Cost-Benefit Analysis for FSIS's 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

This cost-benefit analysis (CBA) is an update to the CBA FSIS published on November 19, 2014,[1] in which FSIS estimated the costs and benefits associated with the implementation of its non-O157 Shiga toxin-producing *Escherichia coli* (STEC) testing on beef manufacturing trimmings and the expansion of testing to ground beef, bench trim, and raw ground beef components other than raw beef manufacturing trimmings (abbreviated as "other components" in this CBA).[2] In this update, FSIS adopted much of the 2014 CBA with the following changes:[3,4]

1. We updated the false positive rate for industry's screening test, in response to industry's comments; and included estimates of product loss value as a cost to the industry.
2. We updated the Agency's budgetary costs. In February 2019, FSIS Field Service Laboratories began using a new technology for STEC testing. Before that, the laboratories employed a technology which required two separate kits to analyze samples for the presence of *E. coli* O157:H7 and the other 6 major STEC O groups. The new technology only requires one kit to test for all 7 *E. coli* O groups.[5] This new technology provided the Agency with the ability to be able to

[1] The 2014 CBA is available at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices.
[2] Examples of "other components" include head meat, cheek meat, weasand (esophagus) meat, product from advanced meat recovery (AMR) systems, partially defatted chopped beef and partially defatted beef fatty tissue, low temperature rendered lean finely textured beef, and heart meat.
[3] The 2014 CBA was posted for public comments. We adopted without change those methodologies and numbers that did not receive any comment.
[4] All the financial figures are in 2019 dollars unless otherwise noted.
[5] References to sensitivity and specificity data on these methods can be found in the FSIS white paper that serves as the study report for the new technology selection. This paper can be found on the FSIS website: "Evaluation of commercial molecular screening platforms for the detection of food-borne bacterial pathogens by FSIS Field Service Laboratories" https://www.fsis.usda.gov/sites/default/files/media_file/2021-09/Molecular-Screen-Evaluation-2018-White-Paper.pdf

simultaneously analyze all samples for *E. coli* O157:H7 and the 6 major non-O157 STEC, thus reducing the resources required and lowering the cost for testing. As a result, the estimated lab cost for expanding Agency testing for non-O157 STEC is lower than the estimate in our 2014 CBA.

3. We updated the cost for conducting for-cause Food Safety Assessments (FSAs) using data from the Agency's analysis of the new FSA methodology.[6]
4. We quantified the benefit from prevented outbreak-related recalls, in response to comments, using survey data from the Grocery Manufacturers Association (whose name changed to Consumer Brands Association in January 2020).

The Agency estimated that industry and Agency cost for conducting the current non-O157 STEC testing of beef manufacturing trimmings is about $42.2 million per year. If the Agency expands non-O157 STEC testing to ground beef, bench trim, and other components, it would add another $6.4 million per year to the estimated cost and bring the grand total up to about $48.6 million per year (see Table 8). On the other hand, the Agency estimated the benefit from each prevented outbreak-related recall to be approximately $25.8 million. If the Agency's non-O157 STEC testing prevents two outbreak-related recalls per year, which the Agency thinks is likely, the quantified benefit ($51.6 million) would exceed the quantified cost ($48.6 million). There are additional benefits from reduced illnesses and improved industry practices (which the Agency did not quantify).

1. Potential Costs to the Industry

This analysis assumes that industry may, of their own initiative, take steps to update their own product testing. We are providing these cost estimates to reflect our best estimate of the

[6] In June 2015, FSIS changed the methodology for conducting FSAs. For details, see FSIS Directive 5100.4. Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology Implementation, 5/22/2015, available at https://www.fsis.usda.gov/policy/fsis-directives/5100.4

impacts that this updated policy is likely to have upon implementation, but also emphasize that FSIS testing does not require the industry to conduct its own testing for non-O157 STEC. Establishments may use validated interventions to address STEC, and verify that they are employing their interventions using the critical operating parameters necessary to address STEC. Similarly, they may verify that their suppliers are meeting their purchase specifications by obtaining necessary information from the suppliers. However, we understand that some establishments started testing (or will start testing) for non-O157 STEC 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 costs for the industry should they choose to update current practice in response to updated FSIS testing procedure. Although the Agency has changed its lab technology for STEC testing, FSIS is unable to estimate whether and how much of the industry will choose to adopt the new technology for STEC testing. Therefore, the industry cost estimates are based on the lab method that is comparable to what FSIS labs used before February 2019.

Although we estimated industry cost based on the lab method that is comparable to what FSIS labs used before February 2019, industry has previously commented that they usually only complete an initial screening test and don't complete additional stages of testing, unlike FSIS. FSIS testing includes three consecutive stages: potential screening, presumptive screening, and a confirming test. Potential screening is the initial screening of the enrichment medium of samples and usually has a higher false positive rate than the presumptive screening. Products that test positive at potential screening will undergo the next step – the presumptive screening. A presumptive positive result means the sample was both determined to be a potential positive and then an FSIS laboratory identified an isolate from the enrichment that also tested positive. Products that are presumptive positive then go through the confirming test. If an establishment chooses to test, most only conduct an initial screening test and make disposition decisions

without waiting for confirmation. In the comments to the 2014 FRN the industry claimed that their screening test for non-O157 STEC is equivalent to FSIS's potential screening test, and that the false positive rates are high.

To estimate the cost of establishments testing for non-O157 STEC, we first estimated the additional tests that the industry may conduct after FSIS starts testing for non-O157 STEC. This is the difference between the number of tests industry conducts before FSIS starts testing (pre-FRN)[7] and the number of tests after the FRN is published (post-FRN). We also estimated the average cost per test, which will be addressed later.

Data from the 2013 Pathogen Controls in Beef Operations Survey[8] (conducted in May-July 2013) allowed us to estimate the numbers of samples tested for non-O157 STEC in a 12-month period. For beef manufacturing trimmings, we used the numbers to represent the post-FRN number since FSIS started testing in June 2012.[9] For other raw beef products (ground beef, bench trim, and other components), 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 other raw beef products.

Table 1. Estimated Annual Number of Samples Tested for Non-O157 STEC by the Industry

Product	# of samples
Beef manufacturing trimmings	107,370

[7] For beef manufacturing trimmings, the FRN refers to the 2012 *Federal Register* notice (77 FR 9889) 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. For other raw beef products, the FRN refers to the one that will announce the expansion of the testing.

[8] The survey is available at Regulations.gov. The survey report is available at: Pathogen Controls in Beef Operations Summary Results (usda.gov), last accessed 7/8/2022.

[9] Since some establishments may not have started testing until after the Agency started in June 2012. Estimates from these establishments may represent less than a full-year if they completed the Survey before June 2013.

Ground beef	3,928
Bench trim	296
Other components	2,102

Source: FSIS 2013 Pathogen Controls in Beef Operations Survey, details of data analysis are in the technical appendix to the 2014 FRN.

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 percent of the establishments that were testing beef manufacturing trimmings for *E. coli* O157:H7 were also testing for non-O157 STEC.[10] The 2013 Pathogen Controls in Beef Operations Survey data show that the percentage of establishments that tested for both non-O157 STEC and *E. coli* O157:H7 after the 2012 FRN was about 33%, which is 13% more (33%-20%) and suggests a 65% increase [(33%-20%)/20%]. Applying this percentage change (of 65%) to the estimates in Table 1, we obtained the number of beef manufacturing trimming samples tested for non-O157 STEC pre-FRN, as well as the numbers of samples for other raw beef products that would be tested after FSIS expands non-O157 STEC testing to these products (see Table 2).[11]

Table 2. Estimated Annual Number of Samples Tested for Non-O157 STEC by the Industry Pre-FRN, Post-FRN,[12] and the Differences

[10] FSIS experts' opinion. We requested public comments on this and did not receive any.
[11] 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.

[12] Please see foot notes 7 and 9. For beef manufacturing trimmings, pre-FRN refers to the one-year period before the 2012 FRN (i.e., 2011 to 2012), and post-FRN refers to 2012-2013. For the other three product categories, Pre-

Product	Pre-FRN	Post-FRN	Difference
Beef manufacturing trimmings	65,073	107,370	42,297
Ground beef	3,928	6,481	2,553
Bench trim	296	488	192
Other components	2,102	3,468	1,366
Total	71,399	117,808	46,409

Note: Some of the totals may not equal the sum due to rounding.

As for the cost of testing, the Agency cannot obtain the actual cost for all STEC testing methodologies that the industry uses 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 season.[13] We do know that for those establishments already testing for *E. coli* O157:H7, adding non-O157 STEC testing will involve switching to different test kits, in most cases. Market information and Agency expert opinion indicate that the test kits for the seven STECs will only cost about $1 or $2 more per test, giving an average of $1.50. If an establishment has to contract out to a different lab, the test will be about $15 to $60 more per test.[14] We do not have data on which establishments switched to different test kits and which ones switched to new labs or purchased new equipment after the 2012 FRN. Therefore, we relied on data about whether the establishments use an in-house lab or a contract-lab from the FSIS 2013 Pathogen Controls in Beef Operations Survey. We used $1.50

FRN will be the one-year period before the FRN announcing the expansion of testing, and Post-FRN will be the one-year period after.

[13] The high prevalence season is the period of time in which more contamination happens, usually in the warmer months.

[14] Besides the testing methodologies, another main price-driver is the number of samples sent to the labs. 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.

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 the average cost per test based on the cost of FSIS's previous testing methodology. We believe using $30 per test for contracting labs is a reasonable assumption, as the FSIS testing methodology is available to the industry. The 2013 Pathogen Controls in Beef Operations Survey results indicated that among the establishments that are already testing for non-O157 STEC, between 70 to 77 percent use contract labs (see Table 3).[15] Therefore, the annual cost to the industry to conduct non-O157 STEC testing is about $1 million; $0.91 million is attributed to increased beef manufacturing trimmings testing after FSIS started testing, and the other $0.09 million is from the predicted increase in testing of other raw beef products after FSIS expands testing (see Table 4).

Table 3. Estimated Percentage of Establishments using Contract Labs and In-house Labs for Non-O157 STEC Testing

Product	Contract lab	In-house Lab
Beef manufacturing trimmings[16]	70%	30%
Ground beef	77%	23%
Bench trim	70%	30%
Other components	77%	23%

Source: FSIS 2013 Pathogen Controls in Beef Operations Survey. Details of the data analysis are in the technical appendix to the 2014 FRN.

[15] Since the percentages are very close across establishment size categories, this table does not present the results by establishment size for the sake of simplicity.

[16] Data for this survey question cannot be separated by beef manufacturing trimmings and bench trim, so we assume the same ratio for both.

Table 4. Estimated Annual Costs of Industry Testing (in 2019 dollars)

	Contract lab		In-house lab		Total	
	# samples	Cost ($)	# samples	Cost ($)	# samples	Total cost ($)
		30/test		1.5/test		
Beef manufacturing trimmings	29,608	888,243	12,689	19,034	42,297	907,277
Ground beef	1,966	58,979	587	881	2,553	59,860
Bench trim	135	4,040	58	87	192	4,127
Other components	1,052	31,562	314	471	1,366	32,033
Total	32,761	982,824	13,648	20,473	46,409	1,003,296

Note: Some of the totals may not equal the sum due to rounding.

As stated above, most of the industry conducts only initial screening and they make disposition decisions without waiting for confirmation. However, the 2013 Pathogen Controls in Beef Operations Survey shows that a small number of establishments conduct product screening and confirmation tests for non-O157 STEC: 28 for trim (which includes beef manufacturing trimmings and bench trim),[17] and 12 for other components. After extrapolating the results by sampling weights, we estimated that about 59 establishments proceed to confirmation testing on non-O157 STEC screening tests positive for trim, which is about 5 percent of the establishments that test; and that 15 establishments proceed to confirmation testing for other components, which is about 4 percent of those establishments that test.[18] We do not 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 that establishments take when products are screened positive. In examining the 2013 Pathogen Controls in Beef Operations Survey data, we found that 43 percent of the establishments that tested for non-O157 STEC took more than

[17] The survey did not collect data on this item separately for beef manufacturing trimmings and bench trim.
[18] Details of the data analysis are in the technical appendix to the 2014 FRN.

one of the four actions (proceeding to confirm, cooking, destroying, and selling)[19] with products that screened positive.[20] The actions the establishments choose often depend on their particular circumstances,[21] with the goal to maximize profits or minimize losses.[22] This information and the finding that only a small percentage of establishments do confirmation testing led us to conclude that the total cost to industry of conducting confirmatory testing is not significant.

For products that test positive for non-O157 STEC, either from FSIS testing or establishment testing, establishments have to prevent the raw products from going into commerce. Some common practices for 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 consumption. When establishments do not do confirmation testing, there is a loss of value from disposed beef products after they have screened positive.

As stated earlier, the industry commented that they act on screening test results and their screening tests are comparable to the Agency's potential screening test. Based on industry comment, the Agency estimated the loss value of products in the following way: (1) multiplying the annual production volume[23] by 13%, which is the additional amount of products that we estimated would be tested;[24] (2) multiplying that amount by the potential positive rate (5.04% for

[19] In the survey question, "selling" means "shipping to another official establishment for disposition (e.g., cooking) under appropriate controls."
[20] For details of the data analysis, see Technical Appendix of the 2014 FRN.
[21] 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.
[22] It was found that establishments behave strategically with regard to the National School Lunch Program regulations 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.
[23] Annual production volumes are for FY 2018, based on Public Health Information System (PHIS) sampling data calculated by FSIS's Office of Planning, Analysis, and Risk Management (OPARM).
[24] Based on results from the 2013 Pathogen Controls in Beef Operations Survey. See discussion between Table 1 and Table 2.

beef manufacturing trimmings; 0.23% for ground beef, 0.32% for bench trim, and 1.57% for other components),[25] which resulted in the amount of products that will be potential-positive, and (3) multiplying that amount by the false positive rates,[26,27] and by the values lost per pound.[28, 29] For example, the annual production volume of beef manufacturing trimmings is 4,635.4 million pounds; 13% of it is 602.6 million pounds, which will be tested for non-O157 STEC. Among the 602.6 million pounds, 5.04% will test positive, which is 30.4 million pounds. Among the 30.4 million pounds, 93% will be false positive, which is 28.2 million pounds. These 28.2 million pounds of beef manufacturing trimming are estimated to lose 2/3 of their market value, which means losing $1.46 per pound. As a result, the total lost product value for beef manufacturing trimmings due to false positive results will be $41.2 million per year. Table 5 presents the results in these steps for each product type. We acknowledge that industry may incur some cost associated with product that was truly positive. However, given that those products are adulterated, if they are not prevented from being sold into commerce, it's very likely there would be severe consequences (such as food-borne illness outbreaks and outbreak-related recalls) whose costs to industry far surpass any minimal loss in value from e.g., diverting

[25] Based on FY 2018 Agency STEC sampling and testing data.
[26] Since we assumed that the industry would not change to FSIS's new, one-kit lab method, we used the false positive rates of the Agency's old, two-kit lab method before February 2019 to estimate the lost value of products for the industry.
[27] Data are from the Office of Public Health Science (OPHS), FSIS for 2018. The false positive rates of the potential screening are: 93% for beef manufacturing trimming, 81% for ground beef, 100% for bench trim, and 94% for other components.
[28] The average prices per pound for raw beef products are: $2.19 for beef manufacturing trimmings, $1.27 for other components, $1.56 for bench trim, and $4.10 for ground beef. The price for ground beef is from 2017 and from the Bureau of Labor Statistics, https://data.bls.gov/timeseries/APU0000FC1101?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true accessed on 12/10/2018. Prices for beef manufacturing trimmings, other components, and bench trim are from 2017 and were provided by USDA's Agricultural Marketing Service's (AMS) Livestock, Poultry and Grain Market News Division in December 2018.
[29] Agency's experts' opinion was that the diverted products would lose about 50-75% value and the industry commented that the range would be 70-75%. However, given that the industry is taking multiple actions regarding screened positive products, as discussed on p.7-8, we feel it's reasonable to assume the lost value to be about two-thirds (67%).

the products to cooking.

Table 5. Estimated Annual Lost Value of Products for the Industry due to High False Positive Rate of Their Screening Method (in 2019 dollars)

	Annual production (lb. million)	Additional volume tested (lb. million)	Potential positive (lb. million)	Diverted/disposed due to false positive result* (lb. million)	Value lost per pound ($)	Lost value ($ million)
Beef manufacturing trimmings	4,635.4	602.6	30.4	28.2	1.46	41.2
Ground beef	6,827.1	887.5	2.1	1.7	2.73	4.6
Bench trim	227.8	29.6	0.1	0.1	1.04	0.1
Other components	735.9	95.7	1.5	1.4	0.85	1.2
Total	12,426.1	1,615.4	34.0	31.4		47.0

Note: Some of the totals may not equal the sum due to rounding.
*See footnote #26.

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. FSIS requires all official establishments to maintain control of their products that have been tested by FSIS for adulterants until acceptable results become available.[30] When FSIS included beef manufacturing trimmings in its non-O157 STEC testing, it analyzed samples collected for *E. coli* O157:H7 analysis for non-O157 STEC, without collecting additional samples from additional lots of product. If FSIS expands the non-O157 STEC testing to ground beef, bench trim, and other components, FSIS will not collect additional samples from additional lots either. Agency testing data for February to September 2019 showed that the screen presumptive positive sample rate for non-O157 STEC in beef manufacturing trimmings is only 2 percent. Therefore, the additional costs to industry of holding products because of additional tests and additional positive samples are likely to be minimal.

[30] Not Applying the Mark of Inspection Pending Certain Test Results, *Federal Register* notice (77 FR 73401).

Each establishment will take the corrective actions and preventative measures that are the most cost-beneficial for it. Therefore, the Agency cannot estimate the cost for increased corrective actions and prevention for the industry.

As we stated in the 2014 CBA, many establishments that produce raw non-intact beef products already have controls for *E. coli* O157:H7.[31] FSIS believes that these methods will be effective in controlling non-O157 STEC.[32] If they are, the industry would incur minimal additional processing costs in controlling non-O157 STEC as a result of FSIS expanding its testing for non-O157 STEC. FSIS requested public comment on this assumption but did not receive any comments.

Table 6 presents the estimated total cost to the industry per year if some establishments decide to test for non-O157 STEC because FSIS is testing. However, we believe the cost would decrease as the testing technology improves and the industry adopts cheaper and more sensitive tests to reduce the cost of testing and the loss from the false-positive testing results. As we discussed earlier, the fact that the industry takes multiple actions with regard to products that screened positive indicate that the actions the establishments choose are often based on their particular circumstances.[33] Therefore, whatever action an establishment takes, the incentive is to

[31] One common measure that establishments use is purchase specifications in a prerequisite program. The specifics of a purchase specification may include: (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 using antimicrobials or other lethality treatments on raw beef product and verifying the effectiveness of those antimicrobials.

[32] 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.

[33] 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.

avoid recalls and potential outbreaks. Given the moral hazard caused by asymmetric information, without such incentive to reduce the moral hazard, establishments are unlikely to take additional food safety measures that will only incur additional net cost.[34] The expected private benefit should outweigh the cost.

Table 6. Estimated Total Annual Costs to the Industry ($ thousand, in 2019 dollars)

	Industry testing	Lost value	Total
Beef manufacturing trimmings	907	41,183	42,091
Ground beef	60	4,570	4,630
Bench trim	4	97	102
Other components	32	1,187	1,219
Total	1,003	47,038	48,041

Note: Some of the totals may not equal the sum due to rounding.

2. Budgetary Costs to the Agency

The Agency estimated that the annual cost of testing beef manufacturing trimmings for non-O157 STEC would be about $79,100 in 2019 dollars. The cost for the Agency to expand testing to ground beef, bench trim, and other components would be another $180,900. In addition to the cost of testing, the cost of conducting additional for-cause FSAs would be about $312,000. Table 7 presents the estimates, and the following sections explain how we obtained these estimates.

[34] For a good discussion on moral hazard and food safety, please see: Starbird, S. A., 2005. Moral Hazard, Inspection Policy, and Food Safety. *American Journal of Agricultural Economics*, 87(1): 15-27.

Table 7. Estimated Annual Costs to the Agency for Non-O157 STEC Testing. ($ thousand, in 2019 dollars)

	Scheduled testing	Follow-up testing	Subtotal for lab testing	For-cause FSA	Total Agency Cost
Beef manufacturing trimmings	66.4	12.7	79.1		
Ground beef	101.8	1.6	103.4		
Bench trim	28.4	2.6	31.0		
Other components	33.8	12.7	46.5		
Total	230.4	29.6	260.0	312.0	572.0
Total without beef manufacturing trimmings	164.0	16.9	180.9		492.9*

Note: * This total number includes the total for-cause FSA cost of $312.0 K.
Some of the totals may not equal the sum due to rounding.

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,[35] and (3) cost to conduct for-cause FSAs.

The direct immediate cost to FSIS laboratories for analyzing samples is about $66,400. Because the new technology screens samples for both *E. coli* O157:H7 and non-O157 STEC at the same time, the additional cost for testing for non-O157 STEC is primarily due to further analyzing the samples screened positive for non-O157 STEC.[36] The key variables behind this cost estimate are:

- An estimated annual number of samples of 3,750,[37] and
- A screen (potential) positive sample rate of 10 percent (based on 2019 February to

[35] Data for sampling and testing are from OPHS, FSIS. Data for for-cause-FSAs are from OPARM, FSIS.
[36] Because the laboratory analysis of samples for non-O157 STEC is an extension of the program for *E. coli* O157:H7, we only estimated the marginal cost. There is also no additional cost for shipping or sample-collection.
[37] Estimates are based on the annual planned and actual sample numbers over recent years, provided by OPHS.

September data).[38]

FSIS conducts follow-up sampling and testing for STEC if FSIS finds a sample positive for *E. coli* O157:H7 or non-O157 STEC. The estimated number of follow-up tests for beef manufacturing trimmings for non-O157 STEC positive samples is 500. As a result, the cost for follow-up testing will be about $12,700.

Adding the costs for scheduled and follow-up testing together, we get a total cost of about $79,100 for FSIS testing of beef manufacturing trimmings for non-O157 STEC.

b. Cost of expanding testing to ground beef

The method of estimating the cost for testing ground beef is the same as the one for beef manufacturing trimmings. The only caveat is that we have to use the numbers associated with *E. coli* O157:H7 testing as proxies for numbers related to non-O157 STEC testing, because the Agency has not been testing ground beef for non-O157 STEC yet.[39] Assuming that the annual number of samples of ground beef is 12,125, and the potential positive rate is 5 percent, we estimated that the cost of scheduled testing would be about $101,800.

The Agency data suggest that there would be around 110 follow-up tests for positive samples of ground beef per year. Using this number, the cost for follow-up testing would be about $1,600. As a result, the total cost of FSIS testing ground beef for non-O157 STEC would be $103,400.

c. Cost of expanding testing to bench trim

The method of estimating the cost for testing bench trim is the same as the one for ground beef. Assuming the annual number of samples of bench trim is 1,500, and the potential positive

[38] Data are from OPHS.
[39] We believe this is a reasonable approximation given that all these samples will be tested for non-O157 STEC as well as O157 when this policy is implemented.

rate is 11 percent, we estimated that the cost of scheduled testing would be about $28,400.

The Agency data indicate that there would be about 100 follow-up tests for positive samples of bench trim each year. Using this number, the cost for follow-up testing would be about $2,600. As a result, the total cost of FSIS testing bench trim for non-O157 STEC would be $31,000.

d. Cost of expanding testing to other components

The method of estimating the cost for testing other components is the same as the one for bench trim. Assuming that the annual number of samples of other components analyzed is 2,550, and the potential positive rate is 11 percent, we estimated that the cost of scheduled testing would be about $33,800.

The Agency data suggested that the number of follow-up tests for positive samples of other components would be around 500. Using this number, the cost for follow-up testing would be about $12,700. Therefore, the total cost for FSIS testing of other components for non-O157 STEC would be about $46,500.

e. Cost of conducting for-cause FSAs

FSIS conducts for-cause FSAs in response to some positive samples.[40] The Agency estimated that the average cost to conduct an FSA is about $4,800.[41] FSIS FSA data from FY 2017 showed 65 for-cause FSAs triggered by STEC positives in raw beef products, of which 10 were associated with manufacturing trimmings, 28 for ground beef, 3 for bench trim, 2 for other components, and 22 involved more than one product. Assuming the number of FSAs triggered by non-O157 STEC positive samples would be similar in 2020, the total cost for conducting for-

[40] The Agency takes enforcement actions without conducting for-cause FSAs if the data from the Public Health Risk Evaluation (PHRE) indicates that an enforcement action is warranted.
[41] Based on the FSIS Office of the Chief Financial Officer (OCFO) preliminary analysis of the average cost per FSA under the new FSA methodology, FY 2016.

cause FSAs would be about $312,000 if FSIS tested all raw beef products for non-O157 STEC.

Adding all the above costs together, we estimated that the total cost to the Agency for the existing non-O157 STEC testing of beef manufacturing trimmings and for expanding the testing to ground beef, bench trim, and other components would be approximately $572,000 per year. Deducting the cost of FSIS's existing non-O157 STEC testing of beef manufacturing trimmings ($79,100) from the total, the cost of expanding the testing to other raw beef products is about $492,900.[42]

Table 8 summarizes the estimated annual costs, for both the industry and the Agency, of starting testing for non-O157 STEC on beef manufacturing trimmings, which began in 2012, and of expanding the testing to ground beef, bench trim, and other components. The total cost is around $48.6 million. Most of the total cost is associated with testing beef manufacturing trimmings, which is already on-going. Therefore, the cost of expanding the testing to all other raw beef products is about $6.4 million. Table 8. Estimated Total additional cost of non-O157 STEC testing ($ million, in 2019 dollars)

	Industry	Agency		Total
		Testing	For-cause FSAs	
Beef manufacturing trimmings	42.09	0.08		
Ground beef	4.63	0.10		
Bench trim	0.10	0.03		
Other components	1.22	0.05		
Total	48.04	0.26	0.31	48.6
Total without beef manufacturing trimmings	5.95	0.18	0.31	6.4

Note: Some of the totals may not equal the sum due to rounding.

3. Expected Benefits

a. Benefits from reduced illnesses and deaths

[42] Note that this is under the assumption that the cost of conducting FSAs is wholly associated with expanding testing to ground beef, bench trim, and other components. This assumption may overestimate the total cost of expanding FSIS non-O157 STEC testing to ground beef, bench trim, and other components. Because many for-cause FSAs are related to more than one product, we couldn't attribute these FSAs to any single product.

One benefit from sampling and testing for non-O157 STEC is the reduction of illnesses and deaths caused by non-O157 STEC because FSIS sampling and testing leads to keeping adulterated product out of commerce. In addition, we believe that establishments take corrective actions in response to positive test results, including appropriate changes to their Hazard Analysis and Critical Control Points (HACCP) systems,[43] improving overall control of STEC. This will further reduce illness. A 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 hospitalizations is 271 (with a range of 0 to 971).[44,45] FSIS economists used these case numbers and estimated the expected cost per illness to be about $450 in 2012 dollars.[46,47]

b. Benefits from reduced outbreak-related recalls, which does not include associated illness and death reduction, 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

[43] 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.

[44] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M, Roy SL, et al. (2011). Foodborne illness acquired in the United States – Major Pathogens. *Emerging Infectious Diseases*, 17(1), 7-15.

[45] Note that Scallan et al. reports the median value for the distribution of deaths caused by non-O157 STEC because of extremely skewed data. See Ibid. Table 3.

[46] Marks, H. M., Tohamy S., & Tsui, F. (2013). Modeling Uncertainty of Estimated Illnesses Attributed to Non-O157:H7 Shiga Toxin-Producing Escherichia coli and Its Impact on Illness Cost. *Journal of Food Protection*, 76(6), 945-952.

[47] The estimate represents a lower bound analysis 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.

inconveniences (e.g., looking for recall information, checking the products purchased, returning or disposing of products identified by the recalls, and so on). The Agency also incurs costs for verifying that companies recalled and properly disposed of product.[48]

Through early detection of products contaminated with non-O157 STEC, testing for non-O157 STEC may prevent outbreak-related food recalls. In FY 2018, FSIS testing found 17 samples positive for non-O157 STEC.[49] 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. This is because outbreak-related recalls are on a larger scale and will cause higher liability cost and reputation damage. There was one recall in August 2010, before FSIS started testing, which was associated with a cluster of reported illnesses.[50] Since FSIS started testing in June of 2012, there have been 19 Class-I recalls associated with raw beef products contaminated with non-O157 STEC.[51] Four of these recalls were outbreak-related, caused by ground beef for which FSIS testing for non-O157 STEC has not started. In the other 15 cases products were recalled before any illnesses were reported.

These early-stage recalls actually carry the benefit of preventing potential outbreaks and

[48] This includes inspectors' activities at the establishments, FSAs, recall effectiveness checks, and dissemination of information about recalls through press releases.

[49] Data are from OPHS, FSIS and based on testing results from the MT60, MT52, MT53, and MT51 programs.

[50] 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 *E. coli* O26.

[51] The list of recalls is on. Recalls & Public Health Alerts | Food Safety and Inspection Service (usda.gov), last accessed on 7/7/2022.

outbreak-associated recalls, which are more costly to the industry, the consumer, and the Government.

To estimate how much an outbreak-related recall could cost, we used a 2011 report by the Grocery Manufacturers Association (GMA) done in collaboration with Covington & Burling LLP and Ernst & Young,[52] which surveyed 36 food, beverage, and consumer products companies that have faced a recall in the past five years. We estimated the average cost of food recalls to companies to be approximately $25.8 million (see Table 9). This cost estimate includes lost profits from business interruption, recall execution cost, liability cost, and financial loss from reputation damage,[53] and does not include the cost of illnesses and deaths. We acknowledge that there are uncertainties associated with this estimate. For one thing, we are not certain that the outbreak-related recalls prevented by FSIS's non-O157 STEC testing program and additional industry testing would have a cost distribution similar to the cost distribution found in the GMA report, (see Table 9). In addition, as shown in Table 9, the last cost range in the GMA survey (>100 $million) does not have an upper bound, so we assumed a median value of $150 million. This assumption could cause an overestimate or underestimate of the average recall cost.

Table 9. Food Recall Costs Based on GMA's 2011 Report

Cost range ($ million)	Median value ($, million)	% of respondents
0 to 9	4.5	48
10 to 29	20	29
30 to 49	40	9

[52] Grocery Manufacturers Association. 2011. *Capturing Recall Costs: Measuring and Recovering the Losses.* Retrieved from https://www.gma.maxx.matrixdev.net/forms/store/ProductFormPublic/capturing-recall-costs. Note that GMA became Consumer Brands Association in January 2020.
[53] Ibid., pp.5-6.

50 to 99	75	9
>100	150*	5
Weighted Average: 25.8		

*There is no median value for ">100", so we assumed $150 million to be conservative.

The annual benefit depends on the number of recalls prevented by the testing. It is difficult to predict how many recalls would be avoided, even with historical data. This is especially true in this case because FSIS has been testing beef manufacturing trimmings for non-O157 STEC since June 2012, so using recall data after 2012 doesn't give the best estimate of the total number of recalls that would be prevented by FSIS non-O157 testing of beef manufacturing trimmings, ground beef, bench trim, and raw ground beef components because recalls of beef manufacturing trimmings may have already been prevented. However, using the theory that

detection can prevent recalls, we examined FSIS's non-O157 STEC testing data for beef manufacturing trimmings to help estimate the potential number of recalls prevented. We will discuss how we calculated these estimates in the "net benefit" section below.

In addition, investigation of these recalls generates other benefits. Through recall investigations, FSIS and industry are 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.

4. Net benefit

The cost for the current testing of beef manufacturing trimmings (including Agency and industry testing) for non-O157 STEC is about $42.2 million. If the Agency expands non-O157 STEC testing to ground beef, bench trim, and other components, it would add another $6.4 million to the cost (Table 10) and bring the grand total up to about $48.6 million.

The benefit from reduced outbreak-related recalls depends on the number of recalls FSIS's non-O157 STEC testing policy prevents annually. With a total estimated cost of $48.6 million, and the estimated quantified benefit of one prevented recall being $25.8 million, total benefit would exceed total cost if the testing policy prevents at least two outbreak-related recalls annually (2 x $25.8 million = $51.6 million). We believe this is likely based on the data related to non-O157 STEC contamination and prevalence. As stated above, between June 2012 and

May 31, 2019, there have been 19 Class-I recalls associated with raw beef products contaminated with non-O157 STEC. Among the 19 recalls, 4 were outbreak-related and 15 were not. However, these 15 recalls could have potentially been outbreak-related if the contamination had not been caught at an early stage. Also, as stated above, in FY 2018, FSIS product testing on beef manufacturing trimmings found 17 samples positive for non-O157 STEC. If any of this product was sold into commerce, there could have been additional illnesses, outbreaks, and recalls. Therefore, we believe that it is not an overestimate to assume that FSIS testing would prevent at least two recalls per year, with an associated benefit of $51.6 million. Additional benefits would accrue from reduced illnesses and deaths, and improved business practices (Table 11). Although there are uncertainties in our estimates, FSIS still concludes that the benefits accrued to industry, Government, and consumers from this new testing policy will justify the cost.

Table 10. Estimated Additional Cost of Expanding Non-O157 STEC Testing ($ million, in 2019 dollars)

		Agency		
	Industry	Testing	For-cause FSAs	Total
Ground beef	4.63	0.10		
Bench trim	0.10	0.03		
Other components	1.22	0.05		
Total	5.95	0.18	0.31	6.4

Note: Some of the totals may not equal the sum due to rounding.

Table 11. Estimated Combined Current and Additional Non-O157 STEC Testing Annual Costs and Benefits ($ million, in 2019 dollars)

	Costs				
		Agency			
	Industry	Testing	For-cause FSAs	Total	Benefits
Beef manufacturing trimmings	42.09	0.08			Around 51.6 from reduced outbreak-associated recalls, plus benefits from reduced illnesses and deaths, and improved business practices.
Ground beef	4.63	0.10			
Bench trim	0.10	0.03			
Other Components	1.22	0.05			
Total	48.04	0.26	0.31	48.6	

Note: Some of the totals may not equal the sum due to rounding.

5. Impact on Small Business[54]

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 their food safety system. The 2013 Pathogen Controls in Beef Operations Survey showed that only 14 percent of the small establishments and 6 percent of the very small establishments that produced trim were testing for non-O157 STEC after the Agency started testing for it.[55] If an individual small or very small establishment chooses to test for non- O157 STEC and product tests positive, there may be a significant impact on that individual establishment (e.g., due to lost product value). However, as stated in the foregoing, historically, only a very small percentage of small and very small establishments chose to test, so the majority of the estimated costs for expanding FSIS's non-O157 STEC testing to other products are not associated with small and very small establishments. Therefore, FSIS's expanding its non-O157

[54] Based on FSIS's HACCP 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.

[55] For details of the data analysis, see the technical appendix to the 2014 FRN.

STEC testing to other products does not impose a significant negative impact on a substantial number of small and very small businesses.