



November 16, 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 2012-0045: Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products*

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. In that regard, many of AMI's member companies will be affected by the recently released compliance guideline, Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to Eat Meat and Poultry Products (Guide or Guideline). AMI appreciates the opportunity to provide comments on this guideline.

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) regulatory requirements to ensure the products are safe, wholesome, affordable, and available. In addition to in-plant procedures, AMI believes product safety is enhanced through education. For the last 12 years, the American Meat Institute Foundation and member companies have utilized the latest "lessons learned" to help control *Listeria monocytogenes*. More than 20 sessions of the Advanced *Listeria monocytogenes* Intervention and Control Workshop have been presented to the industry. Experts in the-ready-to-eat industry have also presented workshops to FSIS and FDA personnel involved with ready-to-eat products.

AMI member companies have the depth of knowledge, experience, and practical utility to make meaningful contributions to the Guideline. As Secretary Vilsack stated in a letter to AMI, “To achieve our shared goal to protect consumers from foodborne illness, we must work together and discuss how to best ensure the safety of our food.”¹ Given the Secretary’s comments, it is somewhat disconcerting that the Guideline was revised using only FSIS data and input. The meat and poultry industry likely would have been able to provide additional assistance or guidance in advance of this draft being issued to field personnel. Revising the Guideline after it has already been adopted may lead to confusion among the industry and/or field personnel, resulting in unintended consequences and the misuse of FSIS resources.

More specifically, the sequence of events appears to be backwards. Notice 59-12, “Notification of Revised *Listeria* Guideline Availability” (Notice) was issued on September 14, 2012, instructing Inspection Program Personnel (IPP) to inform the plant of the revised compliance guide at the next weekly meeting. Additionally, the Enforcement, Investigations, and Analysis Officers (EIAOs) were to review and familiarize themselves with the Guide. The Guide then included a 60-day request for comments, *i.e.*, 60 days after the Guide has been issued and likely adopted.

Success of Prior Regulatory Processes Should be Followed

In the September 21, 2012, FSIS Constituent Update (Update), FSIS stated the creation of the revised guide

“was not driven by any one incident, because percent positive rate has been decreasing in FSIS products, and there have been no major outbreaks from ready-to-eat (RTE) meat and poultry products. However, the guidelines were revised as part of FSIS efforts to continuously assess and improve the effectiveness of policy documents.”

AMI supports and encourages the agency’s efforts to continuously review and improve policies. AMI also applauds the agency for providing this information to constituents and suggests that this statement be included in the background section of the Guide. This success is likely attributable to the codification of the *Listeria* rule that was based on strong scientific underpinnings and creation of the regulations by the agency working with industry to achieve a solid performance for improving public health. This is an excellent example of the objective articulated by Secretary Vilsack. This method of rulemaking, as well as other FSIS regulatory processes, such as the canning and canned products rule and the cooked roast beef requirement,² should become a benchmark for the approach used to create regulatory requirements.

¹ Letter from Thomas J. Vilsack to J. Patrick Boyle, October 22, 2010.

² CFR 318.7 Requirements for the Production of Cooked Beef, Roast Beef, and Cooked Corned Beef and CFR 318.300-318.311 Subpart G: Canning and Canned Products

The industry and the agency are at a unique point in policy development as there is time for a measured, thought-provoking assessment to ensure an appropriate and widely-adopted Guideline. This goal may have been achieved in a more direct manner by consulting all stakeholders and seeking input in the draft Guide before issuing it to field personnel.

Purpose of Compliance Guides and Alternatives Should be Clarified

AMI supports all efforts to communicate and train the industry in the safe production of meat and poultry products. AMI also appreciates that the agency has dedicated time and resources to create the Guide. However, AMI is concerned about the true purpose of compliance guides. FSIS specifically states its intent in the Update,

“information in the compliance guideline does not represent new regulations that establishments must follow. Because establishments can choose whether or not to follow the recommendations in the guidelines, it is not expected to have a significant economic impact. However, by following the recommendations, establishments can strengthen their control programs, and decrease the potential of foodborne illness from their products.”

These statements imply that if the guidelines are not followed safe products will not be produced and establishments could be out of compliance. For example, FSIS Notice 59-12 informs EIAOs that they are to review the information in the compliance guideline as part of their preparation for conducting food safety assessments (FSAs). Does this mean that the guideline can be used in addition to current FSA tools?

The Notice also states that if during an FSA, an EIAO finds that an establishment is using the previous version of the Guideline, he or she is not to recommend that IPP issue a Non-compliance Report (NR) solely for using an older version. The EIAO is to inform the establishment that an updated guidance document is available so that the establishment has a chance to reevaluate its system in light of the new information. This instruction in the Notice is vague. Acknowledging that the IPP is not to issue an NR solely for using the previous version and establishments have a chance to use the updated Guide creates clear regulatory overtones to the statement.

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Detailed analyses of the guideline with comments follow in Attachment 1. 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

Attachment

cc: J. Patrick Boyle
Mark Dopp
Jim Hodges