3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2022-0019]

Use of a Non-Destructive Surface Sampling Device to Sample Domestic Beef Manufacturing Trimmings and Bench Trim

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

ACTION: Notice and request for comments.

SUMMARY: On February 1, 2023, FSIS intends to stop using the N60 excision sampling method to sample domestic beef manufacturing trimmings and bench trim for adulterant Shiga toxin-producing *Escherichia coli (E. coli)* (STEC) and *Salmonella*. FSIS intends to replace the N60 excision sampling method with a non-destructive surface sampling method that uses a cloth manual sampling device. FSIS has found that the cloth sampling method is as effective as the N60 excision sampling method at recovering organisms in beef manufacturing trimmings. Additionally, the cloth sampling method is faster and safer for FSIS inspection program personnel (IPP) to use because it does not require IPP to use hooks or knives to collect samples. Moreover, the cloth sampling method allows FSIS to sample without destroying product, which reduces food waste.

DATES: FSIS will implement the cloth sampling on February 1, 2023, unless the Agency receives substantive comments that

warrant further review. Submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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

• *Federal eRulemaking Portal*: This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to https://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.

• *Mail*: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.

• *Hand- or Courier-Delivered Submittals*: Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350-E, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2022-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to https://www.regulations.gov.

Docket: For access to background documents or comments received, call (202) 205-0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), FSIS carries out an inspection program to ensure that carcasses, parts, and products of amenable species of livestock are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS conducts microbiological sampling to verify that establishments maintain control of their production processes and meet regulatory requirements, including requirements under the hazard analysis and critical control point (HACCP) regulations. Ongoing FSIS sampling and testing at official establishments allows FSIS to verify that establishments effectively address pathogens reasonably likely to occur in their products. The HACCP regulations (9 CFR part 417) require that establishments conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and to identify the preventive measures an establishment can apply to control those hazards in the production of particular products.

Currently, FSIS samples and tests for *E. coli* O157:H7, non-O157 STEC (O26, O45, O103, O111, O121, or O145), and *Salmonella* in raw beef manufacturing trimmings and *E. coli* O157:H7 and *Salmonella* in bench trim verification samples using the N60

excision sampling method, as described in FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products.[1] The N60 excision sampling method is a destructive sampling method that requires inspection personnel to use knives or hooks to cut and collect at least 60 thin slices (approximately 3 inches long by 1 inch wide and 1/8 inch thick) from the external surface of beef tissues in a product lot.[2] The 60 samples are combined into one or more 325-gram units for analytical testing.

In recent years, FSIS and other agencies have been researching different methods for collecting samples from beef manufacturing trimmings that are less destructive and safer for inspectors to collect, yet still produce comparable results to the N60 excision sampling method.[3] Findings from these studies provide strong scientific support for the use of cloth-based sampling for verification testing. Below is a discussion of the findings from different studies.

Agricultural Research Service (ARS) Sampling Studies

In 2018, USDA's ARS performed studies comparing the N60 excision sampling method and the N60 Plus[4] to the cloth sampling method using a continuous sampling device and a manual sampling

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[1] https://www.fsis.usda.gov/policy/fsis-directives/10010.1.

[2] Establishments determine their lot size. A lot is usually made up of no more than five, 2,000-pound combo bins of beef trimmings or less than 10,000 pounds if the establishment is using boxes.

[3] See 85 FR 34397 and FSIS' Constituent Update - December 18, 2020 | Food Safety and Inspection Service (usda.gov), which is available at: https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-december-18-2020.

[4] N60 Plus is similar to the N60 excision sampling method, but it uses a stainless-steel sampling device on a drill to collects surface tissue.

device.[5] The continuous sampling device used a cloth held by a cassette attached to a bracket at the end of a conveyor line to collect samples as the meat rubbed across the cloth[6] and fell into the combo bins. The manual sampling device used the same type of cloth as the continuous sampling device, and it was used to manually rub all trim across the entire top surface of the combo bin to collect a sample. The manual sampling device was found to be best for hand-picked and other bin-fill stations where the continuous sampling device could not be installed. ARS conducted experiments testing for naturally occurring *E. coli* O157:H7 and *Salmonella*, inoculated surrogates (green fluorescent protein–labeled (GFP) *E. coli*), and indicator organisms (aerobic plate count (APC), generic *E. coli*, and coliforms) in five different processing establishments, on multiple days, across multiple lean percentages (50, 80, 90, and 93 percent lean). Experiments with natural contamination (substances already in the environment) found no *E. coli* O157:H7, no statistically significant difference in prevalence of *Salmonella* (continuous sampling device 9.2 percent versus N60 excision sampling device 6.0 percent) and similar levels of indicator organisms for the continuous sampling device compared with both the N60 excision and N60 Plus sampling methods. In additional experiments, the continuous sampling device found the

[5] Wheeler, T. L. & Arthur T. M. (2018). Novel Continuous and Manual Sampling Methods for Beef Trim Microbiological Testing. Journal of Food Protection, 81(10), 1605–1613. https://doi.org/10.4315/0362-028X.JFP-18-197.

[6] ARS initially used the continuous sampling device with a cellulose sponge. However, ARS quickly determined that the cellulose sponge was too expensive for commercial implementation.

same or higher prevalence of naturally occurring *E. coli* O157:H7 and GFP *E. coli*, as well as similar levels of indicator organisms compared with the N60 method. In the next experiment, the manual sampling device found similar prevalence of *E. coli* O157:H7 surrogate organisms, and slightly lower ($P < 0.05$) levels of indicator organisms compared with N60 Plus. An additional experiment showed the manual sampling device found similar prevalence of naturally occurring *E. coli* O157:H7 and the same or slightly higher ($P < 0.05$) levels of naturally occurring indicator organisms compared with N60 Plus. In a further experiment, the manual sampling device detected the same prevalence of naturally occurring *Salmonella* as the N60 excision sampling method. ARS concluded that the results of their experiments collectively demonstrated that sampling beef trim using the cloth sampling method (using either a continuous sampling device or manual sampling device) provides organism recovery that is similar, comparable to or better than the N60 excision sampling method.

In 2021, ARS conducted another study to determine the efficacy of the cloth sampling method in scenarios that included smaller combo bins.[7] ARS collected 1,650 matched (cloth and N60) samples collected at the same time from 540 individual combo bins at six commercial beef processing establishments, comparing the cloth sampling method (using both continuous and manual

[7] Arthur T. M. & Wheeler T. L. (2021). Validation of Additional Approaches and Applications for Using the Continuous and Manual Sampling Devices for Raw Beef Trim. Journal of Food Protection, 84(4), 536–544. https://doi.org/10.4315/JFP-20-345.

sampling devices) to the N60 excision sampling method and N60 Plus. In this second study, ARS analyzed the presence of select virulence associated genes (hemolysin, five non-adulterant O serogroups (O55, O113, O117, O126, and O146), intimin, heme receptor, adhesion siderophore, *tetA* and *tetB*) to act as index targets—measures that would correlate with the percent positive of STEC and *Salmonella*. One experiment observed no difference in the percent positive for pathogen index targets from product at two lean types, between the cloth manual sampling device and N60 excision method (n=185). When evaluated on combo bins with a smaller surface area (≈0.93 m^2 [ca. 1,439 in^2] instead of 1 m^2 [ca. 1,600 in^2]), the manual sampling device had a higher percent positive for the heme receptor gene target (52.5 versus 25 percent) and recovered 0.3 log_{10} more aerobic bacteria (APC) than the N60 Plus method ($P < 0.05$; n=40).

In a further experiment on smaller surface area combo bins, the cloth manual sampling device method recovered more O serogroup positive samples than the N60 Plus (86.3 percent and 63.8 percent respectively; $P < 0.05$). The cloth manual sampling device also recovered 0.2 log_{10} more *Enterobacteriaceae* than N60 Plus (n=80). There was no difference between the cloth manual sampling device and N60 Plus recovery of five other pathogen index target genes and aerobic plate count (APC).

In one final experiment, 80 combo bins were sampled to compare the continuous sampling device, manual sampling device, and N60 Plus methods. There were no significant differences

among the three sample collection methods for any of the pathogen index gene targets. As a result, ARS concluded that their study supports various alternative applications of the cloth sampling method for robust pathogen detection. Based on ARS' research, FSIS issued a letter of no objection in March 2017 to allow industry to use cloth sampling methods for microbiological sampling of raw beef trim and a second letter of no objection in March 2020 for specific in-plant validation procedures.

FSIS In-Field Studies

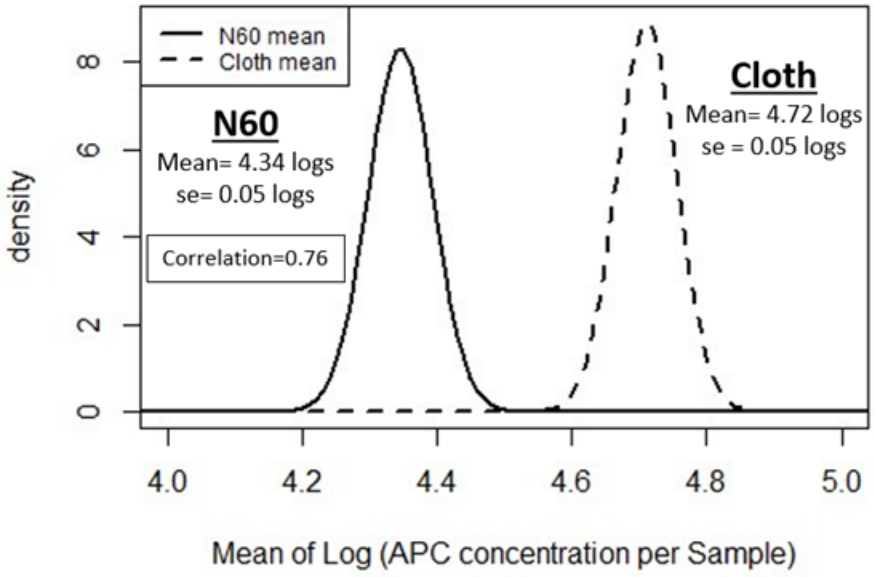
Starting in December 2019, and still ongoing, FSIS performed a combination of laboratory and field studies to compare the N60 excision sampling method to the cloth sampling method. The project began with an initial laboratory study to compare *Salmonella* and STEC recovery using polyurethane sponge and cloth sampling methods against the current N60 excision sampling method. The laboratory used raw beef trim reserves that previously tested negative for *Salmonella* and STEC to prepare samples simulating IPP collected product. FSIS laboratory microbiologists inoculated the beef trim with *E. coli* O157:H7, and non-O157 (O103 and O121)) and *Salmonella* at low levels (3.5 – 7.5 cfu/2--pound test bin). Microbiologists used a dry cloth to sample and simulate the shipment of samples. After reviewing analyte recovery of each technique, the cloth sampling method was selected for additional review in the field because there was no difference in *E. coli* O157:H7 or O103 recovery. Although

the cloth recovered significantly less O121, there was no difference in *Salmonella* recovery. Overall, the cloth sampling method recovered pathogens when present in the product sampled that had been inoculated at very low levels.

FSIS then conducted an exploratory field study to directly compare the manual cloth sampling method as developed by ARS, to the N60 excision sampling method when performing inspection verification of establishment beef trim. IPP collected the beef trim samples in the exploratory study matched with routine N60 samples and analyzed both for APC and *Salmonella*. Based on preliminary results, FSIS considered if the cloth manual sampling method may be improved by addition of a neutralizing buffer before shipping.

The second laboratory study evaluated neutralizing buffer options for the cloth sampling method. FSIS laboratory microbiologists inoculated beef trim with *E. coli* O157:H7 at concentrations of 5-10 cfu/cloth and *Salmonella* ~5 x 10^4 cfu/cloth. FSIS tested three treatments: (1) 25 mL neutralizing Buffered Peptone Water (nBPW) (2), 25mL buffered peptone water (BPW), and (3) a dry cloth. Adding the transport buffer nBPW to the cloth after inoculation and before simulated shipping improved analyte recovery by 0.16 log more than when the dry cloth (i.e., no transport buffer) was used. Using nBPW did not inhibit screening or survival or recovery of *E. coli* O157:H7 compared with the dry cloth.

This led to a final field study where IPP began adding 25 ml of nBPW as a transport buffer to cloth samples after collection and before shipping to further protect sample integrity during transit. This study showed that the cloth sampling method plus the addition of the transport buffer recovered significantly more bacteria (0.38 log Aerobic Count) than the N60 sampling method (see diagram below).[8]



FSIS also tested for *Salmonella*, based on the current data, the differences in results were not significantly different (N60 2.0 percent; cloth 1.7 percent).

FSIS conducted a qualitative review of noncompliance reports (NRs) for establishments failing to detect STEC when FSIS verification sampling detected a STEC positive sample result. FSIS used data from samples of beef manufacturing

[8] The units on the y-axis are probability densities that are calculated for normal distributions with mean and standard error (se) values as shown. Probability density – or density – can be interpreted as relative likelihood of the x-axis values.

trimmings and bench trim collected between April 2015 and December 2021 to determine if establishments using the cloth sampling method failed to detect STEC when concurrent FSIS testing found a positive sample collected using N60. Some establishments began using the cloth sampling method in 2017, but industry more widely adopted cloth sampling after March 2020 when FSIS issued a second letter of no objection for in-plant validation procedures for cloth sampling. NRs, from a total of 15 establishments, citing 9 CFR 310.2 and 417.4(a) issued during three periods were reviewed: before cloth implementation (8 NRs), during the transition period (11 NRs), and after establishments began cloth sampling (4 NRs). The analysis showed that industry adopting cloth sampling did not increase NRs due to missed STEC positive lots. Most of the NRs that were issued after cloth implementation were due to the establishments only testing for *E. coli* O157:H7 and failing to detect non-O157 adulterant STEC-positive product. Careful consideration of these various studies[9] have led FSIS to conclude that there is no significant difference in microbial recovery between cloth manual sampling and N60 excision methods. FSIS has determined the cloth sampling method with nBPW is equivalent to N60 excision sampling.

FSIS Implementation Plan

[9] Scientific Support for FSIS to Use a Surface Sampling Method for Beef Trim PowerPoint available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS_N60vClothSampling-RawBeefTrim_20221107_v2.7B.ppt

FSIS will replace the N60 excision sampling of domestic beef manufacturing trimmings and bench trim with the cloth sampling method, including nBPW transport buffer. At this time, FSIS does not intend to implement any changes to the sample collection method for frozen imported products or any domestic raw beef processed products other than beef manufacturing trimmings and bench trim using the cloth sampling method. No one has evaluated the cloth's ability to recover bacteria from frozen beef products. USDA ARS researchers recommend against sampling frozen beef trim with the cloth since there is no liquid for the cloth to absorb and collect. Also, FSIS will continue to use the current directions in FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin Producing *Escherichia coli* (STEC) in Raw Beef Products[10] for sampling ground beef and other raw ground beef components including head meat, cheek meat, weasand (esophagus) meat, product from advanced meat recovery (AMR) systems, partially defatted chopped beef and partially defatted beef fatty tissue, low temperature rendered lean finely textured beef, and heart meat.

Costs and Benefits Analysis

The Agency does not expect the implementation of cloth sampling for the sampling of beef manufacturing trimmings and bench trim by FSIS to have a cost impact on the industry. As

[10] FSIS Directive 10,010.1 Revision 4 - Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products available at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf.

described before, both ARS studies and FSIS in-field studies have found no statistically significant change in testing results.

The change will enable FSIS to allocate some resources, including supplies, shipping costs, and analysis time, to other sampling verification activities. It may also reduce inspector injuries as they will no longer be using knives to sample product, as well as decrease sample collection time. Finally, the non-destructive sampling will also save food (meat) from being cut and wasted, at about 2 pounds per sample.

Conclusion

Based on the above studies showing the effectiveness of cloth sampling in recovering indicator organisms and pathogens and the resources saved by FSIS, the Agency plans to move forward with using cloth sampling in lieu of N60 excision sampling on beef manufacturing trimmings and bench trim. FSIS also anticipates saving resources by adopting this change.

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Office of the Assistant Secretary for Civil Rights
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Washington, D.C. 20250-9410; or

(2) Fax: (833) 256-1665 or (202) 690-7442; or

(3) Email: program.intake@usda.gov

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Done at Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2022-25333 Filed: 11/21/2022 8:45 am; Publication Date: 11/22/2022]