Understanding the Public Health Significance of Shiga Toxin-Producing E. coli

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Recently, non-O157:H7 shiga toxin-producing *Escherichia coli* (STEC) have been identified by consumer groups and the Food Safety and Inspection Service (FSIS) as an immediate public health concern. Under Secretary for Food Safety Elisabeth Hagen recently reiterated this in congressional testimony, "We cannot wait for another public health emergency to address the range of *E. coli* threats in ground beef that currently exist" (Hagen, 2011). In October 2009, Marler Clark LLP, PS, submitted a citizen petition (Petition Number 09-03) to FSIS seeking an expedited interpretive rule declaring all Enterohemorrhagic STECs to be adulterants within the meaning of the Federal Meat Inspection Act (FMIA). According to the petition, "Issuing a new interpretive rule that declares that all STEC are adulterants within the meaning of the FMIA will encourage increased monitoring efforts and better ensure the safety of the general public, as is required by the FMIA." (Marler, 2009) As of May 2011, FSIS has yet to make a decision on Marler Clark's petition.

Over the past year, this has led to the frequent question, "Why the sudden additional focus on other *Escherichia coli* microorganisms in beef"? The meat industry has long recognized that all STEC, including non-O157: H7 STEC (nSTEC), have the potential to cause illness in humans under the right conditions. The industry has initiated research to show that process control systems currently employed are effective against nSTEC as the originating source of the contamination is the same as *E. coli* O157:H7 and has been supportive in developing new intervention technologies and testing methodologies.

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[1] *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. FSIS collected follow-up samples of ground beef and raw ground beef products from the supplying establishments and analyzed these products for E. coli O26. This action was in accordance with Notice 70-10, Follow-up Sample Collection Procedures for the E. coli O26 Recall.*

In 2000, the Centers for Disease Control and Prevention (CDC) made nSTEC a reportable disease and have actively tracked illnesses and outbreaks since that time. Until August 2010, no confirmed illnesses had been associated with nSTEC on meat products. [1] In 2007 and 2008, FSIS along with CDC and the Food and Drug Administration held two public meetings to consider the public health significance of nSTECs. Using CDC data, FSIS has specifically identified the designation of the following nSTECs as causes for concern in ground beef products and the components that make up ground beef products: O26, O111, O103, O45, O145, and O121.

In January 2011, CDC revised their decade old foodborne illness, hospitalizations, and death estimates. Utilizing public health data acquired in the last 11 years, the CDC estimates 47.8 million illnesses, 127,839 hospitalizations, and 3,037 deaths are attributed to foodborne illness (Scallan *et al.*, 2011), which are lower than the 1999 estimates of 76 million, 325,000, and 5,000, respectively (Mead *et al.*, 1999). Scallan *et al.* (2011) estimated that 112,752 illnesses, 271 hospitalizations and 0 deaths are caused by nSTEC compared to the respective *E. coli* O157:H7 estimates of 63,153, 2,138, and 20. Annual STEC illnesses are estimated to be 2 percent; considerably lower than illness estimates for other known pathogens like *Salmonella, Campylobacter*, and viruses. CDC also estimates that no deaths are attributed to nSTEC compared to 2% of *E. coli* O157:H7 when the pathogens are known. Currently, FSIS estimates the total number of illnesses from all FSIS regulated products to be 571,406 in 2011 and 565,691 in 2012 (FSIS, 2011a). These estimates demonstrate the potential public health risk STEC contamination in food products may have, but these are only estimates and models are only as good as the data and the assumptions used to construct the estimation model. To determine the public significance of STEC, one must also take into account the current food safety systems in place and the past history of STEC in beef products.

From 1998-2008 there were 298 *E. coli* O157:H7 and 12 nSTEC outbreaks attributed to specific foods, which resulted in 6,088 and 1,030 illnesses being reported, respectively (CDC, 2011). Interestingly, during that time period 31% of the *E. coli* O157:H7 outbreaks were attributed to beef products or associated with beef products. None of nSTEC outbreaks were attributed to beef products during that time period. Of the 81 beef related *E. coli* O157:H7 recalls in 2004-2010, 38% were due to illness investigation, while 62% were initiated due to FSIS/company sample (FSIS, 2011b; 2011c). Both *E. coli* O157:H7 and nSTEC outbreaks follow the typical beef seasonal pattern with increased incidences associated with summer months (Mody and Luna, 2011). It is not uncommon for multiple etiology outbreaks to occur among STECs (Mody and Luna, 2011), which is logical as STEC microorganisms originate from the same source and sources of contamination are the same within the food production chain.

Although the accuracy of modeling techniques and improved data do not allow for a comparison between the 1999 and 2011 foodborne illness estimates, one could speculate that improvements by the public health agencies, regulatory groups and the meat and poultry industry have all contributed in making the food supply safer, particularly in reducing *E. coli* O157:H7 contamination. The incidence of foodborne illness due to *E. coli* O157:H7 decreased 55% between 2000 and 2010 as well as meeting the 2010 national health objective in 2004, 2009, and 2010 (CDC, 2010). Also during that time frame, the prevalence of *E. coli* O157:H7 in beef products calculated from FSIS's results of individual raw ground beef products analyzed for *E. coli* O157:H7 in federal plants decreased 72% even as testing methodologies became more sensitive (FSIS, 2011d). Various researchers have estimated the prevalence of nSTEC in the ground beef supply, but FSIS has not performed a baseline to determine the prevalence of nSTEC in the overall U.S. beef supply. This baseline is a needed metric in determining if declaring nSTEC adulterants in beef will improve public health or if food safety measures currently employed by the U.S. beef industry are effective in controlling STEC contamination.

Given the history of STEC outbreaks and industry being successful in reducing *E. coli* O157:H7 prevalence in beef products, *E. coli* O157:H7 is likely the best the microorganism to target in reducing the risk when consuming beef products as the number of confirmed illnesses within the U.S. have been more attributed to *E. coli* O157:H7 than to nSTEC. Also, *E. coli* O157:H7 could be used as an indicator organism in a systematic food safety process control system used to control STEC contamination. Critics of this type of system would likely point out that the reason why there have not been as many outbreaks associated with nSTEC was due to lack of testing. In the past, that would be a viable argument, but in 2010 approximately 5,000 isolates of nSTEC were submitted to the CDC's PulseNet database, slightly more than the number of isolates of *E. coli* O157:H7 (Gerner-Smidt, 2011); a trend that will more than likely continue in the future.

So what is the public health significance of STECs? The pathogenic STEC serotypes are significant and neither CDC, FSIS nor the meat industry will dispute that. But how does one improve the public health risk? That question needs to be answered yet the solution is not simple. The meat and poultry food production continuum is made up of four groups: the meat and poultry industry, regulatory agencies, public health agencies and consumers. Each group has a vital and critical role in food safety, but likely the least understood is the role public health agencies have and their impact on food safety policy.

Public health agencies need to provide more accurate and timely foodborne illness attribution data. This objective data allows food safety stakeholders to allocate resources and scientifically justify the decisions made in their food safety system. By having timely, credible food attribution data, regulators and the meat industry can accurately identify and improve any food safety gaps that may exist. These data also may help to identify emerging foodborne risks, especially when such risks have not been previously associated with specific foods. This rapid adjustment to improve food safety can only occur if accurate data is made available as soon as possible to all food safety stakeholders.

To complement public health data, FSIS should consider and evaluate how public health would be improved by making nSTEC adulterants or if there are alternative regulatory paths that could be more effective. To do this, FSIS needs to better understand the prevalence of all STEC, including nSTEC, in the U.S. beef supply. The meat industry should also employee a process control system that addresses all STEC, which may include using *E. coli* O157:H7 as an indicator organism. Process control systems are used to assess the adequacy of control within a food safety program using microbiological monitoring and could be used to make decisions in mitigating the risk of STEC on beef products. Finally, consumers should better understand the risks associated with raw agricultural products in order to make the best purchasing and handling decisions for their lifestyle.

The last decade has shown the important role cooperation and communication between public health officials, regulators, the meat industry and other allied stakeholders has had on improving food safety. This collaborative story of success, lessons learned and the need for additional research can develop the blueprint in mitigating the STEC risk in beef products.

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