-benefit analysis from the survey data.

1) For number of samples tested for non-O157 STEC, we used answers to nSTECST3, which asked how many raw beef product samples the establishment collected and analyzed for STEC in the last twelve months. Answers to this question were coded into 35 variables: nstecst3q218_a_1 through nstec3q218_e_7; where “_a” through “_e” denote the columns

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and "_1" through "_7" denote the rows in the table in question nSTECST3 in the questionnaire. We summed-up the products of the answers under each of the following variables and the establishment’s sampling weight\textsuperscript{43}:

a) For the number of samples of manufacturing trimmings,
   \texttt{nstecst3q218\_b\_4}

b) For the number of samples of bench trim, \texttt{nstecst3q218\_b\_5}

c) For the number of samples of other components,
   \texttt{nstecst3q218\_b\_6}

d) For the number of samples of raw ground beef,
   \texttt{nstecst3q218\_b\_7}

2) For the percentage of establishments testing for \textbf{E. coli O157:H7} that also test for non-O157 STEC, we started by getting the number of establishments that tested beef manufacturing trimmings for O157 and non-O157. For that, we used answers to question TrimST12, which asked what pathogens were tested as part of establishments’ on-going verification testing. Answers to this question were coded into 8 variables (\texttt{trimst12q129\_a\_1} through \texttt{trimst12q129\_a\_8},) where the last digit number 1 through 8 denotes the rows in the table in question TrimST12 in the

\textsuperscript{43}Calculations performed using STATA’s “svy:total” command. For all results derived from sampling weights, we rounded the results to a whole number (e.g. 1.7 would be rounded to 2.)
questionnaire. We summed-up the weights of the establishments for the following:

a) Those whose answer to trimst12q129_a_4 is “Trimmings (in-house source materials).” This gives the number of establishments that tested beef manufacturing trimmings for E.coli O157:H7.

b) Those whose answer to trimst12q129_a_4 is “Both.” This gives the number of establishments that tested both beef manufacturing trimmings and bench trim for E.coli O157:H7.

c) Those whose answer to trimst12q129_a_5 is “Trimmings (in-house source materials).” This gives the number of establishments that tested beef manufacturing trimmings for non-O157 STEC.

d) Those whose answer to trimst12q129_a_5 is “Both.” This gives the number of establishments that tested both beef manufacturing trimmings and bench trim for non-O157 STEC.

The sum of (a) and (b) is the number of establishments that tested beef manufacturing trimmings for E. coli O157:H7, and the sum of (c) and (d) is the number of establishments that tested beef manufacturing trimmings for non-O157 STEC.

Dividing the sum of (c) and (d) by the sum of (a) and (b) we get the percentage of establishments that tested beef
manufacturing trimmings for *E. coli* O157:H7 that also tested for non-O157 STEC.

3) For the percentage of establishments using contract laboratories and in-house laboratories, we used answers to the following three questions:

a) TrimST13, for manufacturing trimming and bench trim, as the Survey did not ask about beef manufacturing trimmings and bench trim separately. The questions stated: “for each pathogen tested, which type of laboratory does the establishment use for analysis?” Answers to this question were coded into 8 variables: trimst13q229_a_1 through trimst13q229_a_8, where “_1” through “_8” denote the rows in the table in question TrimST13 in the questionnaire.

The ratio of the establishments of those whose answer to trimst13q229_a_5 is “Contract Lab” adjusted by sampling weights is the percentage of establishments that used contract labs.\(^ {44}\)

b) CMPST3, for other components. The question stated: “for each pathogens tested, does the establishment use an in-house lab or send the samples out to a contract lab for analysis?” Answers to this question were coded into 24 variables: cmpst3q230_a_1 through cmpst3q230_a_24, where

\(^{44}\) Calculation performed using STATA’s “svy:tab” command.
"_1" through "_24" denote the cells in the table of question CMPST3 in the questionnaire—from left to right, then down. Because the answers were coded in a different format from TrimST13, we had to use two variables to derive the ratio:

i) For the number of establishments that used contract labs, we summed up the sampling weights of those establishments whose answer to cmpst3q230_a_14 is "Contract Lab."

ii) For the number of establishments that used in-house labs, we summed up the sampling weights of those establishments whose answer to cmpst3q230_a_13 is "In-house Lab."

iii) Dividing (i) by the sum of (i) and (ii) we got the ratio of establishments that used contract lab for analyzing other components samples for non-O157 STEC RGBST2, for raw ground beef. The questions stated: "for each pathogen tested, which type of laboratory does the establishment use for analysis?" Answers to this question were coded into 8 variables: rgbst2q198_a_1 through rgbst2q198_a_8, where "_1" through "_8" denote the rows in the table in question RGBST2.
The ratio of the establishments of those whose answer to rgbst2q198_a_5 is “Contract Lab” adjusted by sampling weights gives the percentage of establishments that used contract labs.45

4) For the number of establishments that proceed to confirmation when products screened positive for STEC, we used answers to the following questions:
   a) TrimST15, for manufacturing trimming and bench trim, as the Survey did not ask separately about beef manufacturing trimmings and bench trim on this issue. The question stated: “If the screen test is positive, or if the test is confirmed positive for STEC or virulence genes, what action does the establishment take?” Answers to this question were coded into 4 variables: trimst15q131_a_1 through trimst15q131_a_4, where “_1” through “_4” denote the rows in the table in question TrimST15 in the questionnaire. We summed-up the sampling weights of the establishments whose answer to trimst15q131_a_1 (Proceed to confirmation) is “Screen positive for STEC.”
   b) CMPST6, for other components. The question stated: “if the test screen is positive, or if the test is confirmed positive for STEC organisms or virulence genes, what

45 Ibid.
action does the establishment take?” Answers to this question were coded into 5 variables: cmpst6q171_a_1 through cmpst6q171_a_5, where “_1” through “_5” denote the rows in the table in question CMPST6. We summed-up the sampling weights of the establishments whose answer to cmpst6q171_a_1 (Proceed to confirmation) is “Screen positive for STEC.”

c) RGBST3, for raw ground beef. The question stated: “if the test screen positive for STEC or virulence genes, what action does the establishment take?” Answers to this question were coded into 15 variables: rgbst3q199_a_1 through rgbst3q199_a_15, where “_1” through “_15” denote the cells in the table in question RGBST3- from left to right, then down. We summed-up the sampling weights of the establishments whose answer to rgbst3q199_a_6 (Non-O157 STEC) is “Proceed to confirmation.”

5) For the number of establishments that take multiple actions when products screened positive, we also used answers to the same three variables used in 4). However, we had to create an excel spreadsheet that looks like the following and input the results from data run into the spreadsheet:
a) TrimST15 (see 4.a above), we listed estnum (establishment number), weight (sampling weight), and their answers to trimst15q131_a_1 through trimst15q141_a_4, then input into the spreadsheet as follows:

i) If the answer from establishment A to trimst15q131_a_1 is “Screen positive for STEC,” that means the establishments checked “Proceed to confirmation” for samples screened positive for STEC. So we put a number “1” in cell A1 in our spreadsheet.

ii) If the answer from establishment A to trimst15q131_a_2 is “Screen positive for STEC,” that means the establishments checked “Cook” for samples screened positive for STEC. So we put a number “1” in cell A2 in our spreadsheet.

iii) If the answer from establishment A to trimst15q131_a_3 is “Screen positive for STEC,” that means the establishments checked “Destroy” for samples screened positive for STEC. So we put a number “1” in cell A3 in our spreadsheet.

<table>
<thead>
<tr>
<th>Estnum</th>
<th>Proceed to confirm</th>
<th>Cook</th>
<th>Destroy</th>
<th>Sell</th>
<th>Other</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A1</td>
<td>A2</td>
<td>A3</td>
<td>A4</td>
<td>A5</td>
<td></td>
</tr>
</tbody>
</table>
iv) If the answer from establishment A to trimst15q131_a_4 is “Screen positive for STEC,” that means the establishments checked “Sell” for samples screened positive for STEC. So we put a number “1” in cell A4 in our spreadsheet.

v) For estnum and weight, direct copy from the results.

(Note: “Other” is not a choice for answer in question TrimST15)

b) CMPST6 (see 4.b above), we listed estnum (establishment number), weight (sampling weight), and their answers to cmpst6q171_a_1 through cmpst6q171_a_5 as follows:

i) If the answer from establishment A to cmpst6q171_a_1 is “Screen positive for STEC,” that means the establishments checked “Proceed to confirmation” for samples screened positive for STEC. So we put a number “1” in cell A1 in our spreadsheet.

ii) If the answer from establishment A to cmpst6q171_a_2 is “Screen positive for STEC,” that means the establishments checked “Cook” for samples screened positive for STEC. So we put a number “1” in cell A2 in our spreadsheet.

iii) If the answer from establishment A to cmpst6q171_a_3 is “Screen positive for STEC,” that
means the establishments checked “Destroy” for samples screened positive for STEC. So we put a number “1” in cell A3 in our spreadsheet.

iv) If the answer from establishment A to cmpst6q171_a_4 is “Screen positive for STEC,” that means the establishments checked “Sell” for samples screened positive for STEC. So we put a number “1” in cell A4 in our spreadsheet.

v) If the answer from establishment A to cmpst6q171_a_5 is “Screen positive for STEC,” that means the establishments checked “Other” for samples screened positive for STEC. We put a number “1” in cell A5 in our spreadsheet.

vi) For estnum and weight, direct copy.

c) RGBST6 (see 4.c above), we listed estnum (establishment number), weight (sampling weight), and their answers to rgbst3q199_a_6 through rgbst3q199_a_10, then input in the spreadsheet as follows:

i) If the answer from establishment A to rgbst3q199_a_6 is “Proceed to confirmation,” we put a number “1” in cell A1 in our spreadsheet.

ii) If the answer from establishment A to rgbst3q199_a_7 is “Divert to cooking,” we put a number “1” in cell A2 in our spreadsheet.
iii) If the answer from establishment A to rgbst3q199_a_8 is “Destroy product,” we put a number “1” in cell A3 in our spreadsheet.
iv) If the answer from establishment A to rgbst3q199_a_9 is “Sell product,” we put a number “1” in cell A4 in our spreadsheet.
v) If the answer from establishment A to rgbst3q199_a_10 is “Other,” we put a number “1” in cell A5 in our spreadsheet.
vi) For estnum and weight, direct copy.

d) We went through the spreadsheet to make sure that if an establishment appeared more than once (e.g. under both TrimST15 and CMPST6,) its weight only counted once. Then we calculated the ratio of the total weight of the establishments that took multiple actions to the total weight of establishments answered the questions.

6. For the percentage of the small and very small establishments producing trim and testing for non-O157 STEC, we divided the number of small and very small establishments that tested for non-O157 STEC by the number of small and very small establishments that produced beef.

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46 In the survey question, “selling” means “shipping to another official establishment for disposition (e.g., cooking) under appropriate controls.”
trimmings. For the numerator, we added together the numbers we got in 2.c and 2.d above. For the denominator, we summed up the weights of those whose answer to question TrimINT1 ["does the establishment produce beef trimmings (including beef manufacturing trimmings and bench trim)?"] is "Yes."