Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
Room 2-2127 George Washington Carver Center  
5601 Sunnyside Avenue  
Beltsville, MD 20705  

RE: Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products  
(Docket No. FSIS-2010-0023, September 20, 2011)  

The Center for Science in the Public Interest (CSPI)\(^1\) appreciates this opportunity to comment on the Food Safety and Inspection Service’s (FSIS) intention to expand its testing program beyond *E. coli* O157:H7 to include six other serogroups of Shiga toxin-producing *E. coli* (STEC) (O26, O45, O103, O111, O121, and O145). Data from the Centers for Disease Control and Prevention indicate that these six strains of *E. coli* are responsible for over 60,000 illnesses each year, and account for 70-95% of all non-O157:H7 STEC infections in the U.S. These STEC can cause illnesses and complications as severe as those caused by O157:H7. Thus CSPI strongly supports FSIS’ efforts to address emerging pathogens in the products it regulates, including these STEC, and urges the Agency to continue acting from a posture of prevention to best protect consumers.  

I. FSIS Should Immediately Designate STEC as a Hazard Reasonably Likely to Occur  

In making its declaration that STEC are considered adulterants, FSIS states that establishments manufacturing raw, non-intact beef components or intact raw beef components “will be expected to evaluate whether these [STEC] are hazards reasonably likely to occur in their products.”\(^2\) CSPI believes that sufficient data exist to support FSIS’ declaration that STEC are in fact hazards reasonably likely to occur in these establishments. Several studies have linked these lesser known STECs to meat. Ground beef was implicated in 76 percent of the *E.  

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\(^1\) CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.  
coli O157:H7 cases and 58 percent of the non-O157 cases in a Minnesota study. In 2008, a private laboratory conducted a nationwide sample survey of retail ground beef and found that the presence of non-O157 STECs was more common than Salmonella in the samples; specifically, of the 5,070 tests, there were 96 confirmed positive results for non-O157 STECs and 86 confirmed results for Salmonella.

We note that in 1994, FSIS declared E. coli O157:H7 as an adulterant, but did not designate it as a hazard reasonably likely to occur at all stages of handling raw beef products until 2002, after it found that many processors (including those involved in outbreaks and recalls) simply didn’t identify O157 as a hazard needing in-plant controls. We see no compelling reason for a similar delay, and urge the agency to designate STEC as a hazard reasonably likely to occur at all stages of handling raw beef products now. There is no compelling reason for each establishment handling beef trim to make an individual determination of whether STEC are hazards reasonably likely to occur.

II. FSIS Should Implement the STEC Policy Without Delay

CSPI urges FSIS to maintain the timeline set forth in the Federal Register, with implementation of the routine sampling program for STEC in raw beef trimmings and other ground beef components by March 5, 2012. The decision to declare these strains as adulterants is both well-supported and well-reasoned as a preventive health measure, and as such it should be implemented without delay. A true focus on prevention necessarily requires the agency to push industry forward to meet new public health thresholds, and any delay in doing so puts consumers at risk. The agency should not wait for a large-scale, severe outbreak of STEC to sicken thousands of consumers, which would be the antithesis of prevention. Notably, the March implementation date allows the agency to begin testing well before the summer season, when rates of E. coli are typically highest.

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CSPI believes that stakeholders, including domestic industry and foreign governments, have had and will continue to have ample time to accommodate the new regulatory requirements for STEC testing by March. In fact, many in the industry have publically indicated that they have already begun testing for these strains, so the policy will not be unduly burdensome while it is significantly protective of the public. With regard to foreign governments, CSPI notes that the U.S. imports 2-3 billion pounds of beef and veal each year from around the world, and thus the safety of these products must be rigorously maintained as well. CSPI urges the agency to work with these governments to prepare them for the March implementation and to develop appropriate and effective protocols for maintaining equivalency with the U.S. program.

In addition, CSPI urges the agency to resist efforts to delay implementation of the STEC policy from stakeholders who assert a need for additional public meetings on the issue. FSIS has held several public meetings as it developed this STEC policy, and stakeholders have had adequate notice that the policy was in development, giving them ample time to prepare for implementation. In addition, FSIS’ action is well within its existing regulatory authority as an interpretive rule that does not require formal notice-and-comment. The agency demonstrated this authority with its 1994 declaration of *E. coli* O157:H7 as an adulterant, and is using the same interpretive power with STEC. CSPI applauds the agency for taking this proactive public health approach, and urges it to consider similar action for additional hazards in the meat supply—such as those posed by antibiotic-resistant pathogens—as it moves forward.

**III. Availability and Access to Testing Kits and Methodology is Important, but Should not Delay or Derail Implementation**

CSPI recognizes that the testing methodology for STEC is fairly new, but believes access to testing kits and methodology should not be a barrier to a March implementation. FSIS has already made testing methodology available in its Microbiology Laboratory Guidebook, and should continue working with industry and foreign governments to ensure that all stakeholders have access to testing materials by the deadline for implementation.

**IV. The Cost of the New STEC Protocol is Reasonable and Judicious**
FSIS estimates the direct, immediate costs to the agency for implementing the new STEC policy to be well under $400,000 per year. CSPI believes that this cost is both reasonable and defensible, when compared to the millions of dollars in direct and indirect costs of foodborne illness. FSIS further estimates the cost to industry of beginning their own screening for STEC and diverting positive product to cooking to be approximately $10 million. Given that the U.S. beef industry is a $155-billion industry, the cost to industry to implement testing represents only a small fraction of the bottom line. Notably, according to a 2009 U.S. Economic Research Service study, five bacterial pathogens are associated with $6.9 billion annually in health care costs, lost productivity, and premature death, which includes $300 million linked to non-O157 STEC5.

V. FSIS Should Identify and Prioritize Other Emerging Hazards in addition to STEC

FSIS’ action raises the broader issue of how best to design and implement a systematic method for identifying and prioritizing emerging pathogens. While the public health risk from STEC has been amply proven, outbreak data indicates the presence of other pathogens of significant public health concern, including antibiotic-resistant strains. For example, a review of 36 documented outbreaks linked to antibiotic-resistant bacteria since the 1970s showed that 42 percent (15 out of 36) occurred in the last decade, including a large proportion linked to meat and poultry. A total of 19,909 people were sickened from these 36 outbreaks, resulting in 3,064 hospitalizations and 26 deaths.6 Earlier this year, CSPI petitioned USDA to declare four of the most commonly identified strains (Salmonella Hadar, Heidelberg, Newport, and Typhimurium) as adulterants using the same regulatory authority the agency applied to these six STEC.

In an effort to better track and respond to these emerging pathogens, FSIS and FDA should develop and implement a process that continually reviews outbreak and illness data to make the process of determining adulterant status more proactive, more predictable, and more transparent.

5 The five pathogens studied were Campylobacter, Salmonella, E. coli O157:H7, E. coli non-O157 STEC, and Listeria monocytogenes. http://www.ers.usda.gov/publications/foodreview/septdec00/FRsept00h.pdf
6 This includes one large Salmonella Typhimurium outbreak caused by milk in 1985 in which 16,659 were sickened, 2,777 were hospitalized, and 18 died. CSPI recognizes that the regulation and oversight of pathogens in milk is not under the authority of USDA, but we include this data to illustrate the potential magnitude of harm.
In addition to developing such a process, FSIS should take steps to provide industry with clear advice on the integration of emerging hazards into their HACCP systems. For example, the agency should identify for the industry which hazards are reasonably likely to occur in specific product types and set clear timelines for the adoption of process controls, validation and verification, and the start of a testing program. The STEC announcement in September 2011 skipped many of these important steps. While government testing is the ultimate checkpoint on industry performance in controlling these emerging hazards, it is not the only important step to which a deadline should attach.

Sincerely,

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