



United States
Department of
Agriculture

Food Safety and
Inspection Service

Washington, DC 20250-
3700

NOV 15 2011

To: American Association of Meat Processors
American Meat Institute
Eastern Meat Packers Association
Meat Import Council of America
National Cattlemen's Beef Association
National Meat Association
North American Meat Processors Association
Southwest Meat Association

Thank you for your October 11, 2011, letter asking for an extension of the comment period for the Federal Register notice "Shiga Toxin-Producing *Escherichia coli* (STEC) in Certain Raw Beef Products" (76 FR 58157; Sep. 20, 2011). You are also requesting a delay in the effective date of the new policy until all comments can be considered, the Agency can publish an additional Federal Register notice, and the affected industry has enough time to prepare for implementation of the new policy.

As we stated in our Federal Register notice and as your letter reminds us, on October 17, 2007, FSIS, the Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA, CFSAN), and the 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 some non-O157 STEC should be considered adulterants (72 FR 57285; Oct. 9, 2007). At that meeting, FSIS indicated that the Agency was considering non-O157 STEC to be adulterants but discussed the need for further research to address the issues associated with these microorganisms. The Agency also acknowledged the need to develop the laboratory capacity to support policy decisions with respect to non-O157 STEC and requested public input on the issues.

FSIS is now in a position to carry out an enforceable program to control non-O157 STEC. By testing samples of trim and other components of non-intact raw beef products for non-O157 STEC, the Agency can provide an immediate measure of public health protection commensurate with the Agency's regulatory requirements.

FSIS has decided to add an additional 30 days to the comment period for the Federal Register notice; the comment period now runs through December 21. However, FSIS still intends to begin implementing a routine sampling program on March 5, 2012, that will include, besides *E. coli* O157:H7, six additional STEC serogroups (O26, O45, O103, O111, O121, and O145).

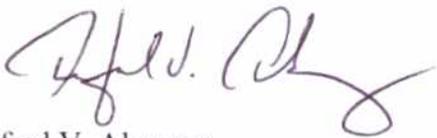
FSIS will initially sample raw beef manufacturing trimmings and other ground beef product components produced domestically and imported, and test the samples for these serogroups.

When FSIS implements its testing program, the Agency will consider other products, including raw ground beef, that are contaminated with any of the six additional STEC serogroups to be adulterated.

As you know, in October we announced the availability of the new methodology that FSIS will use to test for these pathogens. This methodology is described in the Microbiology Laboratory Guidebook, revised Chapter 5B.01, which became effective November 4, 2011, and is available at: http://www.fsis.usda.gov/PDF/Mlg_5B_01.pdf. The Agency encourages establishments to develop equivalent methodology for their own sampling programs. To assist laboratories and test kit manufacturers in evaluating the performance of their test kits for STEC and other pathogens, we posted validation guidance on our website at: http://www.fsis.usda.gov/PDF/Validation_Studies_Pathogen_Detection_Methods.pdf

If you have any further questions, please let me know. We look forward to receiving your comments on the issues relating to this new policy.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alfred V. Almanza', written in a cursive style.

Alfred V. Almanza
Administrator