United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

JAN 27 2010

William Marler, Esq.
Marler Clark, LLP,PS
6600 Columbia Center
701 Fifth Avenue
Seattle, WA 98104

Dear Mr. Marler:

This is in response to your letter dated December 14, 2009, inquiring about the status of petition # 09-03, which was submitted by you on behalf of Marler Clark LLP, PS; Outbreak, Inc; Megan Richards; Shiloh Johnson; and the family of June Dunning. The petition, dated October 5, 2009, requests that FSIS issue an interpretive rule declaring all enterohemorrhagic (EHEC) Shiga toxin-producing serotypes of *Escherichia coli (E. coli),* including non-O157 serotypes, to be adulterants within the meaning of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*). In the petition, you also request that FSIS expedite its review of the petition as provided under 9 CFR 392.8(a) of the Agency's regulations on "Petitions for Rulemaking." In the petition, you assert that the petition qualifies for expedited review because the requested action "...will prompt better monitoring of all enterohemorrhagic *E. coli,* thus decreasing foodborne contamination." The petition also notes that "... the requested action is supported by scientific information that demonstrates that such an interpretive rule will reduce foodborne pathogens that are likely to be present in meat products." The petition includes published journal articles and other documentation to support the requested action. Based on the information provided in your petition, we have determined that it qualifies for expedited review. Therefore, FSIS is reviewing your petition ahead of other pending petitions that request actions that are not related to food safety.

As the Agency noted when it issued its final rule on petitions for rulemaking, however, "...a petition that receives expedited review will still be subject to all other provisions that apply to rulemaking petitions" (74 FR 16104, 16105). Therefore, although FSIS is evaluating your petition ahead of other pending petitions, the Agency intends to carefully consider all relevant data made available to the Agency on non-O157 STEC to determine how it should address the presence of these microorganisms in or on the products it regulates.

As noted in your petition, on October 17, 2007, FSIS, the Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA CFSAN), and the National Centers for Disease Control and Prevention (CDC) held a public meeting to solicit input from industry, consumers, academia, and other public health and regulatory agencies on the issue of whether non-O157 Shiga toxin producing *E. coli* (non-O157 STEC) should be considered to be adulterants (72 FR 57285). At the public meeting, FSIS expressed interest in considering non-O157 STEC to be adulterants but also recognized the need to conduct research and otherwise develop the data that the Agency needs to help address the outstanding issues associated with these microorganisms. At the meeting, FSIS also acknowledged the need to develop the laboratory capacity to support policy decisions with respect to non-O157 STEC. The Agency requested public input on these issues, some of which are addressed in your petition.

Since it held the public meeting, FSIS has been working with USDA's Agricultural Research Service (ARS) to develop a validated laboratory method to detect and isolate certain non-O157 STEC groups of public health importance. Once FSIS's laboratory methods are validated, the Agency will have the capability to collect laboratory data on non-O157 STEC. Because policy development related to non-O157 STEC is among FSIS's highest priorities, the Agency's laboratories have expedited their efforts to complete this effort.

Since the October 2007 public meeting, FSIS formed a group of Agency scientists to study the available data on non-O157 STEC. The action requested in your petition was among the issues under consideration by this group. Therefore, to help expedite the review of your petition, this group is evaluating your petition as part of the proceeding on non-O157 STEC that the Agency initiated by the October 2007 public meeting.

Although FSIS has granted your request for expedited review, the Agency cannot reach a decision on the substance of your petition until it has developed the laboratory capacity to detect and isolate various non-O157 STEC groups. As noted above, the Agency has expedited its work in this area. In addition, FSIS scientists are studying your petition, along with other available data, including information obtained from the October 2007 public meeting, to develop a set of recommendations to the Administrator on how the Agency should proceed with respect to non-O157 STEC. When the Agency has developed a plan for how it intends to address this issue, it will make the plan available to the public for comment. At that time, the Agency will also issue a final response to your petition.

Thank you for your inquiry on the status of your petition. If you have further questions on the status of your petition or on FSIS's petition process, you may contact Mary Porretta, Petitions Manager at (202) 720-5627 or mary.porretta@fsis.usda.gov.

Sincerely,

Philip S. Derfler
Assistant Administrator
Office of Policy and Program Development