Consumer Federation of America

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

RE: Docket No. FSIS-2008-0011

The Consumer Federation of America (CFA) is pleased to provide comments on the Food Safety and Inspection Service's (FSIS) public meeting on Shiga-Toxin Producing *E. coli*, held April 9-10, 2008. CFA is a nonprofit association of 300 consumer groups, representing more than 50 million Americans, that was established in 1968 to advance the consumer interest through research, education and advocacy.

CFA is pleased that FSIS has initiated this public discussion on ways to address *E. coli* contamination in the meat supply. In 2007, FSIS recalls due to *E. coli* O157:H7 were at their highest level in five years: 21 recalls with 10 of them associated with illness. FSIS recalled over 29 million pounds of ground beef in 2007 as a result of *E. coli* O157:H7 contamination. In September 2007, Topps Meat Company announced it was recalling 21.7 million pounds of frozen ground beef products due to *E. coli* O157:H7 contamination; more than 30 illnesses were reported in 8 states. The Topps recall became the fifth largest meat recall in the United States. FSIS investigations into illnesses associated with *E. coli* also increased over previous years.

More importantly, the Centers for Disease Control and Prevention reported that illnesses from *E. coli* O157:H7 in 2007 did not change significantly since 2004-2006[1]. The federal government reached the Healthy People 2010 goal of 1.0 *E. coli* O157:H7 illnesses per 100,000 population in 2004. However, that level has not been sustained and in fact, illnesses have increased. Clearly, the federal government needs to do more to assure that the risk to consumers from *E. coli* and other pathogens is reduced. To that end, we applaud FSIS for exploring the problem of *E. coli* contamination and seeking effective solutions that will assure the safety of the meat supply and protect consumers.

[1] Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Commonly Transmitted Through Food – 10 States, 2007." *MMWR,* 57(14), April 11, 2008, p. 366-370.

In the April 9-10 public meeting, FSIS told attendees that the Agency was considering two major policies to address *E. coli* in the products it regulates: designating selected non-O157 STECs as adulterants and designating primal cuts as adulterated if they were contaminated with *E. coli*.

Non-O157 STECs

FSIS described its policy development on non-O157 STECs (STECs) in several stages. First the Agency would ensure that the laboratory methodology can reliably identify the presence of STECs of interest. Second FSIS would gather data to determine the magnitude of the problem. Third, FSIS would make a determination on declaring selected STECs as adulterants.

CFA is pleased that FSIS is considering declaring selected non-O157 STECs as adulterants and that it is gathering more information about the presence of STECs. It is important for the Agency to have a standardized method of detection and a better understanding of the magnitude of the problem in raw beef. However, we urge the Agency to not wait until it completes its testing to declare selected STECs as adulterants if the Agency determines that such a move would protect the public health.

STECs are currently making consumers sick. A 2000 study demonstrated that non-O157 STEC serotypes are at least as prevalent as O157:H7 in diarrheal samples from Nebraska[2]. Review of data from 2000-2005 in Connecticut showed that non-O157 STEC infections represented a substantial portion of laboratory-confirmed STEC cases in that state[3]. This is consistent with findings from studies in other states. However, because STECs have not received the same focus as O157:H7, doctors and public health officials do not frequently look for STECs when patients present with possible foodborne illness. It is also important for FSIS and CDC to have a better understanding of the burden of STECs on the population. Further delay in addressing STECs in the meat supply will only result in consumers continuing to get sick without a remedy to the problem.

The issue of imports is an important one as well. A 2006 Agricultural Research Service study[4] found high rates of STEC contamination in boneless beef trim samples from Uruguay, a beef exporting partner of the United States. The study also found that STECs are commonly found in samples from multiple other countries. The United States imports much of the lean beef used in the manufacture of ground beef in this country. However, FSIS does not require importing countries to look for STECs in imported beef products. Declaring selected STECs as adulterants would spur increased surveillance of these

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[2] Fey PD, Wickert RS, Rupp ME, Sanfranek TJ, Hinrichs SH, "Prevalence of Non-O157:H7 Shiga Toxin-Producing Escherichia coli in Diarrheal Stool Samples from Nebraska." *Emerging Infectious Diseases*, 6(5): Sept-Oct 2000.

[3] Centers for Disease Control and Prevention, "Laboratory-Confirmed Non-O157 Shiga Toxin-Producing Escherichia coli - Connecticut, 2000-2005." *MMWR*, 56(02): January 19, 2007, p.29-31.

[4] Bosilevac JM, Guerini MN, Brichta-Harhay DM, Arthur TM, Koohmaraie M, "Microbiological Characterization of Imported and Domestic Boneless Beef Trim Used for Ground Beef." *Journal of Food Protection,* 70(2), 2007, p. 440-449.

pathogens in imported countries. As FSIS conducts its STEC testing program, it should alert importers of beef about the steps that it is considering and urge them to take necessary measures. FSIS should also consider including imported beef products in its testing program.

Declaring *E. coli* O157:H7 as an adulterant spurred a number of important changes: the industry focused its attention on the pathogen; new testing methods were developed; and new and innovative technologies were developed to address the pathogen's presence in meat products. Similarly, declaring selected STECs as adulterants will encourage the industry to seek out and eliminate those pathogens from the meat supply. Currently, establishments do not have an incentive to test for STECs because there is no consequence if they are found in meat products. It will also likely encourage the development of new testing methods and testing equipment. Declaring select non-O157 STECs as adulterants could foster similar important changes as were seen with O157:H7.

Primal Cuts

FSIS is also considering the determination that non-designated primal cuts be considered adulterated if they are contaminated with *E. coli* O157:H7. FSIS based this determination in part on results from its *E. coli* checklist that a substantial number of primal cuts are used as source material for non-intact raw beef and that non-designated primal cuts are not being treated like boneless trimmings with regards to interventions and testing. CFA supports further exploration of this determination as the Agency continues to develop policies to reduce the risk of *E. coli*. In the discussion at the public meeting several issues were raised, including the use of N=60 sampling protocol, the response of plants following a finding of *E. coli*, and the use of pre-harvest interventions.

CFA shares the concerns of other consumer groups about the use of N=60 as a sampling protocol for detecting the presence of *E. coli* O157:H7 in trim. CFA supports a scientifically-based sampling protocol as an important element of monitoring the industry's ability to reduce the risk of contamination. However, CFA is concerned that the N=60 protocol may not be sufficiently robust as it is currently being implemented.

The N=60 sampling protocol provides a 95% confidence that you will detect a sample that is positive for *E. coli* out of 60 samples taken if the prevalence rate of *E. coli* in the product is 5%. There is a distinct correlation between the confidence level, the sampling size and the prevalence rate of the hazard. In the public meeting FSIS officials indicated that the actual prevalence of *E. coli* contamination in beef trim was not 5%, but more likely 1.5%. This means that FSIS and the industry would have to take a greater number of samples to still maintain a 95% confidence of finding a positive sample. If FSIS and the industry are only taking 60 samples of product that has a prevalence rate of 1.5%, then the confidence level will be less than 95% that a positive sample will be found.

This issue is particularly important since the Agency's testing regime relies on the N=60 protocol. CFA recommends that the Agency revisit its adoption of the N=60 sampling protocol. FSIS should explain why the Agency believes that it is acceptable that its sampling protocol is less than 95% confident in detecting a positive and how such a

protocol is protective of consumers and assures that contaminated product is not being released into commerce. If the Agency cannot adequately justify the use of the N=60 sampling protocol, then it needs to adopt or develop a more effective protocol that provides sufficient consumer protection.

A second concern is industry response when it does find a positive result for *E. coli*. The results of testing should not simply be a means of determining whether product can be released into commerce or whether it must be diverted to further processing or cooking. More importantly, testing results should inform a plant's food safety system and act as a feedback mechanism as to whether the system is effective in preventing contamination. If the goal of an effective food safety system is to reduce the potential for contamination, then positive *E. coli* findings mean that something in the system failed. Positive findings of *E. coli* should prompt the plant to reassess its food safety plan to determine the failures of its system and then determine what steps need to be taken to address any problems found. This requires careful monitoring of testing data and effective response to the data. If plants are not adequately analyzing their testing data, then plants are unable to verify that their systems are working properly. In addition, if the industry is using the N=60 sampling protocol for product with a lower contamination rate than 5%, then it is likely a plant is testing but not finding *E. coli* due to the problems identified above with the N=60 method. The plant would then assume that its interventions and food safety system were adequate when they are not.

CFA is concerned that not all plants are reassessing their food safety plans after positive findings of *E. coli*. FSIS should instruct its inspectors to verify that plants are analyzing the number of positives on a routine basis. Plants should be feeding this information back into their analysis of their food safety system to assure that interventions are working properly and that contamination is being minimized. FSIS inspectors should be verifying this plant activity on a consistent and routine basis. It is also important for FSIS to have a better understanding of how much product is being diverted because of a positive finding for *E. coli*. This is useful data that could inform Agency understanding of a plant's food safety system and whether the plant is reanalyzing its system or simply diverting product.

One other issue that was raised in the public meeting was the need for pre-harvest interventions to address *E. coli*. CFA agrees that this is an essential area in which greater attention could lead to important public health impacts. Presenters at the public meeting identified the need for licensing approval of particular interventions so that research on the effectiveness of the intervention could be conducted. It is important to stress that pre-harvest interventions should not be considered a "silver bullet" to reducing the incidence of *E. coli*, but rather should be utilized as another intervention in a multi-hurdle approach to food safety. While approval of pre-harvest interventions does not fall under the authority of FSIS, the Agency should actively engage APHIS and FDA on this issue and urge those Agencies to take into consideration the importance of utilizing pre-harvest interventions in reducing the risk of foodborne illness to consumers. FSIS should consider hosting a public meeting on the issue of pre-harvest interventions with its sister agencies, industry, researchers, consumer groups and other stakeholders to more fully explore this important issue.

Sincerely,

Chris Waldrop
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