



December 21, 2011

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Docket Clearance Unit 8-164
Patriots Plaza III
355 E Street SW
Washington, DC 20024-3221

Re: Docket No. FSIS-2010-0023: Final Determination and Request for Comments; Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products; 76 *Fed. Reg.* 58157 (Sept. 20, 2011)

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority and to that end, the industry shares a common goal with the Food Safety and Inspection Service (FSIS or the agency) of ensuring the safety and wholesomeness of meat and poultry products. AMI members have implemented many food safety processes and procedures that go beyond current FSIS regulations and continue to ensure that the meat and poultry products they produce are safe, wholesome, affordable, and available.

The policy announced in the agency's September 20 *Federal Register* publication, *Final Determination and Request for Comments; Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products* (Determination), is flawed in several important aspects. In that regard, the infirmities in the

agency's reasoning, and the absence of legitimate support for the final determination is best captured by the agency's own words:

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.¹

AMI submits the following comments regarding the Determination and in doing so respectfully requests that FSIS delay the policy's effective date until a more complete analysis of its implications are understood.

The Draft Risk Profile Lacks Support for the Shiga Toxin-Producing *Escherichia coli* (STEC) Determination

It is critical that the Determination be based on sound scientific rationale upon which the agency and the affected industry can rely. Unfortunately, that is not the case here. FSIS offered as support for the Determination a "Draft Risk Profile," (the Profile) which poses to an expert panel of three reviewers a series of questions. Significantly, as the agency acknowledges in its summary, the reviewers' comments "raised a number of concerns about the strength of the evidence presented in this Risk Profile for drawing conclusions regarding the actual risk associated with non-O157." Indeed, noteworthy is the fact that the Profile is "draft" and its "incompleteness" is highlighted by the fact it provides that "FSIS will continue to study this issue and update the Risk Profile as information becomes available."

Indeed, several elements of the Profile's "Findings" highlight the absence of information and data regarding this issue.

"(1) What are pathogenic non-O157 STEC, and how can they be distinguished from other STEC? ...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

¹ 76 *Fed. Reg.* 58164.

causing severe human illness to be a pathogenic STEC.
(Emphasis added.)²

(2) Are pathogenic non-O157 STEC present in cattle, and beef, including ground beef? 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. (Emphasis added.)³

(3) Would traditional and accepted cooking practices for raw ground beef kill pathogenic non-O157 STEC? We provide evidence suggesting that traditional and accepted cooking methods would destroy *E. coli* O157:H7 and pathogenic non-O157 STEC at similar rates. However, experiments designed to directly address the question have not been completed. (Emphasis added.)⁴

(4) Can small numbers of pathogenic non-O157 STEC cause illness? ... This evidence is based on outbreak data that does not provide detailed dose-response information, nor is it specific to outbreaks associated with beef. (Emphasis added)⁵

(6) Can pathogenic non-O157 STEC spread from person to person causing illness in settings such as day care facilities?although again, studies that specifically examine the role of secondary transmission of non-O157 serogroups of interest are not available. (Emphasis added.)⁶

In short, the findings that FSIS included in the Profile acknowledge a lack of scientific consensus, the absence of baseline data that indicate the national prevalence, and the fact that experiments designed to answer

² *Draft Risk Profile for Pathogenic for Non-O157 Shiga Toxin Producing Escherichia coli*, Office of Public Health Science, Office of Policy and Program Development, Food Safety and Inspection Service, United States Department of Agriculture, August 2011, at 5.

³ *Id.*

⁴ *Id.* at 5-6.

⁵ *Id.* at 6.

⁶ *Id.*

questions presented have not been done. And all of this speculation is done against a background in which the agency admits that the “majority of non-O157 STEC infections are attributed to non-beef food sources.” Indeed, it may well be more than a majority because previous Centers for Disease Control and Prevention (CDC) outbreak data, not estimates, indicated that there has been only one outbreak in the U.S. attributable to STEC in beef products.⁷

More instructive than the varnished perspective included in the Profile’s Executive Summary are the comments provided by the agency’s independent peer reviewers, who raised a number of concerns about the strength of the evidence, and the conclusions from same, presented in the Profile. In that regard, Reviewer 1 pointedly stated, “[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.”⁸

In challenging the agency’s rationale for expanding the definition of pathogenic STEC to include *E. coli* serotypes beyond *E. coli* O157:H7 that same reviewer stated that missing from the information provided is:

Specific evidence about the relative contribution of O157 and non-O157 STEC to severe disease in the US today. Throughout this document, evidence about the frequency and severity of non-O157 is presented to maximize their apparent importance, and this presentation is not balanced by inclusion of specific information comparing the amount of severe disease that results from these two categories of STEC. Specifically, there is insufficient attention to the etiology of HUS. Yes, non-O157 STEC are known to occasionally result in HUS, but what percentage of HUS in the US today is actually attributable to non-O157 STEC. The evidence in the literature is that >80% of HUS is attributable to O157 STEC, but one would not learn that from this document.⁹

⁷ Interestingly, that reference is not currently included in the CDC Foodborne Outbreak Online Database. <http://wwwn.cdc.gov/foodborneoutbreaks/>. Accessed December 9, 2011. 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 three illnesses in New York and Maine.

⁸ *Peer Review Comments and Responses to the Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing Escherichia coli (non-O157 STEC)*, Office of Public Health Science, Office of Policy and Program Development, Food Safety and Inspection Service, United States Department of Agriculture, August 2011, at 42.

⁹ *Id.* at 3.

Moreover, that Reviewer also cited the lack of:

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. (Emphasis added)¹⁰

Similarly, independent Reviewer 3, although more diplomatic than Reviewer 1, cited deficiencies involving the agency's understanding of the "virulence profile" and problems with the "diagnostic methods for the isolation of non-O157 STEC" as reasons to assert that "the scientific basis of the assessment needs to be strengthened from what is described in this document."¹¹ That there are other problems identified by the reviewers is indisputable and, notwithstanding rationalizations offered by FSIS in response to those problems, those concerns highlight the need to develop more thoroughly the scientific foundation of this policy before its implementation, if warranted.¹²

CDC Data Support the Uncertainty Identified in the Draft Risk Profile.

The concerns expressed by the reviewers regarding the absence of data to support the announced policy is confirmed by a review of CDC data.¹³ Specifically, CDC data regarding the 14,091 foodborne outbreaks for 1998-2009 show that there were 383 total *E. coli* related outbreaks for all foods, with 340 of those attributable to *E. coli* O157:H7 and 12 were attributable the six STEC at issue in the policy.¹⁴ More telling is the fact that of the 340 outbreaks attributed to *E. coli* O157:H7, 113 were beef related and most

¹⁰ *Id.* at 4.

¹¹ *Id.* at 5.

¹² For example, Reviewer 3 cited the agency's use of certain studies and asserted that such use artificially amplifies the Risk Profile of disease-causing STEC on carcasses and in beef. Likewise, in the reporting and assessment of the risks, the drawing of comparisons between O157 risks and "all" other STEC provides an exaggerated impression of the true risk. See *Id.* at 8.

¹³ See Attachment A.

¹⁴ CDC Foodborne Outbreak Online Database. <http://wwwn.cdc.gov/foodborneoutbreaks/>. Accessed December 9, 2011.

significantly, none of the 12 attributable to the six STEC were beef related.¹⁵ (Emphasis added.) In August 2010, the agency announced a recall of ground beef that may have been contaminated with *E. coli* O26. To our knowledge this is the only foodborne outbreak associated with the six STEC at issue in the policy. As the reviewers of the Profile make abundantly clear, one outbreak is insufficient to adopt the announced policy, particularly given the problems and challenges discussed below that such a policy will create.

FSIS Should Conduct a Baseline Survey of STEC on Certain Raw Beef Products to Determine a Need for the Policy

Related to the infirmities of the Profile, FSIS should conduct a baseline survey of non-O157 STEC on beef products including carcasses, ground beef, and raw materials used to manufacture ground beef. That survey, however, should not focus solely on prevalence. For example, including trends in process changes and product design due to market demands would be beneficial. Since the 2007 survey, the industry has implemented improved trim and ground beef interventions that have had a positive impact on *E. coli* O157:H7 levels in ground beef. A baseline survey to demonstrate prevalence of STEC by market segment and producer size would fill a “knowledge gap” identified in the Determination. Moreover, data generated by a broad baseline survey would also provide the agency with support for a more focused and effective regulatory program should one be deemed necessary.¹⁶

A Validated, Commercially Viable Analytical Laboratory Test Method is Needed Before any Policy can be Implemented

A critical issue that has been repeatedly discussed but FSIS has not adequately addressed is the absence of commercially available diagnostic methods to isolate non-O157 STEC. For instance, recognizing the challenges attendant to testing for STEC in the Profile, Reviewer 3 stated that the “diagnostic methods for the isolation of non-O157 STEC are currently quite

¹⁵ *Id.*

¹⁶ Interestingly, FSIS previously acknowledged the importance of a baseline study and suggested that no action would be taken regarding STEC until a study had been completed, and the results made public: “FSIS will soon begin testing ground beef and ground beef components for the presence of the selected non-0157 STECs, the six serogroups Now, the primary objective, initially, is going to be to determine the magnitude of the issue. Once we get a handle on that, we can determine whether a regulatory program is warranted and how we would go about implementing such a program. Dr. Elisabeth Hagen. *Shiga toxin-producing E. coli: addressing the challenges, moving forward with solutions*, April 9, 2008 http://www.fsis.usda.gov/PDF/Ecoli_transcript_040908.pdf.

crude, with around a 10% (or less) recovery rate from PCR-positive samples.”¹⁷

The ramifications attendant to the absence of a commercially viable test method cannot be overstated. Very recently, former Agricultural Research Service researcher Dr. Mohammed Koohmaraie estimated that “confirmed positives for O157 and the so-called ‘Big 6’ strains of non-O157 Shiga toxin-producing *E. coli* (STEC) will be 5 to 10 times higher than currently for O157 alone,”¹⁸ which will result in a notably higher percentage of meat products being diverted to cooking. Dr. Koohmaraie indicated that the “first screening will find a large number of samples to be 'potential positive'.”¹⁹

The agency asserts in the Determination that the development of a test method now allows for implementation of a program to control STEC.²⁰ The method put forth by FSIS, however, does not appear to have been adequately peer-reviewed. Indeed, as with other elements of this Determination, the scientific reports of validation studies have not been published and the continued refining of the method has made validation of commercially available methods extremely difficult to complete within the allotted time. Accordingly, the validity of the studies cannot be evaluated, repeated, or copied by commercial kit suppliers, or exporting countries, which will be required to implement a test program equivalent to that implemented by FSIS.

Thus, the absence of a commercially validated viable test method will cause havoc not only for the domestic industry, imposing substantial costs and will cause U.S. trading partners to consider the value of trade with the U.S., as well as raising questions about the policy’s compliance with our country’s trade obligations. Accordingly, it is imperative that an accurate, precise and commercially available test method be available before any policy is implemented.

¹⁷ *Peer Review Comments and Responses to the Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing Escherichia coli (non-O157 STEC)*, Office of Public Health Science, Office of Policy and Program Development, Food Safety and Inspection Service, United States Department of Agriculture, August 2011, at 5.

¹⁸ <http://www.foodsafetynews.com/2011/11/under-big-six-ecoli-policy-more-positives-predicts-expert/>.

¹⁹ *Id.*

²⁰ 76 *Fed. Reg.* 58159.

The Policy Announced by FSIS Violates the United States' Trade Obligations under the World Trade Organization

At the December 1 public meeting teleconference, the agency again was apprised that the announced policy likely contravenes the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (Agreement). Several governments have expressed concern that the declared policy violates the U.S.'s WTO obligations under Article 5 of that Agreement.

Those comments reference the fact that STEC other than *E. coli* O157:H7 are not considered a major public health concern and, as discussed earlier, the Profile confirms that the vast majority of non-O157 STEC infections are attributed to non-beef food sources. Moreover, conducting a thorough risk assessment that clearly and irrefutably demonstrates the public health ramifications of non-O157 STEC on beef is required pursuant to Article 5 of the Agreement and is necessary in order to demonstrate that the U.S. is not creating a non-tariff trade barrier. Finally, the uncertainty discussed above regarding the reliability and availability of test methods also at odds with satisfying WTO requirements. These facts raise legitimate questions as to whether testing for these serotypes is scientifically justified, particularly given that baseline studies have not been completed.

Testing for *E. coli* O157:H7 Serves as an Indicator for STEC

Process management systems are used by the beef industry 1) to assess the adequacy of control within a food safety program using microbiological monitoring and 2) to make decisions in mitigating the risk of *E. coli* O157:H7 (O157) on beef products. Given the history of STEC outbreaks and the industry's success in reducing O157 prevalence in beef products, O157 is likely the best microorganism to target in reducing risk when consuming beef products because the number of confirmed illnesses within the U.S. has been attributed more to O157 than to STEC.

In the August 2011 issue of the *Journal of Food Protection*, FSIS published a review examining the role of indicator organisms in meat and poultry slaughter operations for use in process control.²¹ Saini and others stated that indicator organisms "are those organisms whose presence in numbers above certain limits indicates inadequate processing for ensuring that pathogens would not be present or would be present in small numbers,

²¹ Saini PK, Marks HK, Dreyfuss MS, Evans P, Cook Jr LV, and Dessai U. 2011. Indicator organisms in meat and poultry slaughter operations: their potential use in process control and the role of emerging technologies. *J. Food Prot.* 74: 1387-1394.

assuming the organism was present, at possibly high levels, before the processing step of concern.”²² Index organisms are organisms “whose presence in numbers above certain limits indicates the possible presence of ecologically similar pathogen.”²³ As an establishment examines how to develop or reassess a food safety process management system, it is necessary to identify index and indicator organisms that correlate to targeted pathogen hazards when determining process control factors.

Beef establishments may struggle to assess the contamination risk between O157:H7 and the six STEC that the subject of the Determination and all other STEC because delineation is difficult. In the current regulatory ideology, O157:H7 can be identified as both the index organism and indicator organism for the target STEC pathogens in beef establishments.

Using Saini’s definition, O157:H7 is a logical index organism for STEC in ground beef products and the components that make up ground beef products. This conclusion is supported by the fact that O157:H7 and STEC outbreaks follow the same, typical beef seasonal pattern with increased incidences associated with summer months.²⁴ It is also not uncommon for multiple etiology outbreaks to occur among STEC, which is logical because STEC microorganisms originate from the same source and sources of contamination are the same within the food production chain.²⁵

O157:H7 also qualifies as an indicator organism for STEC in ground beef products and the components that make up ground beef products because both O157:H7 and STEC originate from the same source – cattle. During the slaughter process, STEC follow the same vectors of contamination transfer, *i.e.* hides, hooves, rumen contents, as *E. coli* O157:H7.²⁶ A robust *E. coli* O157:H7 food safety process management sampling program, *i.e.* N60-Trim, is currently used by beef establishments to assess multiple-hurdle intervention capabilities and individual plant performance, as well as providing valuable historical baseline data for trend analysis and continuous plant improvement.

²² *Id.*

²³ *Id.*

²⁴ Mody R and Luna RE. 2011. Surveillance for Non-O157 STEC Infections and Outbreaks, United States. Presentation to BIFSCO Blue Ribbon Task Force. Atlanta, GA. January 5, 2011.

²⁵ *Id.*

²⁶ Barkocy-Gallagher GA, Authur TM, Rivera-Betancourt M, Nou X, Shackelford SS, Wheeler TL, and Koohmaraie M. 2003. Seasonal prevalence of shiga toxin–producing *Escherichia coli*, including O157:H7 and non-O157 serotypes, and *Salmonella* in commercial beef processing plants. *J. Food Prot.* 66: 1978–1986.

These robust sampling plans for *E. coli* O157:H7 are effective and will continue to be effective if O157:H7 is an indicator organism for STEC contamination, because it would provide (i) an understanding of how the indicator organism's presence at high levels reflects probable process deficiencies; (ii) acceptance that actions to improve the process may eliminate or reduce the number of indicator organisms; and (iii) that said actions could affect the levels or presence of pathogens.²⁷ The meat industry has initiated research to show that the process control management systems currently employed are effective against STEC as the originating source of the contamination is the same as O157:H7.²⁸ Assuming a failure in a food safety process control, this research demonstrates not only higher levels of O157:H7, which would indicate the possibility of greater incidence of STEC subject of the Determination, but also that any corrective actions that are effective for O157:H7 would also be effective for STEC subject of the Determination.

The beef industry has a long history of controlling and measuring O157:H7 in ground beef products and the components that make up ground beef products, which provides the industry critical information needed to select an indicator organism -- prevalence of the indicator, ease of finding the indicator, as well as the purpose of use and the correlation between the indicator and targeted pathogen growth and inactivation kinetics.²⁹

²⁷ *Supra* footnote 17.

²⁸ Geornaras I, Yang H, Andritsos N, Fouladkhah A, Manios S, Moschonas GD, Nunnally MC, Belk K, Nightingale KK, Woerner DR, Smith GC, and Sofos JN. 2011. AMI Foundation funded Final Report: Evaluation of chemical decontamination treatments for beef trimmings against *Escherichia coli* O157:H7 shiga toxin-producing *E. coli* and antibiotic resistance and susceptible *Salmonella* Typhimurium and *Salmonella* Newport. <http://www.amif.org/research/10-119/>. Accessed September 2, 2011; Kalchayanand N, Arthur T, Bosilevac J, Brichta-Harhay D, Schmidt J, Wang R, Shackelford S, and Wheeler T. 2011a. AMI Foundation funded Final Report: Efficacy of commonly used antimicrobial compounds on decontamination of Shiga toxin-producing *Escherichia coli* serotypes O45, O121, and *Salmonella* inoculated fresh meat. <http://www.amif.org/research/10-113/>. Accessed November 21, 2011; Kalchayanand N, Arthur T, Bosilevac J, Schmidt J, Wang R, Shackelford S, and Wheeler T. 2011b. AMI Foundation funded Final Report: Evaluation of the efficacy of commonly used antimicrobial interventions on shiga toxin-producing *Escherichia coli* serotypes O26, O103, O111, O145, and O157. <http://www.amif.org/research/09-112/>. Accessed September 2, 2011; Pohlman F, Ricke S, Dias-Morse P, Mohan A, Milillo S, Cook P, and Beers K. 2011. AMI Foundation funded report: Antimicrobial interventions/application methods for the reduction of *Escherichia coli* O157:H7 and *Salmonella* in beef trimming and/or ground beef. <http://www.amif.org/research/10-107/>. Accessed September 2, 2011.

²⁹ Anonymous. 2011. Private conversations with American Meat Institute Foundation staff regarding *E. coli* O157:H7 and STEC incidence in beef establishments; Arthur TM, Barkocy-Gallagher GA, Rivera-Betancourt M, and Koohmaraie M. 2002. Prevalence and characterization of non-O157 shiga toxin-producing *Escherichia coli* in commercial beef cattle processing plants. *Applied and Environmental Microbiology*. 68: 4847-4852; Bosilevac JM and Koohmaraie M. 2011. Prevalence and characterization of non-O157 shiga toxin-

O157:H7 as an indicator organism for STEC subject of the Determination is logical because there are similar causes within the production of ground beef products that affect the prevalence of these organisms and these organisms can be similarly identified and controlled. Using O157:H7 as a metric within a food safety process control management system, *i.e.* N60-Trim or similar robust sampling programs, can demonstrate that the food safety process can be improved over time, identify any event or loss of process control situations, and support the conclusion that any corrective actions decisions have decreased not only O157:H7 but also the targeted STEC pathogens.

Research Shows Interventions are Effective in Controlling STEC

Current antimicrobial compounds used by meat industry to destroy *E. coli* O157:H7 are effective against non-O157 STEC, according to an American Meat Institute Foundation-funded (AMIF) study conducted by researchers at the Agricultural Research Service's Meat Animal Research Center. In that study researchers evaluated the efficacy of six commonly used antimicrobials on *E. coli* O157:H7 on STEC serogroups O26, O103, O111, and O145 on beef. A complementary AMIF study conducted by the same research team evaluated the efficacy of those same six antimicrobials on non-O157 STEC O45, O121, and non- and multi-drug resistant *Salmonella* strains. The final report provides a similar conclusion, noting that all antimicrobial compounds used by the beef industry were effective against non-O157 STEC and *Salmonella* serotypes.

Additional AMIF-funded research was recently conducted at Colorado State University (CSU) to determine whether interventions known to reduce *E. coli* O157:H7 contamination on beef trimmings are also effective in reducing non-O157 STEC, and multiple drug resistant (MDR) and susceptible *Salmonella* Newport and *Salmonella* Typhimurium. Findings from the CSU study indicated that the antimicrobial effects of these decontamination

producing *Escherichia coli* isolates from commercial ground beef in the United States. *Applied and Environmental Microbiology*. 77: 2103-2112; Centers for Disease Control and Prevention. 2011. Foodborne Outbreak Online Database. <http://wwwn.cdc.gov/foodborneoutbreaks/>. Accessed February 18, 2011; Luchansky JB, Porto-Fett ACS, Shoyer BA, Call JE, Chen V, Kause J, Eblen DR, Cook VL, Mohr TB, Esteban E, and Bauer N. 2011a. Inactivation of non-O157:H7 shiga toxin-producing *Escherichia coli* (STEC) in frozen ground beef patties. IAFP Annual Meeting 2011, Milwaukee, WI. [Poster]; Luchansky JB, Porto-Fett ACS, Shoyer BA, Call JE, Schlosser W, Shaw W, Bauer N, and Latimer H. 2011b. Inactivation of Shiga Toxin–Producing O157:H7 and Non-O157:H7 Shiga Toxin–Producing *Escherichia coli* in Brine-Injected, Gas-Grilled Steaks. *J. Food Prot.* 74: 1054–1064; Vasan A, Leong WM, Ingham SC, and Ingham BH. 2011. Strains of the major shiga toxin-producing *Escherichia coli* serogroups exhibit similar thermal tolerance in lean ground beef. IAFP Annual Meeting 2011, Milwaukee, WI. [Poster].

treatments against the non-O157 STEC serotypes and *Salmonella* Newport/Typhimurium antibiotic resistance phenotypes were generally the same as those against *E. coli* O157:H7.

Prior to these studies it was generally recognized that interventions used in the plant were effective against STEC. These three studies specifically address the effectiveness of six STEC and *E. coli* O157:H7 and significantly many of these interventions have been commercialized during the last five years.³⁰ Given that the research addressed interventions individually and most beef packers use multiple interventions, there is little doubt about the effectiveness of the interventions used by the packing industry.

The Final Determination Grossly Understates the Costs Associated with Implementing the Policy

AMI is encouraged that collection of STEC data during testing will follow the same sampling procedures and confirmation practices as exist for *E. coli* O157:H7. According to the Determination, the costs associated with testing beef trimmings for STEC encompass equipment, supplies, and labor for screening, screen-positive isolations, most-probable-number (MPN) procedures, MPN-positive isolation, pulsed-field gel electrophoresis (PFGE), and PFGE-positive isolation and would range from \$204,100, annually if 2,578 samples are collected and analyzed to \$338,300 if 4,600 samples are collected and analyzed.³¹

Historically, FSIS completes almost five times more ground beef tests for *E. coli* O157:H7 than for beef trimmings. Thus, once fully implemented, the true cost of the policy announced in the Determination would be \$204,100 for trimmings and \$966,464 for ground beef, for a total \$1,170,564 per year of additional expense.³²

In addition, these cost estimates do not account for other costs the agency will incur that flow from positive test results, *e.g.*, the costs attendant to a “for cause FSA” that is conducted when ground beef is confirmed to contain STEC. Based on agency data, the STEC testing likely would generate an additional 61 FSAs annually.³³ FSIS estimates the cost of an FSA is \$14,000. STEC testing would add an additional \$854,000 to the above-

³⁰ *Supra* footnote 28.

³¹ The agency’s costs for expanding testing to raw ground beef products are not included in these calculations.

³² FSIS conducted, on average, 12,209 tests annually from 2006-2010 for ground beef versus 2,578 tests on average for beef trimmings.

³³ Expected positive rate multiplied by the number of tests.

discussed numbers. In sum, the estimated cost to FSIS to implement the policy, including trimmings and ground beef testing and related FSAs, could be an additional \$2,024,564 and not the \$454,910 to \$730,810 included in the Determination.

Not only has the agency underestimated the costs it will incur, it has grossly miscalculated the costs to industry.³⁴ In that regard, the agency makes several seriously flawed assumptions in its cost analysis.

First, FSIS contends that only 33 percent of beef slaughter establishments test for *E. coli* O157:H7.³⁵ The better measure for this analysis, however, would be to use the data from Table 5.2.10-Testing of Source Materials for 03B Establishments. Instead of making a decision based on the percentage of establishments that test for *E. coli* O157:H7, the more accurate approach would be to determine the volume of source material produced by establishments that test for *E. coli* O157:H7, which is likely to represent a vast majority of the production volume.

Second, FSIS asserts that its “best estimate is that about 20 percent of establishments are testing.”³⁶ When asked the source of the 20 percent assertion the agency was unable to provide a data set to support the number proffered. In short, the agency fails to account properly for added lab costs for the industry. Industry analysis estimates added lab costs to the industry to range from \$2.5 million to almost \$2.9 million.³⁷

Third, the agency contends that total beef trimmings production is 2.05 billion pounds. But FSIS data contravene this volume. Specifically, for the year ending June 30, 2010, the industry produced 6.96 billion pounds of ground beef.³⁸ Ground beef is only produced from raw ground beef components, *i.e.*, trimmings. Therefore, the more realistic volume of beef trimmings is also approximately 6.96 billion pounds.

³⁴ The irony of the discussion that follows is that the agency admits in the Determination that “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.” 76 *Fed. Reg.* 58164.

³⁵ FSIS Notice 65-07, Table 5.4.31-Carcass Testing for *E. coli* O157:H7.

³⁶ 76 *Fed. Reg.* at 58163.

³⁷ See BIFSCo Cost Impact: Non O157 STECS Regulation (Attachment C).

³⁸ Data-Driven Inspection for Processing and Slaughter Establishments, Public Health Decision Criteria, September 2010.

Fourth, the Determination estimates the additional cost attendant to diverted product will cost the industry between \$3.9 and \$5.2 million.³⁹ This estimate assumes that approximately the same amount of product will be diverted for STEC test findings as for *E. coli* O157:H7. There are several flaws in this analysis, starting with agency's erroneous estimate of 2.05 billion pounds of trimmings. Because the amount of trimmings is approximately 3.4 times greater than the agency estimate, even using the same values FSIS used for the diverted product, which is too high, a more accurate range of the cost of diverted products is approximately \$13.24 million to \$17.65 million dollars.⁴⁰

Those numbers, however, are likely low because the agency incorrectly assumes the same level of STEC positives as for *E. coli* O157:H7 and also fails to consider the principles of supply and demand. The current screening test methods for STEC have a greater rate of positive results with best estimates that the STEC methods will result in a three to fivefold (3-5 times) increase in the amount of product diverted. The industry's analysis of the current cost of diverted products for *E. coli* O157:H7 is approximately \$19.6 million. Based on the higher estimates screen rate and the fact that the additional product diverted will have even less value, the additional product diverted is estimated to cost the industry an additional \$39.2 million and \$78.4 million annually.⁴¹

The agency also improperly calculates the cost of holding tested product. In that regard, the agency fails to consider the additional time needed to complete the STEC test through the final stage of confirmation and the other costs attendant thereto. In its "Cost to the Industry" discussion, FSIS asserts that "holding one extra day is minimal." Section IV of the Determination, STEC Policy Implementation: Implementation, Status of Laboratory Methods, however, provides that "for samples that screen positive, an additional three to five days may be necessary for a confirmed positive or negative result."⁴² This extra time equates to a loss of 20 percent of the product's shelf life or time to move the product through the supply chain. That shelf life loss has very significant economic ramifications for the

³⁹ 76 *Fed. Reg.* at 58163. FSIS calculates the value of diverted trimmings to be one-half to one-third the wholesale price.

⁴⁰ The volume of additional trimmings diverted would be approximately 35 million pounds -- 6.96 billion pounds multiplied by the FSIS expected rate of 0.5%.

⁴¹ The notable time delays between the initial screens and the perishability of the product will force companies to make disposition decisions based on the initial screens. See Attachment C. The value of the product diverted will fall even further than currently happens because there will be significantly more diverted product on the market, *i.e.* as more product is diverted the value of such product goes down. Moreover, the agency's cost estimate for diversion was based on 2.05 billion pounds of trimmings, which was wrong.

⁴² 76 *Fed. Reg.* at 58161.

industry and was not included in the agency's cost analysis. The industry analysis considers the costs of process disruption, which includes a host of factors such as longer lab test times, which delay shipments, result in additional handling, storage and demurrage costs, and affect production schedules and cause product quality loss. The industry estimates these added costs to range from \$58.8 million to \$98 million.⁴³

Finally, in the Determination the agency acknowledged the very real possibility of more recalls stating that:

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.⁴⁴

Although most tested products are held under company control pending test results, there will be more testing and, unfortunately, there will be more recalls and the agency's economic analysis fails to consider recalls. The industry, however, estimates that the new policy will result in at least an additional 24 recalls annually and perhaps as many as 48 additional recalls. Using agency data those added recalls will cost the industry between \$72 million and \$144 million annually.

FSIS indicated that it intends to provide "a full analysis of costs before expanding the testing policy." Because the agency has miscalculated the costs it will incur and because the cost to industry has been grossly miscalculated, the economic analysis should be recalculated and completed at least 60 days prior to any implementation date. Industry and customers need to and deserve to be made aware of the expected costs associated with this proposed policy.

⁴³ See Attachment C.

⁴⁴ 76 *Fed. Reg.* at 58163-58164.

The Policy is Unnecessary Because there is no Public Health Crisis and Current Processes and Interventions used to Control *E. coli* O157:H7 also Control STEC.

The Profile upon which the agency relies lacks the support necessary to conclude that an “urgent and unusual” situation exists to declare STEC to be adulterants. Indeed, the Determination as currently configured is based upon decision criteria that will not yield improved public health outcomes, will not reduce recalls, and are significantly flawed in their cost estimates.

Rather than move forward with the announced policy, FSIS should gather the necessary data through a survey and conduct the necessary risk assessment to address the unanswered questions that have been raised.⁴⁵ There also must be a more thorough understanding of the how the current methods of processing, as well as role of verification testing before even considering implementation of the STEC determination.

As these comments are reviewed, further processors, distributors, and consumers should remain confident in the safety of the ground beef supply because:

1. Verification testing methods are a good means to validate food safety processes and the agency has intensified its role in verifying sanitary dressing of cattle;
2. The Profile does not demonstrate a need to move forward with regulatory action because there is not a strong argument that non O157-STECS are an unusual or urgent food safety problem;⁴⁶ and
3. Control measures have been implemented by the industry to control *E. coli* O157:H7 and those measures also are effective against STEC;

⁴⁵ See Executive Order 13563.

⁴⁶ See *Peer Review Comments* at 43.

For the foregoing reasons AMI respectfully requests that the policy announced in the Determination be delayed until all the appropriate and necessary steps have been completed and that the policy not be implemented unless a comprehensive analysis of all the data reveals that the announced policy is, in fact, warranted. AMI would be happy to meet with you with discuss the many issues and concerns discussed in these comments

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark Dopp', with a horizontal line extending to the right.

Mark Dopp
Senior Vice President, Regulatory
Affairs & General Counsel

Cc: Dr. Elisabeth Hagen
Al Almanza
Dr. Dan Engeljohn
Patrick Boyle
Jim Hodges
Dr. Betsy Booren
Scott Goltry
Janet Riley
Dale Nellor

Enclosures