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.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that on February 1, 2023, the Agency will expand its routine verification testing for six Shiga toxin-producing *Escherichia coli* that are adulterants (non-O157 STEC; O26, O45, O103, O111, O121, or O145), in addition to the adulterant *Escherichia coli* (*E. coli*) O157:H7, to ground beef, bench trim, and other raw ground beef components in addition to raw beef manufacturing trimmings in official establishments. The raw ground beef components to be tested for these six non-O157 STEC, hereafter "other raw ground beef components," are: 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. Currently, FSIS tests only its beef manufacturing trimmings samples for these six non-O157 STEC and *E. coli* O157:H7. Otherwise, all other raw beef products are tested only for *E. coli* O157:H7 and *Salmonella*. FSIS also will begin testing 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. Additionally, FSIS is responding to comments regarding the STEC testing expansion and the costs and benefits analysis (CBA), as well as its updated STEC laboratory testing criteria for determining whether a result is positive.

DATES: Beginning February 1, 2023, FSIS will implement routine verification testing for the six additional STECs discussed in this document (O26, O45, O103, O111, O121, and O145) in raw ground beef, bench trim, and other raw ground beef components. At this time, FSIS also will implement testing 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.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2020, FSIS announced in the **Federal Register** its plans to expand its routine verification testing for six non-O157 STEC (O26, O45, O103, O111, O121, or O145) that are adulterants in applicable raw beef products, in addition to the adulterant *E. coli* O157:H7, to ground beef, bench trim, and other raw ground beef components for samples collected at official establishments (85 FR 34397). FSIS also announced that

it would 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 stated that it would announce the date for implementation of the new testing in a subsequent **Federal Register** notice. Additionally, FSIS responded to comments on the November 19, 2014, **Federal Register** notice titled, "Shiga Toxin-Producing *Escherichia coli* (STEC) in Certain Raw Beef Products (79 FR 68843)." FSIS also made available its updated CBA on 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.[1]

Recent Changes to FSIS' Laboratory Testing Criteria for Determining Positives

On April 16, 2021, FSIS announced in the *Constituent Update* changes to the laboratory testing criteria for *E. coli* O157:H7.[2] FSIS explained that it had fully aligned the testing criteria for *E. coli* O157:H7 with that for non-O157 STEC. FSIS also explained that identifying specific bacterial genes associated with human illness is important for detecting STECs in food. Under the updated method, consistent with laboratory testing for non-O157 STEC, an *E. coli* O157:H7 isolate is confirmed positive

[1] The CBA is available at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf.

[2] https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-16-2021

if it has a *stx* gene, an *eae* gene, and is identified by the laboratory as O157. Further, under the new method, FSIS no longer performs H7 gene testing for certain O157:H7 isolates. Harmonizing STEC laboratory testing creates a more efficient FSIS laboratory workflow where all regulated STECs are treated the same from initial laboratory screening to full isolate characterization. This update did not affect current FSIS laboratory protocols leading to the reporting of potential and presumptive positive results. To implement this change, FSIS updated the Microbiology Laboratory Guidebook (MLG) Chapter 5C, "*Detection, Isolation, and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STECs) from Meat Products and Carcass and Environmental Sponges*,"[3] and began using the updated STEC method on samples received on or after May 17, 2021.

Aligning the criteria for identifying positives for the top seven STECs of public health interest does not affect FSIS' public health priorities, will not require establishments, or public health partners, or equivalent countries that ship beef to the United States to change their existing STEC laboratory methods that met the previous two separate STEC definitions, and may facilitate commercial test kit technology development.

Implementation

Currently, the only raw beef products FSIS routinely tests for non-O157 STEC are beef manufacturing trimmings. On February

[3] https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/MLG-5C.01.pdf

1, 2023, FSIS plans to implement its expansion of its routine verification testing for the six non-O157 STEC that are adulterants to ground beef, bench trim, and other raw ground beef components for samples collected at official establishments. Once FSIS expands its non-O157 sampling to all raw beef products, for any positive results during routine verification testing, FSIS will conduct follow-up testing. FSIS will analyze all follow-up samples for all seven adulterant STEC and *Salmonella*.

Responses to Comments

In response to a request from multiple industry associations for more time to submit comments on the June 4, 2020 **Federal Register** notice, FSIS extended the comment period by an additional 30 days to September 3, 2020.[4] FSIS received 10 comments. Specifically, FSIS received comments from a small establishment owner and an industry organization opposed to the expanded testing; while a food industry group, a consumer group coalition, and a college organization supported the expansion of testing. A foreign country and a laboratory testing representative also commented on the proposal. Two comments were outside the scope of this document.

In response to comments, FSIS added clarification on the new laboratory method, and a new table showing the additional cost of the expansion; but made no fundamental changes to the CBA. The Agency still plans to expand STEC testing to ground

[4] https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-june-19-2020.

beef, bench trim, and other raw ground beef components. A summary of the issues raised by commenters and the Agency's responses follows.

Cost and Benefits Analysis

Comment: An industry organization stated that the Agency did not adequately explain how it calculated an annual savings of $51.6 million from reduced non-O157 STEC outbreak-related recalls. Also, the commenter stated that the Agency did not provide data to support that the proposal will prevent two outbreak-related recalls per year because, according to the commenter, there were only a few non-O157 STEC outbreak-related recalls before 2012 and they are still rare.

The industry organization argued that FSIS' contention in the CBA that detection can prevent recalls does not include supporting data. According to the commenter, the Agency started testing beef manufacturing trimmings for non-O157 STECs in 2012; therefore, FSIS should compare the number of non-O157 STEC outbreak related recalls before and after implementing this testing program to determine whether the theory has merit.

Response: In the 2020 CBA, FSIS explained how it determined that the proposed policy was likely to prevent, on average, two recalls per year at an estimated cost of $25.6 million per recall. It described the reasoning in detail in section 3.b "Benefits from reduced outbreak-related recalls" and section 4 "Net benefit" (pp. 19-23). FSIS clarified that the estimate was based on Public Health Information System (PHIS) data related to

non-O157 STEC contamination and prevalence (i.e., Agency sampling data), not solely on the historical number of non-O157 STEC outbreak-related recalls.

Before 2012, FSIS did not routinely test raw beef products for non-O157 STEC, so it is not possible to make the proposed comparison between the number of recalls associated with beef products contaminated with non-O157 STEC versus recalls caused by *E. coli* O157:H7. The first non-O157 STEC investigation that led to a recall of ground beef product in the U.S. occurred in 2010. Once the Agency began testing for non-O157 STEC in raw beef manufacturing trimmings, the Agency prevented contaminated raw beef products from entering commerce. Beginning February 8, 2013, FSIS began to withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received (77 FR 73401). A substantial number of recalls (93 recalls) of raw beef products adulterated with STEC occurred between August 2012 and December 2020. Of these recalls approximately 20.0 percent (19 recalls) were caused by non-O157 STEC. Six of the 19 recalls were a result of outbreak investigations and seven were from routine FSIS verification testing. The remaining six recalls were results of: establishment-product testing (four), Agricultural Marketing Service (AMS) testing (one), and a notification from U.S. Food and Drug Administration (FDA) about contaminated flour used to produce a USDA regulated product (one).

As is stated above, currently, the only raw beef products FSIS routinely tests for non-O157 STEC are beef manufacturing trimmings. However, of the 19 non-O157 STEC recalls, 15 of them involved raw non-intact and ground beef products containing non-O157 STEC. Five of the 15 beef products recalled occurred as a result of FSIS routine and follow-up sampling of beef manufacturing trimmings and follow-up sampling verification programs. FSIS may have detected the other ten if FSIS had sampled the product through a routine verification sampling project. Analysis of the Agency's historical testing data indicates that the number of beef manufacturing trimming samples positive for non-O157 STEC (0.71 percent) exceeded samples positive for *E. coli* O157:H7 (0.23 percent). Therefore, other beef samples subject to FSIS testing for *E. coli* O157:H7 may contain non-O157 STEC. As such, we believe it is reasonable to derive the estimate of prevented outbreak-related recalls from the detected prevalence of the pathogen.

Comment: An industry organization commented that the proposed expansion would not contribute to overall lower numbers of positive non-O157 test results. The commenter stated that there have been only two outbreaks of non-O157 STEC attributed to raw beef products since 2006 that resulted in recalls. In the same timeframe, the commenter stated that there have been eight *E. coli* O157:H7 outbreaks. In addition, the commenter stated that from 2006 to present, there have been 129 recalls for O157, compared to 20 for non-O157 STEC. Finally, the commenter stated

that the vast majority of recalls for STEC are not associated with illnesses, because the presence of the pathogen is only part of the equation. Virulence, consumer health, handling, and preparation all play a part.

Response: The STEC pathogen must be present for an individual to show symptoms of the disease caused by that pathogen. FSIS has previously determined that raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, that are contaminated with STEC are adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011). Virulence, consumer health, handling, and preparation may play a part in causing illness, but the key point is that the pathogen must be present.

Between August 2012 and December 2020 approximately 45 million pounds of contaminated raw beef products were prevented from entering commerce by FSIS because of STEC adulteration. Over this timeframe, FSIS tested a total of 167,073 raw beef samples for *E. coli* O157:H7 and 220 (0.13 percent) of these samples were positive. Analysis of the data tested for O157:H7 and non-O157 STEC by FSIS between August 2012 and December 2020 showed that non-O157 STEC were more frequently recovered from verification beef manufacturing trimming samples.

Specifically, FSIS tested 44,457 samples over the same timeframe as above. See table 1 below for the percent of positive samples for the different STEC.

Table 1

Percent of positive samples

in various serogroups

Serogroup	Percent of positive samples
Non-O157	.71
O103	.42
O157:H7	.23
O26	.15
O111	.11
O145	.022
O45	.020
O121	.016

FSIS raw beef verification testing has been effective in helping to protect the public by detecting *E. coli* O157:H7 and non-O157 STEC adulterants and preventing these products from entering commerce.

As mentioned, in response to a previous comment, between August 2012 and December 2020, there were 19 recalls of FSIS regulated products that were caused by adulteration of product by non-O157 STEC serogroups. These recalls show that non-O157 STEC can be present in products intended for commerce and represents a threat to public health.

According to the CDC, the number of culture-confirmed illnesses caused by non-O157 STEC have increased, and outpaced

illnesses caused by O157:H7 STEC.[5] Surveillance data presented by the CDC revealed that the percentage change in incidence of STEC infections in 2019 compared with the annual average incidence from 2016 to 2018 showed that O157:H7 decreased by 20 percent and non-O157 STEC increased by 35 percent.

Comment: An industry organization commented that the CBA relies on the outdated 2013 *Pathogen Controls in Beef Operations Survey* to evaluate the potential costs from expanded industry sampling in response to the proposal. According to the commenter, this survey may not accurately represent industry sampling practices, and, therefore, costs to industry may be underestimated due to outdated data. The commenter stated that the Agency should conduct an updated survey, with specific questions related to the proposal, and update the CBA before finalizing any changes to its STEC sampling program.

Response: FSIS does not require industry testing for STEC. Under the Hazard Analysis and Critical Control Point (HACCP) regulations, the establishment is required to identify the intended use of the product (9 CFR 417.2(a)(2)), conduct the hazard analysis (9 CFR 417.2(a)), determine the hazard(s) reasonably likely to occur (9 CFR 417.2(a)(1)), and support the decision(s)made (9 CFR 417.5(a)(1)). Also, all establishments are required to conduct on-going verification activities to ensure that their HACCP plans are effectively implemented (9 CFR 417.4(a)(2)). Establishments are required to conduct ongoing

[5] Ibid

verification activities to ensure that any critical control point (CCP) is adequately addressing STEC, or that purchase specifications continue to prevent the pathogen from entering the facility. FSIS recommends that establishments' verification activities include testing for STEC (67 FR 62325, 62331).

Lastly, the HACCP regulations in 9 CFR part 417 require that establishments validate the HACCP plan's adequacy to control the food safety hazards identified by the hazard analysis (9 CFR 417.4(a)). These regulations prescribe requirements for the initial validation of an establishment's HACCP plan and require that establishments "conduct activities designed to determine that the HACCP plan is functioning as intended." Validation under 9 CFR 417.4(a)(1) requires that establishments assemble two types of data: (1) The scientific or technical support for the judgments made in designing the HACCP system, and (2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support. Thus, validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis (80 FR 27557).

In 2012, FSIS explained in a **Federal Register** notice (77 FR 31979) how *E. coli* O157:H7 results can be used for non-O157 STEC HACCP decision-making. FSIS considers controls for *E. coli*

O157:H7 to be effective against non-O157 STEC when implemented appropriately (85 FR 34397). How each establishment designs and supports their unique HACCP system can vary, and in-plant testing may or may not be conducted. When employed, testing can be conducted for different reasons, including to establish microbiological independence between lots, fulfill customer purchase specifications for specific products, validate HACCP controls, verify the HACCP system is functioning as intended, or other reasons. The frequency of sampling, products sampled, lot size, sampling method used, and laboratory testing methodology can vary from establishment to establishment based on the purpose sampling serves in each establishment's HACCP system.

In 2013, FSIS conducted a survey of industry practices of STEC controls to evaluate the potential costs to industry of expanding sampling in response to the 2012 change. Since that survey in 2013, the above HACCP requirements have not changed, the Agency's method of verification has not changed, and the Agency's policy regarding the use of *E. coli* O157:H7 as an indicator for STEC has not changed. Though an establishment may conduct STEC testing for a variety of reasons as noted above, FSIS does not have reason to believe the data obtained in the 2013 survey is no longer reliable nor indicative (on the aggregate) of industry practices. Further, innovations in testing methodology have since occurred that can reduce the costs of STEC analysis (see Section of Recent Changes to FSIS' Laboratory Method (85 FR 34397, 34399)). If FSIS assumes

establishments do not adopt these cost-saving innovations, the results of the 2013 survey remain valid for cost estimations.

In response to the comments regarding the use of *E. coli* O157:H7 testing results for non-O157 STEC decision-making, under HACCP, establishments may be able to support using a single STEC serogroup (e.g., *E. coli* O157:H7) as an "indicator" of all STEC as one component for demonstrating overall process control over STEC. If this approach is used, the decision-making for how *E. coli* O157:H7 results indicate control over non-O157 STEC is to be included in the hazard analysis and appropriately supported. Testing for *E. coli* O157:H7 as an indicator of STEC control may be acceptable for validation, verification, and process control because often the same controls address all STEC.

However, as explained in the **Federal Register** notice referenced above, both *E. coli* O157:H7 and non-O157 STECs occur in raw beef at low levels and at low prevalence, and positive tests for these pathogens are not likely to be highly correlated. For this reason, testing for a single STEC serogroup alone cannot serve as an "index" organism for any other STEC, meaning an *E. coli* O157:H7 result alone does not provide direct evidence about the actual presence or absence of any other STEC serogroups in a specific lot. If an establishment produces 2 lots of product from the same source material and if one lot is positive for a non-O157 STEC serogroup, then an *E. coli* O157:H7 negative test in the second lot of product would not be sufficient to show microbiological independence even with

additional process control information. Such microbiological independence determination would include consideration of numerous other factors, including commonalities in the source materials used, sanitation practices employed, antimicrobial interventions applied, any process control information, other sample results, and illness reports. *E. coli* O157:H7 testing results alone are not sufficient evidence for microbiological independence following a non-O157 positive.

In addressing corrective actions after a positive STEC result, FSIS personnel are to consider the impact one or more non-O157 STEC positives may have on the adequacy of the HACCP system to control STEC but should not automatically expect establishments to begin non-O157 STEC testing. When a product tests positive for non-O157 STEC, it is important for the establishment to recognize that even though the *E. coli* O157:H7 results and other processing CCP records may indicate process control was maintained, identification of non-O157 STEC contamination in the production process questions whether design or implementation of the establishment's unique food safety system is sufficient to control STEC. In response to one or more non-O157 STEC positives, establishments must ensure any additional testing conducted includes non-O157 as part of the validation, verification, and reassessment requirements of 9 CFR 417.4 and supporting documentation requirements of 9 CFR 417.5(a)(1), until the establishment is able to demonstrate control over STEC in their unique HACCP system, or the HACCP

system may be deemed inadequate (9 CFR 417.6). For example, it is particularly important in veal establishments to demonstrate control over STEC because FSIS data and other peer-reviewed research shows a higher incidence of non-O157 STEC as compared to *E. coli* O157:H7.[6]

Comment: An industry organization stated that after FSIS starts testing for non-O157 STEC in additional raw beef products, AMS will likely similarly expand its purchase program requirements as it has done in the past in response to FSIS sampling programs, which could increase industry costs.

Response: AMS has a Federal Purchase Program and vendors that choose to participate in that program must comply with AMS's requirements, including any testing requirements. The requirements of AMS's Federal Purchase Program are outside the scope of this **Federal Register** notice about FSIS' non-O157 STEC testing program.

Response to Positive Test Result

Comment: An industry organization commented that the proposal should not affect practices that have proven successful in the industry's continued improvement on STEC control. These practices have predominantly applied to beef manufacturing trimmings but should be accepted for any additional products that FSIS samples and tests when it implements expanded testing.

Response: If an establishment uses the same controls for

[6] https://ask.usda.gov/s/article/When-an-establishment-only-conducts-product-testing-for-E-coli-what-factors-does-the-establi.

STEC on beef manufacturing trimmings as it does on its other raw beef products, even if the other raw beef products were not slaughtered on-site, it should be able to support the decisions made in the use of such controls. How each establishment designs and supports their HACCP system may vary depending on the establishment and its hazard analysis, HACCP plan and the decisions made to support them.

Comment: A consumer group and a college organization commented that they did not support the use of *E. coli* O157:H7 testing results for non-O157 STEC decision-making and encouraged FSIS to amend its instructions to inspection personnel to require establishment non-O157 STEC testing to the same degree as *E. coli* O157:H7 testing. However, an industry organization's comments did support using *E. coli* O157:H7 testing results for non-O157 STEC process control decision-making.

Additionally, an industry organization commented that the Agency and industry must appropriately understand and respond to positive STEC results, regardless of the serovar.

Response: FSIS does not require industry testing for STEC. Under the Hazard Analysis and Critical Control Point (HACCP) regulations, the establishment is required to identify the intended use (9 CFR 417.2(a)(2)), conduct the hazard analysis (9 CFR 417.2(a)), determine the hazard(s) reasonably likely to occur (9 CFR 417.2(a)(1)), and support the decision(s)-made (9 CFR 417.5(a)(1)). To be clear: this notice announces the expansion of non-O157 STEC testing by FSIS when it conducts

routine verification testing. It does not impose testing requirements on industry.

As is stated above, FSIS considers controls for *E. coli* O157:H7 to be effective against non-O157 STEC when implemented appropriately (85 FR 34397). As mentioned above, in 2012, FSIS explained in a **Federal Register** notice (77 FR 31979) how *E. coli* O157:H7 results can be used for non-O157 STEC HACCP decision-making.

International

Comment: A foreign government questioned whether FSIS would provide a reasonable interval between the publication of the final **Federal Register** notice and when foreign countries would be required to implement new testing for non-O157 STEC.

Response: After FSIS expands its non-O157 STEC verification sampling and testing, FSIS will require foreign countries that ship beef product to the United States to implement equivalent government verification testing for non-O157 STEC in the same products included in FSIS' new expanded verification testing program. FSIS acknowledges that foreign countries will need additional time to implement changes to their testing requirements and to provide applicable supporting documentation. FSIS will continue to use the existing equivalence process[7] to ensure that foreign countries implement a government microbiological sampling and testing program equivalent to

[7] https://www.fsis.usda.gov/inspection/import-export/equivalence

FSIS' verification testing program for raw beef products within a reasonable time period. In addition, FSIS will begin testing imported ground beef, bench trim, and other raw ground beef components for non-O157 STEC at the same time as FSIS implements its domestic non-O157 STEC testing program (i.e., on this notice's effective date).

Test Only for Other Raw Ground Beef Components at Slaughter

Comment: Two industry organizations commented that FSIS should only expand testing to other raw ground beef components produced in slaughter establishments because STEC are introduced, and therefore most effectively controlled, at slaughter. Also, conducting the testing at slaughter establishments allows establishments to identify positive product before it enters commerce. The commenters argued that testing other raw ground beef components for non-O157 STEC at slaughter would prevent recalls and allow establishments to address the underlying cause at the source.

The commenters also stated that sampling and testing at further processing establishments makes it more difficult to identify the cause of the positive result and may increase the amount of product implicated in a recall. Also, according to the commenters, sampling ground beef does not provide feedback to either the processing establishments or slaughter establishments on process control. The commenters stated that the Agency should not include ground beef in the Agency's expanded non-O157 STEC testing.

Also, one commenter disagreed with the Agency's argument that by sampling bench trim, the Agency is verifying the product is not adulterated before it is ground. The commenter argued that instead of sampling for non-O157 STEC, FSIS should consider verification tasks at grinding establishments to ensure they maintain effective programs, such as purchase specifications or validated antimicrobial interventions.

Response: FSIS agrees that 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. However, processing establishments that receive product for grinding also have an important role in addressing non-O157 STEC. As explained above, the HACCP regulations require establishments to conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur in their processes and to identify the preventive measures they can apply to control those hazards in the production of particular products (see 9 CFR 417.2(a)). Consistent with the HACCP regulations, processing establishments can control or reduce non-O157 STEC to below detectable levels by using preventive measures, including validated antimicrobial interventions. Processing establishments can also establish as a preventive measure a 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 62325).

As stated earlier in the document, currently, the only raw beef products routinely tested for non-O157 STEC by the Agency are beef manufacturing trimmings, and beef manufacturing trimmings are produced at the slaughter establishment. However, of the 19 non-O157 STEC recalls, 15 of them were a result of raw non-intact and ground beef products containing non-O157 STEC. These 15 recalls support that expansion of routine non-O157 testing to other raw beef products, such as ground beef and other raw ground beef components, is necessary so that adulterated products do not reach the consumer.

Testing Based on Production Volume

Comment: An industry organization commented that FSIS should conduct sampling and testing for non-O157 STEC in applicable product in all establishments, regardless of production volume, for at least one year, and then FSIS should evaluate the data to determine whether continued sampling is warranted. This approach would allow additional components to be tested for non-O157 STECs at all establishment sizes for all products used as components for ground beef.

Response: Currently, per FSIS Directive 10,010.1, all establishments that produce raw beef products are subject to FSIS sampling and testing for STEC and *Salmonella*, regardless of establishment size. Consistent with the sampling frequency set in the directive, FSIS will sample each establishment that

produces raw ground beef products at least three times per year. FSIS also samples establishments that produce bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product. FSIS will continue to assess results and make necessary changes to its sampling and testing program. However, FSIS anticipates that it will continue this sampling and testing on an ongoing basis beyond one year of sampling and testing.

Testing Methods

Comment: One individual commented that STEC testing is much more sensitive than *E. coli* O157:H7 testing. The commenter stated that the STEC test is a presence or absence test that will show positive results with just a couple of cells. The commenter also stated that test results showing low numbers for Aerobic Plate Count (APC) and generic *E. coli* would also test positive for STEC.

Response: As discussed earlier in the document, FSIS updated its laboratory method in 2019 to use 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). The technology used for screening samples allows all seven STEC serogroups to be screened identically. FSIS utilizes the following performance criteria and definitions when evaluating the suitability of an alternative laboratory method for a given analyte and sampling

matrix pair[8]:

- Sensitivity of 90 percent or greater,
- Specificity of 90 percent or greater,
- Accuracy of 90 percent or greater,
- Positive Predictive Value of 90 percent or greater, and
- Negative Predictive Value of 90 percent or greater.

FSIS' internal verification work during the selection of new technologies in 2018 found a sensitivity of 92 percent in STEC samples inoculated with approximately 1 CFU in a 325g sample for that technology.[9] The manufacturer determined the average limit of detection (LOD_{50}) of the iQ-Check STEC VIrX and SerO II method was 0.7 (range: 0.4-1.2) CFU/sample for O157 and other adulterant STEC.[10] There is no difference in sensitivity for *E. coli* O157 and other non-O157 adulterant STEC serogroups. Additional information for using this method may be found in Chapter 5C of the MLG and associated appendices.[11]

Testing Results

Comment: An industry organization commented that follow-up sampling conducted by the Agency in response to an *E. coli* O157:H7 positive in products only subject to *E. coli* O157:H7 testing should continue to be tested for all STEC, but the

[8] MLG 1.01- https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/MLG-1.01_0.pdf
[9] https://www.fsis.usda.gov/sites/default/files/media_file/2021-09/Molecular-Screen-Evaluation-2018-White-Paper.pdf
[10] https://www.bio-rad.com/sites/default/files/2021-08/Bulletin_3213.pdf
[11] https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/MLG-5C.01.pdf

results should not be included in baseline and routine verification data (prevalence). According to the commenter, the Agency also incorrectly included follow-up sampling as part of the aggregated prevalence data in the proposed expansion of products tested for STEC. The commenter noted that FSIS previously reported follow-up sampling independently from routine sampling data and, according to the commenter, should consistently do so moving forward. According to the commenter, follow-up samples should never be included in overall prevalence calculations of O157 or non-O157 STEC. According to the commenter, follow-up sampling is conducted in response to a positive sampling result, which may indicate issues with process control at that establishment and can therefore skew the data.

Response: FSIS collects follow-up samples as a result of a positive from a routine verification sample. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC. As mentioned above, once FSIS expands its non-O157 sampling to all raw beef products, FSIS will analyze all follow-up samples for all 7 adulterant STEC and *Salmonella*. FSIS posts the follow-up sampling results separately on its website.

When calculating prevalence, FSIS does not use follow-up sampling in its prevalence calculations. Also, FSIS does not typically use follow-up samples in its baseline studies.

Reallocating Resources

Comment: Two organizations commented that the Agency should explain its reasoning for changing its allocation of resources for sampling STECs. According to the commenters, the Agency intends to sample once per week in higher volume establishments, a slight increase from four samples per month, by reallocating resources from lower-volume establishments. The commenters argued that the slight increase will likely not cause significant issues in high volume establishments, but there is not enough information about the reallocation to understand the potential impact of decreased sampling at lower volume establishments. The commenters argued that the shift in sampling may represent a significant reduction or elimination of sampling in lower volume establishments. According to the commenters, the data should be analyzed by volume to determine whether a decrease in sampling frequency at lower volume establishments will inhibit the Agency from identifying establishments that may have issues with STEC control.

A college organization noted that diverting current testing resources from lower-volume establishments will result in extending the time required for determining establishment performance, potentially increasing the risk of contaminated products entering the marketplace. According to the commenter, until FSIS has demonstrated that reallocating samples among beef processors will not negatively impact public health, the Agency should focus on requesting additional resources from Congress for sampling and laboratory testing. The commenter encouraged

FSIS to consider how microbial distribution within a product and/or false-positive test results may affect Agency verification results.

Response: FSIS may address allocating resources for sampling in a future **Federal Register** document, but FSIS believes the Agency has sufficient resources to conduct sampling and testing for STEC, ensuring that the nation's commercial supply of raw beef products, whether domestic or imported, is safe, wholesome and unadulterated.

After implementation, the Agency may adjust the numbers of samples collected and tested +/- by approximately 10 percent. FSIS has a set minimum sampling frequency for each establishment. FSIS will sample each establishment that produces raw ground beef products at least three times per year. FSIS also samples establishments that produce bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product.

Sampling Methodology

Comment: An industry organization noted that FSIS is evaluating alternatives to its sampling procedures (e.g., assessing sampling using a surface swabbing with a cloth vs. N60 incision sampling). According to the commenter, methodology often has a significant impact on baseline results, which are used to inform the public health decisions of local, state, and federal bodies and other private entities, and support Agency decisions. The commenter argued that the Agency should conduct a

short-term, targeted baseline sampling program after a change in methodology and make the new information public with explanations. According to the commenter, this approach will help provide context to preclude public uncertainty if prevalence seemingly increases because the new methodology increases sensitivity and detectability.

Additionally, the same commenter argued that potential changes to sampling methodology for pathogen sampling should be available for public comment. According to the commenter, the industry and other interested parties need time to consider impacts of the new methodology and provide information to the Agency to inform its decision-making. Also, an industry association and an individual commented that FSIS should continue to explore rapid and accurate methods to test for all pathogens of concern. One commenter encouraged FSIS to continue to work with industry and academia to develop rapid tests using the latest technology available to identify STEC and other pathogens in FSIS regulated products.

Response: FSIS continues to update its laboratory criteria and posts changes to its laboratory method in the MLG Chapter 5C titled "*Detection, Isolation, and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STECs) from Meat Products and Carcass and Environmental.*" FSIS also usually announces these changes in the *Constituent Update*.

FSIS recognizes the importance of keeping abreast of the latest scientific endeavors as well as its role in promoting

research in areas important to the FSIS mission. FSIS food safety research priorities[12] are presented as suggestions for researchers interested in pursuing food safety objectives that are relevant to FSIS regulated products. This list of research areas of interest may be useful to researchers who are preparing grants for submission to agencies that fund food safety research (e.g., USDA National Institute of Food and Agriculture (https://www.nifa.usda.gov), National Institutes of Health (https://www.nih.gov/), Grants.gov (https://www.grants.gov), or researchers with resources to conduct such research. In 2021 FSIS added a study titled, "Develop a method to detect Shiga toxin-producing *Escherichia coli* (STEC) based on virulence factors," to the Food Safety Research Priority list.

As mentioned in its June 4, 2020 **Federal Register** notice (85 FR 34397), FSIS is conducting an in-field surface sampling study to determine the feasibility of a non-destructive surface sample collection method to collect raw beef manufacturing trimmings verification samples. FSIS will announce any changes to the sample collection method for the beef manufacturing trimmings project in a future **Federal Register** notice.

Data for Agency Policy

Comment: An industry organization commented that FSIS should use relevant scientific data for Agency policy. Specifically, the aggregated data by calendar year publicly available on FSIS' website incorrectly includes sample results

[12] https://www.fsis.usda.gov/science-data/research-priorities

from multiple slaughter classes of cattle, different sampling categories, and is not appropriately stratified. In the aggregated data, the commenter stated that the Agency does not separate samples attributed to different slaughter classes of cattle, such as veal. The commenter stated that different slaughter classes of cattle have varying risks of O157 and non-O157 STEC contamination, and FSIS should evaluate the risk of these different slaughter classes separately.

Response: In the discussion regarding aggregated data, FSIS stated the sampling results from FSIS verification testing programs includes data from veal establishments and follow-up sampling results.[13] Using aggregated sampling results is appropriate because FSIS is not proposing any changes to sampling allocations by slaughter class as part of the lab testing change. Therefore, the portion of samples collected from each slaughter class and the overall aggregate sampling is expected to remain consistent. The information showed that FSIS was finding non-O157 positive results in its verification sampling programs across all slaughter classes.

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[13] https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-escherichia-coli.

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and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) Mail: U.S. Department of Agriculture
Office of the Assistant Secretary for Civil Rights
1400 Independence Avenue, SW
Washington, D.C. 20250-9410; or

(2) Fax: (833) 256-1665 or (202) 690-7442; or

(3) Email: program.intake@usda.gov

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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: https://www.fsis.usda.gov/federal-register.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized

access to selected food safety news and information. This service is available at: https://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Done at Washington, DC.

Paul Kiecker,
Administrator.

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