



**Billing Code 3410-DM-P**

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**[Docket No. FSIS-2010-0023]**

**Expansion of FSIS Shiga Toxin-Producing *Escherichia coli* (STEC) Testing to Additional Raw Beef Products**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is announcing plans to expand its routine verification testing for six Shiga toxin-producing *Escherichia coli* (non-O157 STEC; O26, O45, O103, O111, O121, or O145) that are adulterants, in addition to the adulterant *Escherichia coli* (*E. coli*) O157:H7, to ground beef, bench trim, and raw ground beef components other than raw beef manufacturing trimmings (i.e., 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) (hereafter "other raw ground beef components") for samples collected at official establishments. STEC includes non-O157 STEC; O26, O45, O103, O111, O121, or O145, that are adulterants, and *E. coli* O157:H7. Currently, FSIS tests only its beef manufacturing trimmings samples for these six non-O157 STEC and *E. coli* O157:H7; all

other aforementioned raw beef products are presently tested for *E. coli* O157:H7 only. FSIS also intends to test for these non-O157 STEC in ground beef samples that it collects at retail stores and in applicable samples it collects of imported raw beef products. FSIS is requesting comments on the proposed sampling and testing of ground beef, bench trim, and other raw ground beef components. FSIS will announce the date it will implement the new testing in a subsequent **Federal Register** notice.

Additionally, FSIS is responding to comments on the November 19, 2014, **Federal Register** notice titled "Shiga Toxin-Producing *Escherichia coli* (STEC) in Certain Raw Beef Products." FSIS is also making available its updated analysis of the estimated costs and benefits associated with the implementation of its non-O157 STEC testing on raw beef manufacturing trimmings and the costs and benefits associated with the expansion of its non-O157 STEC testing to ground beef, bench trim, and other raw ground beef components

(<https://www.fsis.usda.gov/wps/wcm/connect/c37a7129-639c-41fa-ab75-be6dddc1c44/placeholder-link?MOD=AJPERES&useDefaultText=0&useDefaultDesc=0>).

**DATES:** Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2010-0023. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development by telephone at (202)720-0399.

**SUPPLEMENTARY INFORMATION:**

**Background**

On September 20, 2011, FSIS announced in the **Federal Register**, its determination that raw, non-intact beef products and raw, intact beef products that are intended for use in raw, non-intact beef products contaminated with non-0157 STEC (O26, O45, O103, O111, O121, or O145) are adulterated under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)) because they bear or contain a deleterious substance that may be injurious to health (76 FR 58157). In support of this determination, the Agency cited evidence of these non-0157 STEC organisms' high pathogenicity, low infectious dose, transmissibility from person to person, and thermal resistance high enough to survive ordinary cooking (76 FR 58157, 58158-58159). FSIS also stated that raw, non-intact beef products and raw, intact beef products that are intended for use in raw, non-intact beef products, contaminated with non-0157 STEC are adulterated because they are unhealthful and unwholesome (21 U.S.C. 601(m)(3)) (76 FR 58157, 58159). FSIS also included information on when the Agency considers an isolate to be "confirmed positive for non-0157 STEC," which is when the isolate contains a *stx* gene, an *eae*

gene, and one of the target O-groups (O26, O45, O103, O111, O121, or O145) and when the isolate is biochemically confirmed to be *E. coli*.

In the 2011 **Federal Register** notice, FSIS included a costs and benefits estimate for non-O157 STEC testing in raw beef manufacturing trimmings (76 FR 58157, 58162-58164). The Agency asked for comments on this costs and benefits estimate (76 FR 58157, 58164).

FSIS implemented a verification testing program for the six non-O157 STEC in raw beef manufacturing trimmings on June 4, 2012 (77 FR 9888). Beef manufacturing trimmings include beef parts of any size, including primal cuts, subprimal cuts, and smaller pieces of trimmings from subprimal cuts, that the producing slaughter establishment intends for raw, non-intact use (FSIS Directive 10,010.1, *Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products* <https://www.fsis.usda.gov/wps/wcm/connect/c100dd64-e2e7-408a-8b27-ebb378959071/10010.1.pdf?MOD=AJPERES>). FSIS did not implement verification testing for non-O157 STEC to ground beef, bench trim, and other raw ground beef components at that time, because the Agency needed to establish additional laboratory capacity to test these products and the Agency wanted to evaluate data gathered from sampling raw beef manufacturing

trimmings before expanding its verification testing to include other products (76 FR 58157, 58160).

On May 31, 2012, the Agency announced in the **Federal Register** (77 FR 31975) that it would update and revise the costs and benefits estimate accompanying the September 20, 2011, determination, respond to comments received on the costs and benefits estimate, and assess the economic effects of testing raw beef manufacturing trimmings, ground beef, bench trim, and other raw ground beef components for non-0157 STEC. FSIS also announced that, when the updated costs and benefits estimate was complete, the Agency would announce its availability, request comments on it, assess the comments, and make any necessary changes to the costs and benefits estimate before finalizing it and expanding FSIS non-0157 STEC testing to include other products in addition to beef manufacturing trimmings.

On November 19, 2014, FSIS announced in the **Federal Register** that it had updated the costs and benefits estimate in the 2014 cost benefit analysis (CBA) associated with the implementation of its non-0157 STEC testing on raw beef manufacturing trimmings (79 FR 68843). In the 2014 CBA, FSIS also reported the costs and benefits associated with the potential expansion of its non-0157 STEC testing to other raw beef products. The estimated annual cost for testing beef manufacturing trimmings for non-0157 STEC was \$1.37 million

(\$0.48 million to the Agency and \$0.89 million to the industry) in 2013 dollars. The expansion of non-O157 STEC testing to all other raw beef products was estimated to cost \$1.0 million (\$0.9 million to the Agency and \$0.1 million to the industry) in 2013 dollars.<sup>1</sup> FSIS also responded to comments that it had received on the previous, September 20, 2011, costs and benefits estimate.

### **Summary of the Updated Costs and Benefits Analysis**

This notice announces updates to the CBA FSIS published on November 19, 2014. In this revision to the 2014 CBA, FSIS made the following changes:

1. The false-positive rate for industry's screening test was updated and an estimate of product loss value was included as a cost to the industry, in response to industry comments.
2. Agency cost was updated to reflect the change in FSIS' laboratory method for STEC testing; the new method screens enriched samples for both *E. coli* O157:H7 and non-O157 STEC at the same time, which reduces the Agency's testing costs.

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<sup>1</sup> The 2014 CBA is available at:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices>.

3. Agency cost for conducting for-cause Food Safety Assessments (FSAs) was updated using data from the Agency's analysis of the new FSA methodology.<sup>2</sup>
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).

When including all of the aforementioned updates, the estimated annual cost for testing beef manufacturing trimmings for non-O157 STEC is \$42.2 million (\$0.1 million to the Agency, and \$42.1 million to the industry). The estimated cost of expanding non-O157 STEC testing to all other raw beef products is \$6.4 million (\$0.5 million to the Agency and \$5.9 million to the industry). Most of the increase in estimated costs above the cost estimates in the 2014 CBA is from the inclusion of the lost value of products to the industry. When establishments do not do confirmation testing, there is a loss of value from disposed of beef products after they have screened positive because some of these are false positives.

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<sup>2</sup> 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/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES>.



The estimated benefits of the new testing are reduced illnesses and deaths, reduced outbreak-related recalls, and improved business practices. Through recall investigations, FSIS and industry are able to determine process failures to help establishments take corrective actions to prevent future contamination and investigation can serve as the basis for education that will benefit the entire industry as well as regulatory organizations. The Agency estimated the benefit from reduced outbreak-related recalls to be at least \$51.6 million per year. There are also benefits from reduced illnesses and improved industry practices, which were not quantified. Therefore, the total benefit of FSIS testing for non-O157 STEC outweighs the total cost.

**Expanding FSIS non-O157 STEC Testing to Ground Beef, Bench Trim, and Other Raw Ground Beef Components**

FSIS intends to expand its non-O157 STEC verification testing to ground beef, bench trim, and other raw ground beef components. Slaughter establishments are in the best position to prevent non-O157 STEC contamination because the introduction of the contaminant to the exterior surface of beef products can occur during the slaughter and dressing operation. Processing establishments that receive product for grinding also have an important role in addressing non-O157 STEC. Hazard Analysis and Critical Control Point (HACCP) regulations require

establishments to conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur in their production processes and to identify the preventive measures an establishment can apply to control those hazards in the production of particular products (see 9 CFR 417.2(a)).

Processing establishments can control or reduce STEC to below detectable levels by using preventive measures, including validated antimicrobial interventions. Processing establishments can also establish as a preventive measure purchase specification that requires suppliers to provide source materials with no detectable STEC. Processing establishments can then verify that these control measures are working as intended through their own product testing (see 67 FR 62326).

Exposure to non-O157 STEC is linked to serious, life-threatening human illnesses. On March 28, 2019, FSIS was notified of an outbreak of *E. coli* O103 illnesses.<sup>3</sup> One hundred and ninety-six (196) case-patients in ten (10) states were linked to this outbreak. Twenty-eight (28) case-patients were hospitalized. Case-patient and traceback information indicated raw ground beef as the likely source of this outbreak and prompted two recalls (Recall #047-2019 and Recall #048-2019). Additionally, on August 16, 2018, FSIS was notified of an

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<sup>3</sup> More information on this outbreak is available at <https://www.cdc.gov/ecoli/2019/o103-04-19/index.html>.

outbreak of *E. coli* O26 illnesses.<sup>4</sup> Eighteen (18) case-patients in four (4) states were linked to this outbreak. Six (6) people were hospitalized, and one (1) died. Case-patient and traceback information for this outbreak also indicated raw ground beef as the likely source, prompting two recalls (Recall #072-2018 and Recall #081-2018). Because of these recent outbreaks, illnesses and a death, FSIS is moving ahead with its plans to expand its non-O157 STEC sampling to ground beef, bench trim, and other raw ground beef components.

Product sampling and testing is one of several activities establishments conduct to verify the effectiveness of their HACCP systems. Since the initiation of FSIS's non-O157 STEC testing program, many grinders and suppliers of raw ground beef components have instituted programs to routinely test their raw beef products for both *E. coli* O157:H7 and for non-O157 STEC.

Before a foreign country can export meat products to the United States, it must demonstrate that its meat inspection system is equivalent to the system FSIS has established under the FMIA and its implementing regulations. After FSIS expands its STEC verification sampling, FSIS will require foreign countries to test the same products for non-O157 STEC and verify that the establishments address STEC as a hazard through an

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<sup>4</sup> More information on this outbreak is available at <https://www.cdc.gov/ecoli/2018/o26-09-18/index.html>.

establishments hazard analysis and HACCP plans. If a country chooses to take a different approach, then the country would need to submit an Individual Sanitary Measure (ISM) equivalence determination.

### **Sampling Beef Manufacturing Trimmings, Ground Beef, Bench Trim, and Other Raw Ground Beef Components**

To sample beef manufacturing trimmings and bench trim, FSIS inspection program personnel (IPP) use the N60 technique to collect 60 pieces of meat from across a production lot (see FSIS Directive 10,010.1, <https://www.fsis.usda.gov/wps/wcm/connect/c100dd64-e2e7-408a-8b27-ebb378959071/10010.1.pdf?MOD=AJPERES>). To sample other raw ground beef components, FSIS IPP randomly select one component type that the establishment produces and aseptically collect a grab sample from one or more components from a production lot consisting of many boxes (typically 100 boxes in very large establishments) (see FSIS Directive 10,010.1). The sampling protocol used for other raw ground beef components, specifically collecting samples from a limited number of units from a given production lot, may reduce the chance of getting a positive since pathogens are not homogeneously distributed throughout a production lot.

FSIS is aware that some establishments are collecting samples of beef manufacturing trimmings and other raw ground

beef components using a sponge or cloth device that is either attached to a conveyor belt that comes into direct, continuous contact with product, or that is used by establishment employees to rub products in boxes or combos. More surface area is sampled using these techniques which theoretically may yield results that better represent the production lot as compared to the sampling methods currently used by FSIS for sampling beef manufacturing trimmings and other raw ground beef components. FSIS is evaluating alternatives to FSIS's current sampling procedures for beef manufacturing trimmings, bench trim, and other raw ground beef components; the Agency is looking for alternatives that provide samples that are more representative of production lots and that are less time intensive and more user-friendly for IPP to use. If FSIS makes changes to its sampling methodology for beef manufacturing trimmings, bench trim and/or other raw ground beef components, it will issue updated sampling instructions to field personnel.

#### **Recent Changes to FSIS's Laboratory Method**

On February 4, 2019, FSIS began using a new laboratory method for the initial screening of regulatory samples for STEC.<sup>5</sup> The instructions for using this method are found in Chapter 5C of the Microbiology Laboratory Guidebook (MLG) and associated

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<sup>5</sup> See

<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2019/ConstUpdate020119>.

appendices.<sup>6</sup> This updated laboratory method allows FSIS to utilize a single, combined workflow to screen samples for the presence of *E. coli* O157:H7 and the six non-O157 STEC that FSIS considers adulterants (O26, O45, O103, O111, O121, or O145). Merging the screening for these seven STEC adulterants into a single laboratory workflow saves time, money, and resources for the Agency without sacrificing sensitivity and specificity.

### **Planned Changes in Scheduling Samples**

As FSIS announced with its proposed *Salmonella* performance standards for ground beef and beef manufacturing trimmings (84 FR 57688, 57690), FSIS's goal is to collect and analyze at least 48 samples per year for each establishment producing greater than 50,000 pounds per day of ground beef or beef manufacturing trimmings by increasing the sample collection frequency from a maximum of four times per month to once per week for these product classes. To achieve this goal, FSIS plans to change how it assigns STEC samples and thus *Salmonella* samples (as all raw beef samples currently are analyzed for STEC and *Salmonella*) in higher-volume beef establishments producing ground beef and/or beef manufacturing trimmings by increasing the sample collection frequency to once per week or four samples per month for these

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<sup>6</sup> The FSIS MLG can be found at:  
<https://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook>.

product classes. FSIS intends to implement this change by reallocating resources from lower-volume beef establishments (i.e., those producing 50,000 pounds or less per day) in a manner that is resource--neutral. The Agency requests comments on the proposed change in sampling frequency.

### **Response to Comments**

FSIS received three comment letters in response to the 2014 **Federal Register** notice on the CBA associated with testing raw beef manufacturing trimmings for non-O157 STEC and the potential costs and benefits of testing raw ground beef, bench trim, and all other raw ground beef components for non-O157 STEC. Specifically, FSIS received comments from a beef-producing company, a testing provider, and an industry organization. The three comment letters FSIS received on the notice did not support the expansion of non-O157 STEC testing by the Agency. Commenters stated that testing just for *E. coli* O157:H7, rather than for both *E. coli* O157:H7 and non-O157 STEC, was adequate. A summary of the comments received and responses to the comments is below.

### **Quantify Benefits and Recalls**

*Comment:* Both the company and the industry organization questioned why FSIS did not quantify the benefits of its non-O157 STEC testing. These commenters also questioned the use in the CBA of two non-O157 STEC-related recalls (Recall #045-2013

and Recall #010-2014) as evidence of public-health benefits because they were not outbreak-related.

*Response:* FSIS has now quantified the estimated benefit from prevented outbreak-related recalls in the CBA associated with this *Federal Register* notice, using survey data from the Grocery Manufacturers Association<sup>7</sup> (whose name changed to Consumer Brands Association in January 2020), and Agency recall data. The Agency estimated the benefit from reduced outbreak-related recalls to be at least \$51.6 million per year. There are also benefits from reduced illnesses and improved industry practices, which are not quantified. Therefore, the total benefit of FSIS testing for non-O157 STEC outweighs the total cost.

The recalls of products contaminated with non-O157 STEC exemplify the preventive approach FSIS takes with respect to product contamination events, as the recalled products could have potentially led to illnesses and outbreaks. While the historical frequency of outbreaks attributable to non-O157 STEC may be lower than that for outbreaks attributable to *E. coli* O157:H7, clinical methods are being developed to better detect and identify non-O157 STEC illnesses (discussed later). In

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<sup>7</sup>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>.



testing beef manufacturing trimmings for STEC, FSIS has found more positive non-O157 STEC than O157 STEC. FSIS conducts verification sampling and testing and other inspection activities to ensure establishments have appropriate controls and verification procedures in place to prevent such illnesses. Since FSIS started its non-O157 STEC verification testing, there have been 19 Class-I recalls associated with raw beef products contaminated with these STEC.<sup>8</sup> Four of these recalls were associated with a ground beef outbreak. Two of the recalls were associated with the O103 serogroup and the other two with the O26 serogroup. The other 15 recalls were conducted based on positive non-O157 STEC results obtained through testing by FSIS, establishments, or various states; these recalls occurred before any attributed illnesses were reported.<sup>9</sup>

On February 8, 2013, FSIS implemented a new policy that requires official establishments and importers of record to maintain control of products produced from livestock that are sampled and tested by FSIS for adulterants and not allow such products to enter commerce until negative test results have been received. This policy, often referred to as FSIS's "hold and

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<sup>8</sup> The list of recalls is available at:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts/current-recalls-and-alerts>.

<sup>9</sup> The list of recalls is available at:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/current-recalls-and-alerts/current-recalls-and-alerts>.

test" policy, has reduced the number of recalls conducted due to FSIS raw ground beef verification samples that test positive for STEC. This policy applies to non-intact raw beef product or intact raw beef product intended for non-intact use that is sampled and tested by FSIS for STEC (77 FR 73401; Dec. 10, 2012).

### **False-Positive Rate**

*Comment:* A major concern of both the company and the industry organization that commented on the proposal was the high false-positive rate for non-O157 STEC screening tests used by industry. The company stated that it was concerned about the rate of false positives obtained using available non-O157 STEC screening tests because of the decisions that are made immediately after and on the basis of the initial screening test results. According to the commenters, industry may hold lots of product with screen-positive test results for non-O157 STEC while waiting for confirmation of the results.

Industry may also conduct product traceback in response to non-O157 STEC screen-positive test results, take action during high-event periods based on non-O157 STEC screen-positive test results, and may have difficulty filling orders on time because of screen-positive test results that limit the availability of raw beef. Also, the commenters were concerned about FSIS conducting additional FSAs in response to industry's non-O157

STEC screen-positive test results. The same commenters stated that screen-positive test results may result in loss of product value. Therefore, the commenters stated, the Agency underestimated the costs of the false-positive rate on industry in the CBA for the proposal.

*Response:* The Agency's 2018 data show, before the February 2019 change in technology, that 90 percent of the FSIS non-0157 STEC presumptive positive test results are confirmed positive.<sup>10</sup> A presumptive positive result in FSIS testing means the sample has first been determined to be a non-0157 STEC potential positive (equivalent to an industry screen-positive non-0157 STEC test result) and then an FSIS microbiologist identifies an isolate from the enriched sample. Note that FSIS confirmed only 7 percent of the Agency's non-0157 STEC potential positive test results before the February 2019 change in technology. FSIS's revised cost estimate, using a range of false-positive rates equivalent to the Agency's 2018 range of false positive rates of STEC potential positive test results of 81 to 100 percent,<sup>11,12</sup> showed that the lost product value from industry's testing of

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<sup>10</sup> Data are from the Office of Public Health Science (OPHS), FSIS.

<sup>11</sup> Since we assumed that the industry would not change to FSIS's new laboratory method in the near future, FSIS used the most recent false positive rates of the Agency's laboratory method before February 2019 to estimate industry costs.

<sup>12</sup> Data are from the Office of Public Health Science (OPHS), FSIS for 2018. The false positive rates of the potential screening are as follows: 93 percent for beef manufacturing trimming, 100 percent for bench trim, 94 percent for other raw ground beef components, and 81 percent for ground beef.

raw beef products would be high - about \$47.0 million. However, there are more sensitive screening tests available to industry that have lower false-positive rates for non-O157 STEC, and industry may choose the test that has the desired cost and benefit result.<sup>13</sup> (FSIS expects that, over time, the cost of both STEC screening and confirmatory tests will decrease as the industry conducts more tests and as the test kits improve. Since implementing STEC testing, FSIS has taken steps to improve the effectiveness of its microbiological testing program for *E. coli* O157:H7 and non-O157 STEC, including implementing the new laboratory method mentioned above. Also, FSIS does not conduct FSAs at establishments based solely on positive industry test results.

### **Morbidity and Mortality Weekly Report**

Comment: In reference to the Centers for Disease Control and Prevention (CDC) Foodborne Diseases Active Surveillance Network (FoodNet) program Morbidity and Mortality Weekly Report (MMWR) (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6418a4.htm>), the company and industry organization asked if the report would affect FSIS's proposed expansion of non-O157 STEC testing.

Response: At this time, the information in the report does not change the Agency's plans to move forward with expanding

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<sup>13</sup> Examples of test kits can be found on the FSIS website: <https://www.fsis.usda.gov/wps/wcm/connect/f97532f4-9c28-4ecc-9aee-0ele6cdela89/validated-test-kit.pdf?MOD=AJPERES>.

non-O157 STEC testing. According to the summary of the most recent MMWR,<sup>14</sup> compared with the 2015-2018 average annual STEC incidence (infections), the 2018 incidence of STEC was higher when compared to the 2015-2017 rates. Various factors contribute to the increase in reported illnesses. This includes the use of updated clinical laboratory methods. Further, the illnesses reported by the FoodNet program are not specific to FSIS-regulated products; reported data encompasses all reported illnesses, regardless of food source.

***E. coli* O157:H7 as Indicator of non-O157 STEC and Collection of Data by FSIS**

*Comment:* The industry organization asserted that *E. coli* O157:H7 can serve as an indicator organism for non-O157 STEC. The industry organization also commented that *E. coli* O157:H7 is a logical indicator organism for non-O157 STEC, if one uses the definition of an indicator organism presented in a research paper by Saini and others. This research paper states, "the term 'indicator' implies that common causes affect the levels of both indicator microorganisms and pathogens and that these causes can be identified and controlled. The use of measured levels of an indicator organism within statistical process control (SPC) is based on the basic premise that the process can be improved over

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<sup>14</sup> [https://www.cdc.gov/mmwr/volumes/68/wr/mm6816a2.htm?s\\_cid=mm6816a2\\_w](https://www.cdc.gov/mmwr/volumes/68/wr/mm6816a2.htm?s_cid=mm6816a2_w)

time, by identifying a cause of higher-than-expected indicator organism levels and taking an action that would result in a decrease of levels of the indicator organism, which in turn could also decrease levels and incidence of pathogens on the product.”<sup>15</sup> The commenter also stated that, given the history of non-O157 STEC outbreaks and the industry’s success in reducing *E. coli* O157:H7 prevalence in beef products, *E. coli* O157:H7 is likely the best microorganism to target in reducing risk when consuming beef products because the number of confirmed illnesses within the U.S. has been attributed more to *E. coli* O157:H7 than to non-O157 STEC.

Additionally, the industry organization stated that FSIS has collected data on non-O157 STEC through testing since 2012. The commenter stated that the data should be reviewed to ascertain the costs and benefits of expanded testing for the six non-O157 STEC adulterants to include raw ground beef and other components used in raw ground beef in addition to raw beef manufacturing trimmings.

*Response:* FSIS has reviewed its STEC verification sampling results obtained since 2012; positive samples for *E. coli* O157:H7 and non-O157 STEC have been observed. While FSIS

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<sup>15</sup> Saini PK, Marks HK, Dreyfuss MS, Evans P, Cook Jr LV, and Dessai U. 2011. Indicator organisms in meat and poultry slaughter operations; their potential use in process control and the role of emerging technologies. *J. Food Prot.* 74: 1387-1394

screening and confirmation methods used collectively permit detection of both *E. coli* O157:H7 and non-O157 STEC in an isolate from a sample, our data indicates that an isolate from a sample is rarely positive for both *E. coli* O157:H7 and non-O157 STEC. Therefore, FSIS verification sample results do not support using *E. coli* O157:H7 as an indicator organism for non-O157 STEC. Rather, the results indicate a need for FSIS to conduct additional verification testing of products for non-O157 STEC.

Analysis of FSIS raw beef manufacturing trimmings STEC verification sample results indicate that positive samples are not occurring in clusters, and are distributed among various states and regions of the U.S. Specifically, between June 2012 and December 2018, raw beef manufacturing trimming sample positives for *E. coli* O157:H7 were from 47 individual establishments in 25 States, while raw beef manufacturing trimming sample positives for non-O157 STEC were from 87 individual establishments in 34 States.

FSIS began verification testing of raw beef manufacturing trimmings (MT60 sampling project) for non-O157 STEC (in addition to *E. coli* O157:H7) in June 2012. Aggregate data by calendar year are publicly available on FSIS's website. In calendar year (CY) 2012, 17 of 32 STEC positive beef manufacturing trimmings samples were positive for non-O157 STEC (see

<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection->

[and-reports/microbiology/ec/stec-annual-report/stec-annual-report-2012](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/stec-annual-report/stec-annual-report-2012), Table 2, Trim Verification [MT60] data). Similarly, in CY 2013, 16 of 25 STEC positive beef manufacturing trimmings samples were positive for non-O157 STEC (see <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/stec-annual-report/stec-annual-report-2013>, Table 2, Trim Verification data). Non-O157 STEC were found in both samples identified as just "beef" and in beef products identified as "veal." Forty-eight (48) of 69 (70 percent) and 23 of 39 (58 percent) of STEC positive samples of raw beef manufacturing trimmings (MT60 sampling project), raw ground beef follow-up samples (MT44 sampling project) and follow-up samples from originating slaughter suppliers (MT52 sampling project) collected in CY 2012 and CY 2013, respectively were positive for non-O157 STEC. From CY 2014 - CY 2018 (see <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/positive-results-current-cy/2015-ecoli-positives>), 105 beef manufacturing trimmings (MT60) samples were positive for non-O157 STEC, and 32 samples were positive for *E. coli* O157:H7.

The Agency has incorporated data from Agency testing in the updated CBA, including an updated false positive rate and Agency testing costs.

#### **Antimicrobial Use and Multiple Interventions**



*Comment:* The industry organization commented that according to three studies funded by the North American Meat Institute, current antimicrobial compounds used by the meat industry to destroy *E. coli* O157:H7 are effective against non-O157 STEC.

*Response:* FSIS considers controls for *E. coli* O157:H7 to be effective against non-O157 STEC when implemented appropriately. However, FSIS testing finds both *E. coli* O157:H7 and non-O157 STEC positive results in its verification testing programs. As stated above, FSIS laboratories rarely find positives for *E. coli* O157:H7 and non-O157 STEC in the same sample. With the sporadic nature of STEC contamination, FSIS believes these results support the need for the Agency to conduct verification testing for non-O157 STEC in additional raw beef products.

### **Products to Sample**

*Comment:* The company and industry organization commented that FSIS should not sample and test raw ground beef and bench trim for non-O157 STEC. While conceding that verification sampling of raw beef manufacturing trimmings yields data that provides insights into the slaughter process, these commenters stated that verification sampling of raw ground beef products is not useful. According to these commenters, FSIS most often takes samples of raw ground beef product that is a blend of raw ground beef components from multiple suppliers; therefore, the commenters stated it is not possible to know which component was

contaminated or to provide feedback of any value to the source establishments.

The company and the industry organization also stated that FSIS may question beef manufacturing trimmings and other raw ground beef component suppliers when downstream establishments that grind raw beef components from multiple suppliers produce product that tests positive for non-O157 STEC.

*Response:* The Agency agrees that FSIS verification sampling and testing of product from slaughter establishments for non-O157 STEC provides useful information on the establishment's process control. The Agency also recognizes that traceback of ground beef made using raw beef components from multiple suppliers to a single slaughter establishment is more difficult than traceback of product made with raw beef components from a single supplier. Moreover, FSIS notes that the 2018 and 2019 outbreaks involved non-O157 STEC from ground beef. Thus, the Agency intends to expand non-O157 STEC sampling and testing to include ground beef, bench trim, and other raw ground beef components, which comprise the other 75 percent of the samples analyzed annually for *E. coli* O157:H7. This will help FSIS verify that certain products (such as bench trim) are not adulterated before they are ground, and that the resulting ground beef is not adulterated.

**Food Safety Assessment Estimate**

*Comment:* With expanded non-0157 STEC testing, the industry organization commented that FSAs based on FSIS non-0157 STEC positive test results alone will unnecessarily increase FSIS and industry expenses. The industry organization noted that FSIS estimated the cost of an FSA to FSIS at \$1,400 in 2014 but in September 2011 estimated that the Agency's FSA cost was \$14,000.

*Response:* The \$14,000 estimate for FSAs in 2011 resulted from high assumptions regarding the resources needed to conduct FSAs related to non-0157 STECs (76 FR 58157) before 2014. For example, it used to take an Enforcement, Investigation, and Analysis Officer (EIAO) over 30 days to complete the in-plant portion of the investigation. The Agency modified the assumptions and the cost estimates for the 2014 CBA based on the new FSA methodology, using the Public Health Risk Evaluation to determine whether an FSA is necessary, which reduced the total number of FSAs. With the new methodology, an EIAO can complete the in-plant portion of the FSA in 5 to 7 days, instead of an average of 38 days, leading to a significant reduction in FSA cost to FSIS. Data collected for FY 2016 suggest that the average STEC-related FSA under the new methodology costs the Agency about \$4,800.<sup>16</sup> FSIS has updated the CBA using this new number.

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<sup>16</sup> Based on OCFO (Office of Chief Financial Officer) preliminary analysis of average cost per FSA under new FSA methodology, FY 2016.

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#### **Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

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Done in Washington, D.C.

**Paul Kiecker,**  
*Administrator.*

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