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Docket No. FSIS-2008-0011

Re: USDA Public Meeting on April 9 –10, 2008 in Washington, D.C.: *Shiga Toxin-Producing E. coli: Addressing the Challenges, Moving Forward with Solutions*.

The Center for Foodborne Illness Research & Prevention (CFI) appreciates the opportunity to comment on USDA's Food Safety & Inspection Service public meeting held on April 9 – 10, 2008, to explore the issues surrounding non-O157:H7 Shiga Toxin-Producing *E. coli* (STEC) and to investigate the 2007 increase in *E. coli* O157:H7 recalls. These are CFI's initial comments on the topics presented at the two day meeting and should not be considered complete.

Background

CFI is a national, nonprofit health organization dedicated to preventing foodborne illness through research, education, advocacy and service. Founded in 2006, CFI hopes to lead America in creating innovative, science-based solutions for the food challenges of the 21st Century. CFI's programs and activities are designed to develop better food protections for all Americans. CFI believes that federal, state and local government, as well as farmers; food processors/distributors/retailers; medical providers; educators; policy makers and consumers share the responsibility of building an environment that promotes food safety throughout the farm to fork continuum. No one sector can achieve this goal alone, so CFI is committed to collaboration in its efforts to improve food safety.

Comments

USDA/FSIS' public meeting, held on April 9th & 10th, 2008, focused on more effective strategies for controlling *E. coli* O157:H7 and to discuss the addition of non-O157:H7 Shiga Toxin-Producing *E. coli* (STEC) testing into Food Safety and Inspection Services' (FSIS) existing programs. CFI applauds the Agency for providing an opportunity to explore these topics and offers the following comments.

In 1996, Hazard Analysis at Critical Control Points (HACCP) was adopted by USDA/FSIS to provide consumers with higher assurance that meat, poultry and egg products were being monitored using robust and scientific methods. To meet that end, USDA/FSIS developed and implemented several microbiological testing programs with the intent of using microbiological testing as a tool in food safety management.

In 1994, USDA declared *E. coli* O157:H7 an adulterant in ground beef, and over the past 14 years, other products, like trim and tenderized roaster steak intended for ground beef production, have been added to FSIS' microbial *E. coli* testing programs. In all cases, when product is found to be contaminated with *E. coli* O157:H7, the product is required to be removed from raw meat retail markets.

Since the adoption of HACCP, multiple research studies have shown that Shiga Toxin-Producing *E. coli* (STEC) have had a significant impact on public health, especially for children, the elderly, and individuals with compromised immune systems. According to CDC, each year there are an estimated 73,000 *E. coli* O157:H7 infections and at least 37,000 non-O157:H7 STEC infections in the United States.[1] CDC also estimates that *E. coli* O157:H7 infections result in 2000 hospitalizations and 60 deaths each year,[2] most of which are caused by hemolytic uremic syndrome (HUS).[3]

In 2007, FSIS issued a large number of recalls for ground beef contaminated with *E. coli* O157:H7. In 2006 CDC reported that the prevalence of *E. coli* O157:H7 has not decreased significantly from the 1996-1998 baselines,[4] indicating that this pathogen is not being consistently controlled by the policies/practices that industry and government have used over the past 10+ years.

Therefore, based on the lessons learned from *E. coli* O157:H7 failures, CFI recommends that FSIS works to increase its monitoring of pathogens that cause human disease in federal and federal-state inspected establishments by:

- Applying HACCP's principles consistently in all of its policies/practices;
- Strengthening its application of statistical quality control and microbial testing;
- Seeking ways to better respond to animal pre-harvest environments;
- Increasing its oversight at federal and federal-state inspection programs;
- Investigating ways to improve product tracing;
- Leveraging its enforcement powers when pathogenic contamination is found.

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[1] Mead, Paul, et al. *Food-Related Illness and Death in the United States*. Emerging Infectious Diseases, Vol. 5, No. 5, September-October, 1999.

[2] Tauxe, Robert. Power point presentation, slide 2, April 9, 2008.

[3] HUS is a serious disease. According to the National Kidney Foundation, it is the most common cause of acute kidney failure in young children. It can also result in long-term gastrointestinal complications, hypertension, diabetes, seizures or chronic cognitive and/or emotional problems. Current treatment for HUS is only supportive. Using/withholding antibiotics as a treatment option is currently being investigated by CDC's FoodNet.

[4] Tauxe, Robert. Power point presentation, slides 7, 8. Washington D.C. April 9, 2008.

In addition, CFI believes that based on FSIS' public health mandate, the Agency should declare all human disease causing pathogens associated with serious illness, including but not limited to *E. coli* O157:H7, selected non-O157:H7 STECs and selected multi-drug resistant *Salmonell*a strains, as adulterants in all raw meat and poultry products.

1. **FSIS should expand its *E. coli* O157:H7 testing program to include non-O157:H7 Shiga Toxin-Producing *E. coli* (STEC).**

Besides *E. coli* O157:H7, there are other STEC strains that can cause serious human illness. The most common of these are: *E. coli* O26, O103, O111, O118, O121 and O145, and of these, only O118 is not associated with HUS.[5] According to the April 9th presentation by Robert Tauxe (CDC), the above six serogroups were involved in 95% of the 22 non-O157:H7 STEC outbreaks reported by FoodNet from 1990-2007. Ten of the non-O157:H7 STEC outbreaks were found by CDC to be associated with food.[6] Further, FoodNet's 2003-2006 data has shown a major increase in the reporting of non-O157:H7 STEC isolates.[7] Additional CDC research on non-O157:H7 STEC has shown that non-O157:H7 STECs demonstrate summer seasonality and that screening for non-O157:H7 is facilitated by using new assays that detect shiga toxins.[8] In 2000, the Council of State and Territorial Epidemiologists requested that public health departments report non-O157:H7 STEC infections to the National Notifiable Diseases Surveillance System; however, this reporting is currently not being done consistently by all states.

At the October 17, 2007, USDA public meeting on *Public Health Significance of Non-O157:H7 Shiga Toxin-Producing Escherichia coli*, Martina Bielaszewska (University of Munster, Germany) highlighted the need for the United States to conduct more research on the incidence of non-O157:H7 STEC infections. According to Bielaszewska, data from sporadic cases of HUS in Germany, reported from 1996-2006, show that 50.2% of sporadic HUS cases are caused by *E. coli* O157:H7, while the remaining 49.8% are caused by non-O157:H7 STEC, with SF EHEC O157:H- being the most prevalent. Further, according to Bielaszewska, SF EHEC O157:H- is spreading worldwide, which accentuates the need for increased surveillance of the non-O157:H7 STEC strains in other countries.[9]

Finally, at the April 9th meeting, Dr. Elizabeth Hagen, FSIS Office of Public Health Science, outlined the purposes and methodology that FSIS is considering to use for future non-O157:H7 STEC testing.[10] FSIS' plan includes using reliable laboratory methodology to

[5] Scheutz, Flemming. *Experiences With Non-O157 STEC and Implications on Public Health Programs.* Statens Serum Institute, Copenhagen, Denmark. Power Point presentation, slide 25. USDA public meeting, *Public Health Significance of Non-O157 Shiga Toxin Producing Escherichia coli*, Washington, D.C., October 17, 2007.
[6] Tauxe, Robert. Power point presentation, slides 21, 22. Washington D.C., April 9, 2008.
[7] Tauxe, Robert. Power point presentation, slide 27. Washington, D.C., April 9, 2008.
[8] Brooks, J. T. et al. *US Non-O157 STEC Infections, 1983-2002*. JID 2005:192 (15 October), p. 1427.
[9] Bielaszewska, Martina. *German Experience With Non-O157:H7 STEC.* Power point presentation, slides 8,11. University of Munster, Germany. USDA public meeting, *Public Health Significance of Non-O157 Shiga Toxin Producing Escherichia coli*. Washington, D.C., October 17, 2007.
[10] Hagen, Elizabeth. *Non-O157:H7 STEC: What We Know and What's Next*. Power point presentation, slides 9, 10. USDA public meeting: *Shiga Toxin-Producing E. coli: Addressing the Challenges, Moving Forward With Solutions*. Washington D.C., April 9, 2008.

identify non-O157:H7 STEC, and the Agency also plans to gather sufficient data to ascertain whether or not non-O157:H7 STEC is a significant public health risk.

Based on this information, CFI feels that implementing non-O157:H7 STEC testing is warranted and within FSIS' capabilities. There is strong evidence that non-O157:H7 STEC is a public health threat and that its incidence is increasing in the United States. In addition, international partners are reporting that emerging strains of non-O157:H7 STEC are spreading throughout the world, a condition that should not be ignored. Therefore, CFI supports FSIS' proposal to test for non-O157:H7 STEC in its microbial testing programs. It is important for FSIS to determine the threat level of deadly pathogens and then design effective strategies to monitor them. Further, based on the available information, CFI feels that there is sufficient evidence that a public health threat does exist and encourages FSIS to act immediately to incorporate non-O157:H7 STEC into its current microbial testing programs.

2. FSIS should test primal and sub-primal cuts of beef for *E. coli* O157:H7 and selected non-O157:H7 STECs.

During 2007, there were 21 FSIS recalls for raw and frozen beef products contaminated with *E. coli* O157:H7. In addition, during 2007, FSIS recalled two years' worth of product for *Salmonella* in poultry pot pies. Recently, in February 2008, FSIS issued its largest-ever meat recall because the producing plant did not follow mandated procedures. Taken together, this record has undermined the public's confidence in meat and poultry products and indicates that the food safety and food oversight practices used by the food industry and regulatory agencies are deficient.

Currently, there is no consensus about what caused the increase in *E. coli* O157:H7 contamination in ground beef products during 2007. CDC reported at USDA's April 2008 public meeting that the 2007 outbreaks that CDC investigated were not caused by changes in laboratory procedures or consumer behaviors.[11] USDA/FSIS has on-going investigations, but they have not assigned a cause.

One of the major topics at USDA/FSIS' public meeting on April 9th and 10th was the source materials that are being used for manufacturing ground beef. According to Christopher Alvares, FSIS Office of Food Defense and Emergency Response, a majority of the establishments responding to FSIS' *E. coli Checklist for Beef Operations* are using primal cuts or trim from primal cuts in their grinding operations.[12] At the meeting, Dr. Dan Engeljohn, FSIS Office of Policy and Program Development, reported that the *Checklist* provided the first time that "the Agency has had a process in place where we [FSIS] could identify what products were produced by which establishments because we currently do not have a data set that captures that kind of information."[13] Based on this evidence concerning the types of products being used in ground beef production, along with the 2007 recalls, it is imperative that

[11] Tauxe, Robert. Power point presentation, slide 30. Washington, D.C., April 9, 2008.
[12] Alvares, Christopher. *E. coli Checklist for Beef Operations*. Power point presentation, slides 17, 19. USDA public meeting: *Shiga Toxin-Producing E. coli: Addressing the Challenges, Moving Forward With Solutions*. Washington, D.C., April 9, 2008.
[13] Engeljohn, Dan. Transcript of USDA public meeting: *Shiga Toxin-Producing E. coli: Addressing the Challenges, Moving Forward With Solutions*. Washington D.C., April 9, 2008, p. 202.

FSIS begin testing all product used to produce ground beef. This is a gap that can and should be closed in FSIS's *E. coli* microbiological testing program. In fact, FSIS has a public health obligation to initiate *E. coli* O157:H7 testing of primal and subprimal categories of beef, and if a decision is reached to declare selected non-O157:H7 STECs as adulterants, then these STECs should also be included in FSIS' *E. coli* microbiological testing programs.

3. FSIS needs to establish consistency in its sampling plans and procedures at all federal and federal-state inspected establishments.

CFI recognizes that it is not possible to test safety into meat and poultry products; however, microbial testing does serve as a very important tool for food safety management. According to the International Commission on Microbiological Specifications for Food (ICMSF), "the purpose of sampling a food is to collect a representative sample to obtain information on its microbiological status." Sampling plans, when designed properly using sound statistical concepts, provide a systematic means for assessing the microbiological status of food with a high degree of confidence. Therefore, in order to provide better public health outcomes, FSIS must establish a standard sampling plan and sample collection procedure for all of its federal and federal-state inspected establishments.

In 1974, ICMSF developed a sampling plan to detect severe or direct health hazards. Basically, the ICMSF plan employs "two limits – '*m*,' a number below which there is no concern, and '*M*,' a number above which serious questions arise about the quality and/or safety of the food."[14] Further, in this plan, ICMSF classifies "foods into fifteen hazard categories, called cases, on the basis of the combined effects of two factors: 1) the type of organism; and 2) the future conditions to which the food will usually be exposed. For each case, a sampling plan can be devised to match the degree of concern. The stringency of the plan increases as the hazard increases, with a plan of n = 5, c = 3 for Case 1, and n = 60, c = 0 for Case 15."[15] While ICMSF's sampling plan *cannot* ensure 100% product safety (no plan can do that), it does take into account "both the non-homogeneity within a lot and the large differences in numbers of microorganisms normally associated with various foods."[16]

ICMSF's N-60 sampling plan is not perfect; however, it does provide a higher level of confidence that hazards have been identified than other plans being used by industry and FSIS. Currently, FSIS reports that only some of the large establishments use N-60, while many of the small and very small plants use other sampling plans. According to FSIS, the "small and very small" categories constitute almost 80% of all of the establishments under FSIS' oversight. This means that overall FSIS is not requiring the best available sampling plan for the majority of its federal and federal-state inspected establishments. That is unacceptable. Therefore, CFI recommends that N-60 be the minimum standard for all federal and federal-state inspected establishments, whether they are large, small or very small, until such time that a better sampling plan is developed.

[14] American Public Health Association. *Protection of the Public Against Foods and Beverages That Are Unfit for Human Consumption.* Public Policy Number: 7925 (PP). Policy Date: 01/01/1979, p. 3.
[15] Ibid., p. 4.
[16] Ibid., p. 4.

First, in working to improve its *E. coli* microbial testing programs, FSIS needs to distinguish between a sampling unit and a production lot. CFI recommends that a sampling unit should be at most 2000 pounds. By setting this as the standard for a sampling unit, establishments that produce less than 2000 pounds of product during a specified time period will achieve at least the minimum standard for testing. In addition, production lot needs to be clearly defined and there should be clear guidelines as to how production lots, with sampling units that fail to meet standards, will be handled. Currently, "production lot" is loosely defined in a variety of ways by different stakeholders, which leads to inconsistencies in food safety management. Therefore, CFI recommends that FSIS hold a public meeting to obtain stakeholder input on the definition for a standard production lot size.

Second, FSIS needs to develop a uniform procedure for collecting representative samples from sampling units. Representative samples, which should reflect the composition of the population of interest, are critical to the interpretability and generalizability of any results. It is well accepted that bacterial pathogens are not evenly distributed within food, increasing the risk that sampling results will not accurately characterize the microbiological safety of the product. Increasing the sample size and using appropriate sampling methods, such as stratified sampling, will minimize this risk and provide a greater degree of confidence in the sampling results.

Currently, N-60 sampling is conducted by selecting samples from the top of a combo bin. However, given the heterogeneous distribution of bacterial pathogens, this decreases the likelihood of correctly identifying contaminated sampling units. To address this, CFI recommends that a stratified and random sampling collection procedure be employed to collect samples at uniform intervals throughout the entire time that product moves past a sampling point. To assign strata, establishments would divide the average amount of time it takes to fill a combo by the number of samples to be taken. Random sampling can be more nearly achieved when samples are selected from a moving stream of product, so FSIS should randomly select samples directly from the conveyor belt, just prior to the product entering the combo bin. Variations of this sampling procedure are acceptable as long as mechanical diverters can accommodate random selection as well as the specified time interval.

CFI reminds FSIS that negative N6-0 test results cannot be used to declare product free of *E. coli* O157:H7 contamination, since the sampling plan is not intended to be used for product acceptance. Instead, the ICMSF's sampling plan is designed to verify hazard control within establishments, and as such, microbial test results are a starting point for food safety management and must be used in combination with validated control measures and appropriate corrective actions when contamination is found.

4. FSIS needs to have its own research capabilities.

FSIS is not allowed to conduct its own research on foodborne pathogens and must rely on other agencies, such as USDA's Agricultural Research Services (ARS) or CDC, to meet its research needs. As a result, FSIS does not have a comprehensive research plan that would allow a steady and progressive growth in the Agency's knowledge about the sources, trends,

health outcomes or preventive strategies for foodborne disease. Obviously, given the important public health concerns related to emerging foodborne pathogens and a global food supply, the status quo on FSIS' lack of research capability needs to be reviewed by Congress.

5. Other concerns

During the April 9th and 10th USDA public meeting, other concerns regarding poor food safety practices in beef production were discussed. Several people mentioned the complex, pre-harvest conditions and FSIS' inability to monitor those ecologies. Others talked about the prerequisite programs and their impact on monitoring food products. A third discussion focused on the fact that the HACCP principles are not being followed consistently.

While CFI will not comment on all these discussion points at this time, it is clear that FSIS needs to remove all ambiguity in its directives, notices, communications and practices that could lead to noncompliance of HACCP's principles. For example in the *Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for Escherichia Coli O157:H7*, issued on April 13, 2004, there is some language that could cause confusion as to how FSIS or an establishment should proceed:

> *If an establishment finds positive E. coli O157:H7 product and has not identified the pathogen as a hazard reasonably likely to occur, and therefore does not have a CCP for E. coli O157:H7 in its HACCP plan, the positive test would be considered an "unforeseen hazard". In this case the plant must conduct corrective actions, including reassessing its HACCP plan under 9 CFR 417.3 (b). However, if an establishment has CCPs that address E. coli O157:H7, and the establishment or FSIS testing detects the pathogen, reassessment is not required but corrective actions under 9 CFR 417.3(a) should be taken.*[17] (Underlining is not part of original text.)

By using the word "should" instead of "must" in the last sentence, along with the previous clause stating that "reassessment is not required," this passage could provide establishments that have CCPs for *E. coli* O157:H7 with a loophole for: 1) taking no action on its own or 2) experiencing no corrective action from the Agency when a positive *E. coli* O157:H7 test result occurs. Again, according to HACCP's principles, when contaminated product is discovered, some type of action is required. Obviously, clarity in USDA/FSIS documents is paramount.

Another example of inconsistent compliance with HACCP's principles would be the use of "test and hold," a practice that was adopted after the ConAgra recall in 2002 to lower the amount of contaminated product being sent to the raw ground beef retail markets. While this practice has the potential to improve public health, it cannot be used in isolation. Ignoring systemic problems can lead to increases in an establishment's pathogenic load. Therefore, on a long-term basis, test and hold is *not* an effective tool for pathogen control *unless* the company responds to its own test results in a thoughtful and proactive manner.

[17] USDA. *Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for Escherichia Coli O157:H.* E.coli O157:H7 Guidance Update, April 13, 2004, p. 15. www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

Unfortunately, it is apparent that between 2004 and 2007, test and hold was primarily a diverting exercise and was rarely used to guide establishments to improve their pathogen control measures, which is in direct conflict with HACCP's principles. As a result, test and hold was only a temporary success, and during the 2007 rash of *E. coli* O157:H7 ground beef recalls, FSIS resumed testing all samples taken at beef producing facilities in order to better monitor the establishments' pathogenic control measures. If FSIS wants test and hold to be effective, the Agency will have to require total transparency in reporting and adopt measures that will assure that establishments respond appropriately when excessive levels of contamination are evidenced during microbiological testing.

Conclusion

In January 2007, the Government Accountability Office (GAO) issued a report to Congress adding the federal oversight of food safety as a high risk area because of the risks to the economy and to public health. In addition, on the GAO 2007 High-Risk List, the following is noted about *Transforming Federal Oversight of Food Safety*: "Legislation is likely to be necessary, as a supplement to actions by the executive branch, in order to effectively address this high risk area." CFI concurs with this assessment.

Despite GAO's action, during 2007, the United States experienced a large increase in ground beef recalls for *E. coli* O157:H7 and more illnesses were reported. Obviously, *E. coli* O157:H7 contamination is a persistent problem, so it is appropriate for the overseeing agency, FSIS, to examine its inspection procedures to determine if any gaps are present in the current system.

After reviewing the materials from the April 9th and 10th USDA public meeting, CFI has identified two factors that could be connected to the 2007 *E. coli* O157:H7 recalls:

1) FSIS currently does not test all of the components that are used to produce ground beef products, even though it is likely that primal and subprimal cuts of beef have *E. coli* O157:H7 and/or non-O157:H7 STEC living on the surface of these products;

2) Beef producing plants seemingly did not use their own test results to ensure that their food safety systems or interventions for controlling *E. coli* O157:H7 were working, and this type of non-action is against HACCP's principles.

In addition to the issues related to the 2007 ground beef recalls, CFI is concerned about the global spread and the domestic increase of non-O157:H7 STECs, since some of these strains, like *E. coli* O157:H7, are capable of causing serious acute and chronic human health outcomes.

Therefore, based on CFI's review of current FSIS' reports and policies, as well as the expert presentations given at the April 9-10, 2008 and October 17, 2007 public meetings, CFI recommends the following:

- FSIS should expand its *E. coli* O157:H7 testing to include non-O157:H7 STECs that have been shown to be associated with HUS;
- FSIS should include testing of primal and subprimal cuts of beef into its *E. coli* microbiological testing programs;
- FSIS should adopt ways to improve consistency and reliability in all of its *E. coli* microbiological testing programs;
- FSIS should seek to secure research capabilities for itself;
- FSIS should consider declaring *E. coli* O157:H7 and selected non-O157:H7 STECs as adulterants in all meat and poultry products;
- FSIS should review its directives, notices and other communications for ambiguous language that could lead to noncompliance with HACCP's principles;
- FSIS should hold public meetings on other food safety issues, in particular on how to define a production lot.

CFI is committed to working with USDA and FSIS to minimize foodborne illness through more effective food safety management, including the development of appropriate regulation. We appreciate this opportunity to comment on the April 9th and 10th, 2008, USDA public meeting, and we look forward to continuing our dialog with the Agency on important food safety issues.

Respectfully submitted,

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