

# USDA's New Shiga Toxin-Producing Escherichia coli Policy

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The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) published in the September 20, 2011 *Federal Register*, a Final Determination and Request for Comments (FDR), which announced six additional Shiga toxin-producing Escherichia coli (STEC) would be deemed adulterants in certain beef products. Non-intact raw beef including ground beef, its components, and tenderized steaks found to contain serogroups O26, O103, O45, O111, O121 and O145 will be prohibited from entering commerce. FSIS will initially launch a trim testing program to detect these pathogens and initiate a ground beef testing program at a later undetermined date. The trim testing program is scheduled to become effective on June 4, 2012.

As justification, USDA said that it is taking this new step as part of a government-wide commitment to dealing with emerging microbial threats. Through the President's Food Safety Working Group, USDA and its federal partners have been working on a new, public health-focused approach to food safety based on the principles of prevention, strengthening surveillance and enforcement, and improving response.

FSIS made some very revealing statements in its *Federal Register* publication that described the regulatory change. The statements acknowledge the uncertainties surrounding implementation of the new policy:

- "We note that the illnesses associated with these strains have not primarily been due to contamination on beef."
- "As we have stated, controls for *E. coli* O157:H7 already in place should be as effective in controlling non-O157 STEC as in controlling *E. coli* O157:H7."
- "As explained in the Expected Costs and Expected Benefits Sections, there are uncertainties in our cost and benefit estimates."

- "For example, we do not know how many illnesses will actually be prevented. It is not clear whether on net there will be a reduction in the number of illnesses."
- "It is also challenging to know what the industry cost will be because it is difficult to predict how many establishments will start to test and what the size distribution will be or to what extent industry will take additional measures that will prevent, reduce, or control those hazards, as they do with regard to O157 STEC."
- "However, on net, the additional testing may increase the total number of recalls as the new policy would require the recall of all products that test positive and have entered commerce, regardless of whether they are associated with an outbreak or not."<sup>1</sup>

Several organizations and individuals have called the policy premature and the process used to develop it flawed. Arguments have been made that a more prudent approach regarding a STEC policy is to collect the data needed to conduct a comprehensive public health risk assessment and determine what, if any, public health actions should be taken. Then, if warranted, a policy can be implemented through appropriate notice and comment rulemaking.

A comprehensive review of the public health significance of STEC was presented at the 2011 American Meat Science Association's Reciprocal Meat Conference.<sup>2</sup> Since that time, surveys of public health laboratories indicate an increased use of Shiga toxin assays that is correlated with increased reported incidence of non-O157:H7 STEC infections, but the survey data also continue to suggest under detection of non-O157:H7 STEC infections.<sup>3</sup>

Nonetheless, an analysis of Centers for Disease Control and Prevention (CDC) foodborne disease outbreak data shows that non-O157:H7 STEC are not an urgent and unique public health crisis. The data indicate that 383 total *E. coli* outbreaks occurred over an eleven year period (Table 1). One hundred thirteen or 31 percent of

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**Table 1.** CDC Foodborne Outbreaks, 1998-2009, Total Outbreaks: 14,091.<sup>1</sup>

	"Top 6"		Other <i>E. coli</i>	Total <i>E. coli</i> Outbreaks
	<i>E. coli</i> O157	Non-O157 <i>E. coli</i> <sup>2</sup>		
All Foods	340	12	31	383
Beef Related	113	0	4	117
% Beef Related	33%	0%	13%	31%

<sup>1</sup>CDC Foodborne Outbreak Online Database. <http://www.cdc.gov/foodborneoutbreaks/>. Accessed December 9, 2011.

<sup>2</sup>In August 2010, FSIS announced a Class I recall for 8,500 pounds of ground beef products that may have been contaminated with *E. coli* O26 and associated with 3 illnesses in New York and Maine.

those outbreaks were beef related. None of these outbreaks were attributed to the six STEC that are the subject of FSIS's new regulatory policy (Table 1).

FSIS acknowledged in its Draft Risk Profile that "Although the majority of non-O157 STEC infections are attributed to non-beef food sources, surveys indicate that pathogenic non-O157 STEC serogroups may be present in cattle, on beef carcasses, in beef trimmings destined for ground beef production, and in ground beef from federally regulated establishments and retail markets. However, due to lack of baseline data, we cannot make definitive quantitative statements about the national prevalence or the likelihood that pathogenic STEC serogroups may be found in either cattle or ground beef."<sup>4</sup>

Additionally on January 31, 2012, the Interagency Food Safety Analytics Collaboration (IFSAC) comprised of CDC, FSIS and Food and Drug Administration (FDA) presented a draft strategic plan to better characterize the sources of foodborne illness. Non-O157:H7 STEC was not included among the four priority pathogens—*Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter*—that were identified by the regulatory agencies as the initial focus of their foodborne illness source attribution work.<sup>5</sup>

CDC said "We reviewed the estimates of foodborne illness, major pathogens and specified sources, papers for the volume of data, severity of illness, our ability to measure change, and we concluded that the non-O157 *E. coli*, at this point in time, was not on par with the other pathogens as far as understanding and implementing interventions to reduce them."<sup>6</sup>

The Draft Risk Profile relied upon by FSIS in its decision-making has been extensively criticized by the scientific experts that FSIS commissioned to review the profile. For example, peer reviewers said:

- [There is no] "Evidence that declaring six serotypes of non-O157 STEC adulterants would have any public health benefit. As it is, the evidence suggests that contamination with these serotypes is prevented or eliminated by exactly the same interventions that are currently in place to prevent or eliminate O157

STEC contamination. In the absence of additional interventions that would specifically affect non-O157 STEC, declaring them adulterants is not likely to have any public health benefit.<sup>7</sup>

- "[T]he document fails to summarize the current state of scientific knowledge in the Risk Profile. Most problematic is the focus of the document on the most severe end of the spectrum of disease associated with the non-STEC."<sup>8</sup>

Even FSIS said in its Draft Risk Profile, "We found no consensus in the scientific community about precisely which features, or virulence factors, make an STEC harmful to humans. Therefore, the Risk Profile considers any STEC capable of causing severe human illness to be a pathogenic STEC."<sup>9</sup>

In addition to the uncertainties regarding the public health benefit of declaring additional STEC as adulterants in non-intact beef products, the implementation of the policy presents several technical, trade and logistical concerns.

Existing diagnostic screening methods to detect non-O157 STEC are not sufficiently advanced to produce reliable results that meet the needs of commercial operations. Preliminary data indicate that the first screening for non-O157 STEC will find a large number of samples to be 'potential positive', but most of those will confirm negative.

The use of lengthy laboratory confirmation methods is not a viable option for in-plant testing. A reliable rapid screening test is needed because beef processors make product disposition decisions based on those results. Currently, product disposition decisions are based on the results of rapid screening tests that are usually obtained in 18 hours or less. Inaccurate rapid screening results cause needless loss of product or downgrading the product value which raises the price of ground beef.

Detection of non-O157 STEC requires sophisticated laboratory equipment and experienced laboratory technicians to run the analyses. This provides challenges for certain segments of beef processors. If FSIS requires testing to validate a plant's HACCP program, small and medium size operations will be forced to upgrade testing protocols that are currently used or use outside fee-for-service laboratories.

Additionally, the announced policy likely violates the United States' World Trade Organization obligations outlined under Article 5 of the Agreement on the Application of Sanitary and Phytosanitary Measures. In comments submitted to FSIS in response to the FDRC, several governments expressed concerns about the absence of an adequate risk assessment, the lack of viable testing platforms, and the potential for an unjustified disruption in trade and its implications.

Canadian Prime Minister Stephen Harper and U.S. President Barack Obama on February 4, 2011 announced a Canada-U.S. Regulatory Cooperation Council (RCC) to

better align regulatory approaches. The Government of Canada, in their comments regarding FDRC, subsequently said “The proposal by FSIS will widen the regulatory gap between Canada and the US and will lead to unnecessary regulations for both the Canadian and the US industry, which is contrary to our Leaders’ RCC commitments.”

In comments submitted to the public record, the Government of Canada also said “[It] is concerned that current evidence does not support the FSIS proposal to elevate six (6) additional *E. coli* serotypes to adulterant status in raw beef products. There is a gap in knowledge and understanding on the prevalence of all of the non-O157 STECs (including the 6 noted in this rule), their prevalence in beef products, dose-response dynamics, severity of illness, and the relative importance of other exposure pathways (for example, through fresh fruit and vegetable products, such as bean sprouts). ...Consequently, the Government of Canada does not consider that there is sufficient scientific evidence to support the USDA-FSIS determination that these six specific *E. coli* serotypes warrant an elevated control status comparative to other STECs.”

The Government of Australia said “STEC other than *E. coli* O157:H7 are not considered a major public health concern within Australia and the FSIS published risk profile confirms that the majority of non-O157 STEC infections are attributed to non-beef food sources, Australia therefore questions whether testing for these serotypes is scientifically justified, particularly as baseline studies have not been completed in the US.”

The Government of New Zealand said “[It] does not consider sufficient scientific evidence has been supplied to justify the necessity of the proposed new measure and agrees with the point specifically acknowledged in the Notice that the evidence has not shown the consumption of contaminated beef within the United States or elsewhere, to be a significant epidemiological factor in cases to date. ... Accordingly, it is unclear how the introduction of the additional measures as indicated in the Notice will lead to either the reduction of current food borne illness cases or the significant prevention of cases which could be reasonably predicted to otherwise occur.”

Finally, many comments submitted to the public record noted the inadequacy of the cost analysis provided by FSIS in the FRDC. FSIS estimates industry implementation costs will range from \$7.9 to 10.5 million. Industry estimates the policy will adversely affect businesses and the costs attendant to the policy could exceed \$300 million annually. (Table 2)

FSIS acknowledged in the FDRC their lack of data to accurately estimate the economic burden imposed on the beef industry. FSIS said “For example, we do not know how many illnesses will actually be prevented. It is not clear whether on net there will be a reduction in the number of illnesses. It is also challenging to know what the industry cost will be because it is difficult to predict how many establishments will start to test and what the size

**Table 2.** Beef Industry Cost Analysis Estimates.<sup>1</sup>

	Industry Estimates (Millions)	
	Low	High
Product Diverted to Cooking	\$39.2	\$78.4
Laboratory Services	2.5	2.9
Process Disruption	58.8	98.0
Recalls	72.0	144.0
Total Annual Costs	172.5	323.3

<sup>1</sup>Comment submitted to the Public Record by Beef Industry Food Safety Council; Docket No: FSIS-2010-0023; Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products.

distribution will be or to what extent industry will take additional measures that will prevent, reduce, or control those hazards, as they do with regard to O157 STEC.”

“However, on net, the additional testing may increase the total number of recalls as the new policy would require the recall of all products that test positive and have entered commerce, regardless of whether they are associated with an outbreak or not. Any recall may have a significant impact on the industry, including the loss of sales revenue, the cost to dispose of recalled products, and the loss of consumer confidence and business reputation.”<sup>11</sup>

Regarding industry’s role in complying with the new adulteration policy, a general consensus has emerged among most beef slaughterers and processors that preventive food safety process management programs for controlling *E. coli* O157:H7 are also effective in controlling non-O157 STEC. Research conducted by USDA’s Agricultural Research Service and other institutions has shown that microbial interventions currently used in beef slaughter facilities to control *E. coli* O157:H7 also control non-O157 STEC and that *E. coli* O157:H7 is an effective indicator organism for other STEC. Therefore, additional pathogen control technologies to specifically target STEC other than *E. coli* O157:H7 are unnecessary and testing for *E. coli* O157:H7 is an effective screening program for other STEC and a method to verify that process control systems are operating as intended.

As of April 15, 2012, FSIS has not issued new verification procedures to its field inspectors regarding how the new adulteration policy will be enforced. Uncertainty about how the new policy will be implemented remains a significant concern to plants producing ground beef, its component or tenderized beef products. As with any new regulatory program, significant questions and issues will arise. A collaborative, inclusive and transparent process will be needed among regulators, the industry and allied stakeholders to implement FSIS’s new STEC policy.

As more information becomes available regarding the process and procedures for implementing USDA’s new Shiga toxin-producing *E. coli* policy, please visit [www.meatami.com](http://www.meatami.com) or contact any of the American Meat Institute’s scientific, technical or regulatory staff listed on the website.

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