Risk-based sampling of Beef Manufacturing Trimmings for Escherichia coli (E. coli) O157:H7

AGENCY:  Food Safety and Inspection Service, USDA.

ACTION:  Notice: Response to comments.

SUMMARY:  The Food Safety and Inspection Service (FSIS) is responding to comments on the September 19, 2012, Federal Register notice, “Risk-Based Sampling of Beef Manufacturing Trimmings for Escherichia coli O157:H7 and Plans for Beef Baseline” and providing updates on how it is scheduling sampling for beef manufacturing trimmings. Additionally, the Agency is announcing that it is changing its existing algorithms for sampling of bench trim and raw ground beef components other than trim to make them more risk-based. Finally, the Agency is making available the following report: “Effective Implementation of Beef Manufacturing Trimmings Sampling Redesign (MT60).”

DATES:  On [INSERT DATE 90 DAYS AFTER PUBLICATION], FSIS will implement design changes in bench trim and other ground beef components besides trimmings.
SUPPLEMENTARY INFORMATION:

Background

On September 19, 2012, FSIS published a Federal Register notice (77 FR 58091) announcing its intention to redesign its *E. coli* O157:H7 verification testing program for 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 trimmings. FSIS also announced additional changes to the trimmings sampling program to increase collection rates and the likelihood of finding positive *E. coli* O157:H7 sample results. FSIS discussed its plans to conduct a beef carcass baseline. Finally, FSIS explained it was planning to conduct a survey, using its employees that are assigned to beef slaughter and processing establishments, to gather information on establishment controls for Shiga toxin-producing *Escherichia coli* (STECs) in beef. Results of the survey are available at:

In June 2012, FSIS implemented the risk-based design and other changes discussed in the 2012 Federal Register notice. FSIS conducted analyses of the trimmings sampling program twelve months after implementation of the new risk-based design. Analyses show that the new design was successful at increasing the number of E. coli O157:H7 positives detected and also significantly increased the collection rate. In the first twelve months of implementation, FSIS analysis of routine sampling of trimmings detected 1.8 times more E. coli O157:H7 positives than FSIS had previously detected in this product. In the Federal Register notice FSIS estimated that the probability of obtaining E. coli O157:H7 results in trimmings during FSIS verification testing would increase by a factor of about 2.5. Possibilities for why FSIS did not detect an approximate 2.5 times as many E. coli O157:H7 positives are numerous and include changes to the data systems and the frame available during
analysis and modeling, changes to the laboratory tests implemented at about the same time as the new statistical design, and positives being collected under follow-up sampling rather than routine sampling. The new statistical design and overscheduling to adjust for nonresponse solved the historically low response rates associated with trimmings. The report is posted at http://www.fsis.usda.gov/wps/wcm/connect/31575c98-2c22-4e9c-a19d-b3511d106082/Analysis-Beef-Trim-Redesign.pdf?MOD=AJPERES.

Therefore, FSIS has concluded that its change in sampling was effective. However, FSIS has not been able to estimate STEC prevalence in trimmings because it has not obtained a sufficient number of sample results. To address this issue, FSIS has increased the number of trim samples scheduled to be collected by inspectors for each month to that of the number of samples it had previously scheduled to be collected during months in the high prevalence season, effective November 2014. FSIS made this change to obtain the number of samples needed to allow ongoing prevalence determinations to be made from the data collected.

FSIS started conducting the Beef-Veal carcass baseline on August 1, 2014, and will complete the survey July 31, 2015. As stated in the previous Federal Register notice discussed above, FSIS plans to use the results of the Beef-Veal carcass baseline and the results of the Pathogen Controls in Beef Operations
survey data to conduct risk analyses 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 will post the survey results. In addition, now that FSIS also is analyzing beef samples for both STEC and *Salmonella* (79 FR 32436), FSIS is able to make statistically-based determinations about the on-going prevalence of these pathogens in beef samples at least on an annual basis.

FSIS conducted a statistical analysis of the results from its sampling of bench trim program and its sampling of other ground beef components besides trimmings to identify factors that would lead to a higher probability of detecting *E. coli* O157:H7. FSIS did not find a higher probability of finding *E. coli* O157:H7 in particular establishments when it looked at the factors considered for these products. Because establishments make different volumes of product, FSIS is changing its existing sampling algorithms for bench trim and other ground beef components besides trim to sample establishments proportional to production volume. Additionally, FSIS intends to overschedule to adjust for nonresponse under the redesigned programs, similar to how FSIS implemented changes to the trimmings program.

Comments and Responses
FSIS received comments from seven industry and consumer organizations in response to the September 2012 notice. Both industry and consumer organizations supported the Agency’s use of statistically significant data to make scientifically supported decisions regarding its sampling programs. Following is a discussion of these comments and FSIS’s responses.

**Sampling Programs**

**Comment:** Two consumer organizations requested that more funding be provided to maintain FSIS’s sampling in the low prevalence season of the year in addition to maintaining the increased sampling during the high prevalence season.

**Response:** As is stated above, the Agency has increased the number of trim samples. FSIS is now maintaining the high prevalence level of sampling throughout the entire year.

**Comment:** One consumer group questioned the statistical validity of using an N-60 collection method for trimmings that the Agency has reported on its website and cited the findings of the 2012 OIG audit report.

**Response:** FSIS’s sampling and testing for E. coli O157:H7 is just one of the activities that FSIS conducts to verify that an establishment’s food safety systems effectively address STEC. FSIS sampling of beef trim works along with other inspection and verification activities, including FSIS sampling of ground beef and other ground beef components and its review of establishment
testing results, to detect and reduce \textit{E. coli} O157:H7 in beef products.

As FSIS explained in response to the Office of the Inspector General’s report on the Agency’s sampling protocol for testing beef trim for \textit{E. coli} O157:H7,\textsuperscript{1} FSIS does not view a single N-60 sampling result apart from other verification activities. Note that along with sampling and carcass-by-carcass inspection, FSIS inspection personnel performed more than 839,000 inspection procedures in CY2014 at roughly 635 slaughter establishments that would also be subject to trim sampling. These inspection procedures, performed daily at slaughter establishments, play an important role in ensuring that establishments are producing safe and wholesome products.

While a single N-60 sample result may not indicate definitively the success or failure of an establishment’s process controls for beef trim, it can be an important part of the establishment’s verification program, especially if the establishment or FSIS takes multiple N-60 samples over time.

FSIS’ mission is not to screen the food supply through testing but to ensure the production of safe and wholesome food through inspection.

\textsuperscript{1} OIG Audit Report 24601-9-KC “FSIS Sampling Protocol for Testing Beef Trim for \textit{E. coli} O157:H7” p. 31
Comment: One industry organization suggested that the Agency consider market class of animal, size of the establishment, and the historical rate of *E. coli* O157:H7 detection at the establishment in Agency testing when making risk-based sampling program decisions.

Response: When considering the redesign of its trimmings sampling program, the Agency did consider establishment size in average pounds produced per day and historical positive sampling results over time. The Agency chose to consider the volume of product that an establishment produced to focus the Agency’s resources on actual product produced.

As explained in the 2012 *Federal Register* notice (77 FR 58091), FSIS redesigned the sampling algorithm to collect more samples from establishments in establishment size categories with the highest probability of producing trimmings contaminated with *E. coli* O157:H7. As a result, the Agency is focusing on small establishments that produce between 1001 and 50,000 pounds per day.

At this time, FSIS does not have the means to collect different types of market class information other than to differentiate between beef and veal. FSIS will continue to report veal results separately from other beef results [http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/positive-results-current-](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/positive-results-current-)
cy/positive-results-current-cy. In addition, FSIS will consider assessing the differences between veal and beef results and issuing necessary guidance and instructions to the field based on these results when appropriate. For example, based on its analysis of results, FSIS issued instructions, in 2011-2012, for inspectors to verify that establishments applied antimicrobial interventions to veal carcasses correctly, and that they maintained procedures to minimize cross-contamination among veal carcasses.

Comment: One industry organization encouraged FSIS to conduct risk-based sampling for ground beef as well.

Response: An FSIS risk assessment, presented in a public meeting on October 28, 1998, and updated thereafter, found that volume of production is a better determinant of risk for *E. coli* O157:H7 in ground beef than size of the establishment. Beginning on January 1, 2008, FSIS initiated an enhanced risk-based sampling and testing program for *E. coli* O157:H7 in raw ground beef. The risk-based sampling program took into account establishment volume, and whether the establishment had any FSIS or Agriculture Marketing Service positive results within the past 120 days. The current sampling is proportional to ground beef production volume. Consequently, the program supports ongoing prevalence estimates from the data.
Comment: One industry organization commented that the Agency concluded that the rate of sanitary dressing procedure noncompliance reports could not be used to identify establishments that have a higher probability of \textit{E. coli} 0157:H7 positive tests result. The industry organization requested that FSIS determine whether the revised cattle sanitary dressing directive improved sanitary dressing procedures, and whether there is a correlation between sanitary dressing procedures and positive \textit{E. coli} 0157:H7 test results. The commenter stated that establishment size and animal market class should also be addressed in this review of sanitary dressing procedures.

Response: When FSIS did the analysis for the statistical redesign, it found that there is no predictive relationship between higher sanitary dressing noncompliances and the probability of \textit{E. coli} 0157:H7 positive sample results. Under the Public Health Inspection System (PHIS), the Agency tracks the inspection activities inspection personnel use to verify whether an establishment’s food safety system meets regulatory requirements. The inspection activities tracked include the procedures used to verify whether establishments maintain effective sanitary dressing procedures. The Agency analyzes the PHIS data on inspection activities on a biannual basis.

FSIS reviewed the data for the relevant inspection tasks performed and FSIS positive results at establishments sampled
under the trimmings (MT50) sampling program. FSIS did not find a correlation between sanitary dressing or sanitation NRs and MT50 percent positive in trimmings.

Comment: One consumer organization recommended that FSIS take additional steps to improve the representativeness of the samples collected by eliminating FSIS’s procedure of pre-notification of testing. The commenter stated that this notification allows establishments to adjust their operations before the sample is taken. The consumer group also recognized that FSIS mailed test kits to establishments before field personnel collected samples for chain of evidence reasons. The commenter stated that the arrival of a sample box would signal that a test is imminent and serves as a pre-notification. The consumer organization suggested that sample boxes be kept stocked by in-plant personnel.

Response: FSIS requires establishments to hold product tested for an adulterant such as E. coli O157:H7 pending the results of FSIS testing. Establishment management needs sufficient pre-notification of sampling in order to hold production lots in a manner such that they are microbiologically independent. Otherwise, FSIS would be collecting samples from production lots that may already be distributed in commerce, resulting in preventable product recalls. FSIS has issued instructions to field personnel to notify establishment that
FSIS will be collecting a sample, but that the notification should only provide enough time for the establishment to be able to hold all affected product.

The Agency has a finite number of resources which makes stocking multiple sample boxes at establishments cost prohibitive. Additionally, some USDA offices in establishments are small and do not allow for storage of multiple sample boxes. If establishments change their food safety system on the days that FSIS collects samples in a manner to influence the sample result, FSIS has instructed inspection program personnel to notify their supervisory chain so that a determination can be made as to how to address this concern. In such circumstances, FSIS may decide to conduct additional sampling at the establishment or to conduct a Food Safety Assessment (which includes in-depth verification that the establishment meets regulatory requirements related to food safety).

Comment: One consumer organization questioned whether the results for FSIS’s sampling programs can be used to develop reliable prevalence estimates.

Response: As noted above, FSIS has increased the number of trimming samples collected to achieve the number of samples needed to allow STEC on-going prevalence determinations to be made from the data collected. FSIS will make E. coli O157:H7 prevalence estimates for ground beef available in the near
future. FSIS will make STEC prevalence (E. coli O157:H7 and other STEC) estimates for trim available in the first quarter of FY 2016.

Industry Survey

Comment: One industry organization had several suggestions regarding the beef survey that FSIS announced in the 2012 Federal Register notice (77 FR 58091). The commenter stated that the survey should: (1) have clear goals and deliverables, (2) not put an economic burden on industry, (3) have questions based on data that pertain to the problem of E. coli O157:H7 contamination, (4) collect data on the volume of source material produced by establishments that test for E. coli O157:H7, and (5) present results as volume-based to address the results from the survey.

Response: Through the survey described above, inspectors provided information on processing practices that establishments employ to reduce the likelihood of contamination of intact and non-intact raw beef products with STEC. FSIS did have clear goals when it put forth the survey. This survey was designed to gather information not collected in the Public Health Information System. FSIS is using the survey results to update the economic analysis to support the full implementation of its non-O157 STEC policy. Data from the 2013 Pathogen Controls in Beef Operations Survey (conducted in May–July 2013) allowed FSIS
to estimate the number of non-O157 STEC tests conducted by the industry for a 12-month period. FSIS is also analyzing the survey results to develop targeted approaches for its risk-based verification testing program and to assist it in prioritizing the scheduling of Food Safety Assessments (FSA) by Enforcement, Investigations, and Analysis Officers (EIAO). FSIS did not collect production volume information in the survey and is not presenting the results as volume based. Establishment profiles contain production volume information in the Public Health Information System.

FSIS has used the numbers obtained in the survey to estimate sampling numbers for industry testing as part of the economic analysis for STEC sampling in all of the Agency’s raw beef microbiological sampling programs. The economic analysis is available at


Additionally, FSIS plans 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 trimmings sampling program and to make risk-based changes as appropriate.
FSIS implemented the survey in such a way as to not cause an undue economic burden on industry.

Comment: One consumer group commented that FSIS should make plans to routinely repeat the survey to inform sampling decisions made by the Agency.

Response: Conducting the survey is very time intensive for field personnel. FSIS must weigh the time spent completing a survey against the time spent conducting regular inspection duties. FSIS will conduct future surveys as necessary.

Carcass Baseline

Comment: An industry organization commented that the beef carcass baseline should include the whole beef trimmings production process, and that it should also include veal.

Response: The Beef-Veal carcass baseline began August 1, 2014. FSIS is including steers, heifers, cows, bulls, stag, dairy cows, and veal carcasses in the Beef-Veal carcass baseline. FSIS is collecting samples at two points in the process, immediately after hide removal (pre-evisceration) and at pre-chill (after all antimicrobial interventions).

Comment: An industry organization suggested that because FSIS is only testing for pathogenic organisms that are adulterants, the Agency should consider alternative baseline testing locations within the production supply chain. The commenter suggested that FSIS collect a post-hide removal sample
to address the hide removal process, where cross-contamination is more likely to occur; a second sample site after antimicrobial interventions; and trim testing for E. coli O157:H7 for products that will be used in ground beef or veal production.

**Response:** The Agency is obtaining samples at two points in the slaughter process for the baseline study: immediately after hide removal but before evisceration, and at pre-chill before the carcasses enter the chillers and after all antimicrobial applications. This study addresses three distinct objectives: to estimate the prevalence and quantitative levels of selected foodborne microorganisms, to obtain data for use in the development of Agency programs, and to obtain data for informing industry guidance related to process control. The sample design and the resulting sample size are limited for this survey by practical constraints such as finite personnel and financial resources, and the problems with implementing scientific studies in real-world production settings. Considering these constraints, FSIS expects that the Beef-Veal carcass baseline study will achieve the stated objectives because FSIS will collect and analyze as many samples as possible to ensure an appropriate level of statistical confidence.

With the two points that the Agency chose to use for sampling for the baseline carcass study, FSIS requires the
establishment to hold or control the movement of sampled carcasses at pre-chill until the establishment is notified of STEC results. FSIS verifies that the establishment does not treat the sampled carcasses any differently than any of the other carcasses it is processing. In the event that a sampled carcass is treated differently, FSIS will randomly select another carcass during the same processing time and collect samples from that carcass.

The results from samples collected during the baseline carcass study become available after all analyses for STEC and Salmonella are complete. Baseline sample results usually are reported in two to six days but may take longer depending on individual circumstances. Post-hide/pre-evisceration and pre-chill sample results are reported through Laboratory Information Management System (LIMS) Direct.

FSIS is not issuing noncompliance records (NRs) for STEC positive results during the baseline. In response to a positive result from the pre-chill sample only, field personnel perform a directed Slaughter HACCP Verification task to verify that the establishment has adequate slaughter controls (including antimicrobial intervention implementation) for the specific production lot represented by the positive STEC carcass result. Field personnel also verify that the establishment implements corrective actions that meet the applicable requirements in 9
CFR 417.3. Field personnel do not verify corrective actions in response to a positive STEC result from the post-hide/pre-evisceration sample. Rather, FSIS verifies that establishments ensure that carcasses found positive for STECs during the pre-chill sampling and testing are not processed into raw non-intact product. The presence of STEC on a pre-chill carcass intended for use as raw non-intact product would adulterate the carcass. The presence of STEC on a carcass intended for use as raw intact product would not adulterate the carcass if the entire carcass is going for intact product. In the event that a carcass tests positive for STEC, establishments may take action to ensure that all products from the carcass go for cooking, or they may take action to recondition the carcass and ensure that the carcass goes for intact use only.

In the event of a STEC positive on a post-hide removal/pre-evisceration sample without a corresponding pre-chill sample on a carcass intended for raw non-intact use, the carcass would not be considered adulterated. The carcass presumably will undergo further interventions after post-hide removal/pre-evisceration. In the event of a STEC positive from a pre-chill test result on a carcass intended for raw non-intact use, the carcass is considered adulterated. The establishment is required to take corrective action.
Comment: One industry organization recommended that FSIS conduct a “shakedown” period at establishments representative of the industry in order to assess the logistics of sampling. The commenter stated that this shakedown should be done to provide a safe sampling environment for inspection personnel and to ensure that sampling will not interfere with the routine slaughter process.

Response: FSIS agrees with the comment. The Agency did conduct a shakedown training period before the actual baseline and confirmed that baseline sampling will not interfere with the routine slaughter process.

Comment: One industry organization commented that while the Agency is developing the baseline, the timeframe for the publication of study results should be outlined.

Response: FSIS posted the study design and sampling plan on the FSIS website at http://www.fsis.usda.gov/wps/wcm/connect/5057f4ef-f924-422c-bafe-771blead78e4/Beef-Veal-Carcass-Baseline-Study-Design.pdf?MOD=AJPERES. FSIS will publish a final report with the national prevalence calculations after the completion of the survey.

Comment: One industry organization commented that sampling immediately after de-hiding may not provide the most meaningful information as to the presence of the various organisms in the
slaughter process. The commenter stated that although the sample may be taken before any on-line interventions, the condition of the carcass, in terms of potential microbial load, is not comparable across establishments. The commenter explained that some establishments have interventions and other practices that occur before de-hiding, such as bacteriophage sprays or hide washes. Likewise, the commenter stated that the effectiveness of hide removal in minimizing contamination of the carcass varies among establishments. If FSIS is seeking to use this baseline to assist establishments in assessing “incoming” contamination levels before on-line interventions, the commenter stated that not taking into account the steps that come before this sampling point at each establishment would likely limit the usability of the results.

Response: FSIS agrees that the incoming microbial load may vary from establishment to establishment depending on whether establishments use bacteriophage sprays or hide washes, and that the effectiveness of establishments in preventing cross-contamination in hide removal may also vary. Nevertheless, FSIS expects that the Beef-Veal carcass baseline study will achieve the stated objectives by collecting and analyzing as many samples as possible to ensure an appropriate level of statistical confidence.
Comment: Two commenters stated that carcass sampling immediately after de-hiding could pose a safety risk to inspection program personnel, as well as to establishment employees. According to the commenters, this location is in the middle of the harvest line, so taking a sample at this juncture will require inspection program personnel to enter an area of the process where hazards, such as dangerous equipment, are present and space is limited. Taking samples at this point could, in turn, also put establishment employees at risk.

Response: FSIS discussed with establishment management before collecting samples for the shakedown the following: (1) Where supervisory personnel could safely collect post-hide removal/pre-evisceration and pre-chill samples, (2) establishment safety requirements and protocols that supervisory field personnel must follow during sample collection, and (3) the potential need for line stoppages for supervisory field personnel to safely and properly collect the samples. FSIS also issued instructions to inspection program personnel for conducting sampling from a safe vantage point, especially when collecting the posterior samples from the post-hide/pre-evisceration and pre-chill locations; following the same safety procedures provided for employees at that establishment which may require the use of a harness; slowing or stopping production lines; and acquiring needed tools to safely collect samples.
Information on the Beef-Veal carcass baseline can be found at the following link:


Comment: One industry organization asked what type of carcass sampling the Agency will use for the carcass baseline study.

Response: As was done during the shakedown, FSIS is obtaining samples following the procedures described in the United States Department of Agriculture Agricultural Research Service Meat Animal Research Center Carcass Sampling Protocol available at the following link:


Comment: One consumer organization stated that FSIS should conduct a baseline study to estimate the prevalence of E. coli O157:H7 in beef manufacturing trimmings and ground beef in order to improve the confidence in FSIS’s efforts to detect contaminated product and effectively verify process controls.

Response: FSIS decided to focus on sampling carcasses for this baseline and not trimmings and ground beef because of resource limitations. The Beef-Veal carcass baseline survey

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2U.S. Meat Animal Research Center (MARC) Carcass Sampling Protocol
will provide FSIS the necessary data on percent positives and quantitative levels of select foodborne bacterial pathogens (e.g., Salmonella, STEC, and certain indicator organisms). FSIS will use the data from the Beef-Veal carcass baseline survey to estimate the national prevalence of select microorganisms in carcasses, not trimmings and ground beef; to develop industry performance guidelines; to assess process control across the industry; and to inform additional policy considerations. Results of this study will be used to estimate volume-weighted prevalence and bacterial loads immediately after hide removal and at pre-chill. Moreover, FSIS has made changes to both the trimmings and ground beef verification testing programs to be able to obtain on-going prevalence of both E. coli O157:H7 and Salmonella (79 FR 32437).

Other Topics

The following comment topics that were received are outside the scope of this notice: disappearing schedule dates from PHIS, returned FedEx sample boxes, FSIS training materials, and purge studies.

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Done, at Washington, D.C.


Alfred V. Almanza,
Acting Administrator.