Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2018–0045]

Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Ground Beef and Beef Manufacturing Trimmings and Related Agency Verification Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing and requesting comment on new pathogen reduction performance standards for *Salmonella* in raw ground beef and beef manufacturing trimmings.

The Agency is also announcing how it plans to assess whether establishments producing raw ground beef and/or beef manufacturing trimmings are effectively addressing *Salmonella,* using a 52-week moving window of FSIS sampling results and other related verification activities. Approximately one year (52 weeks) after the new standards are made final, the Agency plans to post individual establishment performance as either ''meeting'' or ''not meeting'' the pathogen reduction performance standard on the FSIS website, based on the most recent 48 *Salmonella* sample results.

Finally, FSIS is also announcing that it intends to increase *Salmonella* sampling to once per week in beef establishments that produce greater than 50,000 pounds of raw ground beef and beef manufacturing trimmings per day, so that a sufficient number of *Salmonella* samples (*i.e.,* 48) are collected to assess these establishments' performance against the new *Salmonella* performance standards. Note that FSIS will continue to analyze these beef manufacturing trimmings samples for *Escherichia coli* O517:H7 and applicable non-O157 Shiga-toxin producing *E. coli* (STEC); FSIS will continue to analyze these ground beef samples for *E. coli* O157:H7. Although unlikely with this change, if fewer than 48 samples are collected or analyzed in a 52-week window at an establishment, its status would be reported as ''N/A,'' provided the establishment has two or fewer *Salmonella* positives in that window.

FSIS will consider comments received on this notice before announcing the final performance standards in the **Federal Register** and assessing whether establishments meet them.

DATES: Submit comments on or before December 27, 2019.

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 *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, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0045. 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, call (202)720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205–0495.

SUPPLEMENTARY INFORMATION: FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled and packaged.

Salmonella bacteria are among the most frequent causes of foodborne illness. These bacteria reside in the gastrointestinal tract and other organs of food animals; therefore, they also are good indicators for food product contamination with enteric pathogens. *Salmonella* are often introduced during the rearing of live animals, *e.g., Salmonella* may contaminate the exterior of an animal on the farm, remain attached to the animal's hide or carcass, and can contaminate raw beef products during slaughter and subsequent fabrication and further processing. Currently, events that cause contamination of beef carcasses cannot be completely eliminated from commercial slaughter, fabrication, or further processing operations. Contamination can be minimized, however, with the use of proper sanitary dressing procedures and through the application of antimicrobial interventions during the slaughter, fabrication, and further processing of carcasses into beef products, including ground beef.

FSIS began its *Salmonella* verification testing program with the final rule entitled ''Pathogen Reduction; Hazard Analysis and Critical Control Point Systems'' (PR/HACCP Rule), published on July 25, 1996 (61 FR 38805). Among other things, the PR/HACCP Rule established *Salmonella* pathogen reduction performance standards for establishments that slaughter selected classes of food animals [1] and/or that produce selected classes of raw ground products. FSIS continues to use pathogen reduction performance standards as a measure of process control and to ensure that establishments are consistently controlling or reducing harmful bacteria not ordinarily considered adulterants in raw meat and poultry products.[2]

[1] In 2011, FSIS stopped sampling and testing for *Salmonella* in beef carcasses (steers and heifers and cows and bulls) because percent positive findings were very low; less than one percent. FSIS sampling and testing for *Salmonella* in raw ground beef continued, however.

[2] The Agency's ability to directly enforce the pathogen reduction performance standards in 9 CFR 310.25 has been limited since 2001, after a ruling

Because of continued outbreaks of *Salmonella* illness associated with the consumption of ground beef products, FSIS is proposing to update its *Salmonella* performance standard for raw ground beef and establish a new performance standard for beef manufacturing trimmings,[3] the primary component of raw ground beef. These updated and new performance standards would address the market failure from information asymmetry between producers and buyers. Absent these standards, buyers could not readily identify the difference in *Salmonella* levels across producers. A summary of the most recent *Salmonella* outbreaks linked to ground beef and FSIS's responses to these outbreaks that ultimately led to the development of the new performance standards follows.

In 2011, FSIS investigated a multi-State outbreak of 20 *Salmonella* Typhimurium infections linked to the consumption of ground beef.[4] Eight people were hospitalized, and the outbreak strain was resistant to at least seven antibiotics. In 2012, an establishment recalled approximately 30,000 pounds of raw ground beef linked to a multi-state outbreak of *Salmonella* Enteritidis with 46 persons infected.[5] Twelve people were hospitalized. Also, in 2012, the Centers for Disease Control and Prevention (CDC) confirmed a single-State outbreak from ground beef contaminated with *Salmonella* Enteritidis that resulted in 24 illnesses. Two people were hospitalized. In 2013, 22 persons from six States were infected with *Salmonella* Typhimurium linked to ground beef.[6] Seven people were hospitalized.

In response to these outbreaks, on August 28, 2013, FSIS published in the **Federal Register** a notice announcing changes it was making to its *Salmonella* verification testing program for raw beef products intended for non-intact use (78 FR 53017). Specifically, FSIS announced that it would begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that it already collects for STEC testing, including raw ground beef products that FSIS samples at retail stores, and imported shipments of raw ground beef, trim, and other raw ground beef components that FSIS samples at official import inspection establishments. In addition, FSIS announced that it was increasing the raw ground beef analytical sample portion from 25 grams to 325 grams.[7] FSIS explained that the likelihood of detecting positive samples increases with the analytical portion size. FSIS also described how it intended to use the results generated from its raw ground beef (''MT43'') and beef manufacturing trimmings (''MT60'') verification testing programs to estimate the *Salmonella* prevalence in those products and to develop updated or new pathogen reduction performance standards.

Finally, FSIS stated in this notice that it was considering alternatives to set-based sampling for *Salmonella,* including routine sampling throughout the year used in conjunction with a ''moving window'' approach to assess process control in establishments subject to performance standards. FSIS explained that this approach would allow for on-going scheduled *Salmonella* sampling, similar to the approach FSIS has used for STEC sampling and would provide FSIS with more flexibility for scheduling sample collections at different establishments.

After reviewing the comments received on the August 2013 notice, FSIS announced in the **Federal Register** that it was implementing the plans in that notice on June 5, 2014 (79 FR 32436). Thus, on June 29, 2014, FSIS discontinued *Salmonella* sampling set procedures for raw ground beef products (the ''HC01'' sampling program) and stopped assessing whether establishments met the codified pathogen reduction performance standards for ground product, except in those establishments in Category 3.[8] [9] At the same time, FSIS began co-analyzing for *Salmonella* all samples of raw beef products it collects for STEC analysis (including imported raw beef products) using the larger analytical sample portion. FSIS collects raw beef products for STEC analysis and *Salmonella* analysis regardless of production volume; FSIS did not establish a low volume exemption for beef establishments for FSIS STEC or *Salmonella* verification testing. FSIS has posted the aggregate results of this testing as part of its quarterly sampling project results reporting.[10]

Notably, in 2015, the CDC published an analysis of beef-related outbreaks from 1973–2011 and reported that ground beef is now a significant source of *Salmonella* outbreaks and that stronger measures are needed to decrease contamination of raw ground beef with *Salmonella.*[11]

Beginning in 2016 and ending in 2017, the CDC reported 106 illnesses in 21 States associated with *Salmonella* Newport from ground beef.[12] One person died, and 42 people were hospitalized. Notably, the CDC is currently investigating a multi-State illness outbreak from beef products contaminated with *Salmonella* Newport.[13] To date, this outbreak has resulted in 403 illnesses from 30 States, with 117 people hospitalized. On October 4, 2018, approximately 6.5 million pounds of beef products, including ground beef, were recalled due to this outbreak and an expansion of the recall with an additional 5.2 million pounds of beef products occurred on December 4, 2018.[14]

Moving Window Approach

On February 11, 2016, the Agency explained how it would assess performance using a moving window of FSIS sampling results in poultry establishments subject to *Salmonella* and *Campylobacter* pathogen reduction performance standards (81 FR 7285). FSIS stated that the moving window would be 52 weeks and that the Agency

by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc.* v. *USDA.* In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the *Salmonella* performance standards. Since that time, FSIS has used *Salmonella* failures as a basis to conduct an in-depth evaluation of the establishment's Hazard Analysis and Critical Control Point systems, including its HACCP plan and Sanitation Standard Operating Procedures.

[3] FSIS defines ''beef manufacturing trimmings'' as trim produced from cattle (including veal) that are slaughtered at the establishment where the FSIS sampling is occurring. Beef manufacturing trimmings include trim of any size and primal or subprimal cuts, such as chucks, rounds, or shanks, or boneless beef of any size used at the slaughter establishment for non-intact use, or that is intended for raw non-intact use by other establishments.

[4] *https://www.cdc.gov/salmonella/2011/ground-beef-2-1-2012.html.*

[5] *http://www.cdc.gov/salmonella/enteritidis-07-12/index.html;* FSIS Recall 045–2012.

[6] *http://www.cdc.gov/salmonella/typhimurium-01-13/index.html;* FSIS Recalls 008–2013 and 009–2013.

[7] After the Agency increased the analytical sample portion from 25 grams to 325 grams, FSIS stopped using the *Salmonella* performance standard for ground beef Table 2 in 9 CFR 310.25(b) because it was established on the basis of prevalence as measured by a 25-gram sample.

[8] An establishment in Category 3 is exceeding the *Salmonella* performance standard. FSIS Notice 28–14 instructed FSIS inspectors to continue set testing at establishments in Category 3 until the establishment is in Category 1 or 2.

[9] FSIS discontinued all sampling sets for ground beef products in establishments in Category 3 in June 2015.

[10] *http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/sampling-project-results.*

[11] Laufer, A., Grass, J., Holt, K., Whichard, J., Griffin, P., Gould, L., 2015. Outbreaks of *Salmonella* infections attributed to beef—United States, 1973–2011. Epidemiology and Infection 143, 2003–2013.

[12] *https://www.cdc.gov/mmwr/volumes/67/wr/mm6715a2.htm.*

[13] *https://www.cdc.gov/salmonella/newport-10-18/index.html.*

[14] FSIS Recall 085–2018.

would collect samples more frequently in higher-volume establishments and less frequently in lower-volume establishments. The 52-week window obviates the need to account directly for seasonal fluctuations in contamination frequency.[15] FSIS intends to use a similar approach for beef establishments that produce raw ground beef and/or beef manufacturing trimmings that will be subject to the updated or new *Salmonella* performance standards. As further explained below, the category reported for each establishment would be based on the last 48 FSIS *Salmonella* sample results during the most recent 52-week window.

Healthy People 2020 (HP2020) Goals

Food safety is a key component of the Healthy People (HP) initiative, with an entire focus area dedicated to joint FSIS, Food and Drug Administration (FDA), and CDC efforts to reduce foodborne illness, including salmonellosis, in the population. Under the HP2020 goals, FSIS committed, with its public health partners, to a 25-percent reduction in annual cases of salmonellosis.[16] Using published results from the CDC,[17] FSIS estimates a median of about 80,000 annual cases of salmonellosis associated with the consumption of cuts of intact beef and ground beef contaminated with *Salmonella*. FSIS estimates that approximately 53 percent of these illnesses are associated with ground beef. Thus, to meet the 25-percent reduction goal, there would need to be 10,600 fewer annual illnesses caused by raw ground beef contaminated with *Salmonella.*[18]

Pathogen Reduction Performance Standards

With the goal of reducing *Salmonella* in raw ground beef products, the Agency is proposing an updated and a new pathogen reduction performance standard for *Salmonella* in raw ground beef and in beef manufacturing trimmings (the primary component of ground beef), respectively. Because the ground beef industry is highly concentrated by production volume, FSIS developed pathogen reduction performance standards for each product class based on a daily production volume threshold. Both proposed performance standards would be applicable to higher-volume establishments (*i.e.,* those producing greater than 50,000 pounds of these products per day). This approach would account for approximately 91 percent of the total raw ground beef and 96 percent of the total beef manufacturing trimmings production volume annually. And as further explained in FSIS's Public Health Effects of Performance Standards for Ground Beef and Beef Manufacturing Trimmings (2019 Risk Assessment),[19] the approach would also focus Agency resources on raw ground beef establishments shown to have the highest *Salmonella* prevalence. FSIS predicts that most higher-volume beef establishments would meet the proposed performance standards.

FSIS's goal is to collect and analyze at least 48 samples per year for each establishment producing greater than 50,000 pounds of ground beef or beef manufacturing trimmings per day. Analyzing this number of samples would provide strong evidence that an establishment is either meeting or not meeting the performance standards. To achieve this goal, FSIS plans to change how it currently assigns STEC sampling and thus *Salmonella* sampling in higher-volume beef establishments producing ground beef and/or beef manufacturing trimmings by increasing the sample collection frequency from a maximum of four times per month to once per week for these product classes. FSIS intends to implement this change in a resource neutral manner by reallocating resources from lower-volume beef establishments (*i.e.,* those producing 50,000 pounds or less per day). As noted above, FSIS samples less frequently in the lower-volume establishments. The Agency requests comments on the proposed changes.

The methods for developing the proposed pathogen reduction performance standards and predictions for the public health effect of those standards are described in the 2019 Risk Assessment. FSIS used the same methodology to estimate the public health effects for the young chicken and turkey carcass *Salmonella* and *Campylobacter* performance standards in 2011 [20] and to develop pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey products in 2015.[21]

FSIS has opted not to propose pathogen reduction performance standards for raw ground beef and/or beef manufacturing trimmings in lower-volume establishments (*i.e.,* those producing 50,000 pounds or less per day of these products) at this time. FSIS will, however, continue co-analyzing for *Salmonella* in all samples it collects for STEC analysis from these establishments to monitor ongoing pathogen prevalence. A summary of the updated or new performance standards is provided in Table 1.

Since there are not enough data (*i.e.,* samples collected and tested) for components of ground beef other than beef manufacturing trimmings, *e.g.,* esophagus (weasand) meat, head meat, and cheek meat to estimate a national prevalence, FSIS is not proposing a pathogen reduction performance standard for such products at this time. With that said, FSIS will continue to analyze its testing data to better understand the potential for contamination in these products. Such information could be used by the Agency to decide whether a pathogen reduction performance standard for one or more of these components is also necessary. FSIS is seeking comment on the merits of developing a pathogen reduction performance standard for components of raw ground beef other than beef manufacturing trimmings.

[15] FSIS (2015). Public health effects of raw chicken parts and comminuted chicken and poultry performance standards. Washington, DC, United States Department of Agriculture; Williams, M.S., Ebel, E.D., Golden, N.J., Schlosser, W.D. (2014). Temporal patterns in the occurrence of *Salmonella* in raw meat and poultry products and their relationship to human illnesses in the United States. *Food Control* 35(1): 267–273.

[16] Once the Healthy People 2030 objectives have been finalized, FSIS intends to assess whether changes to its performance standards are warranted.

[17] Scallan *et al.,* 2011; Painter *et al.,* 2013

[18] Moving forward, FSIS plans to utilize more recent estimates of foodborne illness source attribution to estimate cases of foodborne illness attributed to FSIS-regulated products. These estimates, produced by the Interagency Food Safety Analytics Collaboration (IFSAC), a tri-agency group with representatives from the CDC, FDA, and FSIS, uses foodborne outbreak data to produce harmonized, annual attribution estimates for *Salmonella, Escherichia coli* O157, *Listeria monocytogenes,* and *Campylobacter.*

[19] Available at *http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES.*

[20] 76 FR 15282; Mar. 14, 2011.

[21] 80 FR at 3940; Jan. 26, 2015.

TABLE 1—UPDATED OR NEW PERFORMANCE STANDARDS FOR SALMONELLA IN RAW GROUND BEEF AND BEEF MANUFACTURING TRIMMINGS

Product (establishment volume (lbs./day))	Maximum number of allowable positive samples	Minimum number of samples needed to assess establishment performance *
Raw Ground Beef (>50,000)	2 of 48	48
Beef Manufacturing Trimmings (>50,000)	2 of 48	48

* Any establishment with three or more *Salmonella* positives in a 52-week window would be categorized as *not meeting* the performance standard even when less than the minimum number of samples (48) are collected/analyzed.

Raw Ground Beef

For raw ground beef, FSIS is proposing a pathogen reduction performance standard for *Salmonella* of two allowable positives out of 48 samples. This standard would be applied to all higher-volume establishments, which includes those producing more than 50,000 pounds of raw ground beef product per day (approximately 75 establishments). As mentioned above, FSIS intends to assign samples weekly in all establishments producing more than 50,000 pounds of eligible product per day with the goal of collecting and analyzing 48 samples in a 52-week window.

FSIS predicts that approximately 18 percent of establishments (about 14 establishments) would initially not meet this performance standard. Once implemented, if about half of the establishments producing more than 50,000 pounds of raw ground beef per day that are not meeting the proposed performance standard subsequently begin to meet this standard, this should result in about a 25-percent reduction in *Salmonella* illnesses from that product. The median expected number of illnesses avoided per year would be about 8,900 (90% Uncertainty Interval: 2,000–20,000).

Specifics of the 52-Week Window Approach and Categorizing Establishments

As stated, the performance standard is intended to apply to 48 samples in a 52-week window. If FSIS collects and analyzes more than 48 samples in a 52-week window, the most recent 48 sample results in that 52-week window would be used to categorize the establishment. Although unlikely with the proposed reallocation of sampling resources, there may be rare occasions when fewer than 48 samples are collected and analyzed in these establishments within a 52-week window. If fewer than 48 samples are collected or analyzed, the establishment's status would be reported as ''N/A,'' provided the establishment has two or fewer *Salmonella* positives in that window. Any establishment with three or more *Salmonella* positives in a 52-week window would be categorized as *not meeting* the performance standard regardless of the number of samples collected/analyzed in that window.

Beef Manufacturing Trimmings

For beef manufacturing trimmings, FSIS is also proposing a pathogen reduction performance standard for *Salmonella* of two allowable positives out of 48 samples in a 52-week window that would be applied to eligible establishments producing more than 50,000 pounds of this product per day (approximately 49 establishments). Approximately 20 percent of establishments (about 10 establishments) are predicted to initially not meet this performance standard.

The specifics of the 52-week window and categorizing establishments are the same as above. Each establishment's category status (*i.e., meeting, not meeting,* or *N/A*) for beef manufacturing trimmings would be reported as described above for raw ground beef.

FSIS has chosen not to attribute any averted illnesses resulting from the proposed performance standard for beef manufacturing trimmings because this product is not consumed directly. FSIS believes, however, that a performance standard is needed for beef manufacturing trimmings to assist grinding establishments that purchase this product for further processing in managing *Salmonella* contamination in their ground beef. For example, a grinding operation may opt to change beef manufacturing trimmings suppliers if its current supplier is categorized as *not meeting* the beef manufacturing trimmings *Salmonella* performance standard and has not taken actions to reduce *Salmonella* contamination in its product; this is especially true if the grinding operation is concerned about not meeting the raw ground beef *Salmonella* performance standard and wants to mitigate the chances of that outcome. Although reductions in *Salmonella* surface contamination on beef manufacturing trimmings should reduce contamination of raw ground beef, the specific magnitude of this reduction is uncertain.

Web-Posting Establishment Performance

FSIS announced that it intended to post the category status for all establishments subject to pathogen reduction performance standards because web posting delivers greater transparency, thereby providing the public with the tools and information it needs to make informed food safety decisions (80 FR at 3948; Jan. 26, 2015). FSIS intends to post the category status for all beef establishments subject to the pathogen reduction performance standards announced in this notice upon implementation.

FSIS currently assesses poultry establishment performance weekly based on the most recent 52-week window of FSIS sample results (83 FR 56046; Nov. 9, 2018). As explained in the November 2018 **Federal Register** notice, FSIS no longer includes follow-up sampling results when calculating an establishment's category. On or about the 20th of the month, FSIS posts the category of individual establishments producing an eligible product on the FSIS website.[22]

Should FSIS move forward with finalizing the proposed pathogen reduction performance standards for *Salmonella* in raw ground beef and beef manufacturing trimmings, FSIS would announce the final standards and an effective date in a subsequent **Federal Register** notice. About one year after the final standards go into effect, FSIS would determine individual establishment performance based on the last 48 FSIS *Salmonella* sample results and then report on the FSIS website the status of each establishment subject to the performance standards as either

[22] Individual establishment category information is posted on FSIS's website at *https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/salmonella-verification-testing-program.*

meeting or *not meeting* the particular standard using the following criteria:

Meeting. Establishments with no more than the allowable number of positive *Salmonella* sample results for that product class during the 52-week window ending the last Saturday of the previous month, based on the last 48 FSIS *Salmonella* sample results.

Not Meeting. Establishments with more than the allowable number of positive *Salmonella* sample results for that product class during the 52-week window ending the last Saturday of the previous month, based on the last 48 FSIS *Salmonella* sample results.

In the interim between the final standards becoming effective and when the status of individual establishments is posted, FSIS intends to make available monthly aggregate information relative to status (*i.e., meeting* or *not meeting* the performance standard) for all establishments subject to sampling under the final performance standards, using the most recent FSIS *Salmonella* sample results. This information will be aggregated and will not identify any specific establishment. FSIS would make this information available to give industry and other stakeholders timely information about progress being made to reduce *Salmonella* contamination in raw ground beef and beef manufacturing trimmings.

Related Agency Verification Actions

An establishment that does not meet a pathogen reduction performance standard or produces product that has been associated with an outbreak may not have adequately addressed the food safety hazard, *Salmonella,* in its HACCP system. If the establishment considers *Salmonella* reasonably likely to occur and addresses *Salmonella* in its HACCP plan, it must take corrective actions as required in 9 CFR 417.3(a). If the establishment considers *Salmonella* not reasonably likely to occur, it must take corrective actions and reassess its HACCP plan for that product to determine whether the plan needs to be modified to address *Salmonella* as a hazard (9 CFR 417.3(b)). To maintain an adequate HACCP system, the establishment may need to address the pathogen *Salmonella* in its HACCP plan, rather than through Sanitation Standard Operating Procedures (Sanitation SOPs) or another prerequisite program. Corrective actions taken in response to exceeding a pathogen reduction performance standard would need to be documented in records subject to verification by FSIS as required in 9 CFR 417.3(c)).

Consistent with FSIS inspection program personnel instructions for poultry establishments currently subject to performance standards, when a beef establishment does not meet a *Salmonella* performance standard (*i.e.,* when the number of positive samples within a specified timeframe exceeds the number of allowable positives for that product class), FSIS may initiate follow-up sampling after the establishment is first categorized as *not meeting* the performance standard to verify the adequacy of corrective actions taken by the establishment. FSIS would likely co-analyze any follow-up samples for STEC, as applicable to that product class. The follow-up samples would not count towards the samples collected as part of the moving window procedure for assessing whether the establishment meets the standards, which is consistent with FSIS procedures for poultry performance standards (83 FR at 56048). Follow-up sampling for establishments that do not meet the raw ground beef and/or beef manufacturing performance standard for an extended period of time, or that fluctuate between meeting or not meeting one or both of these performance standards, would occur at a frequency determined by FSIS.[23]

In addition, FSIS would schedule a Public Health Risk Evaluation (PHRE) for any beef establishment that (a) does not meet a *Salmonella* pathogen reduction performance standard; (b) has produced products with repetitive *Salmonella* serotypes of public health concern [24] or repetitive antibiotic-resistant *Salmonella;* and/or (c) has *Salmonella* whole-genome sequencing (WGS) and/or pulsed-field gel electrophoresis patterns matching those found in recent outbreaks or epidemiologically linked to illnesses (see FSIS Directive 5100.1 at *https://www.fsis.usda.gov/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES*). FSIS would use the results of the PHRE to determine whether to schedule a Food Safety Assessment (FSA) [25] at the establishment.

As explained above, and also consistent with existing FSIS practices,[26] after notifying a beef establishment that it has not met a pathogen reduction performance standard, FSIS would conduct an assessment of the establishment's HACCP plan and SSOPs, through a PHRE and possible subsequent FSA, focusing on the establishment's corrective actions, HACCP plan reassessment (if applicable), and the effectiveness of the establishment's system for controlling *Salmonella* in raw beef products. In addition, when necessary, FSIS would develop a plan to verify whether the establishment implemented corrective actions. If, after 120 days from not meeting the standard, the establishment has not been able to demonstrate reduced variability of process control, as determined from FSIS's follow-up and routine sampling and from the results of the PHRE and in some cases an FSA, and the establishment has not taken corrective actions, FSIS would likely take an enforcement action, such as issuing a Notice of Intended Enforcement (NOIE) or suspending inspection, under the conditions and according to the procedures described in 9 CFR part 500. FSIS would not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a pathogen reduction performance standard for *Salmonella.*

Although establishments producing 50,000 pounds or less of raw ground beef or beef manufacturing trimmings per day would not be subject to the proposed performance standards, FSIS would initiate follow-up sampling and/or conduct a PHRE or a FSA in these establishments when there is evidence of high levels of *Salmonella* contamination, *e.g.,* three or more positive *Salmonella* sample results within a 52-week time period, and for any of the other reasons listed above. Recognizing that these lower-volume establishments are sampled much less frequently than the higher-volume establishments, FSIS requests comments on this approach.

As previously announced, if any beef establishment produces product associated with a *Salmonella* illness outbreak identified minimally through epidemiological and/or traceback investigations, FSIS likely will consider the product to be adulterated under 21

[23] See FSIS Notice 17–19 for additional information on follow-up sampling in poultry establishments, available at *https://www.fsis.usda.gov/wps/wcm/connect/e16cfd59-8f8a-48a5-a607-999c9eecfec2/17-19.pdf?MOD=AJPERES.*

[24] Information about the 20 most frequently reported *Salmonella* serotypes reported to the CDC's Laboratory-based Enteric Disease Surveillance system is available at *https://www.cdc.gov/nationalsurveillance/pdfs/2016-Salmonella-report-508.pdf.*

[25] The purpose of an FSA is to assess and analyze an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements.

[26] FSIS stated in a **Federal Register** notice published April 16, 2003 (68 FR 18593), that it was using *Salmonella* sample-set failures ''as an indication that there is something wrong in the establishment's HACCP system, and that the system needs to be carefully evaluated by the Agency.'' More recently, FSIS announced the same course of action for poultry products subject to pathogen reduction performance standards on February 11, 2016 (81 FR at 7288).

U.S.C. 601(m)(3) because the product is ''* * * unsound, unhealthful, unwholesome, or otherwise unfit for human food'' (77 FR at 72689; Dec. 6, 2012). In such cases, the Agency would request that the establishment recall the product if it is still in commerce. Additionally, in such situations, even if the establishment is meeting a *Salmonella* performance standard, FSIS will scrutinize its corrective actions closely and may conduct an Incident Investigation Team review (see FSIS Directive 5500.3 at *https://www.fsis.usda.gov/wps/wcm/connect/bf3095f8-c6aa-4ed7-b819-45668c05c44b/5500.3.pdf?MOD=AJPERES*).

FSIS monitors relevant databases (*e.g.,* those maintained by the CDC and the National Institutes of Health) for clinical isolates [27] that match (via WGS) food isolates obtained by FSIS in its sampling of products produced by official establishments. This monitoring gives FSIS early warning that an outbreak involving an establishment's product could be developing. FSIS may alert its public health partners if it appears there are human illness (clinical isolates) and food isolate matches indicating a potential emerging outbreak. In such situations, FSIS may also collect distribution information (*e.g.,* the consignee list) for product produced to be able to focus attention on the geographic area in which the affected product was distributed.

Cost-Benefit Analysis

FSIS has considered the economic effects of the proposed pathogen reduction performance standards for *Salmonella* in raw ground beef and beef manufacturing trimmings. The full analysis is published on the FSIS website as supporting documentation to this notice. FSIS is seeking comment on the information and assumptions used in the cost-benefit analysis. A summary of the analysis follows.

Industry Costs

Establishments would incur costs as they make changes to their processes to meet the new performance standards. FSIS predicts that approximately 18 percent of the higher-volume raw ground beef establishments (about 14 establishments) and 20 percent of the higher-volume beef manufacturing trimmings establishments (about 10 establishments) would not initially meet the standards. As discussed above, higher-volume establishments produce more than 50,000 pounds of that particular product per day.

Some establishments that initially do not meet the performance standards but aspire to do so would need to make changes to their production processes to lower the prevalence of *Salmonella* in their products. For example, affected establishments may conduct *Salmonella* sampling, apply antimicrobial interventions (including purchasing necessary capital equipment), reassess their HACCP plans and/or conduct training. FSIS expects that higher-volume raw ground beef and beef manufacturing trimmings establishments would be most likely to begin collecting samples for *Salmonella* testing in an effort to assure they would meet the updated or new performance standards. As an example, if the establishment currently collects samples to test for other pathogens, the establishment may begin including testing for *Salmonella* in its current sampling programs. Or, if the establishment does not currently collect any samples for pathogen testing, the establishment may begin collecting samples for *Salmonella* testing.

Based on available information, FSIS expects that beef manufacturing trimmings establishments subject to the performance standard would be most likely to add antimicrobial interventions and equipment to their production process to meet the performance standard.

FSIS estimates that not all establishments would make changes after not meeting the performance standards. For those establishments initially not meeting the performance standards, FSIS assumes approximately 50 percent would start making changes after one year and eventually would meet the standards in two years by making changes to their production process. To ensure a conservative cost estimate, FSIS assumes that those establishments making changes to their production processes would validate those changes and conduct employee training. For HACCP re-assessment, FSIS assumes that all establishments (100 percent) that do not meet the standard will re-assess their HACCP plan. These costs are summarized and annualized over 10 years at a discount rate of 7 percent in Table 2.

TABLE 2—INDUSTRY COSTS ANNUALIZED

Cost component	Low estimate	Primary estimate	High estimate
Capital Equipment	$1,002	$1,002	$1,002
Antimicrobial Intervention	147,998	147,998	147,998
Sampling	3,393,114	3,393,114	3,393,114
HACCP Reassessment	10,781	21,562	32,344
Employee Training	2,701	2,701	2,701
Total Costs *	3,555,596	3,556,377	3,577,159

Agency Costs

FSIS does not expect the Agency to incur any budgetary impacts as a result of implementing the new or updated performance standards. FSIS intends to implement the two major components of the performance standards, product sampling/testing and follow-up actions, in such a way that they are resource neutral. At this time, FSIS is not expanding the overall number of samples it would analyze or collect. Instead, it would reallocate samples from lower-volume beef establishments. Moreover, since FSIS has already transitioned to continuous sampling for *Salmonella* in beef manufacturing trimmings and in raw ground beef, the number of samples FSIS would collect and analyze after the performance standard is implemented would remain the same. FSIS would not need to invest in additional laboratory equipment or additional personnel.

The resources required for follow-up actions, namely PHREs, which may lead to FSAs, would also remain unchanged because very few establishments are expected to continue to not meet the

[27] In microbiology, the term ''isolates'' refers to strains of microorganisms isolated for study.

performance standards. In addition, in 2015, the FSA methodology was updated to include a PHRE. The PHRE is a remote evaluation performed by FSIS personnel to determine if an establishment's food safety system is effective. Information learned during the PHRE would be used to determine if an onsite FSA is warranted. FSIS personnel have been able to evaluate a greater number of establishments under the updated FSA methodology. FSIS intends to maintain its current FSA scheduling protocol, which combines risk-based and routine PHREs.

Benefits

As beef establishments subject to the proposed performance standards make changes to their production processes and reduce the prevalence of *Salmonella* in raw ground beef and beef manufacturing trimmings, public health benefits would be realized in the form of averted illnesses. As discussed in the 2019 Risk Assessment, FSIS estimated the annual *Salmonella* foodborne illnesses associated with beef products. FSIS then estimated the number of annual illnesses attributed to products under the updated or new performance standards. Finally, FSIS estimated the number of illnesses averted if 50 percent of the establishments that do not meet the standards, meet the standards over the course of two years. Additionally, FSIS estimated the cost savings associated with the percentage reduction in human illnesses as calculated in the 2019 Risk Assessment. The estimated public health benefits from the illnesses averted as a result of the proposed *Salmonella* beef performance standards are summarized and annualized over 10 years at a discount rate of 7 percent in Table 3.

TABLE 3—PUBLIC HEALTH BENEFITS ANNUALIZED

Product	Percentage of establishments initially not meeting the standards, but then meet the standards over 2 years	Averted illnesses due to *salmonella*	Cost of illness *
Raw Ground Beef and Beef Manufacturing Trimmings.	50	8,900	$29,265,796.
		(2,000–20,000) (5th–95th percentile)	($6,576,583–$65,765,834).

* Cost of Illness annualized at a discount rate of 7% over 10 years, occurring one year after establishments would begin making changes.

Industry Benefits

FSIS expects that industry would benefit from reduced *Salmonella* outbreak-related recalls. The negative impacts of recalls on industry include the loss of sales revenue, the cost to dispose of recalled products, and the loss of consumer confidence and business reputation. Recalls negatively impact consumers by creating anxiety and time-consuming inconveniences (*e.g.,* looking for recall information, checking products purchased to determine if they are part of the recall, returning or disposing of products identified by the recalls, and so on).

FSIS expects the raw ground beef and beef manufacturing trimmings performance standards would lead to less contaminated products, because of industry actions taken to reduce *Salmonella* in products to meet the performance standards. The reduction in *Salmonella* would result in less exposure to the consumers that eat beef products and fewer illnesses, outbreaks and recalls.

Summary of Net Benefits

Table 4 displays the total costs and benefits expected from the implementation of the performance standards for beef manufacturing trimmings and raw ground beef. FSIS annualized all values over 10 years at a 7 percent discount rate.

TABLE 4—SUMMARY OF ESTIMATED NET BENEFITS

Compliance rate for establishments initially not meeting the standard	Cost/benefit component	Low estimate ($mil)	Primary estimate ($mil)	High estimate ($mil)
50%	Industry Costs	3.56	3.57	3.58
	Public Health Benefits	6.58	29.27	65.77
	Net Benefits	3.02	25.70	62.19

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC.

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019–23473 Filed 10–25–19; 8:45 am]

BILLING CODE 3410–DM–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: October 30, 2019, 11:00 a.m. EDT.

PLACE: U.S. Chemical Safety and Hazard Investigation Board, 1750 Pennsylvania Ave. NW, Suite 910, Washington, DC 20006.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on Wednesday, October 30, 2019, at 11:00 a.m. EDT in Washington, DC, at the CSB offices located at 1750 Pennsylvania Avenue NW, Suite 910. The Board will discuss open investigations, the status of audits from the Office of the Inspector General, and financial and organizational updates. There will also be a presentation on the ongoing CSB investigation into the March 17, 2019, Intercontinental Terminal Company (ITC) Tank Fire which occurred in Deer Park, TX.

Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the **CONTACT PERSON FOR FURTHER INFORMATION**, at least three business days prior to the meeting.

A conference call line will be provided for those who cannot attend in person. Please use the following dial-in number to join the conference:

1 (888) 424–8151—Audience US Toll Free

1 (847) 585–4422—Audience US Toll

Audience Passcode: 9387 018

The CSB is an independent federal agency charged with investigating incidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes, such as equipment failure, as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their presentations will be limited to three minutes or less, but commenters may submit written statements for the record.

CONTACT PERSON FOR FURTHER INFORMATION: Hillary Cohen, Communications Manager, at *public@csb.gov* or (202) 446–8094. Further information about this public meeting can be found on the CSB website at: *www.csb.gov.*

(Authority: 5 U.S.C. 552b)

Dated: October 1, 2019.

Raymond C. Porfiri,

Deputy General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2019–23545 Filed 10–24–19; 11:15 am]

BILLING CODE 6350–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Minnesota Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Minnesota Advisory Committee (Committee) to the Commission will be held at 6:00 p.m. CDT Tuesday November 12, 2019 to conduct a community forum in St. Paul, Minnesota for the topic of Racial Trauma.

DATES: The meeting will be held on Tuesday November 12, 2019, at 6:00 p.m. CDT.

ADDRESSES: Comunidades Latinas Unidas en Servicio (CLUES), 797 East 7th Street, St. Paul, MN 55106. Public Call Information: Dial: 800–367–2403; Conference ID: 2628752.

FOR FURTHER INFORMATION CONTACT: David Barreras at *dbarreras@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: This meeting is available to the public at the above address and through the above toll-free call-in number. Any interested member of the public may attend the meeting or call the number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the U.S. Commission on Civil Rights, Regional Programs Unit, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may be faxed to the Commission at (312) 353–8324 or emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.