



November 19, 2012

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Avenue, SW
8-163A, Mailstop 3782
Washington, DC 20250-3700

Re: *Docket No. FSIS 2012-0020: Risk-Based Sampling of Beef Manufacturing Trimmings for Escherichia coli (E. coli) O157:H7 and Plans for Beef Baseline*

To Whom It May Concern:

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 member companies account for more than 90 percent of these products. The safety of the meat and poultry products AMI members produce is their top priority. Many members have implemented additional food safety procedures that go beyond current Food Safety and Inspection Service (FSIS or the agency) regulatory requirements to ensure the products are safe, wholesome, affordable, and available.

AMI appreciates the agency's outreach to the industry to solicit input on the beef carcass baseline study design and risk-based sampling plans for beef manufacturing trimmings. AMI offers comments for your consideration on the above-referenced notice.

Risk-Based Sampling Provides a Focused Approach, Historical Data Could be Lost

The May 2012 U.S. Department of Agriculture (USDA) Office of Inspector General (OIG) report,¹ completed as a follow-up to the February 2011 OIG report cited in the notice stated,

¹ United States Department of Agriculture, Office of Inspector General, Audit 24601-0001-3, Application of FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7, May 2012

“Based on our visits to six beef slaughter plants—directly responsible for processing about 17 percent of the U.S. beef supply we found that industry was performing thousands of *E. coli* tests daily generally following FSIS’ recommended procedures. Overall, industry was taking appropriate steps to help ensure that U.S. beef is safe from *E. coli* contamination, recognizing that regardless of how stringently the industry tests for *E. coli*, there are always an inherent risk of its presence in slaughter plants. We found these large plants showed strong initiative in their efforts to control contamination and limit the ability of adulterated meat to make its way in to commerce. Plants took preemptive action, often acting on presumptive positive test results and in some instances, destroying whole days’ worth of production in the name of safety. When positive test results were found, plants were conducting investigations to determine the cause and applied corrective actions to prevent future occurrence of *E. coli* contamination. We also found that these plants generally utilized nationally accredited laboratories for their sample analysis.”

The agency responded in this report by saying,

“FSIS is making certain changes to its trim sampling program to make it risk based. In addition, during this calendar year and next, FSIS intends to identify additional ways to make its testing programs for *E. coli* O157:H7 more risk based, such as consideration of information available through PHIS, from inspection program personnel, and from risk analyses. FSIS intends to announce the changes in its trim sampling program in the *Federal Register* in the next 3-6 months and to ask for comment on the changes and other issues under consideration. Also, next calendar year, FSIS intends to conduct a study to test product from unopened containers or purge material (that is, remaining liquid, fat, and meat particles in containers or combo bins after trim contents have been removed) from suppliers’ product for *E. coli* O157:H7. The purpose of this study will be to identify the source of *E. coli* O157:H7 positive raw ground beef when material from multiple suppliers was used to create the sampled ground beef that FSIS has found positive for *E. coli* O157:H7”.

AMI supports sampling beef trimmings based on risk of potential *E. coli* O157:H7 contamination. This risk-based sampling should take into consideration the market class of animal, size of the establishment as well as the historical rate of *E. coli* O157:H7 detected via agency testing. AMI would also encourage the agency to conduct risk-based sampling for ground beef as well. Furthermore, prior to initiating the study of testing product purge or container/combo bins to track the source of *E. coli* O157:H7, the resulting impact on public health improvement of this study should be determined. The unintended consequences of potential insanitary conditions created by storing used packaging (*i.e.* container/combo bins) supplies and the practicality of this component of the study should also be assessed.

The 2012 OIG report went on to address issues FSIS has already responded to contained in the notice. Many of these types of systems observed by OIG have been in place and have been adopted by other beef packers to control *E. coli* O157:H7.

Sanitary Dressing Related to Positive *E. coli* O157:H7 Findings Needs Further Investigation

In the notice, the agency concluded the rate of sanitary dressing procedure non-compliance reports could not be used to identify establishments that have a higher probability of *E. coli* O157:H7 positive tests result. As a result, the agency revised its sanitary dressing directive in November 2011. AMI requests a review by FSIS to determine if the revised directive now improves correlation to positive *E. coli* O157:H7 tests. Establishment size and animal market class should also be addressed in this review of sanitary dressing procedures.

The Survey Should Consider Input from Industry

AMI supports an agency survey that will assess changes made by the industry in the last five years that impact food safety. The survey should have clear goals and deliverables on how the agency will address the results from the survey. The conduct of this survey should not put an economic burden on the industry. Unlike the results of Notice 65-07, survey questions should be based on data that pertains to resolving *E. coli* O157:H7 contamination and results should be presented as volume-based data.

This information is critical for future risk analysis and cost-benefit analysis. For example, in the Notice 65-07 report, the agency reports only 33 percent of beef slaughter establishments test for *E. coli* O157:H7 (FSIS Notice 65-07, Table 5.4.31-Carcass Testing for *E. coli* O157:H7). While correct, it would be more appropriate to use the data from Table 5.2.10-Testing of Source Materials for 03B Establishments. This table shows the number of establishments testing for *E. coli* O157:H7 and would likely represent more than 90 percent of the beef trim used in the production of ground beef. Therefore instead of making a decision based on the percentage of establishments that test for *E. coli* O157:H7, an improved risk-based approach would be to determine the volume of source material produced by establishments that test for *E. coli* O157:H7. This risk-based approach is likely to represent a majority of production volume. AMI looks forward to providing input into the creation of the new “65-07” type of survey.

The notice states that FSIS will use the survey to make changes to its sampling, testing and other verification activities. AMI supports the efficient use of limited FSIS resources to protect public health and would welcome engagement with FSIS to learn current thinking regarding sampling testing and other verification activities. Specifically, AMI would like to learn how this data could be used to improve the safety of the beef supply. The 2012 OIG report found that “FSIS needs to consider shifting more of its testing resources to sampling trim, instead of ground beef, for *E. coli*.”

The Outcome of the Beef Carcass Baseline is Unclear

Baselines provide a means to gain valuable information about the current products being evaluated. To provide information only on the slaughter process, instead of the complete production of beef trimmings that are used in the production of ground beef (including veal), seems to be too narrow of a focus and limits the knowledge that could be gained during this study.

The proposed baseline on beef carcasses will only test for pathogenic organisms that are adulterants. No other baseline tests products that are considered adulterants. Because of this distinct difference, alternative baseline testing locations within the production supply chain should be considered by the agency. A robust approach to consider would be including: a post-hide removal sample to address the hide removal process where cross-contamination is more likely to occur; and a second sample site post-intervention and trim testing for *E. coli* O157:H7 for products that will be used in ground beef/veal production. The advantage of this recommendation is two-fold: 1) the pre-intervention carcass should not need to be held pending testing results as the product has not yet been subjected to all pathogen interventions nor inspected and passed by USDA; and 2) testing beef trimmings is a process that FSIS and the industry are very familiar with and the lots of trim representing the FSIS baseline sample can more easily be segregated and held pending testing for adulterants. Granted all steps may not be done in the same establishments nor on the same carcass, but this is a common practice in other baseline designs. AMI would welcome feedback on the testing of generic organisms or other indicator organisms that would be tested during the baseline.

AMI Supports a “Shakedown Process” Prior to Baseline

Prior to beginning the baseline project, AMI recommends a “shakedown” period at establishments representative of the industry in order to assess the logistics of sampling. This should be done to provide a safe sampling environment for inspection personnel, while not creating a manufacturing bottleneck that would not be reflective of the routine slaughter process. Typical beef slaughter facilities are not designed to do this type of post-hide removal, post-intervention testing and will require the establishment to shut down production and provide access to the sample locations. Depending on the number of samples, the type of sampling and the skill level of the sampler, this could lead to significant costs to individual establishments participating in this baseline. During the “shakedown” process, manufacturing downtime or other costs that would be incurred by the establishment should be determined and must be a key consideration for the final design of the baseline. Another part of the “shakedown” process or sampling design scheme should include a re-conditioning process if the carcass sampled by USDA tested positive for an adulterant and FSIS’s guidance on the disposition of that carcass(s) should be addressed. The time to receive sample results is a critical component of this baseline and a “shakedown” process could help address the time required to complete testing.

Share Information in a Timely Manner with Industry in Order to Address Processes

While the agency is developing the baseline, the timeframe for the publication of study results should be outlined. This timeframe will allow establishments to enter into discussions among industry to resolve issues if they exist. Data collected and shared with the industry should address the plant size and beef animal class in order to gather as much information as possible so a focused approach for improving public health can be considered.

Should you have any questions or wish to discuss our comments further please contact me at sgoltry@meatami.com or 202-587-4200. Thank you in advance for your consideration.

Respectfully submitted,

A handwritten signature in black ink that reads "Scott J. Goltry". The signature is written in a cursive, flowing style.

Scott J. Goltry
Vice President
Technical Services

cc: J. Patrick Boyle
Mark Dopp
Jim Hodges