

October 15, 2018

Carmen Rottenberg, Acting Deputy Under Secretary
Office of Food Safety
US Department of Agriculture
1400 Independence Avenue SW
Washington DC, 20250

CC by electronic mail: US Department of Agriculture Secretary Sonny Perdue

Dear Acting Deputy Under Secretary Rottenberg:

The undersigned members of the Safe Food Coalition write to express our concern that the Food Safety and Inspection Service (FSIS) may need to revise testing and control requirements for Shiga toxin-producing *Escherichia coli* (STEC) serotypes to adequately protect consumers. Specifically, FSIS should recommend “test and hold” for all STECs, not just *E. coli* O157:H7, and discontinue the assumption that testing and safety protocols for the O157:H7 serotype are sufficient to control or eliminate the risks posed by non-O157:H7 STECs. We are concerned due to the two recent *E. coli* recalls – of two separate STEC serotypes – linked to ground beef produced by Cargill Meat Solutions, Inc.

Cargill’s first recall, 069-2018, was issued on August 23 after the company reported potential contamination to FSIS on August 22. The recall applied to 25,288 pounds of ground beef products that may have been contaminated with *E. coli* O157:H7, the most well-known STEC. In this case, no illnesses were reported, and the recall appears to have been primarily preventive. We commend both Cargill and FSIS for acting quickly to protect consumers.

The second recall, 081-2018, applied to a far greater amount of food product – 132,606 pounds of chuck-based ground beef products – that were contaminated with *E. coli* O26, an extremely virulent pathogen that is one of the six STEC serotypes classified as adulterants in ground beef by FSIS in 2011. The recall was issued on September 19, after FSIS was first notified of illnesses on August 16 and used traceback procedures to identify Cargill as the source of contamination on August 30. The sequence of events and repeated *E. coli* contamination incidents raise concerns as to the effectiveness of Cargill’s procedures for identifying STEC contamination and preventing STEC contaminated product from reaching consumers. We have reached out to company representatives, who have indicated their willingness to share the results of their internal post-event assessment once it is completed. In the meantime, whether Cargill, and other companies, are undertaking best practices for identifying and preventing STEC contamination, including testing for all STEC serotypes, remains unclear. We are also concerned with FSIS’ timeliness in response to the company’s recall request.

Both Cargill recalls reflect Class I status, the most severe risk category FSIS assigns to recalls.¹ It is further worrisome that in both cases, meat products may remain in consumers' homes.² As FSIS notes in the two recall notices, it is "concerned some product may be frozen and in consumers' freezers."^{3,4} While recall procedures and broader consumer education are two important components to the USDA's outbreak response, we believe these incidents require more than just a recall of specific products. They require an in-depth evaluation of current FSIS guidance related to testing for non-O157 *E. coli* serotypes.

The recent Cargill outbreak linked to *E. coli* O26 caused 18 illnesses and one death. It underscores the seriousness of the public health risk and food safety hazard that STECs pose. FSIS has recognized these risks,⁵ and the agency announced in 2011 that it would treat the six most common STECs as adulterants on raw beef like how it treats *E. coli* O157:H7.⁶ The testing and control protocols for STECs, however, differ in important ways from those associated with *E. coli* O157:H7. In particular, FSIS does not direct plants to take specific action to eliminate risks associated with STECs, operating instead under the assumption that testing and safety protocols for *E. coli* O157:H7 are sufficient to eliminate the risk of non-O157 STECs.

The agency confirmed this regulatory posture in August of 2015, when it updated Directive 10,010.2 "Verification activities for Shiga Toxin-producing Escherichia coli (STEC) in Raw Beef Products." According to the directive:

At this time, there are few controls specific to non-O157 STEC that are not also effective against *E. coli* O157:H7. *An establishment may determine that its controls or preventive measures for E. coli O157:H7 effectively control or prevent non-O157 STEC.* 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 unless data such as multiple non-O157 STEC sample results indicate otherwise. (Italics added).

Considering the Cargill outbreak, we are concerned that this assumption is no longer valid and places both beef producers and consumers at risk of greater *E. coli* exposure to non-O157 serotypes. Data from the Centers for Disease Control and Prevention (CDC) indicates the inadequacy of O157 controls and preventions to prevent infections from non-O157 STECs, including O26 linked to the recent Cargill outbreak. Though human infections linked to *E. coli* O157 decreased from 2005 to 2009, infections from

¹ Class I recalls pose the most serious consumer safety risks, defined as "a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death."

² The first recall reflected products produced and packaged on August 16, 2018, with the label "Use/Frz. By September 05." The second recall included products produced and packaged on June 21.

³ USDA FSIS News Release available at: <https://www.fsis.usda.gov>

⁴ USDA FSIS News Release available at: <https://www.fsis.usda.gov/>

⁵ FSIS. 2012. Risk profile for pathogenic non-O157 Shiga Toxin-Producing Escherichia coli. Available online at: https://www.fsis.usda.gov/shared/PDF/Non_O157_STEC_Risk_Profile_May2012.pdf

⁶ FSIS Proposed Rule, Vol. 76, No. 182. September 20, 2011. Available online at: <https://www.gpo.gov>

non-O157 STECs increased by 50% over the same time period.⁷ Further, CDC notes a 4% increase of infections linked to STECs of unknown serogroups from 2004 to 2012.⁸

In particular, FSIS must ensure that beef producers improve their hazard analysis and critical control points (HACCP) protocols to account for *all* of the six STEC serotypes, in addition to *E. coli* O157:H7. We are aware of two beef processors – Costco Wholesale and Beef Products, Incorporated – that have voluntarily conducted “test and hold” procedures for all six STEC serotypes since before FSIS made its adulteration determination,⁹ even though there is a test-and-hold requirement for O157, but not for non-O157 STECs. The recent STEC O26 outbreak linked to Cargill raises the question of whether more comprehensive testing may have prevented a tragedy. Given that producers already employ the testing technology, and that the test itself is a rapid response, why does FSIS not recommend test and hold for all non-O157 STECs?

While we commend Cargill and FSIS for acting quickly and effectively in the first recall, we question why a similar response did not accompany the second recall of *E. coli* O26 contamination. Considering that *E. coli* O157:H7 and the six STECs captured by the FSIS 2011 rule are all adulterants in ground beef, they should receive similar treatment under FSIS regulations and compliance guidelines.¹⁰

Finally, we echo Representative Rosa DeLauro’s pointed questions regarding the delay between Cargill’s contamination confirmation and a formal recall.¹¹ FSIS has the responsibility to ensure more outbreaks do not occur. This involves investigating the two outbreaks of *E. coli* traced to Cargill’s beef, reviewing and explaining the lag time from reports of contaminated beef until the FSIS took action, and the necessity of updating guidance for testing of non-O157 STECs. The results of this investigation should be shared with the public and include effective preventive strategies for Cargill and other meat producers.

⁷ Centers for Disease Control and Prevention, August 2016. National Enteric Disease Surveillance: Shiga toxin-producing *Escherichia coli* (STEC) Annual Report, 2013

⁸ Ibid.

⁹ 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>

¹⁰ FSIS. 2017 Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef (including Veal) Processing Operations.

¹¹ Representative Rosa DeLauro, Letter to USDA. September 26, 2018. <https://delauero.house.gov>

We appreciate your attention to our concerns and look forward to hearing from you.

Sincerely,

National Consumers League
Center for Foodborne Illness Research & Prevention
Center for Food Safety
Consumer Federation of America
Consumers Union
Food and Water Watch
Government Accountability Project
U.S. Public Interest Research Group