

# Proposed Rules

Federal Register

Vol. 76, No. 182

Tuesday, September 20, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 416, 417, and 430

[Docket No. FSIS-2010-0023]

#### Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final determination and request for comments.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) intends to carry out verification procedures, including sampling and testing manufacturing trim and other raw ground beef product components, to ensure control of both *Escherichia coli* O157:H7 (*E. coli* O157:H7) and six other serogroups of Shiga toxin-producing *E. coli* (STEC) (O26, O45, O103, O111, O121, and O145). The Agency intends to implement sampling and testing for the additional STEC. FSIS has determined that they, as well as O157:H7, are adulterants of non-intact raw beef products and product components within the meaning of the Federal Meat Inspection Act (FMIA). The Agency is publishing guidance for use in validating commercial pathogen detection test kits that may be capable of detecting the STEC of concern. Finally, the Agency is planning a comprehensive survey of its field personnel who are stationed in beef slaughtering and processing establishments, similar to the 2007 “checklist” survey, to determine the processing practices that are employed to reduce the likelihood of contamination of intact and non-intact beef products with these STEC.

**DATES:** To receive full consideration, comments should be received by November 21, 2011.

FSIS intends to implement routine testing for the six additional STEC discussed in this document beginning March 5, 2012, following its comment

period. To allow industry time to implement possible changes to food safety systems, FSIS will generally not regard raw, non-intact beef products or the components of such products found to have these pathogens as adulterated until it begins this routine testing. FSIS will affirm, in an additional **Federal Register** notice, the date that it plans to implement sampling and testing.

**ADDRESSES:** FSIS invites interested persons to submit comments on this document. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- *Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Docket Clearance Unit, 8-164, Patriots Plaza III, 355 E Street, SW., Washington, DC 20024-3221.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2010-0023. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Daniel L. Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205-0495.

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#### Background

##### I. Shiga Toxin-Producing *E. coli*: *E. coli* O157:H7

While most strains of common intestinal bacteria of the *E. coli* species are harmless, and are not adulterants of raw meat, some strains are highly pathogenic. The Shiga toxin-producing *E. coli* (STEC) may cause illnesses of varying severity, from diarrhea (often bloody) and abdominal cramps to, rarely, kidney disorders. Shiga toxin is the same toxin as is produced by *Shigella*, the bacteria that cause dysentery. In some instances, the toxin will bind to tissues in the kidneys and cause hemolytic uremic syndrome (HUS), leading to kidney failure and death. STEC also may cause asymptomatic infections and extraintestinal infections.<sup>1</sup>

Since the 1990s, FSIS has considered a particular strain of STEC, *E. coli* O157:H7, to be an adulterant of raw, non-intact beef products and the raw intact components used to manufacture these products. On September 28, 1994, in a speech to the American Meat Institute, then-FSIS Administrator Michael R. Taylor stated, “To clarify an important legal point, we consider raw ground beef that is contaminated with *E. coli* O157:H7 to be adulterated within the meaning of the [FMIA]. We are prepared to use the Act’s enforcement tools, as necessary, to exclude adulterated product from commerce.

<sup>1</sup> U.S. Centers for Disease Control and Prevention. 2005. Shiga toxin-producing *Escherichia coli* (STEC). National Notifiable Diseases Surveillance System (NNDSS), 2005 Case Definition. [http://www.cdc.gov/ncphi/diss/nndss/casedef/shiga\\_current.htm](http://www.cdc.gov/ncphi/diss/nndss/casedef/shiga_current.htm), accessed September 11, 2010.

\* \* \* We plan to conduct targeted sampling and testing of raw ground beef at plants and in the marketplace for possible contamination." Mr. Taylor further stated, "We know that the ultimate solution to the (*E. coli*) O157:H7 problem lies not in comprehensive end-product testing but rather in the development and implementation of science-based preventive controls, with product testing to verify process control."<sup>2</sup>

FSIS currently conducts verification procedures, including testing of ground beef products, beef manufacturing trimmings, and other raw ground beef product components for the presence of *E. coli* O157:H7. This pathogen can cause bloody diarrhea and other serious infections, particularly in vulnerable persons—the very young, the immunocompromised, and the elderly. Very few cells of *E. coli* O157:H7 are necessary to cause illness. While residing on the exterior surfaces of contaminated carcasses and primal and subprimal cuts of meat, the organisms can also contaminate the interior of ground product or other beef products—such as needle-tenderized or vacuum-tumbled product—when the protective surfaces of these products have been penetrated. If these products do not undergo rigorous heat treatment or other effective processing, the organisms can survive to cause human illness.

FSIS issued a policy statement (64 FR 2803; Jan. 19, 1999) that stated, "\* \* \* [g]iven the low infectious dose of [*E. coli* O157:H7] associated with foodborne disease outbreaks and the very severe consequences of an [*E. coli* O157:H7] infection, the Agency believes that the status under the FMLA of beef products contaminated with [*E. coli* O157:H7] must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed." FSIS stated that, with the exception of intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product, *i.e.*, a food that can be consumed safely without further cooking or other preparation. FSIS therefore deemed adulterated *E. coli* O157:H7-contaminated non-intact products and intact cuts that are to be further processed into non-intact products before being distributed for consumption.

<sup>2</sup>Michael R. Taylor, FSIS Administrator. September 29, 1994. "Change and Opportunity to Improve the Safety of the Food Supply. Speech to American Meat Institute Annual Convention, San Francisco, CA.

In October 2002, FSIS published a rule (67 FR 62325; Oct. 7, 2002) requiring all manufacturers of beef products to reassess their HACCP plans relating to *E. coli* O157:H7 because the prevalence of the pathogen on cattle brought to slaughter was higher than expected.<sup>3</sup> FSIS issued compliance guidance for establishments on controlling *E. coli* O157:H7.

The beef industry held a summit in January 2003 to develop a unified plan and "best practices" for *E. coli* O157:H7 reduction. The industry introduced several mitigation techniques to reduce the prevalence of *E. coli* O157:H7 from the slaughterhouse to the grinding establishment. Recommended preventive measures included testing the hides and pre-eviscerated carcasses of cattle in order to benchmark whether and how the sanitary dressing procedures and antimicrobial interventions are effective in reducing bacterial contamination, targeting research on the development of effective interventions and implementing robust microbiological testing schemes. For the production of ground products, the recommendations included stopping the practice of carrying over product from one production day to the next, a practice that had resulted in a major recall of ground beef. The industry continues to use many of these techniques in controlling *E. coli* O157:H7 and has been focusing increasingly on risk reduction from the farm to the table.

## II. Non-O157 STEC

As mentioned above, *E. coli* O157:H7 is not the only STEC that can enter the meat supply and cause illness.<sup>4</sup> FSIS is aware that other STEC serogroups may be present in cattle, and can contaminate beef and other meat products and that consumption of products containing certain pathogenic STEC can produce a range of symptoms from mild, non-bloody diarrhea to HUS and death, primarily in very young, elderly, or immunocompromised individuals.

The most prevalent pathogenic non-O157 STEC serogroups in the United States are O26, O45, O103, O111, O121,

<sup>3</sup>U.S. Department of Agriculture. Food Safety and Inspection Service. *E. coli* O157:H7 Contamination of Beef Products. Oct. 7, 2002. 67 FR 62325.

<sup>4</sup>There are approximately 300 to 400 known STEC serotypes that carry various Stx alleles and many of these serotypes and some of the Stx alleles have not been implicated in illness. These various STEC serotypes can be found in soil, water, and other foods and have even been reported to be present in the intestinal tracts of healthy humans. However, very few of the 300–400 non-O157 STEC have been conclusively identified as having caused illness due to being in the U.S. meat supply.

and O145.<sup>5</sup> While more than 50 STEC serogroups have been associated with human illness, U.S. Centers for Disease Control and Prevention (CDC) data shows that over 70 to 83 percent of confirmed, serogrouped non-O157 STEC illnesses are caused by these six STEC serogroups.<sup>6</sup> All of these non-O157 STEC strains can cause hemorrhagic colitis and all except O45 have been shown to cause hemolytic uremic syndrome.<sup>7</sup> We note that the illnesses associated with these strains have not primarily been due to contamination on beef.

Though limited data are available on dose response, there is evidence that the infectious doses of these non-O157 STEC are relatively low. For example, an investigation of an outbreak of STEC O26 from fermented beef sausage in Denmark yielded an infective dose of 100 cells.<sup>8</sup> From an outbreak of O111 STEC in beef sausage in Australia, investigators extrapolated a dose range of 1 to 10 organisms, given as few as 1 cell per 10 g of sausage.<sup>9</sup> Using the concentrations of STEC O145 in contaminated ice cream in an outbreak in Belgium, the estimated infective dose was 400 CFU.<sup>10</sup> This is comparable to illness from *E. coli* O157:H7, which can result from infection with as few as 10 cells.<sup>11</sup> Although some of these outbreaks were attributable to contamination of products other than those the Agency regulates, the information from them shows how virulent these pathogenic STEC can be.

<sup>5</sup>Brooks, J.T., and E.G. Sewers, J.G. Wells, K.D. Greene, P.M. Griffin, R. M. Hoekstra, and N.A. Strockbine. 2005. Non-O157 Shiga Toxin-Producing *Escherichia coli* Infections in the United States, 1983–2002. *JID* 2005;192 (October 15) 1422–1429.

<sup>6</sup>Centers for Disease Control and Prevention. Bacterial Foodborne and Diarrheal Disease National Case Surveillance Annual Reports, 2003–2006. Available at [http://www.cdc.gov/national-surveillance/case\\_surveillance.html](http://www.cdc.gov/national-surveillance/case_surveillance.html).

<sup>7</sup>See Table 2 of the DRAFT Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* later in this document.

<sup>8</sup>Boel, J., *et al.* 2009.

<sup>9</sup>Paton AW, Ratcliff RM, Doyle RM, Seymour-Murray J, Davos D, Lanser JA, and Paton JC. 1996. Molecular microbiological investigation of an outbreak of hemolytic-uremic syndrome caused by dry fermented sausage contaminated with Shiga-like toxin-producing *Escherichia coli*. *J Clin Microbiol.* 34(7):1622–7.

<sup>10</sup>Buvens G, Possé B, De Schrijver K, De Zutter L, Piérard D, Lauwers S, and Piérard D. 2011. Virulence Profiling and Quantification of Verocytotoxin-Producing *Escherichia coli* O145:H28 and O26:H11 Isolated During an Ice Cream-Related Hemolytic Uremic Syndrome Outbreak. *Foodborne Pathog Dis.* 8(3):1–6.

<sup>11</sup>Tilden J. Jr, Young W., McNamara A.M., Custer, C., Boesel, B., Lambert-Fair, M.A., Majkowski, J., Vugia, D., Werner, S.B., Hollingsworth, J., and Morris, J.G. Jr. 1996. A new route of transmission for *Escherichia coli*: infection from dry fermented salami. *Am J Public Health.* 86(8):1142–5.

There is also evidence that the thermal resistance of these strains is high enough that they can survive ordinary cooking of ground beef products. A recent study examining thermal resistance of STEC-inoculated non-intact beef revealed that *E. coli* O157:H7 and non-O157 STEC (a pooled composite of STEC serogroups O45, O103, O111, O121, and O145) had similar thermal inactivation profiles (Luchansky, unpublished data).<sup>12</sup> The recent outbreak in which ground beef was implicated as the vehicle of infection and other evidence shows that STEC O26 survives typical cooking.<sup>13</sup>

Illnesses from person-to-person transmission of STEC serogroups O26, O45, O103, O111, O121, and O145 have been documented, particularly in daycare settings and nursing homes, where there is close contact between persons with immature or compromised immune systems and/or underdeveloped personal hygiene skills. This occurs when an infected, sometimes asymptomatic, person sheds bacteria in feces and subsequent contamination of food or fomites occurs. STEC serogroups O26, O45, O103, O111, O121, and O145 have been isolated from beef carcasses or retail beef in the U.S.<sup>14 15 16</sup>

With full consideration of the information described above, FSIS has determined that raw, non-intact beef products that are contaminated with these STEC O26, O45, O103, O111, O121, and O145, are adulterated within the meaning of 21 U.S.C. 601(m)(1). Raw, non-intact beef products that are contaminated with these pathogens are also unhealthful and unwholesome (under 21 U.S.C. 601(m)(3)). FSIS also considers adulterated intact cuts that are contaminated with these serogroups if they are to be further processed into raw, non-intact products before being distributed for consumption.

<sup>12</sup> Luchansky, J.B. 2010. Unpublished data. Portions of this research were presented at the Annual Meeting of the International Association for Food Protection, August 1–4, 2010, Anaheim, CA.

<sup>13</sup> Duffy G, Walsh C, Blair IS, and McDowell DA. 2006. Survival of antibiotic resistant and antibiotic sensitive strains of *E. coli* O157 and *E. coli* O26 in food matrices. *Int J Food Microbiol.* 109(3):179–86.

<sup>14</sup> Bosilevac JM and M Koohmaraie. 2011. Prevalence and Characterization of Non-O157 Shiga toxin Producing *Escherichia coli* Isolated from Commercial Ground Beef in the United States. *Appl Environ Microbiol.* Published ahead of print on 21 January 2011, doi:10.1128/AEM.02833–10.

<sup>15</sup> Samadpour M. 2011. Prevalence of Toxin containing non-O157 *Escherichia coli* found in Commercial Ground Beef. In preparation.

<sup>16</sup> Arthur TM, Barkocy-Gallagher GA, Rivera-Betancourt M, and Koohmaraie M. 2002. Prevalence and characterization of non-O157 Shiga toxin-producing *Escherichia coli* on carcasses in commercial beef cattle processing plants. *Appl Environ Microbiol.* 68(10):4847–52.

FSIS has developed a laboratory methodology for detection and isolation of these serogroups from beef, thereby allowing development of an enforceable policy program targeted to control STECs O26, O45, O103, O111, O121, and O145. FSIS will verify establishment controls for these pathogens and will collect product samples in support of its verification efforts as well as to inform the Agency's regulatory program with regard to the pathogens. Establishments that manufacture raw, non-intact beef products or intact raw beef components of those products will be expected to evaluate whether these non-O157 STEC are hazards reasonably likely to occur in their products. FSIS will generally not regard raw, non-intact beef products or the components of such products found to have these pathogens as adulterated until FSIS implements a routine sampling program that will include, besides *E. coli* O157:H7, six additional STEC serogroups (O26, O45, O103, O111, O121, and O145). However, if product is associated with an STEC outbreak before that time, such product will be subject to recall, consistent with current FSIS practice.

### III. Stakeholder Input

On October 17, 2007, FSIS, the Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA, CFSAN), and the 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).<sup>17</sup> At the public meeting, FSIS indicated that the Agency was considering non-O157 STEC to be adulterants but also discussed the need to conduct further research to address the 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.

#### *Petition To Declare All Enterohemorrhagic STEC To Be Adulterants*

On October 5, 2009, Marler Clark, LLP, PS, and other parties petitioned FSIS to issue an interpretive rule declaring all enterohemorrhagic STEC to be adulterants within the meaning of the FMIA. They specifically cited 21 U.S.C. 601(m)(1), under which a meat or meat

food product is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health. The petitioners argued that applying the provision to STEC in addition to serogroup O157 is justified because current scientific and medical research demonstrates that the dangers associated with *E. coli* O157:H7 extend to all pathogenic STEC. They referred to the potential for non-O157 STEC to cause HUS, the prevalence of the non-O157 STEC among foodborne pathogens, cattle as reservoirs of the pathogen, the presence of non-O157 STEC in beef products, and the implication of non-O157 STEC in outbreaks of foodborne illness. Because these non-O157 STEC have the same characteristics as O157 STEC, they argued, these pathogens ought to have the same legal status as O157 STEC.<sup>18</sup>

In an addendum to the petition, filed February 22, 2010, petitioners submitted a copy of a 2007 journal article by FDA scientists detailing a PCR method for identifying isolates that include the six most prevalent non-O157 STEC. The petitioners also provided a study that they commissioned to analyze retail ground beef samples.<sup>19</sup>

In correspondence with the petitioners, FSIS stated that when the Agency had an appropriate laboratory method for conducting regulatory sampling for some non-O157 STEC and had developed a plan for how it intends to address the issue, it would make the plan available to the public for comment. The Agency would then provide a final response to the petition.<sup>20</sup>

The petitioners filed a Supplemental Statement of Additional Grounds on May 7, 2010. In their Supplemental Statement, they cited studies of illness outbreaks linked to non-O157 STEC and a paper on the feasibility of testing ground beef and milk for Shiga-like toxin-producing *E. coli*.<sup>21</sup> The petitioners filed a Second Supplemental Statement of Additional Grounds on September 2, 2010, in light of the STEC

<sup>18</sup> [http://www.fsis.usda.gov/PDF/Petition\\_Marler\\_100509.pdf](http://www.fsis.usda.gov/PDF/Petition_Marler_100509.pdf) (Accessed Nov. 30, 2010).

<sup>19</sup> [http://www.fsis.usda.gov/PDF/Petition\\_Marler\\_Clark\\_022210.pdf](http://www.fsis.usda.gov/PDF/Petition_Marler_Clark_022210.pdf) and [http://www.fsis.usda.gov/PDF/Petition\\_Marler\\_Cover%20Letter.pdf](http://www.fsis.usda.gov/PDF/Petition_Marler_Cover%20Letter.pdf) (Accessed Nov. 30, 2010.)

<sup>20</sup> Philip S. Derfler, Assistant Administrator, Office of Policy and Program Development, FSIS/USDA. April 8, 2010. Letter to William Marler, Esq., Marler-Clark, LLP, PS. At: [http://www.fsis.usda.gov/PDF/Petition\\_Marler\\_Clark\\_Progress\\_Response.pdf](http://www.fsis.usda.gov/PDF/Petition_Marler_Clark_Progress_Response.pdf) (Accessed Nov. 30, 2010.)

<sup>21</sup> Acheson, D.W.K., et al. 1996. Detection of Shiga-like Toxin-Producing *Escherichia coli* in Ground Beef and Milk by Commercial Enzyme Immunoassay. *J. Food Prot.* 59:4:344–349.

<sup>17</sup> For the transcript and presentations, go to [http://www.fsis.usda.gov/News\\_Events/2007\\_Events/index.asp](http://www.fsis.usda.gov/News_Events/2007_Events/index.asp) (accessed Jul. 20, 2010).

O26 outbreak, discussed below, that was linked to ground beef. They attached a May 21, 2010, CDC memorandum on Non-O157 STEC outbreaks in the United States. The memorandum, referring to a recent STEC O145 outbreak in romaine lettuce, expressed the opinion that as the ability of clinical laboratories to detect non-O157 STEC has improved, more of the organisms were being detected.

*Letter to Secretary of Agriculture From American Meat Institute*

In an August 18, 2010, letter from American Meat Institute (AMI) President and CEO J. Patrick Boyle to Secretary of Agriculture Tom Vilsack, AMI offered to work with the Department on the control of STEC. AMI expressed concern that the designation of non-O157 STEC as adulterants might “result in a misdirected regulatory program that would do more harm than good.” AMI addressed several matters relating to FSIS policy on non-O157 STEC and the extent to which the non-O157 STEC are a health risk. We have considered these concerns and recommendations as we have developed this policy.

FSIS regards testing of non-intact raw beef products and components of products as just one of several verification methods the Agency uses. These include verification of establishment HACCP systems, Sanitation Standard Operating Procedures (Sanitation SOPs) and other prerequisite programs, comprehensive food safety assessments, and checks on records of purchases from suppliers.

FSIS actively engages experts and the public in ongoing discussions of public health issues and the science associated with our actions. For example, FSIS held public meetings on non-O157 STEC policy in 2007 and 2008 that involved presentations by domestic and international experts from Government, industry, and academia. Participants discussed the bases for determining non-O157 STEC to be adulterants, epidemiological evidence of increasing incidence of non-O157 STEC, and the importance of barriers and interventions in food production and processing to prevent contamination with STEC. The Agency is planning further evaluations and will use the findings to assess industry compliance and controls for pathogens in raw beef products. FSIS requests comments on whether to hold a technical meeting during the comment period for this document or later.

FSIS has prepared guidance for the validation of test kits for the detection of pathogens, including both *E. coli* O157:H7 and non-O157 STEC (see

below). This guidance should enable test kit developers to determine the effectiveness of their products. Also, as discussed elsewhere in this document, FSIS is making available its screening and isolation methods for non-O157 STEC. These methods were included in the Agency’s Microbiology Laboratory Guidebook.

FSIS intends to perform a nationwide microbiological baseline survey on beef carcasses in late 2011. This microbiological survey will analyze samples from carcasses for the presence of the pathogens *E. coli* O157:H7 and the STEC identified in this rule, *Salmonella*, and indicator bacteria (generic *E. coli*, coliforms, and Enterobacteriaceae). Regarding the analytical method to be used, FSIS is making its method publicly available and will include it in the Agency’s Microbiological Laboratory Guidebook.

#### IV. STEC Policy Implementation

##### *Implementation, Status of Laboratory Methods*

As noted above, FSIS intends by March 5, 2012, to begin implementing a routine sampling program 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 contaminated with any of the six additional STEC serogroups to be adulterated. The Agency is planning later—as soon as laboratory capacity is available—to expand this program to conduct verification testing of ground beef products for these serogroups. Data gathered from the sampling will enable the Agency to gauge more precisely the level of hazard posed by these STEC. In general, FSIS will review the information and adjust its policies and implementation strategies consistent with direction in Executive Order 13563 to retrospectively analyze rules “that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” FSIS will issue a **Federal Register** document informing stakeholders before expanding its verification testing to include raw beef products other than beef manufacturing trimmings and other ground beef components.

When FSIS samples trim or other ground beef components, FSIS will now test up to two portions of product (up to 325 g per portion) collected at an establishment to test for *E. coli* O157:H7 and, upon initiation of the actions outlined in this document, for the additional six non-O157 STEC (serogroups O26, O45, O103, O111, O121, and O145). Also, a single 325-g ground beef sample will now be tested for *E. coli* O157:H7 upon initiation of the actions outlined in this document.

FSIS has previously tested five separate 65-g sub-samples of the sample collected at an establishment for *E. coli* O157:H7. An Agency study showed the new method to be not as sensitive as the old method in detecting the lowest levels (1–4 CFR/325g) of *E. coli* O157:H7 cells. However, the difference in sensitivity was not statistically significant. Using the new method would permit FSIS to analyze more samples at the same or less laboratory costs than the present method. Because the sensitivity of the new method is comparable, if not actually equal, to that of the present method, FSIS expects the new approach to yield laboratory cost efficiencies with no significant statistical difference in the analytical results.

The Agency will use the new modified trypticase soy broth with novobiocin plus casaminoacids (mTSB+n) enrichment medium described in the FSIS Microbiology Laboratory Guidebook MLG chapters 5.06 and 5B.01 the preparation step of its procedure for identifying the six non-O157 STEC. Testing for non-O157 STEC with a polymerase-chain-reaction (PCR) test involves a two-stage PCR screening test: the first stage will detect samples positive for *stx* and *eae* (intimin). In the second stage, samples will be screened for the presence of one of the six public health-relevant serogroups (O26, O45, O103, O111, O121, and O145). A sample will be identified as “potential positive” when it tests positive for the *stx* gene and the *eae* gene and is also positive for one or more of the target O-group genes (on day three of the analysis).

Samples that are “potential positive” are further analyzed by using immunomagnetic beads to capture the target analyte. The immunomagnetic beads are used to inoculate Rainbow Agar plates. After incubation (day 4 of the analysis), the plates are observed for colonies that have an appearance typical of the target analyte. Typical colonies are tested with latex agglutination reagents specific for the target serogroup, if at least one colony tests positive by latex agglutination, the sample is called “presumptive

positive.” This is similar to *E. coli* O157:H7 analysis; typical colonies are tested using latex agglutination reagents on analytical day 4.

Samples that screen positive at the first stage of testing (stx+, eae+) for non-O157 STEC but screen negative at the second stage (O-group negative) will *not* be regarded as potential positive results. FSIS would not consider the results to be evidence of adulteration. However, such screen-positives do indicate the potential presence of an organism capable of producing Shiga toxin (*stx*) and intimin (*eae*) and may indicate conditions that allow pathogenic STEC through the system. Therefore, FSIS will use these results to inform its verifications of HACCP system adequacy, in accordance with 9 CFR 417.8.

In order for a sample to be “confirmed positive,” FSIS will further characterize the isolates by biochemical tests. A confirmed positive sample will be one where an isolate has *stx*, *eae*, and one or more of the target O-group genes and has been biochemically confirmed to be *E. coli*. (By comparison, a sample is confirmed positive for *E. coli* O157:H7 if biochemical tests identify the isolate as an *E. coli*, serological or PCR tests identify it as an O157, and serological or PCR tests detect Shiga toxin production, or are positive for the *stx* gene, or determine the isolate to be “H7.”)

The detection and isolation methodology for non-O157 STEC is described in chapter MLG 5B.00, or current revision, of the FSIS Microbiology Laboratory Guidebook, available at: [http://www.fsis.usda.gov/PDF/MLg\\_5B\\_00.pdf](http://www.fsis.usda.gov/PDF/MLg_5B_00.pdf). FSIS will advise the establishment to hold the sampled product and not release it pending negative test results. If test results are positive and product has been released into commerce, FSIS will request that the producing establishment recall that product.

FSIS estimates that most sampled product will screen negative for non-O157 STEC at the first stage of testing and that the negative results will be available within 48 hours of shipment of the samples to the laboratory. For samples that screen positive, an additional three to five days may be necessary for a confirmed positive or negative result. However, as the Agency gains experience and data, and as the performance of test methods improves, the Agency hopes to reduce the time needed to obtain definitive results.

For imported products tested at port of entry, if the product tests positive at the second stage and has been not been held at the import establishment, it will

be subject to recall. If the product has been held, the product will be refused entry. As always, product subsequently presented for import inspection from the same foreign country and establishment will be held at the official import establishment pending results. The FSIS Office of International Affairs will notify the program officials of the affected exporting country as soon as a positive result is reported, so that they can determine whether the producing establishment has exported any other product from the same production lot to the United States. As in the control of *E. coli* O157:H7, if the foreign establishment has properly defined the product lot on the basis of specific control factors, and accurately tracked the containerization of product produced under those controls, the establishment can reduce the likelihood that adulterated product will enter commerce, and can more easily recover product if a sample is positive.

Control factors recommended by FSIS for use in defining the product and container destined for the United States include *E. coli* sampling programs for distinguishing production subsets; cross-contamination preventions incorporated in Sanitation SOPs; re-work controls; and other prerequisite programs. Other control factors may include sanitary dressing procedures; employee hygiene, processing interventions that limit or reduce *E. coli* contamination; elimination of “carry over” of manufacturing trimmings, raw beef components, or re-work from one production period to the next; and sanitation of product contact surfaces, including machinery and employee hand tools.

Generally, FSIS recommends that establishments develop and implement in-plant sampling plans that define production lots or sub-lots that are microbiologically independent of other production lots or sub-lots. Production lots that are so identified may bear distinctive markings on the shipping cartons and—on exported product—foreign health certificates. If a foreign government or establishment does not apply control factors, FSIS may default to defining the product represented by a microbiological sample as all product produced on a particular production day.

FSIS expects to begin the non-O157 STEC program by analyzing raw beef manufacturing trimmings and other ground beef product components. For imported product, FSIS intends to conduct sampling of imported beef manufacturing trim and ground beef components at official import inspection establishments.

FSIS believes that, by testing trim samples and other components for the non-O157 STEC, the Agency can offer an immediate measure of public health protection commensurate with the Agency’s regulatory requirements. The Agency expects eventually to test ground beef, hamburger, and beef patty products for STEC. In taking a staged approach to the implementation of this new testing program, the Agency should be able to use its resources most effectively.

#### *Expected Industry Response*

The beef industry currently applies a range of sanitary slaughter methods to control *E. coli* O157:H7 in raw non-intact beef products. These include hide washing, sanitary hide removal, pre-evisceration organic acid rinses, spot cleaning of carcasses with viscera contamination, thermal pasteurization of dressed carcasses to reduce microbial loads, and chilled carcass treatments. These methods are typically applied in a slaughter plant sanitation program to prevent the carry-over of bacterial contamination from the farm or feedlot to the slaughter floor and meat processing areas.

Many establishments that produce raw non-intact beef products, such as ground beef, incorporate such antimicrobial interventions as organic acid sprays in their processing. These methods should be as effective in controlling non-O157 STEC as they are in controlling *E. coli* O157:H7. In this respect, the industry would incur no additional processing costs in controlling non-O157 STEC as a result of the policy the Agency is adopting. However, from the experience in controlling *E. coli* O157:H7, FSIS anticipates that many firms will want to implement their own testing programs and even to conduct the same kind of testing that FSIS plans to carry out. Some firms already test their products for *E. coli* O157:H7 and provide the further processing, wholesale, or retail businesses they supply with certificates of analysis on the product testing they have conducted. They may want to test for non-O157 STEC and certify to their customers that they have done so.

FSIS will follow the same procedures with respect to non-O157 STEC as it follows for *E. coli* O157:H7. A first-stage screen positive (*stx* and *eae*) is evidence of the presence of Shiga toxin and intimin and may indicate that an establishment is not adequately addressing hazards reasonably likely to occur. Establishments should reassess their HACCP plans, Sanitation Standard Operating Procedures, or other prerequisite programs on the basis of

this evidence. If the reassessment results indicate that pathogenic STEC are reasonably likely to occur in the production process, the establishment's HACCP plan must address them.

#### *New Checklist*

In addition, in the coming months, FSIS plans to conduct a new "checklist" survey of its field inspection personnel who are stationed in beef slaughtering and processing establishments. As they did in 2007 with respect to *E. coli* O157:H7, inspection personnel at official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting beef products with substances such as marinades will complete an on-line checklist on how the establishments address STEC. This checklist will provide information on this class of establishments regarding the methods they use to prevent product contamination.

#### *State Programs and Foreign Government Programs*

States that have their own meat inspection programs for meat products produced and transported solely within the State are required to have mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the Federal Meat Inspection Act (21 U.S.C. 661(a)(1)). Therefore, these States' sampling procedures and testing methods for non-O157 STEC in raw beef products must be at least as sensitive as FSIS's procedures and testing methods for non-O157 STEC.

Foreign countries that are eligible to export meat products to the United States must apply inspection, sanitary, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 620). Thus, in evaluating a foreign country's meat inspection system to determine the country's eligibility to export products to the United States, FSIS will consider whether the testing methods and procedures for non-O157 STEC that the country applies are equivalent to those that FSIS uses.

#### *Time-Frame for Complete Enforcement*

FSIS intends to be able to begin implementing regulatory sampling for the six non-O157 STEC in March 2012. FSIS would take action on positive samples following the same procedures as those currently followed with respect to samples that test positive for *E. coli* O157:H7.

In an effort to increase awareness of this policy, FSIS will conduct extensive outreach to FSIS- and State-regulated

small and very small meat establishments throughout the U.S. and its territories in 2011 and early 2012 as well as to foreign countries. The Agency plans to hold workshops and webinars throughout the United States. FSIS will announce exact locations and dates of these events once they are determined. In addition, FSIS will extend its outreach to these establishments by participating at conferences, trade shows, and meetings that cater to meat producers, and developing and disseminating written articles, and audio podcasts on the changes. FSIS welcomes comments on this implementation plan and on whether the Agency should hold a public meeting on the issues addressed in this document during the public comment period.

#### *Validation Guidance for Pathogen Detection Test Kits*

FSIS is announcing the availability of a compliance guide on validating performance of pathogen test kit methods. FSIS will post this compliance guide on its Significant Guidance Documents Web page ([http://www.fsis.usda.gov/Significant\\_Guidance/index.asp](http://www.fsis.usda.gov/Significant_Guidance/index.asp)). FSIS encourages those organizations that design or conduct validation studies for foodborne pathogen testing methods to avail themselves of this guidance document in meeting the pertinent regulatory requirements. FSIS is also soliciting comments on this compliance guide. The Agency will consider carefully all comments submitted and will revise the guide as warranted.

**Note:** The use of "validation" in the guidance document is not intended to have any application to the implementation of 9 CFR 417.4(a)(1) (Validation, Verification, Reassessment) on initial validation of HACCP plans.

#### **V. Anticipated Costs and Benefits Associated With This Policy**

FSIS has estimated that implementation of its non-O157 STEC testing policy will result in costs to FSIS laboratories and to the regulated industry. However, the costs are low for a policy that we believe is warranted, given the information presented above, and we believe that the benefits justify the costs.

#### *Budgetary Costs to the Agency*

There will be direct, immediate costs to FSIS laboratories for analyzing trim samples for non-O157 STEC. The Agency has estimated these costs to be approximately \$204,050 to \$338,270 per year in 2010 dollars, depending on the

number of samples analyzed.<sup>22</sup> The costs include equipment, supplies and labor for screening, screen-positive isolations, most-probable-number (MPN) procedures, MPN-positive isolation, pulsed-field gel electrophoresis (PFGE), and PFGE-positive isolation.<sup>23</sup> Some key assumptions behind these cost estimates are as follows:

- Because the laboratory analysis of samples of beef trim and other components for non-O157 STEC is an extension of the program for *E. coli* O157:H7, we only have to estimate the marginal or additional cost. There is no additional cost for shipping or sample-collection time.
- The annual number of samples is the same as the number of *E. coli* O157:H7 beef trim samples—currently an average of 2,578 samples for beef trim and other components are analyzed per year (2008–2010, sample collection rate about 45 percent).<sup>24</sup> However, the Agency is aiming to increase the sample collection rate to 80 percent. In that case, the annual number of samples to be analyzed will be about 4,600.
- Screen-positive sample rate is 2 percent, the same as with *E. coli* O157:H7.
- Confirmed positive sample rate is 0.5 percent, again the same as with O157:H7.<sup>25</sup>

FSIS will conduct follow-up testing as it does for *E. coli* O157:H7. The Agency data show that the average number of domestic follow-up testing in 2008–2010 is about 880.<sup>26</sup> The Agency also estimates that the cost per follow-up testing is about \$80. Therefore, the cost for follow-up testing will be about \$70,400.

In addition, FSIS will conduct a for-cause food safety assessment (FSA) for every positive sample, as it does currently for *E. coli* O157:H7-positive samples. The Agency estimates the average cost to conduct an FSA (including laboratory work) to be about \$14,000. Assuming the foregoing, the cost to FSIS to conduct the for-cause FSA related to non-O157 STECs will be

<sup>22</sup> The costs are about \$204,100 if 2,578 samples are collected and analyzed, or \$338,300 if 4,600 samples are collected and analyzed. Please see assumption in the text.

<sup>23</sup> Data are from the Laboratory Director, Office of the Assistant Administrator, Office of Public Health Science, FSIS.

<sup>24</sup> Data are from the Data Analysis and Integration Group, the Office of Data Integration and Food Protection, FSIS. The numbers of samples include both domestic and imported product samples.

<sup>25</sup> Data are from the Laboratory Director, Office of the Assistant Administrator, OPHS, FSIS.

<sup>26</sup> Data is from Data Analysis and Integration Group, the Office of Data Integration and Food Protection. The numbers of samples include both domestic and imported product.

about \$180,460 to \$322,140 per year (*i.e.* cost per FSA  $\times$  annual number of samples  $\times$  confirmed positive sample rate).<sup>27</sup> Adding the cost to conduct sample testing, follow-up testing and for-cause FSAs, the total cost to the Agency is about \$454,910 to \$730,810. Note that these cost estimates do not include the costs of expanding testing to raw ground beef products. FSIS intends to provide a full analysis of costs before expanding the testing policy.

#### Costs to the Industry

The major costs to the industry will be two-fold: (1) Costs to establishments of starting their own screening for non-O157 STEC and (2) costs of diverting the positive product to cooking or other treatment that would render the product suitable for human food. (Positive-testing product also can be destroyed—sent to a landfill, incinerated, etc.—or rendered into pet food and other products not for human food.) To estimate these costs with precision, we need to know how many establishments will be testing for non-O157 STEC under this document and their HACCP sizes (large, small, or very small). Because the Agency cannot predict with certainty either the number of establishments or the size distribution, our estimate is preliminary.

FSIS is not aware of data on how many establishments are currently testing for non-O157 STEC, or the size distribution of these establishments. The Agency's best estimate is that about 20 percent of the establishments are testing.<sup>28</sup> According to information collected under FSIS Notice 65-07, 33 percent of the beef slaughter establishments test for *E. coli* O157:H7.<sup>29</sup> Assuming that the percentage of establishments testing for non-O157 would increase to the same level (*i.e.* 33 percent), we would see 13 percent more establishments starting to test for non-O157 because of this document. The most current Agency beef trim volume survey data, computed from the number of bins of trim produced, show that the total beef trim production is about 2.05 billion pounds per year.<sup>30</sup> Given that in commercial

testing a combo bin is 2,000 pounds, an additional 133,000 combo bins will be tested (total beef trim production/weight per combo bin  $\times$  additional percentage that will test). Further assuming the cost per test is \$30 to \$40, the preliminary estimate for the cost of the additional 13 percent of establishments testing for non-O157 is about \$4.0 million (if \$30 per test) to \$5.3 million (if \$40 per test).<sup>31</sup> This is a preliminary estimate and we invite the regulated industry and the public to comment.

To estimate the loss of value from diverting the products to cooking once they test positive, we rely on market data on the wholesale price for beef trim and on internal experts' opinion on the price differential between beef trim and cooked beef products. Market data show that the 3-year average wholesale price for beef trim is about \$1.47 per pound.<sup>32</sup> Agency experts estimate that the value for cooked beef products is significantly lower—only about one-half to one-third of the value of beef trim, because the quality of product directed to cooking is generally inferior. On the basis of this assumption, we calculate the loss to the industry from diverting the products to cooking to be about \$3.9 to \$5.2 million.<sup>33</sup> Again, this is a very preliminary estimate, and we invite comment.

As for the cost of holding the products while awaiting test results, Agency data show that the great majority of the establishments are already holding their products while awaiting the results of other pathogen testing.<sup>34</sup> The Agency cannot estimate with precision how many more products will be held as a result of FSIS testing for one more pathogen group, but given that the great majority of the products are already

being held, the addition is not likely to be significant. Because non-O157 STEC tests will use the samples collected for existing sampling programs, there will be no additional collection of samples. For the establishments that are already holding products for O157 and other pathogen test results, the additional cost will only be holding for one extra day waiting for the confirming non-O157 STEC results, which is minimal. For the few establishments that are not holding products, they would have to do so under the proposed "Test and Hold" Notice, and the additional cost would also only be holding for one more day waiting for the non-O157 STEC results.

As we have stated in this document, many establishments that produce raw non-intact beef products implement controls for *E. coli* O157:H7. These methods should be as effective in controlling non-O157 STEC as in controlling *E. coli* O157:H7. In this respect, the industry would incur no additional processing costs in controlling non-O157 STEC as a result of this document.

Note that these cost estimates do not include the costs associated with expanding FSIS testing to raw ground beef products. FSIS intends to provide a full analysis of costs before expanding the testing policy.

#### Expected Benefits

##### Reduced Illnesses and Deaths

One benefit from sampling and testing for non-O157 STEC is the reduction of illnesses and deaths caused by non-O157 STEC, if testing leads to preventative controls that reduce the risk of illness. As we have stated, controls for *E. coli* O157:H7 already in place should be as effective in controlling non-O157 STEC as in controlling *E. coli* O157:H7, and the industry would not need to take additional measures to control non-O157 STEC as a result of the document. However, to the extent that establishments reassess their HACCP plans after receiving positive test results and make appropriate additional changes, overall control of pathogens may improve and illness reductions may result.

##### Avoided Recalls

Through early detection of products contaminated with non-O157 STEC, this new program may prevent some food recalls. However, on net, the additional testing may increase the total number of recalls as the new policy would require the recall of all products that test positive and have entered commerce, regardless of whether they are

<sup>27</sup> Data are from the Laboratory Director of Office of the Assistant Administrator, OPHS, FSIS and from the Budget Division, Office of Management, FSIS.

<sup>28</sup> This is based on internal experts' opinion.

<sup>29</sup> U.S. Department of Agriculture. Food Safety and Inspection Service. August, 2008. Results of Checklist and Reassessment of Control for *Escherichia coli* O157:H7 in Beef Operations. Table 5.4.31, p. 57.

<sup>30</sup> Data are from Applied Analysis Branch, Data Analysis and Integration Group, Office of Data Integration and Food Protection/FSIS/USDA as of October 12, 2010.

<sup>31</sup> Other assumptions behind this estimate include: (1) Positive sample rate being 2 percent—the same with the positive sample rate in FSIS sampling, (2) one test per sample, and (3) using IEH methodology.

<sup>32</sup> Economic Research Service (ERS), USDA, Market and Trade Economics Division provided the data; which are originally from Red Meats Yearbook (<http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1354>) and Livestock, Dairy, and Poultry Newsletter tables (<http://www.ers.usda.gov/publications/ldp/LDPTables.htm>) [both accessed Jan. 20, 2011]. The 3-year range is September 2007 to August 2010.

<sup>33</sup> The equation for calculating the cost for diverting product to cooking is: annual beef trim produced (in pound)  $\times$  screening positive sample rate  $\times$  percentage of the value lost  $\times$  dollar value per pound  $\times$  percentage of additional establishments testing for STEC.

<sup>34</sup> According to the most recent full-year data (2009) from Data Analysis and Integration Group/Office of Data Integration and Food Protection, the percentages of beef trim and components held by establishments pending FSIS *E. coli* O157:H7 test results are: 99 percent by large, 97 percent by small and 88 percent by very small establishments. Data are as of December 23, 2010.

associated with an outbreak or not. Any recall may have a significant impact on the industry, including the loss of sales revenue, the cost to dispose of recalled products, and the loss of consumer confidence and business reputation. Recalls negatively impact consumers by creating anxiety and time-consuming inconveniences (e.g. looking for recall information, checking the products purchased, returning or disposing of products identified by the recalls, etc.). For the Government, the Agency incurs costs for conducting recalls<sup>35</sup> and recovery of adulterated products. The Food and Drug Administration has estimated that a Class I recall<sup>36</sup> may cost as much as \$3 to \$5 million for the manufacturer, retailers, and State, local, and Federal authorities.<sup>37</sup>

The first and only FSIS non-O157 STEC recall to date took place in August 2010. It is not clear how many recalls would have occurred if the new testing policy had been implemented or whether, on net, the policy will decrease or increase the number of recalls.

#### Net Benefits

As explained in the Expected Costs and Expected Benefits Sections, there are uncertainties in our cost and benefit estimates. For example, we do not know how many illnesses will actually be prevented. It is not clear whether on net there will be a reduction in the number of illnesses. It is also challenging to know what the industry cost will be because it is difficult to predict how many establishments will start to test and what the size distribution will be or to what extent industry will take additional measures that will prevent, reduce, or control those hazards, as they do with regard to O157 STEC.<sup>38</sup>

<sup>35</sup> This includes inspectors' activities at the establishments, FSAs and recall effectiveness checks, and dissemination of information about recalls through press releases.

<sup>36</sup> A Class I recall is defined as a health hazard situation where there is a reasonable possibility that the use of the products will cause serious, adverse health consequences. Non-O157 STEC outbreak fits in this category.

<sup>37</sup> Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice Products, 63 FR 24258, May 1, 1998.

<sup>38</sup> One common measure that establishments use is purchase specifications in a prerequisite program. FSIS Directive 10,010.1 stipulates that FSIS expects the establishment to have: (1) A document from each supplier that provides assurance that the supplier employs CCPs (critical control points) that address *E. coli* O157:H7, (2) certificates of analysis and the sampling method used by the supplier, and (3) records that verify on an on-going basis that the receiving establishment is executing its program effectively. Other measures establishment can use include (a) treating or washing the product when removed from Cryovac bags and trimming the outer surface before processing non-intact product, and

However, the Agency has determined that the potential public health benefits justify the costs.

#### Impact on Small Business<sup>39</sup>

This FSIS document on non-O157 STEC does not impose a testing requirement on official establishments. As mentioned above, establishments are already required to identify hazards reasonably likely to occur and to take measures that will prevent, eliminate, or reduce those hazards under HACCP. The measures could include purchase specifications in a prerequisite program, sanitary activities, and using antimicrobials or other lethality treatments on raw beef product. Establishments that produce non-intact raw beef products, such as ground beef, or the intact raw components of those products, must already operate food safety systems that control STEC O157. Therefore, this document does not impose significant negative impact on a significant number of small and very small businesses. FSIS is requesting comment on the impact of this document on small businesses.

#### Summary of Requests for Comment

FSIS is requesting comment on the following specific subjects discussed in this document related to non-O157 STEC serogroups O26, O45, O101, O121, and O145:

- FSIS regulatory sampling plan for non-O157 STEC for the above serogroups
- Suggestions for baseline survey of non-O157 STEC prevalence in certain raw beef products
- Whether a technical meeting on methods for controlling non-O157 STEC should be held during the comment period
- Whether to hold an additional public meeting on the plan for implementing the policy on non-O157 STEC
- Validation guidance for pathogen detection test kits
- Preliminary estimates of the cost per test for non-O157 STEC
- Estimates of the loss to industry of diverting positive-testing product to cooking
- The usefulness of technical workshops for small and very small establishments

(2) using antimicrobials or other lethality treatments on raw beef product and verifying the effectiveness of those antimicrobials. (FSIS Directive 10,010.1)

<sup>39</sup> Based on FSIS' HACCP (Hazard Analysis and Critical Control Points) size definition: very small establishments have fewer than 10 employees or generate less than \$2.5 million in annual sales; and small establishments have 10 or more but fewer than 500 employees and generate more than \$2.5 million in annual sales.

- What obstacles might prevent establishments from adjusting to the FSIS policy on non-O157 STEC by March 5, 2012 and what alternative implementation date would be more practical
- What education, outreach, or training materials would be of greatest assistance to establishments in preparing for implementation of the Agency's policy
- For foreign governments, what additional information would be helpful in addressing equivalency or implementation concerns not already addressed in this document and accompanying materials

We are also requesting comment on the DRAFT Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* that we are making available at [http://www.fsis.usda.gov/PDF/Non\\_O157\\_STEC\\_Risk\\_Profile.pdf](http://www.fsis.usda.gov/PDF/Non_O157_STEC_Risk_Profile.pdf). FSIS undertook the preparation of the risk profile to help clarify the extent of the scientific literature available for evaluating the issues raised by the Citizen's Petition.

#### USDA Nondiscrimination Statement

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#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this document, FSIS will announce it on-line through the FSIS Web page located at [http://www.fsis.usda.gov/regulations/2010\\_Notices\\_Index/](http://www.fsis.usda.gov/regulations/2010_Notices_Index/).

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices,



FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at [http://www.fsis.usda.gov/News\\_&\\_Events/Email\\_Subscription/](http://www.fsis.usda.gov/News_&_Events/Email_Subscription/). Options range from recalls, export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done, at Washington, DC, September 13, 2011.

**Alfred V. Almanza,**  
Administrator.

[FR Doc. 2011-24043 Filed 9-19-11; 8:45 am]

**BILLING CODE 3410-DM-P**

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Parts 50, 52, and 100**

**[Docket Nos. PRM-50-97, PRM-50-98, PRM-50-99, PRM-50-100, PRM-50-101, PRM-50-102; NRC-2011-0189]**

**Petitions for Rulemaking Submitted by the Natural Resources Defense Council, Inc.**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petitions for rulemaking; notice of receipt.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC or the Commission) has received six petitions for rulemaking (PRM), dated July 26, 2011, from the Natural Resources Defense Council, Inc. (NRDC or the petitioner). The petitioner requests that the NRC amend its regulations to require emergency preparedness (EP) enhancements for prolonged station blackouts; EP enhancements for multiunit events; licensees to confirm seismic hazards and flooding hazards every 10 years and address any new and significant information; licensees to improve spent nuclear fuel pool safety; each operating and new reactor licensee to establish station blackout mitigation strategies and resources; and more realistic, hands-on training and exercises on Severe Accident Mitigation [sic] Guidelines and Extreme Damage Mitigation Guidelines for specified licensee staff. The NRC is not instituting a public comment period for these PRMs at this time.

**ADDRESSES:** You can access publicly available documents related to this action, including the six petitions for rulemaking, using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and

have copies made, for a fee, publicly available documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). For the ADAMS accession numbers to the six PRMs, see Section I, Procedural Processing, of this document.

- *Federal Rulemaking Web Site:* Supporting materials related to the six petitions for rulemaking can be found at <http://www.regulations.gov> by searching on the related Docket IDs. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

**FOR FURTHER INFORMATION CONTACT:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-492-3667, e-mail: [Cindy.Bladey@nrc.gov](mailto:Cindy.Bladey@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Procedural Processing**

The petitions for rulemaking were docketed by the NRC on July 28, 2011, and have been assigned the following Docket Numbers and can be accessed in ADAMS under the associated ADAMS accession number:

Title	Docket Nos.	ADAMS ML No.
Emergency Preparedness Enhancements for Prolonged Station Blackouts .....	PRM-50-97 .....	ML11216A237
Emergency Preparedness Enhancements for Multiunit Events .....	PRM-50-98 .....	ML11216A238
Seismic Hazards and Flooding Hazards .....	PRM-50-99 .....	ML11216A239
Spent Nuclear Fuel Pool Safety .....	PRM-50-100 .....	ML11216A240
Station Blackout Mitigation .....	PRM-50-101 .....	ML11216A241
Training on Severe Accident Mitigation [sic] Guidelines .....	PRM-50-102 .....	ML11216A242

Each submission separately cites the "Recommendations for Enhancing Reactor Safety in the 21st Century: The Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident" (Fukushima Task Force Report, ML111861807), dated July 12, 2011, as the rationale for the petition for

rulemaking. The Commission has recently directed staff to engage promptly with stakeholders to review and assess the recommendations of the Fukushima Task Force Report for the purpose of providing the Commission with fully-informed options and recommendations. See U.S. Nuclear

Regulatory Commission, "Near-Term Report and Recommendations for Agency Actions Following the Events in Japan," Staff Requirements Memorandum SECY-11-0093, August 19, 2011 (ADAMS Accession No. ML112310021) and U.S. Nuclear Regulatory Commission, "Engagement