



September 27, 2013

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

**Re: Changes to the *Salmonella* Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing *Escherichia coli* and *Salmonella*; 78 Fed. Reg. 53017 (August 28, 2013)**

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, 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. To that end AMI submits the following comments regarding the announced changes.

### **Improved Data Collection Will Enhance Food Safety**

AMI applauds the agency for advancing the interests of food safety by engaging in more sophisticated data collection. As methods improve and the ability to identify the sources of foodborne illness outbreaks is enhanced it is incumbent upon both FSIS and the industry to embrace those changes to produce the safest food supply possible. AMI is hopeful these changes will also improve the food attribution process within federal agencies.

Given the change in sample size from 25 grams to 325 grams it is imperative that FSIS consider several other factors as it begins to analyze and use the information that the agency gleans from this sampling program. In that regard given that the large sample size will likely yield more positive results, it is critical that the agency keep that fact in context as it reports program results. Likewise, it is important that FSIS consider the differences between the FSIS approach and the sampling procedures followed by the Food and Drug Administration (FDA) when the agency is deciding on how to conduct the risk assessment referenced in the *Federal Register*.<sup>1</sup>

Analyzing the risk *Salmonella* presents in ground beef cannot be done in a vacuum. In that regard, the risk that *Salmonella* presents in beef, pork, chicken, turkey, and ready-to-eat products also must be considered. For that reason, the agency should conduct a risk assessment that includes all these products. Moreover, the risk assessment should incorporate the following elements.

- The risk assessment needs to address the differences in isolates identified from carcass testing compared to product specific testing such as ground product or parts.
- The risk assessment should identify data gaps among the commodity classes, *i.e.* address gaps regarding effective interventions on trim and ground product across all species commodity classes. This information should be collected and identified for the various market classes of beef, with geographic considerations also part of the assessment.
- The risk assessment should assist in developing and implementing effective food safety process management programs to prevent pathogen contamination.
- The risk assessment should consider the human dose-response to *Salmonella* serotypes, be quantitative in nature, and include enumeration of serotypes throughout a food safety management system.

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<sup>1</sup> That FDA utilizes the 25 gram sample approach while FSIS is moving to 325 grams this could influence decision-making the risks associated with certain food categories.

- The risk assessment should consider that in some cases sampling is biased because there may be duplicative sampling of 1) trim that is made into ground beef, 2) ground beef that is reformatted by portioning, and 3) sole source raw beef components that are used in ground beef. In these circumstances the impact of multiple sampling should be considered when completing the risk assessment.

Furthermore, the meat and poultry risk assessment must be one component of a larger, more comprehensive risk assessment determining the public health risk attributable to *Salmonella* in all foods. Accurately analyzing and placing in context the risk associated with meat and poultry products cannot be done without the analysis extending to all food sources. This risk assessment should be conducted by FSIS, FDA, and the Centers of Disease Control and Prevention. AMI is willing to help develop these risk assessments and encourages FSIS to follow the transparent stakeholder processes utilized by the FDA/FSIS Interagency Retail *Listeria monocytogenes* Risk Assessment Group.

AMI also concurs with the agency's decision to "continue to evaluate *Salmonella* isolates from the screen-positive samples for multi-drug resistance, to serotype the samples, and to use pulsed-field gel electrophoresis (PFGE) to identify specific strains of *Salmonella*. Only through such a process can the agency determine whether the positive results yielded by the testing program have "human health significance."<sup>2</sup>

Finally, AMI concurs with the agency's decision to include in the *Federal Register* publication an affirmation that "FSIS does not recognize *Salmonella* as a pathogen that would ordinarily render the product injurious to health, and thus as an adulterant within the meaning of 21 U.S.C. 601(m)(1), individual *Salmonella* sample results will not result in regulatory control actions" and that "after receiving STEC (O157:H7 and non-O157) results, establishments will not need to continue to hold product that has tested negative for STEC."<sup>3</sup> This statement will alleviate possible confusion regarding both establishments' and inspectors' obligations in this new testing program.

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<sup>2</sup> 78 Fed. Reg. 53018 (Aug. 28, 2013).

<sup>3</sup> *Id.* Earlier parts of the document, however, discussed outbreaks associated with *Salmonella* in ground beef and did not discount the possibility of future "after the fact" recalls of ground beef because of a link between illnesses and *Salmonella*.

**Development of *Salmonella* Performance Standards Requires Government Transparency.**

The objective of the new sampling program is to enable the agency to “develop new *Salmonella* performance standards for ground beef product and to estimate *Salmonella* prevalence in raw ground beef and beef manufacturing trimmings products.”<sup>4</sup> Early in his administration, President Obama issued a memorandum, “Transparency and Open Government,” in which the President stated that government, and his administration in particular, needed to be transparent, participatory, and collaborative.<sup>5</sup>

That FSIS published the above-referenced request for comments is an indicator of the agency’s willingness to be transparent and work with the affected industry to enhance food safety. The *Salmonella* performance standards that the agency contemplates changing, however, are substantive in nature and were promulgated through the notice and comment rulemaking process provided by the Administrative Procedure Act (APA).<sup>6</sup> As FSIS moves forward with this new sampling plan, and as it collects the data necessary to develop a new performance standard for ground beef, it is critically important that FSIS adhere to the Obama Administration’s promise to be transparent, participatory, and collaborative and to do so by utilizing the same rulemaking process to amend regulations that it adopted in 1996 via the APA.<sup>7</sup>

One area of concern is the short time period the agency seemingly intends to collect and analyze samples before conducting a risk assessment and developing a new performance standard. Specifically, FSIS stated that “[A]fter collecting at least three months of data using the new sampling and testing procedures, FSIS intends to conduct a risk assessment and develop a revised *Salmonella* performance standard for raw ground beef at a 325 gram sample size.”<sup>8</sup> As the agency has acknowledged, however, beef products have the greatest seasonal variation of all products subject to FSIS sampling programs.<sup>9</sup> Because of that seasonality and to enable the agency and the industry to be able to draw reasonable conclusions from the data it is imperative that the agency collect data over at least a 12 month

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<sup>4</sup> *Id.* at 53017. “FSIS intends to conduct a risk assessment and develop a revised *Salmonella* performance standard for raw ground beef at a 325 gram sample size.” *Id.* at 53019.

<sup>5</sup> [http://www.whitehouse.gov/the\\_press\\_office/TransparencyandOpenGovernment](http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment)

<sup>6</sup> 61 *Fed. Reg.* 38886 (July 25, 1996).

<sup>7</sup> 9 CFR 310.25(b) and 9 CFR 381.94(b).

<sup>8</sup> 78 *Fed. Reg.* 53019.

<sup>9</sup> Williams, MS, Ebel, ED, Golden, NJ, Schlosser, WD - Temporal Patterns in the Occurrence of *Salmonella* in Raw Meat and Poultry Products and Their Relationship to Human Illnesses in the United States. Food Control (In review). FSIS presentation to AMI Meat Inspection Advisory Committee, September 10, 2013.

period. To utilize data from a lesser time frame would compromise any conclusions that might be drawn from the risk assessment.

Such an approach is consistent with the agency's own Science and Technology Microbiology Division recommendation, which said, "Sampling of establishments occurred over relatively short period of time (August 1993-March 1994) and not over yearly period. As a result, the estimate may not reflect possible seasonal differences."<sup>10</sup> Indeed, more recently the agency was faulted by the United States Government Accountability Office for its "use of snapshots of data for two 2-year periods instead of data for the duration ...."<sup>11</sup> FSIS should take steps to ensure that, at a minimum, it has data from at least one year before conducting the risk assessment and developing a performance standard. To do otherwise undercuts the credibility of the process and the standard developed.

FSIS also indicated it intends to develop new performance standards, which likely will lead establishments to adjust ground beef production practices to strengthen their *Salmonella* control measures. A performance standard alone, however, cannot serve as a control measure for *Salmonella* in ground beef. Indeed, in light of the marked progress the meat and poultry industry has made with respect to reducing the incidence of *Salmonella* in its products since 1998 concomitant with no notable decrease in incidence of salmonellosis, AMI submits that the agency should be considering alternatives to performance standards that might yield better public health outcomes. In that regard, verification data, along with the risk assessments discussed above, likely will help the industry develop new pre- and post-harvest interventions and technologies that could be used in an establishment's food safety management program and will help mitigate the food safety risks of the products processed.

Finally, the agency announced that it may move from the current "set-based approach" to a continuous sampling and "moving window" approach for all products that it tests for *Salmonella*.<sup>12</sup> In that regard, in discussing such a system the agency explained that it "would evaluate a set number of sequential results [e.g. 20 results] from single establishment to assess process control."<sup>13</sup> Although the agency specifically invited comment on this issue, without a more detailed explanation of how FSIS contemplates this approach working it is difficult to provide meaningful

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<sup>10</sup> *Nationwide Federal Plant Raw Ground Beef Microbiological Survey August 1993- March 1994*, FSIS, Science and Technology, Microbiology Division, April 1996, at p. 5.

<sup>11</sup> Report to the Chairman, Subcommittee on Livestock, Dairy, Poultry, Marketing and Agriculture Security, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, *More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, August 2013, <http://www.gao.gov/assets/660/657145.pdf>

<sup>12</sup> 78 Fed. Reg. 53019.

<sup>13</sup> *Id.*

comment. To that end it would be prudent for FSIS to provide a more detailed discussion regarding the “moving window” concept to enable affected interests to offer substantive comments.

The American Meat Institute appreciates the opportunity to submit these comments. If you have any questions regarding the information provided in these comments or anything else regarding this issue, please contact me.

Respectfully submitted,

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

Mark Dopp Senior Vice President,  
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