

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

FSIS NOTICE

06-23

1/27/23

EXPANSION OF FSIS NON-O157 SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC) TESTING TO ADDITIONAL RAW BEEF PRODUCTS

NOTE: DO NOT IMPLEMENT THIS NOTICE UNTIL FEBRUARY 1, 2023.

I. PURPOSE

This notice informs inspection program personnel (IPP) at official establishments and official import inspection establishments about the expansion of routine verification testing for six non-O157 Shiga toxin-producing *Escherichia coli* (STEC) that are adulterants. Currently, FSIS only tests beef manufacturing trimmings for non-O157 STEC. This testing will be expanded to ground beef, bench trim, and other raw ground beef components. FSIS is also merging the individual *E. coli* O157 and non-O157 STEC reported results into a single "Shiga Toxin-Producing *E. coli*" reported result. There are no changes to the sample collection procedures for these projects or product eligibility. IPP should continue to follow the sample collection procedures located in [FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* \(STEC\) in Raw Beef Products](#).

II. BACKGROUND

A. On November 18, 2022, FSIS announced in the Federal Register ([87 FR 69242](#)) that it will begin analyzing all raw beef samples for non-O157 STEC. Currently, FSIS tests domestic beef manufacturing trimmings samples (MT60) and imported beef manufacturing trimmings samples (MT51) for *E. coli* O157:H7 and six non-O157 STEC. Beginning February 1, 2023, FSIS will implement routine verification testing for the six adulterant non-O157 STEC (O26, O45, O103, O111, O121, and O145) in all raw beef sampling projects subject to FSIS STEC testing. These products include raw ground beef (MT43), bench trim (MT65), other raw ground beef components (MT64), imported ground beef samples (MT08), and all associated follow-up sampling in response to positives. All raw beef samples are also co-analyzed for *Salmonella*.

B. FSIS has fully aligned the testing criteria for *E. coli* O157 with that for non-O157 STEC as announced in the *Federal Register* ([87 FR 69242](#)) on November 18, 2022. Under the updated criteria, a sample is confirmed positive if it has an *stx* gene, an *eae* gene, and is identified by the laboratory as O157, O26, O45, O103, O111, O121, or O145. This update does not affect current FSIS laboratory protocols leading to the reporting of potential and presumptive STEC positive results.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 2/1/24

OPI: OPPD

III. EXPANSION OF ROUTINE VERIFICATION TESTING

Table 1. Comparison of previous analyses and expanded analyses by project code.

Project Code	Product Type	Previous Analyses	Expanded Analyses
MT60_C	Beef manufacturing trimmings	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT64	Raw ground beef components other than trim	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT65_C	Bench trim derived from cattle not slaughtered onsite	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT43	Raw ground beef products	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT05	Retail ground beef products	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT08	Imported ground beef products	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT51	Imported beef manufacturing trimmings	O157:H7 STEC, 6 non-O157 STEC, and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT51	Imported other raw ground beef components	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT44, MT52_C, MT53_C, MT44T_C	Follow-up sampling in response to a positive result on domestic products	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT08	Follow-up sampling in response to a positive result on imported ground beef products	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT51	Follow-up sampling in response to a positive result on imported beef manufacturing trimmings	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>
MT51	Follow-up sampling in response to a positive result on imported other raw ground beef components	O157 STEC and <i>Salmonella</i>	O157 STEC, 6 non-O157 STEC, and <i>Salmonella</i>

IV. AWARENESS MEETING WITH PLANT MANAGEMENT

A. Upon issuance of this notice, IPP at beef establishments that produce product(s) listed above or at import establishments that receive raw beef product(s) listed above are to review the information in this notice with establishment management during the next weekly meeting. IPP are to advise establishment management that the additional analyses will begin on or after February 1, 2023. IPP are to explain that, consistent with current requirements, establishments are required to hold the sampled production lot pending the receipt of STEC sample results, and positive product is considered adulterated unless it is further treated to destroy the pathogen.

B. IPP are to document the awareness meeting in a memorandum of interview (MOI) as described in [FSIS Directive 5010.1](#) section IV.

V. SAMPLE RESULTS REPORTING

A. FSIS is merging the individual *E. coli* O157 and non-O157 STEC reported results into a single “Shiga Toxin-Producing *E. coli*” reported result in the Laboratory Information Management System (LIMS)-Direct and the Public Health Information System. The “*Escherichia coli* serogroup” result will be reported, and that result will contain the serogroup(s) identified during testing (e.g., O26, O157) (See attachment). The change to results reporting will occur automatically. There is no action required by IPP or the establishment.

B. LIMS-Biological Information and E-mail System (BITES) notifications will be updated to include this new information. The BITES notifications will include the identified *E. coli* serogroups in both the subject line and body of the message. See [Attachment](#) for comparison examples of previous and new result reports.

VI. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select **Sampling** as the **Inquiry Type**.

NOTE: Refer to [FSIS Directive 5620.1](#), Rev. 1, *Using askFSIS*, for additional information on submitting questions.





Assistant Administrator
Office of Policy and Program Development

UPDATED FORMATTING FOR REPORTING OF RESULTS

I. LIMS-DIRECT

FSIS is merging the individual *E. coli* O157 and non-O157 STEC reported results into a single “Shiga Toxin-Producing *E. coli*” reported result. A new “Characterization Information” report field will report the “PCR O Group” result that will identify any of the adulterant STEC serogroup(s) detected during testing (e.g., O26, O157).

A. REPORT

Previous				New			
 Food Safety and Inspection Service U.S. DEPARTMENT OF AGRICULTURE		Release specific establishment results only to the establishment from which they were collected.		 Food Safety and Inspection Service U.S. DEPARTMENT OF AGRICULTURE		Release specific establishment results only to the establishment from which they were collected.	
Lab Result Report				Lab Result Report			
Date Posted	01/31/22	FSIS Establishment	M00000	Date Posted	01/31/22	FSIS Establishment	M00000
Form Number	100000000	District-Circuit	90	Form Number	100000000	District-Circuit	90
LIMS No.	300000000	Producer		LIMS No.	300000000	Producer	
Collection Date	01/31/22	Producer State		Collection Date	01/31/22	Producer State	
Date Received At Lab	01/31/22	Production Lot Number	A0000000	Date Received At Lab	01/31/22	Production Lot Number	A0000000
Certificate Number	NA	Project Code	MT60	Certificate Number	NA	Project Code	MT60
Project Name	Sampling of Beef Manufacturing Trimmings			Project Name	Sampling of Beef Manufacturing Trimmings		
Slaughter Class Or Product	Beef			Slaughter Class Or Product	Beef		
Product Held	Yes	Retain Tag Number		Product Held	Yes	Retain Tag Number	
Establishment Contact Name		Contact Phone		Establishment Contact Name		Contact Phone	
Collector Name	John Doe	Lab	Midwestern Lab	Collector Name	John Doe	Lab	Midwestern Lab
Foreign Establishment Number		Country Name		Foreign Establishment Number		Country Name	
Analysis Result: Not Acceptable				Analysis Result: Not Acceptable			
Tissue	Test	Result	Units	Tissue	Test	Result	Units
	E. coli O157:H7	Positive			Salmonella sp.	Negative	
	Salmonella sp.	Negative			Shiga Toxin-Producing E coli	Positive	
	Non-O157 Shiga Toxin-Producing E coli	Negative					
Characterization Information				Characterization Information			
Organism	Test	Result		Organism	Test	Result	
Shiga Toxin-Producing E coli	PCR O Group	O157		Shiga Toxin-Producing E coli	PCR O Group	O157	

B. EMAIL

Previous	New
<p>From: LIMS-Direct <LIMSDirect@fsis.usda.gov> Sent: Monday, January 31, 2021 12:00 PM To: LIMS.Direct.Test@test.com; Subject: LIMS-Direct - Potential Positive Result - Form# 100000000 -- Establishment#M00000</p> <p>Potential Positive Result Notice</p> <p>Report Date: 1/31/2021 Establishment: M00000 District/Circuit: 90 Form No: 100000000 LIMS No: 300000000 Collection Date: 1/31/2022 Date Received At Lab: 1/31/2022 Project: Sampling Beef Manufacturing Trimmings Slaughter Class or Product: Beef Producer: Test Producer Producer State: MA Production Lot No: A000000 Product Held: Yes Retain Tag No: Tags: Lab: USDA, FSIS, Midwestern Lab</p> <p><i>The initial screen test in the analysis for the organism or toxin noted below is positive. Further testing is required to confirm the presence or absence of the organism or toxin. Additional updates on sample status (confirmed negative, presumptive positive, confirmed positive) will follow.</i> Organism or Toxin: <i>Non-O157 Shiga Toxin-Producing E. coli</i></p> <p>Analysis is expected to be completed by: 1/31/2022</p>	<p>From: LIMS-Direct <LIMSDirect@fsis.usda.gov> Sent: Monday, January 31, 2021 12:00 PM To: LIMS.Direct.Test@test.com; Subject: LIMS-Direct - Potential Positive Result - Form# 100000000 -- Establishment#M00000</p> <p>Potential Positive Result Notice</p> <p>Report Date: 1/31/2021 Establishment: M00000 District/Circuit: 90 Form No: 100000000 LIMS No: 300000000 Collection Date: 1/31/2022 Date Received At Lab: 1/31/2022 Project: Sampling Beef Manufacturing Trimmings Slaughter Class or Product: Beef Producer: Test Producer Producer State: MA Production Lot No: A000000 Product Held: Yes Retain Tag No: Tags: Lab: USDA, FSIS, Midwestern Lab</p> <p><i>The initial screen test in the analysis for the organism or toxin noted below is positive. Further testing is required to confirm the presence or absence of the organism or toxin. Additional updates on sample status (confirmed negative, presumptive positive, confirmed positive) will follow.</i> Organism or Toxin: <i>Shiga Toxin-Producing E. coli - O26, O157</i></p> <p>Analysis is expected to be completed by: 1/31/2022</p>

II. BITES MESSAGING

BITES messages will be updated to include this new information. The BITES messages will include the identified *E. coli* serogroups in both the subject line and body of the message.

Previous

From: LIMSBITESservice@fsis.usda.gov
To: [FSIS - BITES1 Potential-List](#)
Cc: [FSIS - OPHS/MWL/BITES](#)
Subject: BITES - Potential Positive -- Non-O157 Shiga Toxin-Producing E coli -- MXXXXX-- Held: Yes
Date: Monday, January 31, 2022 12:00:00 PM
Attachments: 100000000.ncf
Importance: High

Confidential Information - See Notice at Bottom of Message

Establishment: MXXXXX -- Test Producer
Product Name/Site Description: Beef
Product Held: Yes
Establishment State: MA
District: 90
Date Collected: 01/31/2022
Project Code: MT60
Lab: Midwestern Laboratory
Form Number: 10000000
Laboratory Sample Number: 300000000
Lot Number: A000000
Est. Contact: NA
Est. Phone: NA
Application-Lot #: NA
Foreign Est. #: NA
Country: NA
Process Category: Product-Raw-Intact-Beef
Collector: JOHN DOE -- 555-555-1234

Report Number: BITES_2_2022-01-31_18-20-08

New

From: LIMSBITESservice@fsis.usda.gov
To: [FSIS - BITES1 Potential-List](#)
Cc: [FSIS - OPHS/MWL/BITES](#)
Subject: BITES - Potential Positive -- Shiga Toxin-Producing E coli - O26, O157 -- MXXXXX-- Held: Yes
Date: Monday, January 31, 2022 12:00:00 PM
Attachments: 100000000.ncf
Importance: High

Confidential Information - See Notice at Bottom of Message

Shiga Toxin-Producing E. coli O group(s): O26, O157

Establishment: MXXXXX -- Test Producer
Product Name/Site Description: Beef
Product Held: Yes
Establishment State: MA
District: 90
Date Collected: 01/31/2022
Project Code: MT60
Lab: Midwestern Laboratory
Form Number: 10000000
Laboratory Sample Number: 300000000
Lot Number: A000000
Est. Contact: NA
Est. Phone: NA
Application-Lot #: NA
Foreign Est. #: NA
Country: NA
Process Category: Product-Raw-Intact-Beef
Collector: JOHN DOE -- 555-555-1234

Report Number: BITES_2_2022-01-31_18-20-08