

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

63-12

9/27/12

VERIFICATION ACTIVITIES FOR NON-O157 SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (NON-O157 STEC) UNDER MT60, MT52, AND MT53 SAMPLING PROGRAMS

I. PURPOSE

In the *Federal Register* notice published May 31, 2012, "Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products: Response to Comments on Final determination; Planned Implementation for Testing Raw Beef Manufacturing Trimmings," FSIS announced that it would begin conducting for-cause food safety assessments (FSAs), in response to FSIS positive non-O157 STEC results, approximately 90 days after implementation of Agency sampling and testing for non-O157 STEC. In addition, FSIS Notice 40-12 explained that, beginning 90 days after FSIS' implementation of sampling and testing of beef manufacturing trimmings for non-O157 STEC on June 4, 2012, establishments will be required to reassess their HACCP systems in response to FSIS or establishment non-O157 STEC positive test results, if they have not already addressed the hazard in their HACCP system. This notice provides instructions to inspection program personnel (IPP) concerning for-cause FSAs in response to FSIS positive non-O157 STEC results and verification of reassessment requirements in response to FSIS or establishment non-O157 STEC results. This notice makes clear that during routine FSAs, Enforcement, Investigations and Analysis Officers (EIAOs) will assess whether establishments can support their decisions regarding controlling all adulterant STECs, including non-O157 STECs. This notice also provides some additional clarification of current verification activities related to FSIS and establishment non-O157 STEC results.

KEY POINTS:

- *IPP are to have an awareness meeting with establishment management notifying them that the Food Safety and Inspection Service (FSIS) will begin scheduling for-cause FSAs in response to FSIS positive non-O157 STEC results and will begin verifying that establishments reassess, when required as part of 9 CFR 417.3(b), in response to FSIS or establishment positive non-O157 STEC results.*
- *District Offices are to schedule for-cause FSAs in response to FSIS positive non-O157 STEC results.*
- *EIAOs are to assess the adequacy of an establishment's HACCP system controls and supporting documentation concerning adulterant STECs (*E. coli* O157:H7 and the six non-O157 STECs) during routine and for-cause FSAs.*

DISTRIBUTION: Electronic

NOTICE EXPIRES: 10/1/13

OPI: OPPD

II. BACKGROUND

FSIS declared six non-O157 STEC (O26, O45, O103, O111, O121, and O145) to be adulterants in raw non-intact beef products and product components. On June 4, 2012, FSIS initiated a testing program for these six non-O157 STECs in beef manufacturing trimmings derived from cattle slaughtered on-site on or after June 4, 2012. [FSIS Notice 40-12, FSIS Verification Testing for Non-O157 Shiga Toxin-Producing *Escherichia coli* \(Non-O157 STEC\) under MT60, MT52, and MT53 Sampling Programs](#) outlined IPP and EIAO responsibilities.

III. IPP RESPONSIBILITIES FOR ESTABLISHMENT AWARENESS MEETING

A. After receipt of this notice, at the next weekly meeting, IPP assigned to slaughter establishments that produce beef manufacturing trimmings are to meet with establishment management to discuss the information in this notice. IPP are to inform establishment management that:

1. During routine FSAs, EIAOs will assess whether establishments can support their decisions regarding controlling adulterant STECs (*E. coli* O157:H7 and the six non-O157 STECs).
2. FSIS will treat positive test results for relevant non-O157 STECs the same as *E. coli* O157:H7 positive test results. With the issuance of this notice, FSIS will begin scheduling for-cause FSAs in response to FSIS non-O157 STEC positive results. If an EIAO determines during either a routine or for-cause FSA that an establishment cannot support its decisions regarding controlling adulterant STECs (*E. coli* O157:H7 and the six non-O157 STECs), regulatory or enforcement actions (such as noncompliance reports [NRs], Notices of Intended Enforcement, suspensions, or other actions) may result. At this time, there are no controls that specifically address non-O157 STECs. FSIS considers controls for *E. coli* O157:H7 to be effective against non-O157 STECs when implemented according to the scientific support. EIAOs will apply the same methodology to evaluating controls for non-O157 STEC as they do for *E. coli* O157:H7.
3. FSIS will verify that establishments reassess their HACCP plans, when required as part of 9 CFR 417.3(b) corrective actions, in response to FSIS or establishment positive non-O157 STEC results. Establishments are required to reassess in response to FSIS or establishment non-O157 STEC results if the establishment has not already addressed non-O157 STECs in its HACCP plan. Alternatively, establishments can provide scientific support that their existing controls for *E. coli* O157:H7 effectively control the non-O157 STEC and data to demonstrate that the establishment is implementing those controls according to this support.

B. Additionally, IPP are to make the establishment aware of additional information available in Attachment 1 of this notice.

C. IPP are to document their awareness meeting in a Memorandum of Interview (MOI) according to [FSIS PHIS Directive 5000.1](#) and provide a copy to establishment management.

IV. IPP AND EIAO ACTIONS FOLLOWING A POSITIVE FSIS TEST RESULT

A. IPP are to follow the same actions for each non-O157 STEC analysis positive result as outlined in [FSIS Directive 10.010.1, Rev 3](#), Chapter III, as they do for *E. coli* O157:H7, with the following clarifications related to Chapter III, Sections III A and III B:

1. If FSIS finds the product to be positive for non-O157 STEC or *E. coli* O157:H7, and the establishment also tested the product, IPP are to check establishment test results (see [FSIS Directive 5000.2](#)) to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7 or non-O157 STEC.
2. IPP are not to issue an NR in response to the positive result if:

- a. The establishment held the product or maintained control of the product (e.g., the establishment moved the product off-site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and
- b. FSIS and the establishment found the product positive for either *E. coli* O157:H7 or non-O157 STEC.

NOTE: If FSIS finds the product positive for any of the adulterant STECs (whether *E. coli* O157:H7 or any non-O157 STEC), and establishment testing finds the product positive for a different STEC that FSIS considers an adulterant, then IPP are not to issue an NR because the establishment effectively identified contamination and held the product.

3. If FSIS finds the product positive, and the establishment testing found that the product was negative (or the establishment did not perform testing), then IPP should issue an NR, as instructed in Chapter III of FSIS Directive 10,010.1.
4. IPP are to verify that the establishment performs the appropriate corrective actions. If the establishment fails to take appropriate corrective actions, IPP are to issue an NR at that time.

NOTE: If FSIS finds the product positive for *E. coli* O157:H7, and the establishment holds or controls the product and finds it positive for any of the non-O157 STEC, the instructions above apply. FSIS will update Directive 10,010.1 to incorporate these instructions.

B. In response to a positive result:

1. IPP are to assess the sanitary dressing procedures and process controls that cattle slaughter establishments employ in their food safety systems, in the manner described in [FSIS Directive 6410.1](#). Such controls are likely to include decontamination and antimicrobial intervention treatments. IPP are to focus especially on how the establishment is preventing visible contamination on the carcass at all stages of the hide removal process, not just after the hide is completely removed.
2. When verifying compliance with 9 CFR 417.3(b), IPP are to verify that the establishment has reassessed its HACCP plan for non-O157 STEC or maintains support demonstrating that its existing controls for *E. coli* O157:H7 effectively control the non-O157 STEC and data to demonstrate that it is implementing these controls according to scientific support.
3. When FSAs are scheduled by the District Office (DO), EIAOs are to conduct a for-cause FSA following a non-O157 STEC positive sample result from FSIS testing.
4. If an EIAO determines, during an FSA, that an establishment cannot support its decisions regarding controlling adulterant STECs (*E. coli* O157:H7 and the six non-O157 STECs), he or she is to recommend regulatory or enforcement actions as described in FSIS Directive 10,010.1 Rev 3 Chapter VI, and [FSIS Directive 5100.1](#) Chapter 13.
5. At this time, there are no controls specific to non-O157 STECs. Interventions validated to control *E. coli* O157:H7 should be effective in controlling the non-O157 STECs when properly implemented as described in the establishment's supporting documentation.
 - a. For example, an establishment may adequately support its intervention with a scientific article that demonstrates that the intervention reduces *E. coli* O157:H7 and can demonstrate that the establishment can implement the intervention so that it meets the critical operating parameters identified in its support.

- b. Another example of adequate supporting documentation is an establishment that has scientific support on-file demonstrating that the intervention, as applied, reduces surrogates for *E. coli* O157:H7 and can demonstrate the establishment can implement the intervention so that it meets the critical operating parameters identified in its scientific support. (Five strains of surrogate *E. coli* O157:H7 indicator organisms that have been researched in peer review scientific journals are American Type Culture Collection strain numbers BAA-1427, BAA-1428, BAA-1429, BAA-1430, and BAA-1431.)

6. When conducting FSAs in establishments producing beef manufacturing trimmings, EIAOs are to follow the same methodology as they would for *E. coli* O157:H7. EIAOs are to incorporate any findings associated with non-O157 STEC into questions that currently refer to *E. coli* O157:H7 in the 03J and 03C meat FSA tools.

NOTE: As FSIS learns more about establishment practices that may impact non-O157 STEC, the Agency may modify existing FSA questions and develop additional FSA questions on non-O157 STECs within the 03J and 03C FSA tools.

7. IPP are to collect follow-up samples as directed in FSIS Directive 10,010.1, Rev 3. Collecting follow-up samples because of an FSIS positive adulterant STEC result is a high priority task (priority 2), as directed in [FSIS PHIS Directive 13,000.1](#).

V. HACCP IMPLEMENTATION TASK

A. While performing the HACCP implementation task for the relevant HACCP processing category, IPP at establishments that produce beef manufacturing trimmings are to follow the instructions in FSIS PHIS Directive 5000.1. IPP are to perform both components (recordkeeping review and observation) of the procedure when they perform the HACCP implementation task.

1. While performing the recordkeeping review component, IPP are to determine whether the establishment has incorporated control measures for non-O157 STEC (as CCPs or in Sanitation SOPs or prerequisite programs) or whether the establishment has determined that its controls for *E. coli* O157:H7 are adequate for non-O157 STEC. If the establishment has determined that its controls for *E. coli* O157:H7 are effective for non-O157 STEC, IPP are to verify that the establishment has records to demonstrate that it is implementing its controls according to this support.
2. While performing the review and observation component, IPP are to verify that the establishment is implementing its controls according to the critical parameters identified in its support documents. Critical parameters are those parameters (e.g., carcass or product coverage, temperature, concentration, contact time, etc.) of an intervention that must be met in order for the intervention to operate effectively and as intended.

B. If IPP have concerns about the adequacy of the HACCP system, they are to discuss their concerns with their supervisor.

C. Attachment 1 provides additional information regarding adequate establishment controls for non-O157 STEC.

1. IPP at establishments that produce beef manufacturing trimmings are to review the information in Attachment 1.
2. IPP are to use this information to assist them in verifying that establishments that produce beef manufacturing trimmings are implementing their HACCP systems in a way that meets the regulatory requirements in 9 CFR 417.

D. IPP are to record any identified non-compliance on an NR according to FSIS PHIS Directive 5000.1.

VI. SCHEDULING FOR-CAUSE FSAs FOLLOWING FSIS NON-O157 STEC POSITIVE RESULTS

A. DOs are to follow the instructions in [FSIS PHIS Directive 5100.4](#) and schedule for-cause FSAs following confirmed positive FSIS non-O157 STEC test results.

B. EIAOs are to conduct for-cause FSAs, per the DO schedule, following confirmed positive FSIS non-O157 STEC test results.

VII. EIAO RESPONSIBILITIES RELATED TO AN ESTABLISHMENT'S CONTROLS FOR *E. coli* O157:H7 and Non-O157 STEC

A. When conducting a routine FSA, an EIAO is to assess whether the establishment has properly supported its controls for adulterant STECs (*E. coli* O157:H7 and the six non-O157 STECs), as they would during a for-cause FSA.

B. EIAOs are to refer to Section IV B 4, B 5, and B 6 in this Notice for direction on conducting routine FSAs in establishments producing beef manufacturing trimmings. EIAOs are to follow the methodology in FSIS Directive 5100.1 and FSIS Directive 10,010.1 Part VI.III. When conducting FSAs in establishments producing beef manufacturing trimmings, EIAOs are to follow the same methodology as they would for *E. coli* O157:H7 and document findings in the 03J and 03C meat FSA tools.

VIII. DATA ANALYSIS

The Office of Public Health Science (OPHS), the Office of Policy and Program Development (OPPD), and the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) will evaluate FSIS non-O157 STEC sample results. Specifically, OPHS will produce a bi-weekly report on sample findings, and OPPD will produce an annual summary report that will be published on the FSIS Web site. DAIG may conduct ad hoc analyses within a year to address specific Agency questions.

IX. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Division through [AskFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter FSIS Notice 63-12
Question Field:	Enter question with as much detail as possible.
Queue Field:	Sampling
Product Field:	Select General Inspection from the drop-down menu.
Category Field:	Select Sampling <i>E. coli</i> O157:H7 from the drop-down menu.
Policy Arena:	Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press the **Submit** button.



Acting Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1

Additional Information on Adequate Establishment Controls for Non-O157 STECs

Question: Are establishments required to make changes to their food safety systems to address non-O157 STEC?

Answer: No. However, establishments producing raw beef product need to make sure that they effectively address the hazard. At this time, there are no controls specific to non-O157 STECs. Interventions validated to control *E. coli* O157:H7 should be effective in controlling the non-O157 STECs when properly implemented as described in the establishment's supporting documentation. Slaughter establishments may implement a comprehensive written sanitary dressing program to address the hazard. This written program could include the measures the establishment will take to prevent contamination from occurring throughout the slaughter process and describe on-going information that the establishment will gather to ensure that employees perform the procedures as written. Further, the program could explain how the establishment uses its trim testing results to assess the effectiveness of its sanitary dressing procedures and to identify criteria for when the slaughter process is out of control. Another change establishments may make to their food safety systems could include starting a testing program for non-O157 STECs. Slaughter establishments that do so may make changes to the certificates of analysis they provide to receiving establishments to include non-O157 STEC test results. Another change slaughter establishments may make is to apply bacteriophage interventions to reduce non-O157 STEC contamination.

Should establishments choose to implement non-O157 STEC testing and use such testing information to support food safety decisions, establishments should maintain supporting documentation regarding the sampling and testing method. An example of such documentation includes "No-objection letters" for a non-O157 STEC test method that FSIS has reviewed. A prudent establishment would use a test method that includes all hypothetical strains of *E. coli* O157:H7 and the target non-O157 STEC, typical or variant, that would be identified using FSIS's confirmatory testing procedures and criteria, and that increases the likelihood of detecting low level contamination by these pathogens.

Question: If beef slaughter establishments would like to make changes in response to the non-O157 STEC policy, for example by starting a testing program for non-O157 STEC, where could they find more information on this?

Answer: Establishments can use the information in [FSIS Directive 6410.1](#) to identify points in the slaughter process where carcasses are vulnerable to contamination and to develop preventative measures. Further, establishments can use the information provided in the [Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* \(STEC\) Organisms or Virulence Markers](#) to develop and implement procedures to assess the effectiveness of their controls for preventing contamination during the slaughter operation. Establishments may find useful information in the Attachment to [FSIS Notice 40-12, FSIS Verification Testing for Non-O157 Shiga Toxin-Producing *Escherichia Coli* \(Non-O157 STEC\) Under MT60, MT52, and MT53 Sampling Programs](#). In addition, FSIS has published askFSIS Questions and Answers on [non-O157 STEC](#) issues. Finally, establishments may find useful information in the *Federal Register* (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023FRN.pdf>).

Other available resources on non-O157 STEC are available:

FSIS askFSIS Q&A on [Use of Non-pathogenic *Escherichia coli* \(*E. coli*\) Cultures as Surrogate Indicator Organisms in Validation Studies](#)

FSIS [Summary Table of No-Objection Letters Issued by FSIS for Non-O157 STEC Test Methods](#)
[FSIS Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* \(non-O157 STEC\)](#)

Question: For establishments that make changes to their food safety systems, what supporting data should they gather to demonstrate that those changes effectively control non-O157 STEC?

Answer: Establishments that make changes to their food safety systems can ensure that those changes adequately control non-O157 STEC by gathering the following supporting data:

- For slaughter establishments that develop a testing program for non-O157 STECs, they could include any test results as well as support for the sampling and testing method.
- For slaughter establishments that incorporate new interventions, they could include scientific support for the new interventions and data demonstrating that they implement the interventions in a manner that achieves the critical operating parameters identified in the scientific support.
- For establishments that make changes to their sanitary dressing procedures, they could include the written sanitary dressing procedures, documentation showing that employees perform the procedures as written, and associated trim testing results related to STEC (*E. coli* O157:H7; non-O157 STECs; or associated virulence factors such as *eae/stx*) that demonstrate that the sanitary dressing procedures prevented contamination from occurring.

Question: Are there any interventions that are specific to control non-O157 STECs?

Answer: At this time, FSIS is not aware of any specific interventions to control non-O157 STECs. Available scientific information indicates that interventions that control *E. coli* O157:H7 also control the non-O157 STECs (Geornaras et al., 2012; Kalchayanand et al., 2012), when applied following critical operating parameters. The adulterant STECs, including *E. coli* O157:H7 and the six non-O157 STECs, may be present on hides and in the gastrointestinal tract and feces of cattle. Consistently applying effective sanitary dressing procedures should reduce or eliminate contamination of carcasses with the adulterant STECs.

(Citations for above references:

Geornaras I, Yang H, Manios S, Andritsos N, Belk KE, Nightingale KK, Woerner DR, Smith GC, and Sofos JN. 2012. Comparison of Decontamination Efficacy of Antimicrobial Treatments for Beef Trimmings against *Escherichia coli* O157:H7 and 6 Non-O157 Shiga Toxin-Producing *E. coli* Serogroups. J Food Sci. 2012 Sep;77(9):M539-44.

Kalchayanand N, Arthur TM, Bosilevac JM, Schmidt JW, Wang R, Shackelford SD, Wheeler TL. 2012. Evaluation of Commonly Used Antimicrobial Interventions for Fresh Beef Inoculated with Shiga Toxin-Producing *Escherichia coli* Serotypes O26, O45, O103, O111, O121, O145, and

Question: What happens when a sample from an establishment tests positive?

Answer: Product that tests positive for one or more of the seven relevant STECs (six non-O157 STECs and O157:H7) is adulterated. If an establishment performs non-O157 STEC testing, FSIS will consider a confirmed positive sample or a screen positive that is not confirmed negative to be positive. FSIS policy and procedures for establishment positive test results for specified non-O157 STECs is the same as for *E. coli* O157:H7 positive test results.

Therefore, in response to FSIS positive non-O157 STEC results, FSIS will take actions similar to those described in [FSIS Directive 10,010.1](#), including scheduling follow-up samples and a for-cause FSA. Similarly, FSIS will take further actions, as described in FSIS [Directive 6410.1](#), including assessing the sanitary dressing procedures and process controls employed in the establishment's food safety system. If an establishment has identified non-O157 STEC as a hazard in its hazard analysis, then the establishment will be required to complete corrective actions as described in [9 CFR 417.3\(a\)](#). If an establishment has not identified non-O157 STEC as a hazard in its hazard analysis or does not have controls for *E. coli* O157:H7 that would also address non-O157 STEC, the establishment will be required to complete corrective actions as described in 417.3(b).

Should an establishment's own testing result in a positive sample test for non-O157 STEC, the establishment is required to take appropriate corrective action and to ensure the proper disposition of adulterated products, just as the establishment would for a positive *E. coli* O157:H7 result.