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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: Response to comments on final determination; planned implementation for testing raw beef manufacturing trimmings.

SUMMARY: The Food Safety and Inspection Service (FSIS) is confirming that it will implement routine verification testing for six Shiga toxin-producing *Escherichia coli* (STEC), in addition to *E. coli* O157:H7, in raw beef manufacturing trimmings beginning June 4, 2012. FSIS is also responding to comments on the final determination published September 20, 2011, in the **Federal Register** regarding the June 4, 2012, implementation of STEC sampling and related issues.

DATES: Beginning June 4, 2012, FSIS will implement routine verification testing for the six additional STECs discussed in this document (O26, O45, O103, O111, O121, and O145), in raw beef manufacturing trimmings (domestic or imported) derived from cattle slaughtered on or after June 4, 2012. To allow industry time to implement any appropriate changes in food safety systems, including control procedures in their processes, FSIS will generally not regard raw, non-intact beef products or the components of these products found to have these pathogens as adulterated until June 4, 2012. FSIS will announce in a future **Federal Register** document the date it intends to implement routine verification testing for the specified STECs in additional raw beef products tested by FSIS for *E. coli* O157:H7, including ground beef.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2011, FSIS published a document in the **Federal Register** announcing its determination that raw, non-intact beef products, or raw, intact beef products that are intended for use in raw non-intact product, that are contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, and O145 are adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011). The products are adulterated because they contain a poisonous or deleterious substance that may render them injurious to health. FSIS stated that raw, non-intact beef products that are contaminated with these STEC are also unhealthful and unwholesome (under 21 U.S.C. 601(m)(1) and (m)(3)) (76 FR 58157 at 76 FR 58159). FSIS also considers intact cuts that are contaminated with these pathogens to be adulterated, unhealthful, and unfit for human food if they are to be further processed into raw, non-intact products before being distributed for consumption (76 FR 58157 at 76 FR 58159).

FSIS announced that it intended to implement sampling and testing for the six non-O157 STEC, as it already does for *E. coli* O157:H7. The Agency said that it would begin this verification and testing program on March 5, 2012. The Agency noted that it would initially sample only raw beef manufacturing trimmings and other ground beef components for the six non-O157 STEC, but that it would consider other products, including raw ground beef contaminated with these STEC, to be adulterated (at 76 FR 58160). The Agency asked for comments on its plans for implementing the program (at 76 FR 58157, 58164).

In addition, FSIS asked for comments on Agency plans for a baseline survey of the prevalence of the specified STEC in raw beef products, whether to hold technical or other public meetings, various cost estimates, the type of outreach and information that would be most useful to establishments preparing for implementation by the Agency of its sampling and verification testing program, and information that foreign governments might need to address inspection equivalency or implementation concerns.

FSIS extended the public comment period from November 21, 2011, to December 21, 2011, and held a public meeting by teleconference on December 1, 2011. (76 FR 72331; Nov. 23, 2011).

In response to comments received from industry, FSIS issued a **Federal Register** notice (77 FR 9888; Feb. 21, 2012) in which FSIS moved the implementation date to June 4, 2012, for routine verification activities, including testing, for the six specified STEC in raw beef manufacturing trimmings derived from cattle slaughtered on or after June 4, 2012. To allow establishments time to implement appropriate changes in their food safety systems, including changes in process control procedures, FSIS will generally not treat as adulterated raw beef products found to have these pathogens until June 4, 2012. Additionally, FSIS will begin conducting for-cause food safety assessments (FSAs) in response to FSIS positive non-O157 STEC results approximately 90 days after FSIS implements non-O157 STEC sampling and testing in beef manufacturing trimmings. This 90-day period will provide establishments sufficient time to make any necessary changes to their food safety systems.

When FSIS laboratories analyze the samples, FSIS anticipates that there will be some samples that will, in the first stage of the FSIS screen test, test positive for Shiga toxin gene (*stx*) and for the intimin gene (*eae*) but screen negative for all the target O-groups (O26, O45, O103, O111, O121, and O145). Such samples will be referred to the USDA-Agricultural Research Service (ARS) for further microbiological analysis to determine whether they are positive for other target O-groups. FSIS expects to collect and analyze these screen results from its verification tests for at least the first year of testing. FSIS will not consider the product associated with non-confirmed results to be adulterated. FSIS believes that the information on these screen results will be useful to establishments in enhancing the preventive controls in

their food safety systems and believes that establishments will benefit from knowing whether they have screen-positive but not confirmed sample results for *E. coli* O157:H7 or the specified non-O157 STECs. Therefore, FSIS is contemplating providing individual establishments with this information every quarter. In addition, FSIS expects to regularly make aggregate information known to stakeholders in order for stakeholders to be aware of and to consider the relevance of the information.

FSIS, as a public health regulatory agency, has adopted a preventive, risk mitigation strategy that takes into consideration the fact that the specified STECs are adulterants of certain raw beef products. In support of this strategy, FSIS has finalized its risk profile to reflect comments, the results in a recent article on thermal resistance of STEC-inoculated non-intact beef steaks with strains of *E. coli* O157:H7 and non-O157 STEC (a pooled composite of STEC serogroups O45, O103, O111, O121, and O145) by USDA–ARS (Luchansky et al., 2012), and information from articles on how much more common non-O157 STEC infections are compared to *E. coli* O157:H7 infections (Blanco et al., 2004; Elliott et al., 2001; Nielsen et al., 2006; Vally et al., 2012). The final risk profile is available on the FSIS Web site at *http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp*

In the September 20, 2011, **Federal Register**, FSIS also announced the availability of, and requested comments on, the guidance document, *Validation Guidance for Pathogen Detection Test Kits.* FSIS explained that the Agency prepared this guidance for the validation of test kits for the detection of pathogens, including both *E. coli* O157:H7 and non-O157 STEC. FSIS encouraged organizations that design or conduct validation studies to avail themselves of this guidance document in meeting the pertinent regulatory requirements. FSIS received numerous comments on this document, will update it as necessary in response to comments, and will announce the availability of the updated guidance document when it is ready.

I. Implementation plan

In finalizing the plan for implementing its verification activities, including the sampling and testing program for the specified STECs, FSIS considered all comments submitted in response to the September 2011 final determination, as well as comments provided at the December 1 teleconference, and is clarifying certain aspects of the implementation of the verification activities.

FSIS will issue a **Federal Register** notice announcing when FSIS will begin routine sampling and testing for the seven STECs of all raw beef products subject to Agency *E. coli* O157:H7 sampling and testing, from both domestic and international sources, regardless of the slaughter date of cattle from which the product is derived. When expanded testing begins, mixtures of raw beef derived from cattle slaughtered either before or after June 4, 2012, whether the production lot contains raw beef manufacturing trimmings, other raw ground beef components, bench trim, or ground beef, will be subject to testing for the seven specified STECs.

The Agency is updating the economic analysis published in the September 20, 2011, **Federal Register** notice in response to public comments received. To respond more thoroughly to the comments, FSIS will incorporate any additional data on establishment and Agency testing for the specified STECs that may be available upon FSIS's implementation of routine testing for non-O157 STECs in beef manufacturing trimmings. As indicated in the September 20 notice (at 76 FR 58163), the Agency will update and revise the September 20, 2011, economic analysis, will respond to comments received on the earlier analysis, and will assess the economic effects of testing for the specified STECs on raw beef manufacturing trimmings, other raw ground beef components, and ground beef. When the Agency completes the updated analysis, FSIS will announce its availability and request comments on the analysis. The Agency will then assess comments and make any necessary changes before finalizing the economic analysis and before expanding FSIS testing to include other raw ground beef components and ground product.

II. Comments and Responses

FSIS received approximately 34 comments in response to the September 2011 notice. Comments received from consumer groups supported the implementation of the final determination that six additional STEC serotypes are considered adulterants in non-intact raw beef products and intact beef products used to produce such products and encouraged FSIS to resist delaying the implementation date. Several consumer advocacy groups, citing the incidence of foodborne disease caused by these organisms, expressed support for FSIS's final determination. Comments submitted by industry, trade associations, and foreign countries expressed concerns about the final determination and implementation of the verification sampling and testing program.

Following is a discussion of comments that requested more information or clarification regarding the verification testing program that will begin on June 4, 2012.

Delay Implementation

Comment: Many commenters requested a delay of the implementation date for the testing of the specified STECs for various reasons, including their view that FSIS needs to conduct a baseline of non-O157 STECs on beef products, needs to wait until commercially available test kits for these organisms become available and can be validated, needs to hold a technical meeting, and needs to conduct a risk assessment.

Response: FSIS has concluded that a baseline is neither necessary nor warranted before implementation of the FSIS verification sampling and testing program. These organisms are present in beef products in the United States; the evidence for this is presented in the risk profile. FSIS considers the data on non-O157 STECs obtained by the Agricultural Research Service (ARS) at a limited number of slaughter establishments to be evidence that the pathogens should be considered adulterants and are capable of causing illness. FSIS also considered data collected by the person who petitioned the Agency to declare these pathogens to be adulterants in a limited geographical retail area. The Agency has concluded, on the basis of information in a report from the Centers for Disease Control and Prevention (CDC), that these organisms pose a significant public health burden in the United States.[1] FSIS and the CDC believe that there are more unreported and unconfirmed illnesses associated with the specified non-O157 STECs than with *E. coli* O157:H7.

Nonetheless, in 2013 FSIS intends to conduct the carcass baseline survey discussed in the September 20, 2011 **Federal Register** notice. This microbiological survey will analyze samples from carcasses for the presence of the pathogens *E. coli* O157:H7 and the specified STECs, *Salmonella,* and indicator bacteria (generic *E. coli,* coliforms, and Enterobacteriaceae). This baseline will be designed to identify the type, level, and frequency of

[1] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, and Griffin PM. 2011. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis.

contamination of carcasses immediately after hide removal but before decontamination treatments and evisceration. When the baseline study is being developed, FSIS will share the study design with stakeholders.

Regarding a baseline for raw beef manufacturing trimmings, other raw ground beef components, and ground beef, FSIS is assessing its current verification testing programs to see how those programs can be modified to yield on-going baseline information and obviate the need for stand-alone baseline studies.

At this time, FSIS is not planning to host a technical meeting relating to non-O157 STEC. Commenters did not identify any specific need for a technical meeting. If there is evidence that a technical meeting would be helpful to industry, FSIS will, of course, reconsider this issue.

Screening and confirmation methods for non-O157 STEC are available to industry. In addition, reagents are commercially available to those companies planning to use the FSIS method. Some establishments have been testing for non-O157 STECs for a year or more.

Several companies have submitted test kits to detect at least the six specified STEC O-groups for review by validation bodies. Using the FSIS compliance guidelines related to validating test kits, FSIS has reviewed validation data from test kits and issued no-objection-letters (NOLs) to several manufacturers. The NOLs provide establishments with supporting documentation regarding the reliability of verification testing results. Confirmation testing is available to industry through commercial reagents.

Regarding the contention that a risk assessment is needed, the Agency has assessed scientific data from several fields on the risk posed by non-O157 STECs and determined that these pathogens are adulterants under the FMIA. To make this determination, the Agency prepared a risk profile, which has been independently peer reviewed in accordance with Office of Management and Budget (OMB) guidelines. Both, the CDC and the Food and Drug Administration (FDA)/Center for Food Safety and Applied Nutrition reviewed the document and provided input on FSIS' approach. The risk profile lays out all available information on the public health concerns posed by these organisms and supports the adulteration determination regarding these *E. coli* serogroups.

FSIS Sampling Plan

Comment: Several commenters stated that FSIS has not adequately justified the initiation of the non-O157 STEC sampling program, given that non-O157 STECs are found at levels comparable to *E. coli* O157:H7, and infection from the non-O157 STEC tends to be less severe than that from *E. coli* O157:H7. One commenter questioned whether FSIS's testing program will be adequate for determining process control and stated that FSIS's end-product testing will have no impact other than to consume resources that could be better spent on food safety research.

Response: The FSIS verification testing program is intended to assess whether the industry, collectively, is controlling for the presence of a designated food safety hazard in products regulated by FSIS. Adding the six non-O157 STECs to the group of pathogens for which FSIS tests will help in improving food safety. The purpose of the new testing program for non-O157 STECs is to verify that establishments producing raw beef products have adequately addressed these pathogens.

FSIS acknowledges that the best approach to reducing STEC contamination lies not in comprehensive end-product testing but in the development and implementation of science-based preventive controls, with end-product testing to verify process control. FSIS's non-O157 STEC testing program will improve food safety because FSIS anticipates that establishments may voluntarily make changes to their food safety systems in response to the new testing. For example, establishments may initiate a testing program for non-O157 STECs or may add new interventions to address pathogens. FSIS is aware that some companies have added new bacteriophage interventions to address non-O157 STEC. FSIS is not requiring such changes but anticipates establishments may make these types of changes in response to the testing.

The non-O157 STECs may cause illnesses of varying severity. Though limited data are available on dose-response, there is evidence that the infectious doses of the pathogens are relatively low. Hence, their potential to cause illness is relatively high. Although there is variability in virulence severity of non-O157 STECs, the six specified non-O157 STEC organisms can cause severe foodborne illness requiring hospitalization. Numerous illnesses in the United States have resulted from all six of the non-O157 STECs. CDC data show that the six STEC organisms for which FSIS will be testing are known to cause more than 80 percent of human illnesses attributed to non-O157 STEC.

The number of illnesses and deaths caused by non-O157 STECs and associated with beef consumption or a beef source is likely to decline if establishments voluntarily make changes to their food safety system that result in greater public health protection. Also, FSIS's current testing for *E. coli* O157:H7 may not detect other STECs that may be present in the product.

Comment: One industry commenter asked whether FSIS intends to collect two samples for N–60 sampling, and if so, would *E. coli* O157:H7 testing be performed on one sample and non-O157 STEC testing on the other sample. Another commenter noted that FSIS does not specify the number of samples it intends to collect in the sampling plan.

Response: FSIS inspection personnel will collect one N–60 sample (in multiple containers) that will be tested for all the STECs, including *E. coli* O157:H7. Eventually, FSIS will analyze all the raw beef samples collected for both *E. coli* O157:H7 and non-O157 STEC.

Comment: Several commenters stated that FSIS's sampling plan should be designed to estimate prevalence of the STEC pathogens in raw beef products.

Response: FSIS verification testing programs are not designed at this time to assess statistically-based national prevalence for select organisms. FSIS verification testing assesses establishment control of a food safety hazard in products regulated by FSIS. The number of tests FSIS will annually conduct for non-O157 STECs will exceed the number typically analyzed in a structured baseline. Although FSIS's testing will not provide a true prevalence estimate upon implementation, it will provide helpful information about whether establishments' food safety systems adequately address food safety.

Comment: One commenter asked how FSIS intends to increase its collection rates for its beef manufacturing trimmings testing program.

Response: The Agency has a number of different initiatives underway to increase its collection rates for the beef manufacturing trimmings testing programs. Importantly, the new Public Health Information System (PHIS), which is now implemented nationwide, can schedule samples for laboratory analysis. PHIS does so in a way that ensures that requests are sent only to establishments whose profiles (information on establishment

characteristics) indicate that they are producing the targeted product at the time of sample scheduling. In addition, if an establishment no longer makes the product, PHIS allows inspection program personnel to modify the establishment profile (information on establishment characteristics) to reflect this change so that future samples are not scheduled for that establishment.

FSIS Testing Method

Comment: One association questioned whether the FSIS method published in the Microbiology Laboratory Guidebook (MLG) on November 4, 2011, was appropriately peer-reviewed. Commenters questioned whether industry is required to test for non-O157 STECs, and whether industry would be required to use the FSIS method.

Response: Initial results from the method-development phase were published in a peer-reviewed journal with ARS and FSIS authors.[2] The MLG method was validated and then verified for internal use by FSIS Laboratory Services. In addition, when designing the screening and confirmatory strategy for the regulatory test, FSIS sought input from the CDC, ARS, and the FDA and worked closely with ARS in transferring the method to use in the FSIS laboratories.

FSIS is not requiring STEC testing by industry, nor will it establish a requirement for the FSIS testing methodology to be used. Also, foreign government central competent authorities and foreign establishments can determine what testing to conduct and can use any test that they determine is sufficient to identify the presence of the specified STECs. As with the domestic beef establishments, foreign government central competent authorities and foreign establishments are expected to ensure that raw beef product is controlled for the presence of the specified non-O157 STECs.

Comment: One commenter asked whether the most-probable-number (MPN) enumeration was included in the FSIS method.

Response: No, the FSIS MLG method 5B.01 as described does not include an MPN method for enumerating non-O157 STEC in positive samples.

Comment: Several commenters questioned the Agency's statement referring to expected establishment actions following *stx*- or *eae*-positive first-stage screen results (at 76 FR 58161, col. 3): ''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.'' Commenters were concerned that an establishment would be required to reassess its Hazard Analysis and Critical Control Point (HACCP) plan after such results.

Response: The Agency regrets any confusion that this statement created. The first- and second-stage screening steps of the FSIS method are performed concurrently, not sequentially. Establishments are not required to take corrective actions or reassess their HACCP plans in response to positive FSIS screen results. However, establishments would be required to take corrective actions or reassess their HACCP plans in response to FSIS confirmed positive results for the specified non-O157 STEC.

Some establishments may use the FSIS laboratory method or another method that could indicate the presence of *stx* or *eae* genes or the presence of one of the relevant ''O'' subgroups. Such screen-positive results indicate the presence of an organism capable of causing illness. If an establishment does not perform additional testing, it should treat lots that test positive in screen tests as positive. Similarly, FSIS will consider those results positive for non-O157 STEC if not confirmed negative. This is consistent with how FSIS regards positive *E. coli* O157:H7 screen results.

Therefore, if an establishment finds product positive for any of the specified non-O157 STECs in screen testing, does not confirm the finding as negative, and has not addressed the hazard in its HACCP system, the establishment would be required to take corrective actions, including reassessing its HACCP plan (9 CFR 417.3).

Comment: Commenters stated that a large number of samples will screen positive using the screening method described in MLG 5B.01. Commenters also stated that the isolation and confirmation process takes a long time to complete and that producers cannot hold fresh product pending the completion of isolation and confirmation described in the MLG 5B.01.

Response: FSIS does not agree with these assertions. Based on available data, FSIS estimates that 2 percent of raw beef samples tested using the FSIS method would test positive for non-O157 STEC in screen tests, with a significantly lower percentage being confirmed. This is comparable to what FSIS has found with the FSIS screening method for *E. coli* O157:H7. The amount of time to obtain a confirmation result from the new FSIS non-O157 STEC method is the same as that for the current *E. coli* O157:H7 method. The reagents for the FSIS test method, including the confirmation method, are commercially available to industry.

Establishment Testing

Comment: One commenter asked whether, if an establishment only tested for *stx* (Shiga toxin) and *eae* (intimin) genes using a polymerase-chain-reaction (PCR) screening test, and the sample tested negative, FSIS would accept this result as negative for *E. coli* O157:H7 and the specified non-O157 STECs.

Response: FSIS would accept as negative for *E. coli* O157:H7 and the specified non-O157 STECs a sample that tests negative for *eae* and *stx* on a screening test performed by an establishment.

FSIS recognizes that industry uses non-culture methods that detect alternative target analytes for *E. coli* O157:H7 including, but not limited to, *eae* and *stx.* An establishment may increase the likelihood of detecting all hypothetical strains and low-levels of contamination with these pathogens in a variety of ways, including but not limited to using a test method that is also used by a regulatory body, or that is validated and certified by an independent body (e.g., AOAC International, the French Association for Standardization (AFNOR), the European organization for the validation and certification of alternative methods for the microbiological analysis of food and beverages (MicroVal), or the Nordic system for validation of alternative microbiological methods (NordVal)). An establishment may also opt to use a test method for detecting the specified STECs that is subjected to a robust validation using the FSIS cultural method as a reference. In this case, a test kit manufacturer may choose to ask the Agency through AskFSIS to review the method. If the method is found to be adequate, FSIS will issue a NOL to the test kit manufacturer for filing with the establishment.

Comment: A law firm representing beef industry clients asked whether, during the transition period (until June 4, 2012), when establishments are ''beta testing'' STEC analytical methods and possibly refining their food safety

[2] Fratamico, P.M., Bagi, L.K., Cray Jr, W.C., Narang, N., Medina, M.B., Liu, Y. Detection by multiplex real-time PCR assays and isolation of Shiga toxin-producing *Escherichia coli* serogroups O26, O45, O103, O111, O121, and O145 in ground beef. Foodborne Pathogens and Disease 2011; 8(5):601–7.

system, a stage-one positive test result would be considered positive.

Response: No, after the June 4 implementation date for the FSIS verification testing program, positive ''beta tests'' will not be considered by FSIS to be conclusive evidence that one or more specified STECs is present in the sample. However, if product from the establishment is associated with a non-O157 STEC outbreak, FSIS will take steps to ensure that associated product is removed from commerce and will expect the establishment to take corrective actions, including reassessment of its HACCP plan, if necessary, to prevent a recurrence of this food safety hazard.

FSIS encourages establishments to maintain records from ''beta testing'' as part of the documentation of the development of their food safety systems. Establishments may use these records to show the controls they have in place and the disposition of their products.

Comment: An industry commenter asked where industry can obtain the non-O157 STEC strains for testing purposes.

Response: Non-O157 STEC strains may be obtained from public collections, including the STEC collection at Michigan State University, the *E. coli* Center at Penn State University, the American Type Culture Collection in Manassas, Virginia, and at other locations.

Comment: One trade association asked whether *E. coli* O157:H7 could be used as both an indicator and an index organism for non-O157 STEC in beef production.

Response: If source materials are sampled at a sufficiently high frequency and in a consistent manner, test results for the presence of *E. coli* O157:H7 or non-O157 STEC can serve as indicators of process control during beef production. In fact, in data [3] from inspection personnel at the top 33 (by volume) beef slaughter establishments, 60 percent of establishments had defined high-event periods when the establishments could discern subtle changes in the percent-positive screening test results as evidence of a process out of control. FSIS believes that the screening tests that the industry has been using are capable of indicating the presence of more than just *E. coli* O157:H7.

Because both *E. coli* O157:H7 and non-O157 STECs occur in raw beef at low levels and at low prevalence, however, positive tests for these pathogens are not likely to be highly correlated. Therefore, neither *E. coli* O157:H7 nor non-O157 STEC are expected to provide reliable index measurements. An index organism is one whose concentration or frequency correlates with the concentration or frequency of another organism.

FSIS-Recommended Cooking Temperatures

Comment: One commenter stated that if STECs can survive ''ordinary'' or ''typical'' cooking, FSIS should reconsider its cooking temperature recommendations. Another commenter stated that there is insufficient data regarding heat tolerance of non-O157 STECs.

Response: FSIS's temperature recommendation for consumers to cook ground beef to 160 degrees Fahrenheit is adequate to achieve a safe product. There is no reason to believe that a higher temperature is necessary (*http://www.fsis.usda.gov/Fact_Sheets/Ground_Beef_and_Food_Safety/index.asp*). However, FSIS is well aware that some consumers ordinarily or typically do not cook ground beef to 160 degrees Fahrenheit, in spite of the extensive outreach and education efforts conducted by the Agency and its public health partners to change behaviors.[4] In addition, FSIS believes that most consumers do not use a thermometer to confirm the end-point temperature for safety. Consequently, the handling and preparation practices of many consumers are not ''ordinarily'' or ''typically'' capable of rendering the cooked ground beef safe without further risk mitigation.

The September 20, 2011, **Federal Register** notice cited the August 2010 STEC O26 outbreak and other evidence (at 76 FR 58159—Luchansky et al., published in 74 *J. Food Prot.* (2011)7:1054–1064) that demonstrates that the strain survives ''typical'' cooking employed by some consumers, and that further risk mitigation was necessary. Researchers at USDA–ARS examined the effect of various cooking temperatures on strains of five serogroups (O45, O103, O111, O121, and O145) and *E. coli* O157:H7 inoculated into beef steaks that were then tenderized. Results show that the non-O157 STECs exhibited thermal inactivation similar to that for *E. coli* O157:H7.[5] In another study (Duffy et al., 2006), STEC O26 also showed similar thermal tolerance to *E. coli* O157:H7.

Equivalency and Implementation Concerns of Foreign Governments

Comment: Several commenters noted that the September 20, 2011, **Federal Register** notice states (at 76 FR 58161, col. 1–2): ''For imported products tested at port of entry, if the product tests positive at the second stage and has 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.'' These commenters asked whether FSIS intended to treat imported product tested for non-O157 STEC differently from such product tested for *E. coli* O157:H7.

Several trade associations and foreign governments addressed various topics relating to the treatment of imported products at port of entry, the equivalency of foreign inspection systems, and United States obligations under World Trade Organization agreements. Governments and industry trade groups expressed concern that the new non-O157 STEC policy may violate the United States' obligations under the Agreement on Sanitary and Phytosanitary (SPS) Measures. Finally, governments and trade associations questioned the adequacy of the FSIS risk profile with respect to how it addresses characteristics of non-O157 STEC.

Response: Consistent with FSIS's procedures for testing for *E. coli* O157:H7 in imported product, if a product offered for import tests positive at port of entry for non-O157 STEC in the screen test and has not been held at the import establishment, it will not be subject to recall. However, if the product is still at the import establishment, FSIS will retain the product until it is confirmed negative.

If the product is confirmed positive and has been held by the establishment or retained by FSIS at the import establishment, FSIS will refuse entry of the product. If the confirmed-positive product has not been held at the import

[3] To help develop the operational criteria for industry to use to identify high-event periods and for Enforcement, Investigations, and Analysis Officers to consider when conducting traceback procedures, FSIS examined industry data collected by FSIS inspection personnel from the top 33 slaughter establishments, representing 80 percent of industry production volume (number of cattle slaughtered).

[4] Ecosure. 2007 U.S. Cold Temperature Evaluation. October 15, 2008.

[5] Luchansky J.B., Shoyer B.A., Call J., Schlosser W., Shaw W., Bauer N., Latimer H., Porto-Fett A. 2012. Fate of Shiga-toxin producing O157:H7 and non-O157:H7 *Escherichia coli* cells within blade-tenderized beef steaks after cooking on a commercial open-flame gas grill. Journal of Food Protection. 75:62–70.

establishment, FSIS will request that the importer of record recall the product.

FSIS has notified its trading partners about the new non-O157 STEC testing policy. The Agency has committed to video conferencing and teleconferencing exchanges to assist foreign governments in understanding the policy and how it applies to them. The Agency expects countries that export products to the United States to address non-O157 STEC under existing agreements and to prevent contamination of their raw beef products with these adulterants. Foreign countries may use any method that will ensure, with reasonable confidence, that products that they export to the United States will not be contaminated with detectable non-O157 STEC. Because of the nature of non-O157 STECs, FSIS would not exclude any country importing product subject to testing from non-O157 STEC verification testing by FSIS.

Finally, the Agency has assessed scientific data from several fields on the risk posed by non-O157 STECs and determined that these pathogens are adulterants under the FMIA. To make this determination, the Agency prepared a risk profile, which has been independently peer-reviewed in accordance with Office of Management and Budget (OMB) guidelines. Both CDC and FDA reviewed the document and supported FSIS's approach.

The risk profile, in its final version, incorporates CDC data that show that the organisms for which FSIS will be testing are known to cause more than 80 percent of human illnesses attributable to non-O157 STECs in the United States.

In addition, FSIS refined the risk profile substantially in response to comments that were received during peer review. Accordingly, the risk profile represents the best characterization of the science associated with the risk from the specified non-O157 STECs.

One commenter raised a concern about the attribution of a non-O157 STEC outbreak in 2007 to a beef product. This outbreak was included in the risk profile.

CDC has information, including a May 21, 2010, memo, stating that, ''The preliminary data in the table were obtained primarily from reports voluntarily made by state health departments to CDC. In 2010, we supplemented NORS [National Outbreak Reporting System] data from the on non-O157 STEC outbreaks by contacting state and federal health agencies, by reviewing the scientific literature, and by other methods.'' The data reported in the memo may be more complete than the data submitted by the reporting agency to the Foodborne Disease Outbreak Surveillance System (FDOSS), which is a component of NORS. In the memo, CDC listed the confirmed or suspected vehicle for this outbreak as ground beef. This was based on a posting on the North Dakota State Health Department Web site.

FSIS recognizes that the availability of attribution data for the non-O157 STECs is partially a function of the number of clinical laboratories that test for the pathogens, as well as of the robustness of epidemiological investigations. In this case, however, the only available information suggests that the non-O157 STEC outbreak may have been linked to a beef product.

Summary of Changes and Clarifications Made in Response to Comments

As noted earlier in this document, in response to comments on the September 20, 2011, notice (76 FR 58157), FSIS extended the public comment period from November 21, 2011, to December 21, 2011 (76 FR 72331; Nov. 23, 2011). Also in response to public comments, FSIS held a technical meeting December 1, 2011, to solicit additional comments. FSIS later moved the implementation date of the non-O157 STEC verification policy for beef manufacturing trimmings to June 4, 2012 (77 FR 9888; Feb. 21, 2012). The purpose of the delay in implementation was to allow the regulated establishments time to effect any necessary changes in their food safety systems, including process control procedures, and to allow time for improvements in testing methods.

In addition, in response to comments, the Agency made available to foreign governments reagents used in the FSIS method. To allay other concerns of foreign governments, the Agency affirmed that it would treat incoming foreign product in the same way that it treats such product FSIS tests for *E. coli* O157:H7.

On the matter of using indicator organisms, FSIS has affirmed that testing of source materials of raw, non-intact beef products for STEC to verify process controls can be effective if the materials are sampled at sufficiently high frequencies. However, FSIS has clarified that *E. coli* O157:H7 is not an index organism for non-O157 STEC.

In response to questions, FSIS has clarified that establishments are not required to take corrective actions in response to FSIS screen positive results. However, FSIS has also clarified that if establishments find product positive for non-O157 STECs in their screen tests and do not conduct further testing to confirm that the product is negative, FSIS will consider the product positive for non-O157 STECs, just as FSIS considers product that screens positive for *E. coli* O157:H7 to be positive if an establishment does not conduct further testing.

Finally, the Agency has finalized the risk profile on the non-O157 STECs and has incorporated relevant information conveyed by commenters.

Executive Order 13175

The policy discussed in this notice does not have Tribal Implications that preempt Tribal Law.

USDA Nondiscrimination Statement

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce it on-line through the FSIS Web page located at—*http://www.fsis.usda.gov/regulations_&_policies/Interim_&_Final_Rules/index.asp.*

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 email 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 email 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/.* 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, May 25, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–13283 Filed 5–29–12; 4:15 pm]

BILLING CODE 3410–DM–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701, 703, 713, 721, 723, and 742

RIN 3133–AD98

Eligible Obligations, Charitable Contributions, Nonmember Deposits, Fixed Assets, Investments, Fidelity Bonds, Incidental Powers, Member Business Loans, and Regulatory Flexibility Program

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule and interim final rule with comment period.

SUMMARY: NCUA is removing certain regulations and eliminating the Regulatory Flexibility Program (RegFlex) to provide regulatory relief to federal credit unions. NCUA is also removing or amending related rules to ease compliance burden while retaining certain safety and soundness standards. Those rules pertain to eligible obligations, charitable contributions, nonmember deposits, fixed assets, investments, incidental powers, and member business loans. In addition, NCUA is issuing an interim final rule with a request for comment to amend a provision in the fidelity bond rule to remove references to RegFlex.

DATES: *Effective dates:* The final rule, as well as the interim final rule pertaining to the revisions in the fidelity bond rule, § 713.6, will go into effect on July 2, 2012.

Comment date: We will consider comments on the interim final rule portion (the fidelity bond rule, § 713.6), as discussed in section IV of the preamble of this rulemaking. Send your comments to reach us on or before July 30, 2012. We may not consider comments received after the above date in making any decision whether to amend the interim final rule.

ADDRESSES: In commenting on the interim final rule, you may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Web Site: http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Interim Final Rule, Section 713.6, Fidelity Bond'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You can view all public comments on NCUA's Web site at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Chrisanthy Loizos, Staff Attorney, Office of General Counsel, at the above address or telephone (703) 518–6540, or Matthew J. Biliouris, Director of Supervision, or J. Owen Cole, Director, Division of Capital Markets, Office of Examination and Insurance, at the above address or telephone (703) 518–6360.

SUPPLEMENTARY INFORMATION:

I. Background

a. Why is NCUA adopting this rule?

On July 11, 2011, President Obama issued Executive Order 13579, ordering independent agencies, including NCUA, to consider whether they can modify, streamline, expand, or repeal existing rules to make their programs more effective and less burdensome. Consistent with the spirit of the Executive Order and as part of NCUA's Regulatory Modernization Initiative, the NCUA Board (Board) is adopting this rule to streamline its regulatory program by eliminating RegFlex. The final rule relieves regulatory burden on federal credit unions (FCUs) because they will no longer need to engage in any process for a RegFlex designation. In addition, the final rule provides regulatory relief to FCUs that are currently not RegFlex eligible because it extends to them most of the flexibilities previously available only to RegFlex FCUs.

The Board issued a Notice of Proposed Rulemaking (NPRM) in December 2011. 76 FR 81421 (Dec. 28, 2011). The comment period on the proposed rule ended on February 27, 2012. NCUA received seventeen comment letters on the NPRM: Four from FCUs, three from trade associations (1 representing banks, 2 representing credit unions), nine from state credit union leagues, and one from a law firm. The majority of the commenters supported the rulemaking generally. Four commenters did not support the rule as proposed, and the remaining commenters offered comments on particular provisions but did not take a position on the initiative as a whole. For the reasons discussed below, the Board is adopting the amendments almost exactly as proposed. As such, the Board does not restate the legal analysis it presented in the NPRM's preamble and incorporates it by reference here in this rulemaking. *Id.*

b. What was RegFlex?

The Board established RegFlex in 2002. 66 FR 58656 (Nov. 23, 2001). RegFlex relieved FCUs from certain regulatory restrictions and granted them additional powers if they demonstrated sustained superior performance as measured by CAMEL rating and net worth classification. An FCU could qualify for RegFlex treatment automatically or by application to the appropriate regional director. Specifically, an FCU automatically qualified for a RegFlex designation when it received a composite CAMEL rating of ''1'' or ''2'' for two consecutive examination cycles and maintained a net worth classification of ''well capitalized'' under part 702 of NCUA's rules for the last six quarters. An FCU subject to a risk-based net worth (RBNW) requirement under part 702 could also qualify for RegFlex treatment