

SAFE FOOD COALITION

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September 3, 2020

Dr. Mindy M. Brashears
Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture

ON-LINE SUBMISSION VIA REGULATIONS.GOV

RE: Expansion of Shiga Toxin-Producing Escherichia coli Testing to Additional Raw Beef Products

Dear Under Secretary Brashears:

The undersigned members of the Safe Food Coalition write to express our support for the Food Safety and Inspection Service's (FSIS's) planned expansion of testing for Shiga Toxin-Producing Escherichia coli (STECs) in certain raw beef products.¹ Under current FSIS rules, *E. coli* O157:H7 and six non-O157 STECs are considered adulterants in non-intact raw beef products and product components. However, FSIS tests a much broader range of beef products for *E. coli* O157:H7, despite non-O157 STECs contaminating the same meat products and indeed, causing a larger number of infections among consumers each year. Now, FSIS is announcing plans to expand testing for the non-O157 STEC. These plans have languished for nearly a decade, and public health has suffered as a result. Accordingly, we urge you to act expeditiously in announcing the date that the agency will implement the new testing, and to implement testing no later than 180 days from the date of this Notice (December 1, 2020).

At the same time, the agency should amend current guidance, which does not adequately require establishments to include non-O157 STECs in their private HACCP testing programs. Specifically, FSIS continues to allow establishments to avoid separately verifying controls for non-O157 STECs, meaning they need only test for O157:H7 as part of their food safety programs. We therefore encourage the agency to revise its guidance to industry,² and its Directive 10,010.2 to inspection personnel,³ to clarify establishments' obligations to prevent non-O157 STEC contamination.

¹ FSIS. "Expansion of Shiga Toxin-Producing Escherichia coli Testing to Additional Raw Beef Products," FSIS-2010-0023-0045 (June 4, 2020), <https://www.regulations.gov/document?D=FSIS-2010-0023-0045> (hereinafter "Notice of Testing Expansion").

² FSIS. "FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers," (August 2014), *available at*: <https://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance-Guide-Est-Sampling-STEC.pdf?MOD=AJPERES>

³ U.S. DEPT. OF AGRIC., FSIS DIRECTIVE 10,010.2 (REVISION 1), VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING ESCHERICHIA COLI IN RAW BEEF PRODUCTS 2–3 (2020) [hereinafter 2020 FSIS DIRECTIVE], *available at*:

I. The Proposed Expansion of Testing is Necessary and Long Overdue

Almost nine years ago, FSIS announced that it had determined that six serogroups of STECs, in addition to *E. coli* O157:H7, “are adulterants of non-intact raw beef products and product components.”⁴ At the time, however, the agency set a date only for plans to test a subset of the products to which its determination applied. According to the 2011 announcement, the agency would implement a routine sampling program for the six non-O157 STECs in “beef manufacturing trimmings and other ground beef components” as of March 5, 2012.

The policy contrasts starkly with the FSIS verification testing protocol for *E. coli* O157:H7. As FSIS explains in its recent Notice, the agency tests many more products for *E. coli* O157:H7 than it does for the non-O157 STECs, including “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.”⁵ In other words, FSIS has determined that two sets of pathogens—*E. coli* O157:H7 and six non-O157 STECs—both represent adulterants in “non-intact raw beef products and product components.”⁶ But for one of these adulterants, the agency tests a much smaller fraction of the products to which its determination applies.

The agency indicated in 2011 that it would, at some later date, “issue a Federal Register document informing stakeholders before expanding its verification testing to include raw beef products other than beef manufacturing trimmings and other ground beef components.” Consumers have been waiting for FSIS to follow through on the promised expansion of testing for non-O157 STECs ever since.

Non-O157 STEC infections have soared over the same period that illness from *E. coli* O157:H7 has declined. Members of the Safe Food Coalition pointed this out in a letter to FSIS following an August 2018 outbreak of *E. coli* O26 (a non-O157 STEC) illnesses linked to ground beef.⁷ That outbreak resulted in 18 confirmed illnesses, with six hospitalizations and one death, and the eventual recall by Cargill Meat Solutions of 132,606 pounds of chuck-based ground beef products. The groups noted then that non-O157 STEC infections had increased by over 30% between 2011 and 2016, while *E. coli* O157:H7 infections had declined by 1% during the same period.⁸ Some of this change may reflect the introduction of new clinical diagnostic technologies, but more recent data shows that the trend has become more pronounced. Non-O157 STEC infections increased by 35% in 2019 compared with the average number of infections over the three previous years, while *E. coli* O157:H7 infections declined by 20%.⁹

<https://www.fsis.usda.gov/wps/wcm/connect/01356525-06b7-4f20-af3a-037bf24dc16e/10010.2.pdf?MOD=AJPERES> (last visited Sept. 3, 2020).

⁴ FSIS. “Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef,” 2011-24043, (Sept. 20, 2011), <https://www.regulations.gov/document?D=FSIS-2010-0023-0001>

⁵ FSIS. Notice of Testing Expansion, at 34397.

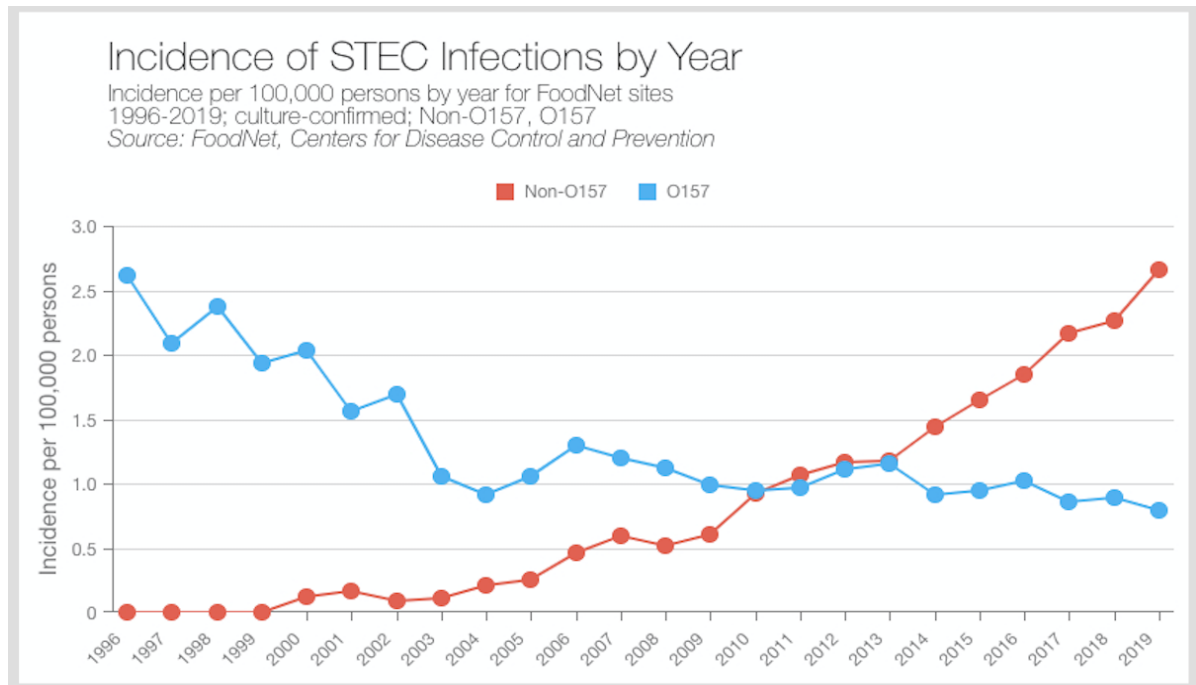
⁶ *Id.*

⁷ *Id.*

⁸ Centers for Disease Control and Prevention. Shiga toxin-producing *Escherichia coli* (STEC) Annual Report, 2016, <https://www.cdc.gov/ecoli/surv2016/index.html>

⁹ Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019. *MMWR Morb Mortal Wkly Rep* 2020;69:509–514. DOI: [http://dx.doi.org/10.15585/mmwr.mm6917a1external icon](http://dx.doi.org/10.15585/mmwr.mm6917a1external%20icon)

The failure to reduce the incidence of both types of STEC adulterants has grave consequences. CDC estimates that, overall, STECs cause more than 265,000 illnesses each year in the United States, with more than 3,600 hospitalizations and 30 deaths.¹⁰ As the graph below illustrates, the illnesses due to non-O157 STECs have now overtaken those due to O157, to account for an estimated 75% of total STEC illnesses.¹¹ While CDC maintains that “as a whole, the non-O157 serogroups are less likely to cause severe illness than *E. coli* O157,”¹² studies have documented how non-O157 STEC strains cause severe illness, comparable to that caused by *E. coli* O157:H7.¹³ Given the magnitude of the public health burden, even a small percentage reduction of non-O157 STEC infections could avoid the needless suffering of tens of thousands of people.



The arguments for continuing to forgo testing for the non-O157 STECs, effectively treating them as less serious adulterants, do not withstand scrutiny, as FSIS makes clear in its Notice. The proposed policy change is cost-effective based on the cost associated with avoided recalls alone.¹⁴ Testing technology has evolved to relieve barriers it may have posed, such as the need for separate

¹⁰ Centers for Disease Control and Prevention (CDC). National Shiga toxin-producing *Escherichia coli* (STEC) Surveillance Overview. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2012. Available at: <https://www.cdc.gov/ncezid/dfwed/pdfs/national-stec-surveillance-overview-508c.pdf>

¹¹ Minnesota Department of Health, “Non-O157 Shiga toxin-producing *E. coli* (STEC),” <https://www.health.state.mn.us/diseases/ecoli/basicsnon.html> (last visited Sept. 3, 2020).

¹² Centers for Disease Control and Prevention (CDC). *E. coli* (*Escherichia coli*) Questions and Answers, <https://www.cdc.gov/ecoli/general/index.html> (last visited Sept. 3, 2020).

¹³ Brooks, et al. 2005. Non-O157 Shiga Toxin-Producing *Escherichia coli* Infections in the United States, 1983-2002. *J Infect Dis*, 2005(192):1422-1429.

¹⁴ FSIS. “Cost-Benefit Analysis for FSIS’s Implementation of Its Non-O157 STEC Testing on Beef Manufacturing Trimmings and Expansion of Its Testing to Ground Beef and Ground Beef Components Other Than Beef Manufacturing Trimmings” available at: <https://www.fsis.usda.gov/wps/wcm/connect/c37a7129-639c-41fa-ab75-be6ddcd1c44/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf?MOD=AJPERES>

testing to detect the different strains of STEC.¹⁵ Moreover, by creating an incentive for innovation, expanded testing will likely result in even faster, cheaper and more accurate tests, particularly if FSIS takes additional steps to encourage private testing, as discussed in the next section. Finally, the challenges associated with traceback of non-O157 STEC contaminated ground beef made from multiple sources are no different than for those associated with ground beef adulterated with *E. coli* O157:H7. We therefore fully support the agency's proposal to expand testing for non-O157 STECs so that it covers the same scope as testing for *E. coli* O157.

II. FSIS Should Clarify Establishments' Obligations to Prevent Non-O157 STEC Contamination.

A guiding principle in FSIS policy on non-O157 STECs should be that, as adulterants in raw beef products, these pathogens deserve the same treatment as *E. coli* O157:H7. Toward that end, FSIS must not only expand its internal testing for non-O157 STECs, it should also clarify in its guidance to industry, and in its directives to inspection personnel, that establishments may not forgo testing of non-O157 STECs in their private testing programs.

Unfortunately, some major meatpacking firms have followed the agency's lead in treating non-O157 STECs as lesser adulterants. While these firms routinely test raw beef products for *E. coli* O157, they have declined to test for non-O157 STECs with the same rigor. For example, the meatpacker JBS has asserted:

It is the opinion of JBS that testing beef manufacturing trimmings and ground beef for non-O157 STECs would not increase the robustness of our food safety programs. Therefore, we will not test our beef manufacturing trimmings or ground beef for the non-O157 STECs.¹⁶

This decision appears to be driven at least in part by an assumption that testing for *E. coli* O157 is adequate to verify food safety controls for all STECs, essentially treating O157 as an indicator organism for all STECs. This assumption is faulty: the absence of *E. coli* O157:H7 does not prove the absence of non-O157 STECs. As the recent FSIS Notice explains, "FSIS verification sample results do not support using *E. coli* O157:H7 as an indicator organism for non-O157 STEC." This follows from the fact that "an isolate from a sample is rarely positive for both *E. coli* O157:H7 and non-O157 STEC."

At least a few in the meat industry have recognized this fact and implemented independent testing for non-O157 STECs. Companies such as Costco Wholesale and Empirical Foods (formerly Beef Products, Incorporated), for example, have tested for non-O157 STECs since before FSIS made its adulteration determination.¹⁷ But these practices, although feasible, represent significant

¹⁵ See, *id.* at 1. ("In February 2019, FSIS Field Service Laboratories began using a new technology for STEC testing. Before that, the laboratories employed a technology which required two separate kits to analyze samples for the presence of *E. coli* O157:H7 and the other 6 major STEC O groups. The new technology only requires one kit to test for all 7 *E. coli* O groups.")

¹⁶ Letter from Art Rogers, Technical Services, JBS USA Food Company, (Jan. 7, 2020), available at: <https://jbssa.com/food-safety/documents/beef/beeffoodsafetyletter.pdf>

¹⁷ See Safe Food Coalition letter to Carmen Rottenberg, Acting Deputy Under Secretary, USDA Office of Food Safety (Oct. 15, 2018), available at: <https://consumerfed.org/wp-content/uploads/2018/10/safe-food-coalition-letter-on-cargill.pdf>; see also Neuman, W. July 15, 2011. Food companies act to protect consumers from *E. coli* illness. New York Times. Available online at: <https://www.nytimes.com>.

investments in food safety, and not all companies are necessarily willing to make a similar investment. These important verification steps should be implemented across the board, ensuring that American consumers have access to safe and unadulterated products, regardless of where they shop.

The IPP Directive entitled *Verification Activities for Shiga Toxin-Producing Escherichia coli in Raw Beef Products* is particularly relevant to this Notice. FSIS updated this directive on July 1st, not long after it issued the Notice. The earlier (2015) version of the directive downplayed the need for non-O157 STEC testing, even if FSIS testing came up positive. According to the 2015 directive:

“When verifying compliance with 9 CFR 417.3(b) in response to a non-O157 STEC positive from FSIS testing, **IPP are not to expect the establishment to initiate a testing program for non-O157 STEC if it does not already have one at this time.** IPP are to verify that the establishment has reassessed its HACCP system for non-O157 STEC or maintains support demonstrating that its existing controls or preventive measures for *E. coli* O157:H7 effectively control or prevent the non-O157 STEC.”¹⁸ (emphasis added).

The updated 2020 FSIS Directive removes the bolded language above on what to do in the event of a positive non-O157 test, directing IPP instead to verify “whether any additional establishment testing conducted includes non-O157 STEC as part of the validation, verification and reassessment requirements of 9 CFR 417.4 . . . until the establishment is able to demonstrate control over STEC in their unique HACCP system.”¹⁹ This language, while an improvement, remains ambiguous as to whether establishments are expected to proactively include non-O157 testing in their HACCP testing program.

In addition, following a recent stakeholder meeting, members of the Safe Food Coalition asked whether beef processing establishments are currently expected to test for non-O157 STECs, similar to the expectation that they test for *E. coli* O157:H7, or if that expectation only applies once FSIS testing has turned up non-O157 STECs. The official FSIS response was: “Generally, controls that are validated to address O157 are also effective against non-O157 STEC. Therefore, if establishments test for O157:H7, FSIS considers that sufficient verification testing for the non-STECs, unless the establishment or FSIS has found product positive for non-O157 STECs.”²⁰ This statement contradicts FSIS’s own decision to expand testing, and makes clear that private testing will only be expected following the rare occasions where FSIS testing first reveals a non-O157 STEC positive. Such a reactive approach treats non-O157 STECs as less of a priority adulterant than *E. coli* O157 and is inconsistent with the relative public health importance and adulterant status of these pathogens. We therefore encourage FSIS to further amend its instructions to inspectors to make clear that non-O157 STEC testing should be required to the same degree as *E. coli* O157 testing.

¹⁸ See U.S. DEPT. OF AGRIC., FSIS DIRECTIVE 10,010.2 (REVISION 1), VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING ESCHERICHIA COLI IN RAW BEEF PRODUCTS 2–3 (2015) [hereinafter 2015 FSIS DIRECTIVE]; see also Dennis R. Johnson, “FSIS STEC verification activities,” *The National Provisioner*, Nov. 6, 2015, <https://www.provisioneronline.com/articles/102559-fsis-stec-verification-activities> (last visited Sept. 3, 2020).

¹⁹ See 2020 FSIS DIRECTIVE, available at: <https://www.fsis.usda.gov/wps/wcm/connect/01356525-06b7-4f20-af3a-037bf24dc16e/10010.2.pdf?MOD=AJPERES> (last visited Sept. 3, 2020).

²⁰ Email from Shayla Mae Bailey, Director, Digital & Executive Communications Staff, Office of Public Affairs and Consumer Education, Food Safety and Inspection Service, USDA, to Thomas Gremillion, Director of Food Policy, Consumer Federation of America (July 29, 2020).

FSIS guidance to industry should likewise direct establishments to test for non-O157 STECs, and make clear that testing for *E.coli* O157:H7 cannot be used to validate controls against non-O157 STECs, as the agency itself has indicated is the case. In particular, the agency should revise its 2014 guidance document entitled “FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers.” The guideline recommends that establishments “conduct verification testing for associated organisms that include STEC (e.g., a screen methodology for pathogenic STEC).”²¹ The guideline goes on to say that a “prudent establishment would use a test method that includes all hypothetical strains of *E. coli* O157:H7 and the target non-O157 STEC, either typical or variant organisms with these STECs serotypes, that would be identified using FSIS confirmatory testing procedures . . .” FSIS should revise this guidance to clarify that *all* establishments, not just the “prudent” ones, should use testing that detects non-O157 STECs.

So long as FSIS expects establishments to treat non-O157 STECs as adulterants, it should expect them to test for them, just as it does for *E. coli* O157:H7. This approach is consistent with the rationale advanced by FSIS for expanding its own testing. *E.coli* O157 is not a reliable indicator organism for non-O157 STEC. This is true even if establishments rely on the same antimicrobial treatments and other controls for both pathogens. As the data show, *E.coli* O157:H7 and non-O157 STECs appear very infrequently in sampling, and they almost never appear together in the same sample sets. To adequately protect the public from all adulterated beef, FSIS must not tolerate half-measures at the facilities it regulates.

III. Conclusion

Just as FSIS determined, in 1994, that *E.coli* O157:H7 is an adulterant in beef, so too did it determine, in 2011, that the six non-O157 STECs are adulterants. Yet FSIS has treated the non-O157 STECs as lesser adulterants, without justification. The agency’s announcement that it will expand testing for non-O157 STECs is welcome, and long overdue. For the reasons above, we urge you to act expeditiously to level the playing field and align industry towards preventing all adulterated food from entering commerce.

Sincerely,

Center for Foodborne Illness Research and Prevention
Center for Food Safety
Consumer Federation of America
Consumer Reports
Food & Water Watch
Government Accountability Project
National Consumers League
Stop Foodborne Illness

²¹ 2020 FSIS DIRECTIVE at 19.