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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. FSIS–2012–0038]

Changes to the Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producin Escherichia coli and Salmonella

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing changes to its procedures for *Salmonella* verification sampling program of raw beef products. On the date that FSIS will announce in the **Federal Register** document that responds to any comments on this document, FSIS will discontinue *Salmonella* sampling set procedures (''HC01'') in ground beef products, except in establishments with results that exceeded the standard for *Salmonella* in that establishment's most recently completed sample set (i.e., in those establishments in Category 3). At the same time, FSIS will begin analyzing for *Salmonella* all raw beef samples that it collects for Shiga toxin-producing *Escherichia coli* (STEC) analysis. Therefore, FSIS will begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that it collects for STEC testing. To be consistent with the Agency's STEC analytic sample portions, FSIS laboratories will increase the raw ground beef analytic sample portion for *Salmonella* analysis from 25 grams to 325 grams. This notice describes how FSIS intends to use the results from its verification sampling program to develop new *Salmonella* performance standards for ground beef product and to estimate *Salmonella* prevalence in raw ground beef and beef manufacturing trimmings products. Finally, this document discusses changes that the Agency is considering related to FSIS *Salmonella* sampling and testing of other products.

DATES: Submit comments on or before September 27, 2013. Interested parties need to get their comments in on time because the Agency does not intend to grant any extensions of the comment period.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by one 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 on-line instructions at that site for submitting comments.

Mail, including CD–ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8–163B, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2012–0038. 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 to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 164, Washington, DC 20250–3700 between 8 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495; or by Fax: (202) 720–2025.

SUPPLEMENTARY INFORMATION: FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) that is intended to ensure that meat and meat food products distributed in commerce are wholesome; not adulterated; and properly marked, labeled, and packaged. As part of its inspection program, FSIS collects samples of these products for laboratory analysis (21 U.S.C. 642(a)).

History of the Salmonella Verification Sampling Program

The *Salmonella* verification sampling program formally began with the Agency's final rule, entitled ''Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems,'' which FSIS published on July 25, 1996 (61 FR 38805–38989; *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf).* Among other things, the PR/HACCP rule set *Salmonella* performance standards for establishments producing selected classes of raw meat products, including ground beef, steers and heifers, and cows and bulls (9 CFR 310.25(b)). In 2011, FSIS stopped sampling and testing for *Salmonella* in steers and heifers and cows and bulls because percent positive findings were very low (less than one percent), and this carcass sampling was expensive for the Agency. As stated in the PR/HACCP rule (at 61 FR 38835), FSIS selected *Salmonella* for the performance standard because it is the most common cause of foodborne illness associated with meat and poultry products; it is present to varying degrees in all major species; and the interventions targeted at reducing *Salmonella* may help reduce contamination by other enteric pathogens.

FSIS uses the *Salmonella* performance standards to verify process control in slaughter and certain processing operations. The performance standard for ground beef is based on the industry average (percent positive samples) estimated from baseline surveys conducted before PR/HACCP was implemented.

Under the existing *Salmonella* verification sampling program, the Agency assesses whether establishments meet the *Salmonella* standard by collecting randomly selected product samples using the risk-based, 3-category establishment classification system announced on February 27, 2006 (71 FR 9772). FSIS inspection program personnel collect samples and submit them to FSIS laboratories for analysis over a defined number of sequential

days of production to complete a sample set. As detailed in the February 2006 notice, the maximum number of positive samples per set for the ground beef product category is 5 of 53.

FSIS presently categorizes establishment performance as follows:

I. Category 1. Consistent Process Control: Establishments with percent positive Salmonella samples at 50 percent or less of the performance standard in the two most recently completed sample sets.

II. Category 2T. Variable Process Control but Transitioning Towards Consistent Process Control: Establishments with percent positive Salmonella samples at 50 percent or less of the performance standard in the most recently completed sample set, but greater than 50 percent of the performance standard in the previously completed sample set.

III. Category 2. Variable Process Control: Establishments with percent positive Salmonella samples above 50 percent but not exceeding the standard in the most recently completed sample set.

IV. Category 3. Highly Variable Process Control: Establishments with percent positive Salmonella samples exceeding the performance standard in the most recently completed sample set.

FSIS collects ground beef samples under project code ''HC01'' as part of the *Salmonella* verification sampling program and under project code ''MT43'' as part of the *E. coli* O157:H7 verification sampling program.

Following the implementation of PR/HACCP, FSIS analyzed only one pathogen per sample. Then, in 2008, FSIS began analyzing for *Salmonella* and *E. coli* O157:H7 ground beef samples from establishments producing less than 1,000 pounds of product per day (under the MT43S code). Using this approach, FSIS effectively gained sampling efficiencies without overly burdening the establishment with additional sample collection.

Public Health Concerns

Salmonella bacteria are among the most frequently reported causes of foodborne illness. In December 2011, a multi-state outbreak linked to a multi-drug resistant strain of *Salmonella* sickened 19 people in the Northeast United States (*http://www.cdc.gov/salmonella/typhimurium-groundbeef/010512/index.html*). In June 2012, FSIS was notified of a cluster of *Salmonella enteriditis* illnesses linked to ground beef consumption with approximately 50 case-patients across nine states (*http://www.cdc.gov/salmonella/enteritidis-07-12/index.html*). The outbreaks referenced here and others suggest that *Salmonella* in ground beef is a continuing public health concern.

The changes described below will likely improve FSIS's ability to detect *Salmonella* by increasing the raw ground beef analytic sample portion for *Salmonella* analysis and increasing the number of establishments being sampled at any given time. As is also discussed below, FSIS intends to develop new performance standards that will likely lead establishments producing ground beef to strengthen their own *Salmonella* control measures. Such changes at establishments will likely have a positive impact on public health.

Changes to Salmonella Verification Sampling Programs for Raw Ground Beef Products

Beginning on the date FSIS will announce in the **Federal Register** notice that responds to any comments on this notice, FSIS will discontinue *Salmonella* sampling sets (''HC01'') for ground beef product except for establishments in Category 3. At the same time, FSIS will begin analyzing for *Salmonella* all raw beef samples it collects for STEC testing. Therefore, FSIS will begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that its personnel collect for STEC testing, including raw ground beef products FSIS samples at retail stores and ground beef, trim, and other raw ground beef components FSIS samples at import establishments.

Whenever FSIS finds a product sample positive for *E. coli* O157:H7 or a non-O157 STEC, FSIS conducts follow-up sampling of product from the establishment that produced the positive product and at all suppliers that provided the source materials for the product. When FSIS begins analyzing for *Salmonella* the product collected for STEC analysis, FSIS will also begin analyzing for *Salmonella* the follow-up samples it collects in response to STEC positive results.

FSIS analyzes beef manufacturing trimmings for *E. coli* O157:H7 and the following non-O157 STECs: O26, O45, O103, O111, O121, and O145. FSIS analyzes raw ground beef and raw ground beef components other than beef manufacturing trimmings for E. coli O157:H7 only. FSIS is not making any changes to the STEC sampling and testing programs at this time.

The changes that FSIS is announcing to its *Salmonella* sampling procedures will permit FSIS to analyze more samples at the same time for lower Agency costs than the present method. Also, as noted above, FSIS stopped testing beef carcasses for *Salmonella* because the Agency sampling costs did not justify the results FSIS was able to obtain. Through this new approach, FSIS will be able to analyze for *Salmonella* beef manufacturing trimmings and other raw ground beef components at slaughter establishments. FSIS believes sampling these products will provide FSIS more information about *Salmonella* at these establishments than FSIS was able to gather through carcass testing.

FSIS will increase the raw ground beef analytic portion for *Salmonella* analysis from 25 grams to 325 grams to be consistent with the STEC analytic sample portions. To support an increase in the sample size analyzed, FSIS evaluated the FSIS *Salmonella* detection method (FSIS Microbiology Laboratory Guidebook Chapter 4.06) using 325 gram samples. Based on this analysis, FSIS expects the increase in the analytical portion size to have at least the same, but likely more of a positive, impact on public health because the likelihood of detecting positive samples increases with the analytical portion size. As is explained above, FSIS will continue to schedule sets for raw ground beef in those establishments in Category 3. FSIS laboratories will continue to evaluate raw ground beef product samples collected as part of a set using a 25-gram analytic sample portion.

FSIS intends to enumerate samples that confirm *Salmonella*-positive using the Most Probable Number (MPN) quantitative procedure. FSIS will continue to evaluate *Salmonella* isolates from the screen-positive samples for multi-drug resistance, to serotype the samples, and to use pulsed-field gel electrophoresis (PFGE) to identify specific strains of *Salmonella.*

Through this analysis, FSIS will determine whether Agency-positive *Salmonella* results are associated with illnesses or serotypes of human health significance. As is currently the case, if FSIS finds that establishments have produced product associated with illness, FSIS will typically conduct an Incident Investigation Team Review or Food Safety Assessment at the establishment.

Estimating Prevalence

In developing all of its prevalence estimates, FSIS defines prevalence as the proportion of applicable product that would test positive for a given pathogen if the entire population were sampled and analyzed during a specified time period. Although it provides a useful indication of process control within that establishment, set-based verification sampling that FSIS currently uses for *Salmonella* sampling and testing in many products is not

designed to estimate national prevalence of *Salmonella* by class of products. As is discussed above, under the set-based approach, FSIS collects samples from the same establishment on a daily basis until it has collected the necessary number of samples in the applicable performance standard. In 2012, FSIS evaluated many of its sampling programs as a means to calculate prevalence estimates for pathogens in FSIS-regulated products (*http://www.fsis.usda.gov/wps/wcm/connect/56b2ccbd-ad57-4311-b6df-289822d28115/Prevalence_Estimates_Report.pdf?MOD=AJPERES*). The Agency concluded, given the construction of the FSIS pathogen verification sampling programs at that time, that it was only possible to utilize the *E. coli* O157:H7 pathogen verification testing program for raw ground beef (''MT43'') to estimate national prevalence. Since that time, FSIS has redesigned its beef manufacturing trimmings verification sampling program such that, with a larger number of analyzed samples, it too is suitable for estimating prevalence (*http://www.fsis.usda.gov/wps/wcm/connect/15e75329-978f-43f0-b8fe-101845d898f0/Redesign_Beef_Trim_Sampling_Methodology.pdf?MOD=AJPERES*).

When FSIS begins analyzing all STEC samples for *Salmonella,* FSIS will be able to estimate the prevalence of *Salmonella* in raw ground beef and beef manufacturing trimmings. Therefore, FSIS will avoid the added expense of conducting separate baseline studies at periodic intervals to determine *Salmonella* prevalence in these products and will enhance the use of inspection resources. In addition, by using these continuous sampling programs rather than scheduled sets, FSIS will be able to analyze findings over time to determine trends and evaluate program effectiveness.

Because of the limited number of available samples scheduled and collected, FSIS does not believe it is possible to estimate prevalence for *Salmonella* in raw ground beef components other than beef manufacturing trimmings (such as bench trim).

New Performance Standards

After collecting at least three months of data using the new sampling and testing procedures, FSIS intends to conduct a risk assessment and develop a revised *Salmonella* performance standard for raw ground beef at a 325 gram sample size. FSIS will publish the revised *Salmonella* performance standard in the **Federal Register** before implementing the standard.

In 2011, FSIS estimated the national prevalence of *Salmonella* in beef manufacturing trimmings (*http://www.fsis.usda.gov/wps/wcm/connect/f07f5e1d-63f2-4ec8-a83a-e1661307b2c3/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf?MOD=AJPERES*). After careful consideration, FSIS does not believe the low incidence of *Salmonella* on beef manufacturing trimmings supports development of a *Salmonella* performance standard for beef manufacturing trimmings. FSIS is considering using the results of this estimation to develop guidance that will assist establishments in preventing *Salmonella* contamination in beef manufacturing trimmings.

FSIS recently revised other existing *Salmonella* performance standards to achieve a public health objective. In July 2011, FSIS implemented new performance standards for both *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broilers) and turkey slaughter establishments (76 FR 15282; March 21, 2011). By December 2011, the young chicken industry was meeting the acceptable *Campylobacter* percent positive reflected in the new standard at 9.43 percent (10.4 percent acceptable). Should FSIS develop new *Salmonella* performance standards for ground beef, FSIS believes that ground beef establishments would improve process control to meet the new performance standard in a similar manner.

Except for Category 3 establishments, FSIS will discontinue set testing at least until it establishes a revised *Salmonella* performance standard for ground beef. Meanwhile, FSIS is considering alternative sampling plans. One option that FSIS is considering is a ''moving window'' sampling plan in which FSIS would evaluate a set number of sequential results from single establishment to assess process control. For example, if FSIS chose to evaluate 20 results under the moving window approach, FSIS would assess the most recent 20 FSIS results for a particular establishment. This new approach would allow for on-going scheduled FSIS *Salmonella* sampling, similar to the approach FSIS uses for STEC testing, as compared to a set-based approach in which FSIS schedules a large number of sequential samples at an establishment as part of a set. The ''moving window'' approach would provide FSIS with more flexibility for scheduling sample collection at different establishments. The Agency requests comment on the ''moving window'' approach.

Other Sampling Procedures

Consistent with current sampling procedures, when an establishment either processes all raw ground beef product into ready-to-eat (RTE) product or moves it to another federally-inspected establishment for further processing into RTE product, the product will be excluded from Agency verification sampling for *E. coli* O157:H7 and *Salmonella.*

Individual sample results generated from this program will be reported through the Agency's Public Health Information System. FSIS will ensure that result information is made available to establishments. Because FSIS does not recognize *Salmonella* as a pathogen that would ordinarily render the product injurious to health, and thus as an adulterant within the meaning of 21 U.S.C. 601(m)(1), individual *Salmonella* sample results will not result in regulatory control actions. Therefore, after receiving STEC (O157:H7 and non-O157) results, establishments will not need to continue to hold product that has tested negative for STEC. If raw, non-intact beef product or raw, intact beef product that is intended for use as raw, non-intact product tests positive for STEC, the product is adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011) unless further processed to destroy the pathogen.

Other Changes Under Consideration

In addition to ground beef, FSIS is considering moving *Salmonella* sampling from a set-based approach to a continuous sampling and ''moving window'' approach for all classes of products subject to FSIS sampling and testing for *Salmonella.* As is discussed above, this approach will allow FSIS more flexibility in scheduling and collecting samples.

In addition, FSIS is considering implementing new sampling of product classes not subject to FSIS sampling and testing for *Salmonella.* For example, FSIS is contemplating initiating sampling and testing for *Salmonella* in pork trim, pork parts, ground pork, chicken parts, and lamb carcasses.

Before FSIS makes any change of this type in its testing, it will provide notice and an opportunity for comment in the **Federal Register**.

Should FSIS decide to start testing new products for *Salmonella,* it would begin by sampling to assess the prevalence of *Salmonella* in each of the new products sampled. Upon completion of the exploratory sampling period (at least three months and possibly longer), FSIS would develop

new performance standards. FSIS would announce the tentative standards in the **Federal Register** and request comment on them before finalizing.

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Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register*.

FSIS will also 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 constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic 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/wps/portal/fsis/programs-and-services/email-subscription-service*. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: August 16, 2013.

Alfred V. Almanza,

Administrator.

[FR Doc. 2013–20995 Filed 8–27–13; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

[NRC–2012–0008]

Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final Branch Technical Position.

SUMMARY: In 2010, the U.S. Nuclear Regulatory Commission (NRC) staff published a final rule amending its regulations concerning export and import of nuclear equipment and material. Among other things, it added the phrase ''of U.S. origin'' to the first exclusion to the definition of ''radioactive waste'' to confirm that the return of U.S. origin radioactive sources is not classified as the import of radioactive waste. The NRC staff drafted the Branch Technical Position (BTP) on the Import of Non-U.S. Origin Sources to provide additional guidance on the application of this exclusion in the regulations.

In developing this BTP, the NRC staff has engaged with States, Low-Level Waste Compacts, industry, and the public by providing two opportunities for public comment via **Federal Register** Notice and a public meeting in 2012. The exclusion in 10 CFR part 110 reflects the United States' commitments to the policy of safe storage and disposal of disused sources in the international context, including under the Code of Practice on the International Transboundary Movement of Radioactive Waste (Code of Practice), Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (Joint Convention), and the International Atomic Energy Agency's (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct—along with the supplementary Guidance on Import and Export). The United States' commitments include not exporting radioactive waste to other countries for disposal and, in light of the United States' strong domestic regulatory program, allowing return of disused sources manufactured or distributed from the United States in order to prevent sources from being orphaned overseas where regulatory programs may not exist or function to an optimal level.

DATES: The BTP is effective on September 27, 2013.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to *http://www.regulations.gov* and search for documents filed under Docket ID [NRC–2007–0009]. Address questions about NRC dockets to Ms. Carol Gallagher at 301–492–3668 or by email *Carol.Gallagher@nrc.gov*.

NRC's Public Document Room (PDR): The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Public File Area 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 electronically at the NRC's electronic Reading Room 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 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 email to *pdr.resource@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Jennifer C. Tobin, Office of International Programs, U.S. Nuclear Regulatory Commission, MS–O4E21, Washington, DC 20555–0001; telephone: (301) 415–2328; email: *jennifer.tobin@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. History

The NRC published ''Notice of Public Meeting and Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources,'' 77 FR 2924 (January 20, 2012), and received five comment letters as a result of that publication. The NRC staff made no substantive changes to the draft BTP based on these comment letters. However, minor editorial changes were made to the draft BTP to provide greater clarity.

The NRC published ''Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources,''