AMERICAN MEAT INSTITUTE

July 6, 2012

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
355 E. Street, SW
8–163-A, Mailstop 3782
Washington, DC 20250-3700

Re: Docket No. FSIS-2011-0009; Changes to FSIS Traceback, Recall Procedures for *Escherichia coli* O157:H7 Positive Raw Beef Product, and Availability of Compliance Guidelines

To Whom It May Concern:

Formed in 1906, the American Meat Institute (AMI) is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. AMI members manufacture more than 90 percent of these products. Also, approximately 80 percent of AMI member companies are classified as small or very small according to Small Business Administration standards. AMI members continue to adopt food safety practices to produce meat and poultry products, which are safe, affordable, and available. The safety of the products AMI members produce is their top priority.

AMI appreciates the opportunity to comment on *Federal Register* Notice, FSIS-2011-0009 (Notice), as well as two Compliance Guidelines, the Compliance Guideline for *E. coli* O157:H7 Sampled and Tested Claims for Boneless Beef Manufacturing Trimmings (Trim) (Claims Guideline) and the Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers (STEC Guideline).

1150 Connecticut Avenue, 12th Floor, Washington, DC 20036
(202) 587-4200 • fax: (202) 587-4300 • www.meatami.com

FSIS-2011-0009; CHANGES TO FSIS TRACEBACK, RECALL PROCEDURES FOR *ESCHERICHIA COLI* O157:H7 POSITIVE RAW BEEF PRODUCT

Circumstances for New Recall Policy Need Refinement

AMI agrees that eliminating contaminated source material from commerce is an agency priority and a core business practice that AMI members take seriously. Based on illness data as well as agency feedback, the beef industry has been successful at achieving this objective. The industry continues to make improvements, but an expectation of public health improvements through downstream testing and then recalling product after the product has been distributed to multiple locations seems archaic.

The Notice states that FSIS intends to have the supplier recall product if any of five circumstances occur. Included in this Notice is a revised recall policy that will add clarity for grinders and suppliers. However, improvements to this downstream testing program should be considered by the agency. To that end, AMI suggests that alternative locations of testing be considered based on controlling the lot of product used in producing the ground beef.[1]

When a FSIS sample is taken at a downstream grinding facility[2], the question asked by FSIS is whether the product was held, which refers to whether the product was held at the downstream grinder. This question should be expanded to include whether the sample is taken from the complete lot or is it a split lot and if so is the complete lot under control. If the product is under control, *i.e.* intact lot or no split lot, then FSIS would proceed with sampling. If the complete lot is not under control then the sample should be taken at the supplying plant which produced the complete lot. The Notice discusses "implicated lots" and "split lots". Although not discussed, based on past FSIS practice, the implicated lot would be the lot from which the positive *E. coli* O157:H7 was detected and the split lot would refer to a divided microbiologically independent lot.[3]

The recall criteria also discuss the agency's ability to determine if cross contamination occurred at the grinder. Understanding how FSIS would complete this review, *i.e.*, what records to review, would accelerate the review and possibly prevent illnesses. AMI has stated previously, and reiterates here, that samples taken by FSIS should be taken from product that is routinely manufactured and representative of the process from which the sample is taken. For instance, if the grinder is making ground beef and routinely uses bench trim, then ground product from bench trim is the representative product and should be sampled. Sampling the correct product that enters commerce to be consumed only makes food safety sense.

---

[1] AMI petitioned the USDA in 2008 to consider a Test and Control procedure that would also reduce the amount of recalls because product was not properly controlled pending FSIS testing.

[2] A grinding facility is an establishment that blends and grinds beef trimmings to produce ground beef. The reformatting of ground beef without addition of beef trimmings or other ingredients is not a grinding facility.

[3] FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers, May 2012, page 17.

COMPLIANCE GUIDELINE FOR *E. COLI* O157:H7 SAMPLED AND TESTED CLAIMS FOR BONELESS BEEF MANUFACTURING TRIM

Since 2008 Communication of Test Results and Methods Have Evolved: The Need for Labeling Information is Questioned

On October 14, 2008, FSIS issued draft guidance entitled *Labeling Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings Concerning E. coli O157:H7*. This Compliance Guideline has been revised to address sampled and tested claims and clarifies issues that were addressed in stakeholder comments submitted in 2008. Four years have passed and the industry has adopted methods to communicate to customers *E. coli* O157:H7 testing and sampling processes. Even though the testing and labeling claims are voluntary and the level of acceptance by the industry is unknown, to gain a more thorough understanding of the label approval procedures of this claim guide, AMI submits the following questions:

Do all labels that will carry the sampling and testing claim need to be submitted separately?

How long does it take to receive label approval with this sampled and testing claim?

Does the occurrence of a High Event Period cause labels to be rescinded?

"For Cooking Only" and "Beef Manufacturing Trimmings" Terms to be Clarified

AMI suggests that FSIS develop labeling direction based on the intended use of a product that contains beef trimmings. For instance, if the raw beef trimmings have tested positive or presumptive for *E. coli* O157:H7 and is diverted to be cooked, that product should be labeled "for cooking only" and FSIS Directive 10,010.1, Revision 3 would apply. However, if product has not tested positive or presumptive for *E. coli* O157:H7 and is also lethality treated to destroy *E coli* O157:H7, should the same "for cooking only" labeling be applied? AMI submits that this type of labeling introduces confusion into the market place. AMI recommends that FSIS review the use of cooking only labeling to differentiate product that has tested positive or presumptive for *E. coli* O157:H7 from product that has not. Also, AMI suggests that the agency reconsider or clarify using the description "beef manufacturing trimmings" because those trimming can be used in lethality treated products that are not typically treated for *E. coli* O157:H7. A better description to use in guidance or policy documents is "beef trimming for raw ground beef" or "manufacturing trimming used in raw ground beef." In the alternative, a more complete definition of "beef manufacturing trimmings" in the Notice would be beneficial.

COMPLIANCE GUIDELINE FOR ESTABLISHMENT SAMPLING BEEF TRIMMINGS FOR SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC) ORGANISMS OR VIRULENCE

Guidance Documents Provide Useful Information for Establishing a High Event Period (HEP) Program and Sampling Plan Design

The STEC Guideline provides a realistic approach for establishing high event period programs, and sampling plans for testing of *E. coli* O157:H7, and should be considered when sampling programs are developed or reviewed for *E. coli* O157:H7 testing.

First referred to as High Event Day programs, the industry has been on a journey of sharing information and experiences over the last five years to understand and correct very infrequent and abnormal occurrences of *E. coli* O157:H7 positive test results. Through these discussions of recall lessons learned the time of high rate contamination was less than a day; hence the current name high event period. The agency's use of establishment data, as well as the two stage (local and systemic) approach of HEP, is a workable approach while not compromising public health. With these improvements to the 2008 draft compliance guide, additional suggestions to improve the Guideline are:

Providing HEP development guidance to establishments that produce less than 50,000 pounds of beef trimmings per day; and

Having FSIS review HEP programs to provide feedback to establishments in a manner similar to the agency's review of robust systematic animal welfare programs, which would serve as a preventive means to enhance public health.

Thank you for allowing our comments to be submitted and considered. If you have any questions regarding these comments, or anything else regarding these issues, please contact me at 202 587 4254 or sgoltry@meatami.com.

Respectfully submitted,

Scott J. Goltry
Vice President
Technical Services

cc: J. Patrick Boyle
Jim Hodges
Mark Dopp