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Mr. Keith Payne
US Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW.
Room 1175, South Building,
Washington, DC 20250.

[Docket No. FSIS-2008-0011] Shiga Toxin-Producing *E. coli* Public Meeting; 73 *FR* 18257; April 3, 2008

Dear Mr. Payne:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over $1 trillion in added value to the nation's economy. For more information, visit the GMA Web site at www.gmaonline.org.

We appreciate the opportunity to comment on shiga toxin-producing *E. coli* (STEC), which was the subject of the recent USDA Food Safety and Inspection Service (FSIS) public meeting held on April 9-10. We commend the Agency for hosting the meeting, but caution the Agency against radical changes in policy in the absence of sound risk assessments that strongly support the effectiveness of the changes.

GMA supports any effort which has the potential to improve public health protection from foodborne illness resulting from STEC. However, GMA believes that the initiatives to expand the FSIS adulteration policy to either *E. coli* O157:H7 in intact beef (such as primal cuts) intended for consumption as intact product, or to non-O157 STEC in beef (non-intact or intact products) will not significantly increase public health protection for the reasons listed below. Before such a quantum shift in regulatory policy can be considered or justified, quantitative risk assessments using current data should be conducted to evaluate the potential risk reduction, if any.

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Specifically:

Intact beef

- The control of *E. coli* O157:H7 in/on ingredients for raw ground beef depends upon execution of sanitary dressing procedures and application of effective interventions during the slaughter process, not on testing. Admittedly, testing will result in the removal of some contaminated product, but the greatest value derived from testing is verification of the effectiveness of interventions applied during the slaughter process. Data from such testing allows processors to make adjustments to the process in order to reduce contamination.
- Expansion of the definition of adulteration to include intact cuts adds no additional information to judge the effectiveness of interventions and thus will not achieve the result desired by the Agency. It has already been proven that testing of intact cuts is not an effective means of contamination control. Current testing of ingredients intended for the production of raw ground beef is more than adequate to determine the effectiveness of the interventions applied to carcasses.
- The risk of illness from consuming ground beef made from intact beef not intended to be used for raw ground beef in comparison to that from non-intact source material has not been quantified. Although FSIS conducted a risk assessment on *E. coli* O157:H7 in ground beef in 2001, that assessment quantified the risk per serving for ground beef consumed in the summer months vs. the winter months, it did not quantify risk for ground beef from different source materials (e.g., from intact vs. non intact beef).
- According to comments by a representative from the Beef Industry Food Safety Council (BIFSCo) at the FSIS meeting, the prevalence of *E. coli* O157:H7 on intact primal cuts is very low and when present, the number of organisms detected is also very low, at <0.357 CFU/cm^2. Forcing testing of primals via expansion of the adulteration provision will either increase the cost of testing for both industry and the Agency or will divert testing resources toward samples that are not likely to result in any meaningful data.
- Recent data on the prevalence and number of *E. coli* O157:H7 on intact products have not been factored into the risk assessment. Given that there has been no documented *E. coli* O157:H7 outbreak attributed to intact products or ground beef made from intact products, the lack of an up-to-date risk assessment to demonstrate an unacceptable level of risk makes it premature to declare *E. coli* O157:H7 an adulterant in intact beef such as primal cuts.

Non-O157 STECs

- Available epidemiological data from CDC on non-O157 STEC do not suggest that non-O157 STEC is a risk in beef products. Since 1990, there have been 23 outbreaks due to non-O157 STEC in the US – only half of which are attributable to foods and none of which have been linked to meat products.
- Many non-O157 serotypes do not cause illness. In fact, FoodNet data identified just six serogroups (O26, O45, O103, O111, O121, and O145) as responsible for 83% of reported non-O157 STEC infections during 2000-2006. However, in this study, cases were defined as "isolation of a non-O157 STEC from the stool of a resident of a FoodNet site." As we discuss below, non-O157 STECs are also isolated from healthy

controls, so there is a basis for questioning the assumption that finding non-O157 STEC in a stool sample equals illness.

- A molecular definition for pathogenic non-O157 STEC and a validated reference method to detect the pathogenic serotypes are yet to be established to support regulation implementation. Data on the prevalence and levels of pathogenic non-O157 STECs in beef products are lacking.
- Industry programs in place to control *E. coli* O157:H7 should be effective in controlling non-O157 STECs as well.
- The scope and magnitude of public health risk from pathogenic non-O157 STECs in beef products (non intact or intact) should be quantified in a risk assessment to help determine effective risk reduction strategies and to support a risk-based regulation.
- It would be premature to declare certain non-O157 STECs as adulterants in beef without a definition for the pathogen, a validated method and a risk assessment to support the need for such a policy.

We question the scientific basis for comments by Agency and Department officials that human illnesses from non-O157 strains of *E. coli* are "at least as prevalent" as *E. coli* O157:H7 illnesses. While it is undeniable that non-O157 strains of *E. coli* are frequently found in diarrheal specimens from sick patients, they have been documented to be present at about the same prevalence in normal stools from healthy controls.

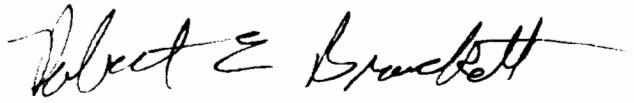
For example, a study conducted in Montana concluded that: "...we cannot state with certainty that the non-O157:H7 STEC identified were the etiologic agents of the diarrhea, although we eliminated from analysis patients whose stool samples yielded another bacterial enteric pathogen. The patients whose stool samples contained non-O157:H7 STEC were plausibly made ill by them, but we cannot assign a categorically pathogenic role to these organisms, without control subjects. In this regard, it is noteworthy that in several studies that attempted to address the pathogenicity of non-O157:H7 STEC, control subjects without diarrhea had the same frequency of fecal excretion of non-O157:H7 STEC as did patients with diarrhea" (Jelacic et al., 2003. Shiga toxin-producing *Escherichia coli* in Montana: Bacterial genotypes and clinical profiles. J. Infect. Dis. 188:719-729). The investigators reference multiple studies in multiple countries that show that when healthy controls were considered, the prevalence of non-O157:H7 STECs was the same in diarrhea samples as in normal control stool samples. Humans very commonly carry these bacteria in their flora with no symptoms.

Also, many public health labs only test for the shiga toxin in stool samples, using an EIA assay. If they have a diarrheal sample that tests negative for other pathogens including *E. coli* O157:H7, but tests positive for shiga toxin, they often assume the illness was caused by a non-O157:H7 STEC, and report it this way. This has caused erroneous public health reaction in at least two outbreaks, one in North Carolina and one in Virginia, where the actual cause of illness turned out to be norovirus (CDC. 2006. Importance of Culture Confirmation of Shiga Toxin-producing *Escherichia coli* Infection as Illustrated by Outbreaks of Gastroenteritis --- New York and North Carolina, 2005. MMWR 55(38): 1042-1045).

The majority of putative illnesses due to non-O157:H7 STEC are sporadic infections that occur typically in rural areas. "This latter observation suggests that an association with animals, rather than the consumption of animal products, may play a significant role in the epidemiology of these infections" (Thompson et al., 2005. Enhanced surveillance of non-O157 verotoxin-producing *Escherichia coli* in human stool samples from Manitoba. Can. J. Infect. Dis. Med. Microbiol. 16:329-334).

Nevertheless, GMA supports FSIS efforts underway to further develop and validate a reference method for pathogenic non-O157 STECs. Certainly, some non-O157 STECs can and do cause human illness. We believe that more study needs to be done to understand the impact that these organisms have on public health, determine which strains are the real pathogens, and make sure that the most effective control measures are targeted to the root causes of human illness.

Sincerely,



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