



Public Comment
Presented by
James H. Hodges
Executive Vice President
American Meat Institute
At
Food Safety and Inspection Service
Public Meeting Teleconference
December 1, 2011

The American Meat Institute appreciates the opportunity to comment on the Food Safety and Inspection Service's plans to regulate an additional six shiga toxin-producing *E. coli* serogroups as adulterants in ground beef and other raw beef products for grinding. AMI members slaughter and process the vast majority of ground beef and ground beef components produced in the U.S. Our members also operate facilities in several major beef exporting countries including Canada, Brazil and Australia.

As an initial matter, AMI respectfully disagrees with FSIS's decision to implement this new regulatory program because the scientific evidence shows that it is unlikely to make beef safer than it is today. AMI has several concerns and recommendations that it wishes to share with the agency.

First, the Draft Risk Profile is appropriately named because it is incomplete and includes significant data gaps. Independent experts commissioned by FSIS to review the Draft Risk Profile raised several concerns about the strength of the evidence used to draw conclusions about the public health risk associated with non-O157 STEC. The panel's responses illustrate the enormous knowledge gaps that exist and the lack of a solid foundation for the new policy. They said, for example, "We found no consensus in the scientific community about precisely which features, or virulence factors, make an STEC harmful to humans" and "...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." Even FSIS seems unsure that the new policy will have the intended effect of improving beef safety by stating in its *Federal Register* notice that "It is not clear whether or not on net there will be a reduction in the number of illnesses."

The available public health data do not indicate that these particular STEC pose an unusual or urgent public health challenge. To our knowledge, one outbreak in the U.S. involving three individuals has been associated with non-O157 STEC in ground beef. Given the data gaps and unknown outcomes that the agency's actions will have on public health, a more considered approach is warranted. FSIS should complete a comprehensive risk assessment to provide a better understanding of the public health impact associated with non-O157 STEC in beef products and conduct a baseline survey on the prevalence of these organisms in various beef products to assess the impact of implementing this new regulatory program.

Second, FSIS and the consuming public can be assured that a new regulatory policy is not a prerequisite for controlling non-O157 STEC. Existing industry practices are controlling all STEC, not just *E. coli* O157:H7. In fact, FSIS appears to agree by stating in its *Federal Register* notice that “controls for *E. coli* O157:H7 already in place should be as effective in controlling non-O157 STEC as in controlling *E. coli* O157:H7” and “the illnesses associated with these strains have not primarily been due to contamination on beef.”

AMI agrees with FSIS that current production practices control non-O157 STEC. For the past several years, the AMI Foundation has documented through peer reviewed research that the microbial interventions used to control *E. coli* O157 are equally effective for controlling other STEC and the existing microbial monitoring programs that target *E. coli* O157 can be used as a reliable indicator of process control for all STEC. In-plant food safety technologies do not discriminate; they destroy all strains of *E. coli*. USDA’s new plan likely will have no impact other than to consume resources that could be better spent on food safety research. FSIS is proposing a solution in search of a problem.

Third, FSIS needs to initiate an open and transparent process to validate its analytical laboratory methods under field conditions. Considerable misinformation and confusion exists regarding test methods. The issue is not about the availability of rapid screening methods that can provide quick results. The issue is how many of the commercial samples that initially screen positive will actually be confirmed positive by accepted laboratory methods. Because fresh beef is perishable, it is logistically impossible to hold excessive amounts of products that initially screen positive and ultimately are confirmed several days later to be negative for the target pathogen. Consequently, companies make product disposition decisions based on validated rapid test results that are available in less than 24 hours.

Finally, FSIS should commission an independent firm to conduct an economic analysis of implementing the new STEC policy. AMI’s preliminary analysis indicates that the cost of implementing this policy has been grossly underestimated by the agency. Our initial estimates show that costs will exceed \$100 million dollars annually for trim testing alone and may approach \$300 million annually with the implementation of ground beef testing. AMI will provide a comprehensive cost analysis in its written comments, but it should be readily apparent to the agency that a more complete cost analysis should be conducted to assure compliance with Executive Order 13563.

The lack of a detailed cost estimate for this new policy calls it into question further. Considering the scientific concerns that have been raised, it is foolhardy to spend millions on a policy that has little likelihood of improving public health while USDA’s food safety research program – a program that has had a real and meaningful impact – faces significant budget cuts. The money dedicated to this new testing program should be redirected to find tools and strategies that will have meaningful impact.

In very plain terms, implementing this policy is premature. AMI strongly urges FSIS to delay the arbitrary March 5 implementation date for testing beef trim until a thorough understanding of the policy’s impact and implications can be assessed.

AMI members share a common goal with FSIS: to produce safe and wholesome products for all consumers. The safety of the meat and poultry supply is AMI member’s first priority. Preventing human illness is not something we strive for in response to the agency’s regulatory agenda. We do so by continuously improving food safety processes in plants.

We stand ready to assist the Department in implementing scientifically-based public policies that improve the safety of the nation's meat and poultry supply. AMI appreciates the opportunity to provide our views to FSIS.