# Safe Tables Our Priority

*America's Voice for Safe Food*

**3149 Dundee Road #276, Northbrook, IL 60062 847.831.3032 www.safetables.org**


May 30, 2008

14

2008-0011
2008-0011-14
Nancy Donley
Donna Rosenbaum

Docket Clerk via Keith Payne
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 1175, South Building
Washington, DC 20250

VIA FACSIMILE (202) 690 6519 and email Keith.Payne@FSIS.USDA.gov

**Re: Docket No. FSIS-2008-0011**
**Shiga Toxin-Producing *E. coli*: Addressing the Challenges, Moving Forward with Solutions**

S.T.O.P.—Safe Tables Our Priority appreciates the opportunity to comment on the initiatives proposed by the Food Safety and Inspection Services (FSIS) at its April 9-10 public meeting.

S.T.O.P. is a national, non-profit public health organization dedicated to preventing illness and death due to pathogens in our food supply by advocating sound public policy, by building awareness of foodborne risk and its management, and providing victim assistance. S.T.O.P. was founded in 1993 in the aftermath of the Jack-In-The-Box *E. coli* O157:H7 epidemic from contaminated ground beef that occurred in California and throughout the Pacific Northwest.

We commend the agency for advancing strong measures to better protect public health against *E. coli* O157:H7 disease despite the intense pushback from the beef industry. 2007 proved that these measures are vital to public health as evidenced by record number of recalls and the Centers for Disease Control and Prevention (CDC) annual FoodNet report that shows no measurable improvement in *E. coli* infections since 2004 with subsequent years actually reporting a slight up tick. S.T.O.P. has long advocated the need for FSIS to broaden its definition of adulterated products to include primal (intact) cuts of meat and the need to aggressively address the incidence of disease-causing non-O157 Shiga toxin-producing *E. coli* (STEC) in the meat supply. We appreciate these initiatives and have several suggestions on how FSIS can make them even stronger in protecting the public's health and safety.

## Non-O157 STEC

S.T.O.P. has been working with foodborne illness victims and their families for nearly 15 years. Among the roughly 5,000 households in our database are victims of non-O157 STEC. Some have survived their illness, some have not. S.T.O.P. has advanced the argument about the need to

address the problem of non-O157 STEC in the food supply over the past 10 years with the CDC, FSIS and the Center for Food Safety and Nutrition (CFSAN). These discussions occurred primarily in a different administration and we are grateful that FSIS is finally addressing this very serious public health threat.

Over the years, S.T.O.P. has been in contact with hundreds of foodborne illness victims or their families who were diagnosed with Hemolytic Uremic Syndrome (HUS), preceded by bloody diarrhea, who were not O157 culture-confirmed. This could happen for a number of reasons. Some were never cultured at all. Others were cultured too late where, if they had the O157 strain, the bacteria itself had passed through the system although the toxins remained. And others, we believe, may have had a non-O157 STEC but were not cultured for them, either because they had not been cultured for *E. coli* at all or because they had been cultured for *E. coli* O157:H7, received a negative result and were never further cultured for a different serogroup.

**The United States does not know the extent of illness and death from non-O157 STEC because it's not looking for it.**

The October 17, 2007 public meeting that launched this discussion, "The Public Health Significance of Non-O157 Shiga-toxin Producing *Escherichia coli* (STEC)" had several presentations from other countries where non-O157 STEC are more prevalent than O157, where they laid out their country's response to an obvious public health concern. We have those same STEC here and should be responding accordingly.

Furthermore, in 2007 the United States imported 1.3 billion pounds of beef trim, ground beef or other components of ground beef from Australia, Canada, New Zealand, Nicaragua and Uruguay, all countries with higher prevalence of non-O157 STEC, including the six identified by CDC as of concern here in the United States. These 1.3 billion pounds represents 22% of the materials used for producing ground beef domestically.[1] But until we develop a domestic policy on non-O157 STEC in meat, we cannot require countries that export to the United States to adopt sampling programs to prevent non-O157 STEC-contaminated product from entering our borders. This clearly represents a public health risk.

The beef industry made several allegations in its letter presented on April 10, 2008 at the public meeting regarding non-O157 STEC. In its letter they stated:

> "At the public meeting held in October of '07, CDC reported though (sic) outbreaks linked to non-O157 STECs from beef. The scientific literature clearly indicates that not all serotypes of STEC are pathogenic to humans and much is still unknown concerning virulence factors and their relationships to human disease. FSIS has no published validated and accepted laboratory protocol for determining pathogenic STEC in beef and many analytical changes remain related to adopting laboratory methodology for industry

[1] Sally White, Director, International Equivalence Staff, Office of International Affairs, FSIS in her presentation, "*E.coli* O157:H7 and Certain Beef Exporting Countries" at the April 9-10, 2008 public meeting.

use. Given these facts, declaration of all non-O157 STECs as adulterants is not technologically feasible, nor would it be a wise use of food safety resources."[2]

S.T.O.P. agrees that not all non-O157 STEC present the same level of risk of debilitating illness to consumers. The Centers for Disease Control and Prevention (CDC) has identified six serogroups of concern—O26, O111, O103, O121, O45 and O145. These six serogroups have been associated with HUS and death in foodborne illness victims.

**We urge FSIS to, at a minimum, immediately declare these six serogroups, in addition to O157:H7, as adulterants in all beef products and to immediately expand its testing regimen to include them. S.T.O.P. has no objection to FSIS' plan to conduct a baseline study to determine prevalence but we do object to it as preclusion in declaring them as adulterants, thereby putting the public's health and safety at continued risk.**

Extensive data exist showing these pathogens to be found in both animal reservoirs and contaminated humans; pathogens that have been proven to cause serious adverse health effects to humans. There is no excuse for delay.

Furthermore, S.T.O.P. rejects industry's assertion that "declaration of non-O157 STEC as adulterants is not technologically feasible". Technology follows policy. Technology is much farther advanced and progressive than it was 15 years ago when *E. coli* O157:H7 was declared an adulterant. 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. This is true for testing both in humans and food products. Current tests may have shortcomings but one must recall that tests for O157 evolved as demand increased and testing became more widely used. S.T.O.P. has no doubt in the technology industry's being up to the challenge of developing faster and better testing protocols as it did when O157 was declared an adulterant.

Lastly, we are appalled by industry's claim that this would not be a wise use of food safety resources. People **die** from these pathogens. Industry's attempt to dodge what's best for the health and safety of consumers because of added cost and inconvenience to the industry is shameful. And FSIS would be disavowing its public health mission if it does not move immediately on declaring these six serogroups adulterants.

## Adulterated Primal Cuts of Beef

Pathogenic *E. coli* can and does kill people, not just from ground beef or beef trimmings or beef products destined to become ground, as are now the categories deemed adulterated by FSIS. We don't know the scope of illness and death from intact cuts of beef because we're not looking for it. The issue of cross-contamination is one that is chronically overlooked, or ignored, by all sectors of society. But S.T.O.P. knows for a certainty that it exists.

[2] Transcript from the April 9-10, 2008 public meeting "Shiga Toxin-Producing *E. coli*: Addressing the Challenges, Moving Forward With Solutions", p.438-439, of a letter submitted by the Beef Industry Food Safety Council (BIFCo).

The 2000 Sizzler *E. coli* O157:H7 outbreak is a sobering example of cross-contamination from contaminated intact meat to another food, in this case watermelon. The Wisconsin Department of Health reported 62 confirmed cases linked to food eaten at a local Sizzler restaurant. 23 people were hospitalized including four who developed HUS. Tragically, little 3-year-old Brianna Kriefall, died from her infection. In addition to confirmed cases, there were another 551 probable cases reported, linked by strong epidemiological evidence, and another 122 possible cases.[3] The State Health Department stated in its conclusion:

> "Based on the results of the case-control study, the test results of the opened and intact food samples from the restaurant and the conclusions of the restaurants inspections, it is most probable that the watermelon was the vehicle for infection, cross-contamination of fresh watermelon with raw meat product was the mechanism by which the vehicle became contaminated, and the raw sirloin tri-tips product was the mechanism by which the vehicle became contaminated, and the raw sirloin tri-tips were the source of *E. coli* O157:H7 organisms in this outbreak." [4]

In October 2007, *E. coli* O157:H7-contaminated London broil was found to be the vehicle in a foodborne illness outbreak in North Carolina in which there were 83 cases, 4 of which were culture-confirmed; 2 required hospitalization with one evolving into HUS.[5] And on March 26, 2008, 14 people were sickened, including a 7-year-old child, and four people hospitalized from *E. coli* O157:H7-contaminated roast beef served at a reception hall in Sarpy County Nebraska. Garlic cloves were inserted into the meat, possibly pushing the bacteria into the interior of the meat that didn't reach a temperature sufficient to kill it. These examples totally refute industry's claim that, "Steaks and roasts from intact beef have not been implicated in foodborne illness."[6]

FSIS has found evidence that non-designated primal cuts are **not** (emphasis FSIS) being treated similarly as boneless manufacturing trimmings regarding interventions and testing and that a substantial amount of primal cuts are used as source material for non-intact beef.[7]

The industry letter further states, "Based upon available research, the prevalence of O157:H7 on the surface of sub-primals is rare."[8] They base their conclusion on two self-funded studies and make no mention of their having been peer-reviewed and published. S.T.O.P. cannot put any

---

[3] "PREEMPTING FOOD SAFETY: An Examination of USDA Rulemaking and its *E. coli* O157:H7 Policy in Light of *Estate of Kriefall ex rel. Kriefall v. Excel Corporation*", Dennis Stearns, Fall 2005 "Journal of Food & Law Policy".
[4] Ibid.
[5] David Bergmire-Sweat, MPH North Carolina at the May 15-16, 2008 meeting and round-table exercise, "USDA Better Communications, Better Public Health Outcomes—Strategies for Improved Communications During Foodborne Outbreaks" in St. Louis, MO.
[6] Transcript from the April 9-10, 2008 public meeting "Shiga Toxin-Producing *E. coli*: Addressing the Challenges, Moving Forward With Solutions", p.437, of a letter submitted by the Beef Industry Food Safety Council (BIFCo).
[7] Daniel Engeljohn, Deputy Assistant Administrator, Office of Policy and Program Development, "Treatment of Primal Cuts", April 9, 2008 meeting.
[8] Ibid, p. 436

merit on self-serving studies such as these and neither should FSIS in making public health policy decisions.

## N-60 Testing Regimen

S.T.O.P. has several areas of concern regarding the use of an N-60 testing regimen as a verification program for *E. coli* O157:H7. One is that the United States government is allowing an industry-sponsored protocol that has not been published, peer reviewed or open to public debate to be used as an accepted standard in a public health-based verification program. Another is that N-60 testing is totally inadequate in detecting to the estimated prevalence level of this pathogen in beef.

From what S.T.O.P. can ascertain, the N-60 testing program seems to have been developed by the beef industry.

> "Tyson Total N60™ is a nickname for a Tyson-developed, extremely comprehensive and sensitive testing system to prevent *E. coli* O157:H7 from contaminating ground beef. Tyson tests all raw beef components destined for ground beef production. The Tyson Total N60™ program provides a 95 percent or greater assurance of finding and eliminating
> *E. coli* O157:H7 from beef which is used for ground product. Tyson Total N60™ is among our most powerful food safety tools, as it augments the other antimicrobial programs. It is so powerful that it has been adopted across the industry **and recognized by the USDA** (emphasis added). Tyson believes that programs such as Tyson Total N60™ that find and remove O157:H7 containing meat from the ground beef supply chain, have contributed significantly to the significant decline in incidence the U.S. over the last several years."[9]

It is clear that N-60 was industry developed. S.T.O.P. cannot find any peer-reviewed science supporting its use as a reliable detection tool for *E. coli* O157:H7. Had it been peer-reviewed, we believe that it never would have been adopted.

**Confidence Levels**

N-60 is based on a totally flawed premise that it provides a 95% confidence level in detecting the presence of O157. This is completely incorrect and totally misleading. **The ICMSF calculator or chart clearly states that for there to be a 95% confidence level, prevalence levels of O157:H7 would have to be at 5% or higher.** With conservative estimates of the prevalence of O157:H7 in trim at somewhere between 1-2%, N-60 is extremely ineffective as a tool in finding it because it doesn't detect down to a level low enough. This would have become crystal clear had the program been peer-reviewed.

Specifically, at a 1% prevalence rate, there would need to be N298, not N-60 for a 95% confidence level. At a 2% prevalence rate, there would need to be N148 for a 95% confidence

[9] Dr. Richard Roop, testifying before the House Agriculture Committee on behalf of Tyson Foods, October 30, 2007.

level. **At N-60 and with a 1.0% prevalence rate of O157 the confidence levels plummets to only 45%; at 1.5% it's at 60%; and at 2.0% the confidence level is a mere 70%.** This is key information that Tyson Foods, in promoting this system to USDA and in testimony before Congress, irresponsibly neglects to mention. Furthermore, it is very alarming to S.T.O.P. that USDA either did not do the math themselves and just blindly accepted the industry's information, or worse, were comfortable with a 45-70% confidence rate as being sufficient to protect public health from a deadly pathogen.

The Beef Industry Food Safety Council (BIFSCo) says that the N-60 level of sampling "should be sufficient to identify **highly contaminated** (emphasis added) lots of product".[10]

S.T.O.P. finds this to be very enlightening about the true abilities of N-60. Identifying "highly contaminated" lots may be appropriate for indicator organisms, it is astoundingly inappropriate for O157 control. Why would there only be concern for highly contaminated lots when this pathogen is so virulent that as few as 10 organisms can cause devastating human disease and death?

## Lot size

From what S.T.O.P. can ascertain, N-60 has been in place since 2004, presumably as a tool for detecting the presence of *E. coli* O157:H7. As stated previously, S.T.O.P. has not been able to find any peer-reviewed science upon which the move to N-60 was based, and is skeptical that due to the originally misstated confidence level of 95%, that it was ever appropriate as a tool for *E. coli* O157:H7 control. That being said, decisions made over time, seem to have eroded its effectiveness even further and have been based on conjecture and pressure from the industry and have not been based on unbiased science.

For example, prior to N-60, policy dictated that if any contaminated product was found, the company would have to discard or divert all product produced from the same lot from clean-up to clean-up, sometimes a full days worth of production. When N-60 began in 2004, companies were allowed to make their own determination of lot size. Most companies, and FSIS, recognized 5 combos as the norm, with no clean up required between each lot. N-60 was conducted taking 12 samples from the tops of each of the 5 combos. In early 2007 the decision was made that it is acceptable to use on N-60 testing on just a single combo and then allowing all of 5 combos worth of product to be released if the N-60 results came back negative. Once again, this decision was based on faulty reasoning and not peer-reviewed science.

While ostensibly you do have a greater chance of finding O157:H7 if a sample size of 60 is taken in 1 lot versus spread out over 5, we still have the problem of only a 45-70% confidence level of detecting it. So now companies are being allowed to test a single combo, and based upon a negative result, are allowed to declare the entire lot as negative and to release all 5 combos. **S.T.O.P. does not agree that a negative N-60 result in a single combo can be interpreted to include the other four. The fact that N-60 in and of itself is inadequate to detect to the**

[10] BIFCo "Best Practices for Using Microbiological Sampling", March 2008.

**estimated level of prevalence of O157 makes it all the more inexcusable as a public health policy.**

**S.T.O.P. requests clarification from FSIS on what industry is currently allowed to do if a single combo is found positive as the result of N-60 testing. Must the other 4 combos also be diverted or destroyed or is industry allowed to conduct additional sampling on the other 4, and if found negative, are they allowed to release the product?**

**Economic Incentive Versus a Public Heath Policy**

S.T.O.P. suggests that this policy is rooted in economical advantages for industry rather than the promotion of public health.

> "A better improvement would be a reduction of lot sizes, he said. Not only would this increase detection sensitivity, it would reduce the beef processor's liability should the test run positive, as less potentially contaminated product would need to be diverted.
>
> Where a product is tested during the process also is an important factor, particularly as it relates to homogenized products such as ground beef, for which it may be more effective to test the finished product, but also is less efficient. The problem with testing after the beef is ground, Seward said, is "you have all that additional value in the product." Discovering the pathogen in finished ground beef is very costly."[11]

What's important here is that industry liability and the economics of not wasting product are the clear objectives, not public health. Dr. Seward's statement about the better efficacy of finished product versus trim testing in finding O157 is an assertion that S.T.O.P. has been making after 15 years of researching and studying the issue.

Tyson Foods, in promoting the N-60 program to FSIS, represented that their own internal data showed trim excision testing to be more effective in detecting O157 then end product testing. S.T.O.P. wants to know where the peer-reviewed scientific literature is on this issue. S.T.O.P. has asked FSIS for copies of these studies showing the efficacy of testing trim vs. ground product and we have yet to see them. It may be that trim testing should only be done when product intended for ground beef changes hands, such as from the slaughter facility to a further grinder. However, if testing ground product is more effective at finding this elusive and devastating product, then all companies who maintain control over the product from slaughter through the grind ought to be testing after the grind. This needs to a topic for further study and public debate.

## Process Control

[11] Skip Seward, Vice President of Regulatory Stewardship for the American Meat Institute, "Quality Assurance Magazine", January 3, 2008.

It appears to S.T.O.P. that over the last several years FSIS has allowed a series of new policies that make it much more likely to have larger volumes of untested and unsampled product on the market. We hypothesize that it may not be a coincidence that when N-60 of a single combo became the norm in early 2007, that a large increase in *E. coli* O157:H7-contaminated ground beef flooded the marketplace. Over time as N-60 has evolved there is a disincentive for companies to adequately put controls in place for O157:H7 because a positive finding, unlikely to be found because of the inadequacies of the N-60 program, will only lead to the diversion of, at most, 5 combos of product, far less than what used to occur when there was a "clean-up to clean-up" policy in place.

Furthermore, under HACCP the USDA application of the seal of inspection is supposed to be dependent on continuous demonstration that a plants process is in control. N-60 has been instituted and encouraged with very little oversight by FSIS that S.T.O.P. is aware of and no consequences for mishandling or improperly taking samples. If a company takes only 30 samples instead of 60, there are no consequences. If a company irresponsibly takes internal instead of external samples, there are no consequences. Even BIFSCo in their guidance document of March 2008 entitled "Best Practices for using Microbiological Sampling" states that proper sampling is key to the success of the N-60 program. Because of the lack of oversight by USDA on the N-60 in-plant sampling, USDA is putting the seal on product without continuous demonstration that the plants process in control.

The reliability of N-60 testing as a "best practice" for verifying control of *E. coli* O157:H7 is a very slippery slope which relies on a long string of suppositions that are not even close to being factual or true. The first of these is that to have the required confidence level in N-60 testing, the prevalence of the pathogen in the product needs to be minimally at 5%. From what we know, even conservative estimates place the prevalence at 2% and it may well be under 1%, particularly during seasonal times of low prevalence.

The second assumption is one of point source contamination which ignores the cross-contamination issue.

The third assumption is one of sampling integrity and best practices in sampling being done by the plants without any oversight by FSIS. This assumption was disproved by the information provided from in-plant data and presented by Dr. Samadpour at the April 9$^{th}$ meeting.

S.T.O.P. has many unanswered questions about what is done with the results of the testing program. How many positives lead to HACCP plan reassessment? Is there any mandatory requirement for address of problems in the plant even when there are multiple positives in a short time period. An effective regulatory program based on public health would have all of this laid out and set into standards before permitting product to enter the marketplace. Is anyone required to keep track of volume of diverted product in U.S. plants as a measure of *E. coli* control? If plants can hide contaminated product by diverting it to cooking there is another disincentive vs. public disclosure of this information.

**A Public Meeting on Sampling/Testing**

Peer-reviewed science seems to be missing from every step of the decision making process in changing policies on ground beef and beef trim sampling protocols. Starting at the beginning, we need clear concise data on prevalence in the various product classes before even contemplating an adequate sample testing number.

We need continuous data on seasonal variances in this prevalence in order to make science-based policy decisions. It is inconceivable to S.T.O.P. that 15 years after the Jack-in-the-Box outbreak we still don't have this data and that we're attempting to control a deadly pathogen in the dark.

Furthermore, by its own admission, FSIS, after consultation with ARS and industry scientists, decided to use N-60 testing to determine prevalence in the current baseline study underway.[12] We do not believe this to be a literature-supported decision and believe that the results may be skewed as a result of the inaccurate confidence level of the N-60 program. At the very least this decision should have been subject to an open debate and question period by all constituents before USDA started down this path.

What S.T.O.P. finds most objectionable is that these new sampling policies revolving around using an N-60 standard testing program have been adopted behind closed doors, with a lot of industry data and input and very little if any transparency.

**At this point USDA needs to re-visit the policies surrounding N-60 testing and have an in-depth extensive public meeting on the sampling of beef in regulatory protocols. If this had happened before these new polices were instituted perhaps the large *E. coli* burden on the economy and threat to public health of 2007-2008 could have been avoided.**

In summary, the N-60 testing program for determination of *E. coli* O157:H7 control is arbitrary at the least, is subject to abuse due to little USDA oversight, and at its best will not provide a public health-based confidence level needed specifically for control of *E. coli* O157:H7. A public meeting on sampling will help identify the systemic weaknesses in the current testing program and give all stakeholders the opportunity to advocate for something better.

## Conclusion

S.T.O.P. again wants to reiterate its strong support of FSIS' intention to strengthen public health protections by extending the definition of adulterated to include all beef products.

We cannot urge USDA strongly enough to immediately declare an additional six serogroups of *E. coli*—namely O26, O111, O103, )121, O45 and O145—as adulterants in all beef products and to immediately begin testing for them in conjunction with *E. coli* O157:H7. A baseline study must not be a preclusion to enacting this public health strategy immediately.

[12] Loren Lange, Deputy Assistant Administrator, Office of Public Health Science, "Beef Trim Baseline Results and How FSIS Will Use Them", *E. coli* Public Meeting, April 9, 2008.

The N-60 program is fraught with problems and can be seriously putting the public at risk by not detecting to low enough levels in preventing *E. coli* O157H7-contaminated product from being identified and shipped into commerce. FSIS should immediately host a public hearing to discuss this sampling program in particular and also host of general discussion on the systemic weaknesses in developing sampling policies.

Respectfully submitted,

Nancy Donley
President and mother of Alex (1987-1993)

Donna Rosenbaum
Executive Director