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Done at Washington, DC, on: September 13, 2012.

Alfred V. Almanza,
Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0020]

Risk-Based Sampling of Beef Manufacturing Trimmings for *Escherichia coli* (*E. coli*) O157:H7 and Plans for Beef Baseline

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice; Request for comments.

SUMMARY: FSIS is announcing its intention to redesign its *E. coli* O157:H7 verification testing program for beef manufacturing trimmings to make the program more risk-based and to enable the Agency to calculate on-going statistical prevalence estimates for *E. coli* O157:H7 in raw beef manufacturing trimmings. This notice also discusses FSIS's plans to perform a beef carcass baseline. FSIS seeks public comment on its plans, which have been developed in response to a 2011 audit by the U.S. Department of Agriculture's Office of Inspector General (OIG) of FSIS's

protocol for N-60 sampling of beef manufacturing trimmings for *E. coli* O157:H7. This notice also announces changes that FSIS has made to its beef manufacturing trimmings program to increase both the collection rate and the likelihood that FSIS will find positive samples. Finally, this notice summarizes a 2012 OIG report and the actions that FSIS has taken to address the recommendations in that report.

DATES: Comments on this notice must be submitted on or before November 19, 2012.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. 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 the 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, OPPD, RIMD, Docket Clearance Unit, Patriots Plaza III, 1400 Independence Avenue SW., 8-163A, Mailstop 3287, Washington, DC 2024-3221.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0020. 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: Rachel Edelstein, Acting Assistant Administrator for the Office of Policy and Program Development, FSIS, USDA, Room 351-E, Jamie Whitten Building, 14th and Independence Avenue SW., Washington, DC 20250-3700; telephone (202) 720-0399, fax (202) 720-2025; rachel.edelstein@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

In 1994, FSIS determined that *E. coli* O157:H7 adulterates raw ground beef product within the meaning of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(1)). FSIS began testing ground beef for *E. coli* O157:H7 in 1994. In 1999, FSIS determined that, besides

ground beef, *E. coli* O157:H7 adulterated all non-intact raw beef product and intact raw beef product intended for use in raw, non-intact beef product (64 FR 2803; Jan. 19, 1999).

Starting in 2007, FSIS began testing beef manufacturing trimmings and other raw ground beef components (raw esophagus (weasand) meat, head meat, cheek meat, beef from advanced meat recovery systems, low temperature rendered lean finely textured beef, partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat) for *E. coli* O157:H7 at the originating slaughter establishment. FSIS also began verifying that grinders, fabricators, and supplying slaughter establishments had effective controls for *E. coli* O157:H7.

FSIS sampled beef manufacturing trimmings under a simple random sampling plan in which each slaughter establishment had an equal chance of being scheduled for sampling, regardless of production volume or previous history. FSIS collects approximately 1,300 samples per year. From calendar year 2007 through June 2011, FSIS found an average of about seven *E. coli* positives per year, resulting in an average *E. coli*-positive rate of about 0.60% in beef manufacturing trimmings during this period. Each slaughter establishment producing beef manufacturing trimmings was sampled about 3.5 times per year.

Inspection personnel collect beef trimmings samples for testing using N-60 procedures. Under these procedures, inspection personnel collect 60 slices of beef manufacturing trimmings cut to a specific size and also collect an additional, separate "grab sample" of smaller pieces of trim from the same production lot. FSIS laboratories use the 60 slices for the first part of the analysis for *E. coli* O157:H7. If the 60 slices are confirmed positive, laboratory personnel do quantitative (most probable number or MPN) analysis on the "grab" sample.¹

When an FSIS beef manufacturing trimming sample tests positive, FSIS takes a number of steps including: Collecting follow-up samples at the establishment where the positive sample was found; documenting production of adulterated product in a noncompliance record when appropriate; conducting a food safety assessment (FSA) (a comprehensive review of the establishment's food safety

¹ FSIS's *E. coli* O157:H7 test results are reported on the Agency's Web site at: http://www.fsis.usda.gov/Science/Ecoli_Raw_Beef_Testing_Data_YTD/index.asp (accessed June 20, 2012).

system); and verifying that the establishment accurately executed all steps in its Hazard Analysis and Critical Control Point (HACCP) plan for production of trim and implemented appropriate corrective actions.

OIG Audit

OIG audited the efficacy of FSIS testing for *E. coli* O157:H7 in beef manufacturing trimmings in 2010 and reported the audit results in February 2011.² On the basis of its audit, OIG recommended that FSIS:

(1) Develop a plan to perform baseline studies of beef manufacturing trimmings and ground beef to determine the estimated prevalence rate of *E. coli* O157:H7 for the purpose of redesigning FSIS's verification testing program. The report also recommended that the plan prescribe how often that initial prevalence estimate should be reassessed.

(2) Re-evaluate sample parameters (size and confidence level) to provide a higher confidence level for FSIS' ability to detect contaminated product and to more effectively verify process controls at beef slaughter establishments.

(3) Document the scientific support and rationale for the revised verification testing program design, including the contamination level that will be associated with the new sample parameters, and how the estimated prevalence rate has informed the redesigned verification testing program. Publish in the **Federal Register** FSIS's revised beef testing verification program and solicit public comment.

(4) Focus *E. coli* O157:H7 sampling and testing resources at establishments that are likely to be of higher risk, and consider the use of specialized sample collection teams.

In response to the first recommendation, FSIS plans to make changes in its *E. coli* O157:H7 verification testing programs for beef manufacturing trimmings and ground beef to calculate prevalence of the pathogen in these products. FSIS conducted an evaluation of the Agency's current sampling programs to determine whether they provide sufficient data to calculate prevalence estimates for pathogens in FSIS regulated product: http://www.fsis.usda.gov/PDF/Prevalence_Estimates_Report.pdf. FSIS is also considering implementing similar sampling designs in its programs for bench trim and other components, so

that they are consistent with the sampling designs for ground beef and beef manufacturing trimmings. Should the Agency adopt and implement these changes, it will endeavor to generate statistical prevalence estimates in ground beef and beef manufacturing trimmings. Prevalence estimation in bench trim and other components may not be possible because of limited sampling resources and data concerns.

In 2013, FSIS intends to initiate a beef carcass baseline survey to determine the presence and levels of the pathogenic *E. coli*, including O157:H7 and the six non-O157 Shiga toxin-producing *E. coli* (STEC) most commonly associated with illness in the United States; *Salmonella* species; and certain indicator organisms. As the Agency does with other baseline studies, FSIS will make the study design and sampling plans available on its Web site and will solicit comments on the study design and sampling plans before carrying out the study. In this survey, FSIS plans to collect samples from beef carcasses immediately after de-hiding and before evisceration in order to identify the type and level of contamination before antimicrobial interventions are applied to the carcass. FSIS may also collect samples from carcasses slaughtered that same day, pre- and post-chill.

As the Agency has done with previous baseline surveys, FSIS will report the results of this survey on its Web site and incorporate them into compliance guidance for industry to use in assessing individual establishment performance against the national performance. Controls to reduce the risk of enteric pathogen contamination at slaughter are crucial. Under 9 CFR 310.18(a), establishments must handle beef carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter. Because these sources of contamination, whether visible or not, may contain pathogens, a principal objective of proper sanitary dressing and process control procedures is to reduce the potential for exposure of carcasses and parts to any contamination or food safety hazard during the removal of the hide, feet, head, gastrointestinal tract, and other internal organs. If establishments implement effective controls during sanitary dressing procedures, it is likely that it will prevent or reduce contamination significantly. This survey will be important to the Agency in assessing the prevalence of the load of pathogens and certain indicator organisms on carcasses throughout the slaughter process. In addition to informing the future Agency

compliance guidance, FSIS will also use the baseline survey results to make changes to its sampling, testing, and other verification activities.

In response to OIG recommendation #2, FSIS decided to revise the N-60 program to provide for more frequent sampling at establishments that the Agency determines have problems controlling *E. coli* O157:H7 in beef manufacturing trimmings. In changing the N-60 program, FSIS considered sanitary dressing verification data, product traceback activities, and other inspection and data collection activities. The paper discussing this analysis is posted with this notice as a related document at (http://www.fsis.usda.gov/PDF/Redesign_Beef_Trim_Sampling_Methodology.pdf). In the analysis, FSIS examined *E. coli* O157:H7 test results as a function of beef manufacturing trimmings volume class from calendar year 2007 through June 2011. Establishments that produce beef manufacturing trimmings are grouped in four volume classes: Very small, producing less than 1001 pounds per day; small, 1001 to 50,000 pounds per day; medium, 50,001 to 250,000 pounds per day; and large, more than 250,000 pounds per day. FSIS found that the large-volume establishment class (total volume CY 2007-2011: 13,500,000,000 pounds) has the lowest *E. coli* O157:H7 percent positive, while the small-volume class (total volume CY 2007-2011: 1,268,625,000 pounds) has the highest *E. coli* O157:H7 percent positive. The analysis found that sampling in the small volume class is twice as likely to yield an *E. coli* O157:H7-positive result as sampling in large volume establishments. FSIS found that sampling volume classes in proportion to the percent positive in the volume class is approximately 2 times as likely to yield an *E. coli* O157:H7-positive test result as is sampling under the simple random sampling program.

FSIS also found that the percent-positive rate in the high-prevalence season (now considered to be May through October, rather than April through September, on the basis of FSIS data) is about 2 times as high as it is the rest of the year. Accordingly, the analysis concluded that increasing the sampling of beef manufacturing trimmings during May through October should increase the probability of detecting *E. coli* O157:H7 positives.

FSIS determined that there are about 480 slaughter establishments in the beef manufacturing trimmings sampling frame that are eligible for sampling. FSIS selects between 200 and 250 establishments from the frame every month for sampling. Annually, FSIS

² U.S. Department of Agriculture, Office of Inspector General. February 2011. FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7. Audit Report 24601-9-KC. Washington, DC. See this report at: <http://www.usda.gov/oig/webdocs/24601-9-KC.pdf> (accessed June 20, 2012).

distributes approximately 2,600 sample forms to its personnel. However, in FY 2010, only 1,274 samples were successfully collected, a response rate of about 49 percent. One reason a sample request may not result in successful sample collection is that a sample may be taken but discarded because of, for example, late sample delivery to the laboratory or container leakage. Additionally, if establishments were not producing the product during the 30-day sample-collection period, FSIS field personnel were not able to collect the sample. To address the low collection rate that results when establishments are not producing the product at the time of sample collection, FSIS increased its sample collection window from 30 days to 60 days and has overscheduled sampling to adjust for non-response. The goal of these changes is to ensure that all 2,600 samples are collected.

Based upon the results of its analysis, FSIS has already redesigned its *E. coli* O157:H7 testing program for beef manufacturing trimmings so that sampling is weighted by production volume and volume class-specific risk factors. FSIS will ensure that each slaughter establishment producing beef manufacturing trimmings is sampled at least once per year. FSIS also increased sampling during the high prevalence season (May through October in the United States) by up to 20 percent. Because of resource constraints, however, increased sampling during the high-prevalence season will require a decrease in sampling during the low prevalence season.

FSIS will take measures to increase the number of samples that the Agency successfully collects. As stated above, FSIS has already increased the time during which field personnel may collect a sample from 30 days to 60 days. This increase allows field personnel additional time to collect samples for testing in establishments that infrequently produce manufacturing trimmings. FSIS also plans to over-schedule the sampling to increase the total number of samples actually collected. On the basis of the changes FSIS has made to its N-60 program to date, FSIS estimates that the probability of obtaining *E. coli* O157:H7-positive results in beef manufacturing trimmings during FSIS verification testing will increase by a factor of about 2.5.

FSIS does not plan to increase the annual statistical sample size but will redistribute the samples on the basis of an analysis of the Agency's sampling program for beef manufacturing trimmings. The changes to the sampling

program, however, may increase the number of follow-up samples collected as a consequence of finding more *E. coli* O157:H7-positive samples. FSIS is also considering changes to its sampling programs for bench trim and other raw ground beef components. The changes are likely to be similar to those discussed above in its beef manufacturing trimmings program.

In its response to OIG, FSIS suggested that sanitary dressing noncompliances may be related to *E. coli* O157:H7-positive results in beef trim because carcass contamination is the primary cause of ground beef component adulteration with the pathogen. FSIS reviewed and evaluated the sanitary dressing procedure noncompliance records for slaughter establishments that produce beef manufacturing trimmings found to have tested positive. The Agency concluded that it did not appear that the rate of sanitary dressing procedure noncompliances could be used to identify establishments that have a higher probability of having an *E. coli* O157:H7-positive test result.

In November 2011, FSIS revised its sanitary dressing verification directive (FSIS Directive 6410.1) to improve and clarify for FSIS inspectors the procedures that they are to follow in verifying sanitary dressing compliance. This revision and the expected improvement in inspector verification of sanitary dressing procedures may result in a higher correlation between sanitary dressing noncompliances and *E. coli* O157:H7 positives in beef trim. FSIS intends to perform analyses of verification sampling results to determine whether the correlations have changed.

As is discussed above, in responding to an Agency *E. coli* O157:H7-positive finding in beef manufacturing trimmings, FSIS collects multiple follow-up samples and conducts verification activities at the originating slaughter establishment. FSIS intends to implement new traceback procedures at beef manufacturing trimming suppliers that provided source materials for ground product or bench trim (that is, trim derived from beef at an establishment other than the originating slaughter establishment) that FSIS finds positive.³ When FSIS implements these new traceback procedures, the Agency expects that the data gathered will enable it to better target sampling at slaughter establishments.

³ See the FR notice on traceback (77 FR 26725; May 7, 2012) at: http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp (accessed June 20, 2012).

OIG recommended that FSIS re-evaluate sample parameters (size and confidence level). Sample size calculations were not performed as part of the statistical assessment in order to stay resource neutral. FSIS intends to evaluate the allocation of sampling resources within the *E. coli* O157:H7 sampling program to estimate prevalence.

Additionally, FSIS intends to better identify establishments likely to have problems with *E. coli* O157:H7 through analysis of data collected through sanitary dressing verification, new product traceback activities, Public Health Information System (PHIS) data (including any relevant data available through the Hazard Analysis Verification procedure and establishment profile), and other inspection and data collection activities. Because *E. coli* O157:H7 and the other STECs are enteric pathogens, analysis of FSIS sanitary dressing verification data may help the Agency to identify establishments that should be sampled more frequently for the pathogens. PHIS and hazard analysis verification (HAV) procedures will likely allow FSIS to gather more information on establishment-specific controls and how effective they are. Again, FSIS hopes to use this data to identify establishments that should be sampled more frequently for these pathogens.

As the Agency announced in the September 11, 2011, notice on non-O157 STEC (76 FR 58157), FSIS is also planning to conduct a survey, using its employees that are assigned to beef slaughter and processing establishments, to gather information on establishment controls for STECs in beef. This survey will be similar to a previous "65-07 Checklist" survey.⁴ The results of the survey will provide FSIS with information regarding establishment practices that the Agency may be able to use to further develop risk-based sampling in the future. FSIS plans also to conduct risk analyses, as appropriate, to determine the relative impact of various establishment factors on the probability of *E. coli* O157:H7 contamination and subsequent illnesses, hospitalizations, and deaths. FSIS intends to use the data generated by the actions listed above to assess and evaluate its *E. coli* O157:H7 beef manufacturing trimmings sampling program and make risk-based changes as appropriate.

OIG recommended, and FSIS considered, the use of specialized

⁴ Available at http://www.fsis.usda.gov/PDF/Ecoli_Reassessment_&_Checklist.pdf (accessed June 20, 2012).

sample collection teams for collecting N-60 samples in establishments. FSIS has concluded that the Agency does not have the resources to implement this recommendation. The use of the specialized sample collection teams would be cost-prohibitive.

2012 OIG Audit Report

In a more recent audit, reported in May 2012, OIG studied the variation of the beef industry's *E. coli* O157:H7 sampling and testing protocols among slaughter plants, and how FSIS and the beef industry use the test results to improve food safety.⁵ OIG found that the beef industry was conducting thousands of tests daily and generally complying with FSIS's guidance for how to perform those tests.

OIG made several additional recommendations to FSIS, and the Agency has already responded to some of them. For example, OIG recommended that FSIS issue guidance for industry on sampling and how the industry might plan for and react to high-event periods (HEPs)—when slaughter establishments have a high rate of positive test results for *E. coli* O157:H7 or other STEC or virulence markers in trim samples.

On May 7, 2012, FSIS announced the availability of compliance guidance for establishment sampling and testing for Shiga toxin-producing *E. coli* (STEC) organisms or virulence markers (77 FR 26725). This guidance includes criteria that establishments can use to determine if they are experiencing an HEP. The document explains that extensive sampling of trimmings and careful evaluation of test results can help establishments identify places in their processes where controls are poor, and where they can take corrective actions. It recommends that establishments continually strive to reduce the percentage of test results that are positive for *E. coli* O157:H7 (or STEC organisms or virulence markers).

During an HEP, adulteration may be more widespread than a positive-testing lot of product may indicate. By following the guidance and withholding adulterated product from commerce during HEPs, establishments are more likely to avoid costly recalls. While establishments can use the guidance now, FSIS requested comments on it and will update it as necessary in response to the comments.

⁵ U.S. Department of Agriculture, Office of Inspector General, May 2012, Application of FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7, Audit Report 24601-0001-31, Washington, DC. This report is posted at: <http://www.usda.gov/oig/webdocs/24601-0001-31.pdf> (accessed June 20, 2012).

OIG also recommended that FSIS re-evaluate and improve its policies on inspector collection of trim samples by, for example, ensuring that inspectors randomly select product for sampling, ensuring that inspectors collect samples of proper weight, and ensuring that they do not take multiple samples from single pieces of trim.

To ensure that all raw ground beef, beef manufacturing trimmings, and bench trim samples are the necessary weight, FSIS recently issued instructions to inspection program personnel on the use of new sample collection bags that have fill-lines.⁶ In addition, in response to other recommendations, FSIS will evaluate its instructions for sampling and determine what other changes may be needed.

OIG recommended that FSIS improve communication with industry by issuing guidance to assist establishments in selecting laboratories according to the laboratories' testing capabilities. On March 8, 2012, FSIS announced the availability of guidance for establishments in the selection of commercial and private microbiological testing laboratories (77 FR 13999). The guidance includes a checklist for industry on the issues to consider and also the types of documents that establishments should maintain to support their testing programs.⁷ Establishments can use the guidance now. FSIS asked for comments on the guidance and will make any necessary changes to it after evaluating the comments.

OIG further recommended that FSIS determine whether to increase sampling of trim, assess its performance measures for *E. coli* O157:H7, clarify current instructions to inspection personnel in its directive on verification of controls for the pathogen (FSIS Directive 10,010.1), and assess the quality of inspection in Talmadge-Aiken establishments. FSIS is evaluating these issues and will respond to these recommendations.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at: http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

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⁶ The notice is available at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/35-12.pdf> (accessed June 20, 2012).

⁷ The guidance is available at: http://www.fsis.usda.gov/PDF/Guidance_Selecting_Micro_Testing_Lab.pdf (accessed June 20, 2012).

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Done at Washington, DC, on: September 13, 2012.

Alfred V. Almanza,
Administrator.

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DEPARTMENT OF AGRICULTURE

Forest Service

Central Idaho Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.