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**“The Public Health Significance of Non-O157 Shiga-toxin Producing
Escherichia coli (STEC)”**

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George Mason University, Arlington, Virginia

I'd like to thank FSIS, FDA and the CDC for holding this meeting. I'm especially heartened to see the three agencies working together on the need to address non-O157 STEC in our food supply. As a country, we've learned the hard way—through foodborne illness outbreaks—that animal-reservoir pathogens are not of concern solely in the possible contamination of meat. Once considered “the hamburger disease”, E. coli O157:H7 and its STEC cousins are now known to contaminate a wide range of foods including produce, juice, sprouts and milk. It would be unusual—to the point of delusional—to think that disease-causing non-O157 STEC would veer from the same paths of contamination that occurred with O157. That's why I want to commend you for collectively analyzing pathogenic contamination of foods as a whole instead of through the tunnel vision approach of looking at single-product categories individually.

It will be through the pooling of interagency talents and resources that we can most effectively create a proactive approach to food safety, rather than the reactive one that we have had in place for so many years. I think that it's safe to say that leaders in all sectors of food safety—industry, academia, government and consumer advocates—would agree that a prevention strategy to keep disease-causing pathogens from making it into commerce, is the best strategy to employ to most effectively protect public health.

Although the association of STEC with human disease dates back to 1982, it wasn't until the 1993 Jack-In-The-Box E.coli O157:H7 epidemic, that the dangers of foodborne pathogens first made it onto the airways, and catapulted the issue of unsafe food to the public's attention. That outbreak alone sickened more than 700 people and killed at least four children.

For those of you unfamiliar with the consumer organization that I'm representing, let me briefly explain who we are. S.T.O.P.—Safe Tables Our Priority, was born in the aftermath of the Jack-In-The-Box outbreak. Our founders include parents of children impacted in that epidemic as well as others impacted by O157 nationwide. S.T.O.P. is a national, non-profit organization whose mission is to prevent illness and death from pathogens in the food supply. Our work involves sound policy advocacy, building awareness of foodborne risk and its management, and providing victim assistance. Our members include families who have suffered illness and loss from a broad spectrum of food types including contaminated meat and poultry, produce, juice and RTE processed foods. I became involved with S.T.O.P. shortly after its inception, after the death of my 6-year-old son, Alex, from E. coli poisoning in 1994. Alex's case was an isolated occurrence; he suffered from both HUS and TTP. My goal as president of this fine organization is to put us out of business by working to see practices and policies enacted

that will lead to a significantly safer food supply with a corresponding decline in the number of foodborne diseases and deaths.

S.T.O.P. has been keenly interested in the topic of non-O157 STEC for years and we appreciate the opportunity to participate in today's discussion. Over the years we've had conversations with the CDC and both FSIS and CFSAN about the need to expand programs to include the detection and prevention of non-O157 STEC-contaminated foods making it into the marketplace. These discussions were, frankly, during the prior administration. We've wasted a lot of time, but I hope that today's meeting will lead to a fast-track of ratcheting up food safety by putting preventive measures in place to keep disease-causing STEC out of the food supply.

S.T.O.P. has been working with foodborne illness victims and their families for nearly 15 years. We are aware of many situations involving victims diagnosed with HUS, preceded by bloody diarrhea, but who were not O157 culture-confirmed. Some were never cultured at all. Others were cultured too late, and if they had the O157 strain, the bacteria itself had passed through the body although the toxins remained. And many others, we feel, may have had non-O157 STEC but were not cultured for them.

I want to share with you the story of a S.T.O.P. family where it took 2 years to determine what had taken the life of their 2-year-old daughter, Ana, in 2002. Ana was the youngest of three daughters. The Nelsons lived in Wisconsin, close to the Wisconsin/Minnesota border. The family routinely dined at restaurants and bought groceries in both states. Ana fell very ill and was hospitalized in the Minneapolis/St. Paul Children's Hospital where her condition spiraled into HUS and she died in a matter of days. Her culture for O157 had come in—after her death—as negative. The public health department then did—nothing. Even though she had died from HUS, a syndrome which is closely associated with E. coli poisoning, they were not required to, nor did they, investigate the possible cause of her death.

When Ana's parents returned home, Ana's father had the presence of mind to take his toddler's blood-soiled diapers out of the diaper pail and store them in their deep freeze. While doing some internet research sometime later, he discovered S.T.O.P. and called for our help and support. S.T.O.P. was able to find a lab willing to conduct tests and Ana's father, an airline pilot, air-shipped his daughter's diapers to a lab half-way across the country to get tested.

Lab results detected shigatoxin and it was then that the Minnesota health department agreed to get involved. Another round of lab testing went on that ultimately showed that Ana had died from E. coli O121, a pathogen that was then in 2002, and still is, off the radar screen for both diagnostic testing in humans and as an adulterant in the food supply. In Ana's tragic illness, had non-O157 STEC testing been done, and had its finding been reportable, it could have led to an investigation that might have determined the vehicle of transmission and identified populations exposed to this risk. Had O121 been classified as an adulterant in food, perhaps that food would never have made it into commerce at all, and Ana might be alive today.

I've used a lot of "perhaps" and "might's" and "could have's" in what I've just said. I'm neither a scientist nor a physician, but I will tell you this; I am a very well-educated consumer on the dangers of contaminated foods and the tragic consequences that can result. I cannot stress enough the brutal pain and suffering victims of foodborne illness, and specifically STEC infection, endure as they struggle to stay alive. Nor can you imagine the pain of the survivors.

You have heard a lot of information from doctors and scientists on the subject of STEC, about its ability to infect and kill and I'm not going to reiterate the statistics and studies. One point, however, not raised, is the issue of imported trim used in the production of ground beef. An ARS study published in the Journal of Food Protection this year, titled "Microbiological Characterization of Imported and Domestic Boneless Beef Trim Used for Ground Beef", compared trim produced in the United States, Australia, New Zealand and Uruguay. Their study showed about 30% of the total samples from all four countries were positive for the stx genes, some common, some different. They also identified 11 new STEC serotypes and concluded, "there are many STEC serotypes yet to be identified." Any discussion and decisions on STEC must also take into consideration meat products that we import from other countries that get co-mingled in our domestic food supply. This would apply to non-meat food products that we import as well.

Tests already exist to detect STEC in both humans and in foods. Current tests may have some shortcomings, but remember that testing for O157 also had shortcomings in the beginning. Testing procedures for O157 have improved and evolved as demand increased and testing became more widely used. The technology industry has already identified the need for and exhibited innovation in developing testing methods for non-O157 STEC, even before any significant market demand. And if history can be considered an indicator, it will certainly rise to the challenge of developing even better products as demand for better, faster protocols are expected.

S.T.O.P. is calling on all sectors of industry and government to make the detection and prevention of STEC in our food supply a priority in order to prevent another foodborne illness epidemic like the one 15 years ago.

Specifically:

We are asking FSIS to declare all pathogenic STEC as adulterants, in ground beef and in beef products destined to be ground, under a zero tolerance policy. We are also calling on FSIS to expand its current O157 random testing program to include all pathogenic STEC and to require countries exporting trim to the United States to do the same.

We urge ARS to conduct research on the possibility of swine being a reservoir for STEC and a link, if any, to human illness. FSIS' white paper cited a 2004 study that, "determined that 70% of 687 swine fecal samples tested positive for the presence of Shiga toxin, and found that most of the serogroups isolated have been associated with

human illness.” We find this particularly alarming because of the many sausage products, both RTE and raw, made from ground pork.

We are calling on FDA to develop a meaningful sampling program, for both domestic and imported products, to detect pathogenic STEC in foods most at risk of being contaminated. We also ask that whenever FDA is conducting environmental sampling when doing an investigation on a product, such as spinach which has an historical link to the O157 strain of STEC, that they look for all STEC, and not just a strain that was associated in the product in the past.

We commend the CDC for recommending that physicians and labs routinely screen for all STEC infections when doing stool cultures and for also recommending that states adopt mandatory reporting laws for all STEC infections. We ask that you stress those recommendations even more-so and that you recommend that physicians and labs simultaneously test for O157 and non-O157 shiga toxins. When a child is very ill and the parents are told, “We’re going to test your child for E. coli”, their response is one of extreme panic. If the physician initially tests for only O157 and it comes back negative, valuable time is wasted while additional testing is being conducted, delaying diagnosis and keeping the family in fear. It also delays getting the results to the CDC.

And lastly, industry, please take ownership and leadership in working in a proactive way to prevent another major epidemic by organisms that we know today can be in widely distributed products. Please don’t fight this like you did testing for O157. We’re sorry if it is an inconvenience to you or too costly, but foodborne illness is a lot more than an inconvenience and is very costly.

January 2008 will mark the 15th year-anniversary of the Jack-In-The-Box outbreak. What better way to mark that milestone, and restore public confidence both in the government’s commitment to its citizens’ welfare, than by the USDA’s declaration that ALL potential-deadly E. coli’s as an adulterant in ground beef? It would be a win/win/win...for government, for the food industry that has been shaken by a record number of recalls and foodborne illness outbreaks, and by a nation that is better served and protected from deadly bacteria in their food.

Thank you.