Billing C

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2019-0023]

Changes to the *Salmonella* Verification Testing Program: Proposed Performance Standards for *Salmonella* in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts 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 proposed pathogen reduction performance standards for *Salmonella* in raw comminuted pork and raw intact or non-intact pork cuts. The Agency is also announcing how it plans to assess whether establishments producing these products are effectively addressing *Salmonella* using a moving window of FSIS sampling results. Approximately one year (52 weeks) after the new performance standards are made final, the Agency plans to post online each establishment's performance category, based on the most recent 52 *Salmonella* sample results. The notice discusses other verification activities related to FSIS *Salmonella* sampling and testing of raw pork products. Finally, the notice provides a brief summary of the Agency's recent announcements concerning *Salmonella* in poultry products. FSIS will consider comments received on this notice before announcing the final performance standards in the

Federal Register and assessing whether pork establishments meet them.

DATES: 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, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2019-0023. 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)720-5627 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:

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

Salmonella bacteria are among the most frequent causes of foodborne illness. These bacteria reside in the gastrointestinal tract and hide or hair 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 hair, or be transferred to the carcass, and can contaminate raw products during slaughter and subsequent fabrication and further processing). Currently, events that cause contamination of pork 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 pork carcasses into products, including raw comminuted pork and raw intact or non-intact pork cuts.[1]

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 and/or that produce selected classes of raw meat products, including pork carcasses, based on FSIS baseline study data (9 CFR 310.25(b)).[2] In 2012, FSIS stopped sampling and testing for *Salmonella* in pork carcasses because percent positive findings were very low[3] and the carcass sampling was not

---

[1]FSIS defines "comminuted pork" as pork that has been ground, mechanically separated, or otherwise processed to reduce particle size; an "intact pork cut" as a smaller cut derived from a pork primal cut that has not been subjected to processing that renders it non-intact; and a "non-intact pork cut" also as a smaller cut but that has been injected, mechanical tenderized, reconstructed, vacuum-tumbled, scored and marinated, or otherwise processed to render it non-intact.

[2]As noted in Table 2 at 9 CFR 310.25 (b), FSIS intended to add a pathogen reduction performance standard for fresh pork sausage. FSIS collected data in 1998 and 1999 but a performance standard for fresh pork sausage was never finalized.

[3]At the time, FSIS estimated the prevalence of *Salmonella* in market hogs was 1.66% with a 95% confidence interval between 0.82% and 2.51%. See the *Nationwide Microbiological Baseline Data Collection Program: Market Hogs Survey August 2010 – August 2011*; available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Market_Hogs_2010-2011.pdf#:~:text=The%20Market%20Hogs%20Baseline%20Survey%20%28MHBS%29%20was%20conducted,at%20pre-evisceration%20and%20post-chill%20and%20between%20production%20shifts.

a good use of Agency resources. In the 2019 rule to modernize swine slaughter, FSIS removed the *Salmonella* pathogen reduction performance standards associated with pork carcasses and sausages from the regulations (84 FR 52300; Oct. 1, 2019). In that rule, FSIS also noted that it is testing pork cuts and comminuted pork products for *Salmonella* and expected to decide in 2019 whether to develop new pathogen performance standards for these products (82 FR 52318).

The Centers for Disease Control and Prevention (CDC) first estimated the role of pork products in salmonellosis cases by analyzing outbreak data collected between 1998 and 2008.[4] The estimated percentage of foodborne illnesses attributed to pork for this time period was 6.2 percent, with lower- and upper-bound estimates of 3.6 and 11.4 percent, respectively.[5] In 2011, the CDC, Food and Drug Administration, and FSIS teamed up to form the Interagency Food Safety Analytics Collaboration (IFSAC). Using outbreaks between 1998 and 2017, the IFSAC estimates suggest pork is responsible for 10.3 percent of domestic cases of salmonellosis among all foods, with lower- and upper-bound estimates of 7.7 and 13.1 percent, respectively.[6] This represents about 30 percent of all domestic foodborne

---

[4]Painter, J.A., Ayers, T., Woodruff, R., Blanton, E., Perez, N., Hoekstra, R.M., Griffin, P.M., Braden, C., 2009. Recipes for foodborne outbreaks: A scheme for categorizing and grouping implicated foods. Foodborne Pathogens and Disease 6, 1259-1264.

[5]Painter, J.A., Hoekstra, R.M., Ayers, T., Tauxe, R.V., Braden, C.R., Angulo, F.J., Griffin, P.M., 2013. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities, United States, 1998-2008. Emerging Infectious Diseases 19, 407-415.

[6]IFSAC, 2019; available at https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2017-report-TriAgency-508-revised.pdf.

Salmonella illnesses among FSIS-regulated products. This makes pork the second highest contributor to *Salmonella* illnesses associated with products regulated by FSIS, behind chicken.

In 2013, FSIS committed to a 25-percent reduction in annual salmonellosis illnesses attributed to the products it regulates.[7] The 25-percent reduction goal was set to meet Healthy People 2020 objectives. FSIS will continue to use a 25-percent reduction as its intended target for salmonellosis illness reductions to meet Healthy People 2030, under which the objectives are unchanged.[8] FSIS requests comment on this intended target for salmonellosis illness reductions and whether the Agency should consider a more stringent reduction (e.g., 30 percent).

Recent Announcements Concerning Salmonella in Poultry

On October 19, 2021, USDA announced that FSIS would be mobilizing a stronger and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products.[9] A key component of this effort is identifying ways to incentivize use of preharvest controls to reduce *Salmonella* contamination coming into the slaughterhouse.

In November 2021, FSIS held roundtable listening sessions with industry and consumer groups to answer questions about establishment pilot projects. On December 3, in its *Constituent*

---

[7] FSIS *Salmonella* Action Plan; available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-10/SAP-120413.pdf.
[8] Available at https://health.gov/healthypeople.
[9] https://www.fsis.usda.gov/news-events/news-press-releases/special-alert-constituent-update-usda-launches-new-effort-reduce.

Update, FSIS invited poultry slaughter and processing establishments to submit proposals for pilot projects that will test different control strategies for *Salmonella* contamination in poultry products.[10] FSIS explained that Pilot projects will last for a defined period of time, during which establishments will experiment with new or existing pathogen control and measurement strategies and share data collected during the pilots with FSIS. FSIS also explained that data will be analyzed by FSIS to determine whether it supports changes to FSIS' existing *Salmonella* control strategies.

In this notice, FSIS is proposing *Salmonella* performance standards for certain pork products. If we adopt a revised approach to performance standards for *Salmonella* in poultry, the Agency may also propose future changes to the pork standards.

Public Health Concerns

There have been multiple outbreaks attributed to the consumption of pork in recent years. Between 2014 and 2016, CDC identified a total of approximately 772 persons sickened and 93 persons hospitalized with *Salmonella* resulting from 19 pork associated outbreaks. One individual died[11]. Two of these outbreaks resulted in recalls. In 2015, the CDC confirmed a multi-state outbreak of *Salmonella* I 4,[5],12:i:- and *Salmonella* Infantis that resulted in 192 illnesses and 30

[10]USDA FSIS Constituent Update, Dec. 3, 2021, available at: https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-december-3-2021.
[11]Available at https://www.cdc.gov/norsdashboard/.

hospitalizations.[12] This outbreak led to a recall of approximately 523,000 pounds of pork products.[13] In 2016, the CDC confirmed a single-state outbreak of *Salmonella* I 4,[5],12:i:- that resulted in 15 illnesses. This outbreak led to a recall of approximately 11,700 pounds of pork products.[14] Between 2017 and 2019, a total of approximately 475 persons were sickened and 93 persons hospitalized with *Salmonella* resulting from 15 pork associated outbreaks. One individual died.[15]

The outbreaks referenced here suggest that *Salmonella* in raw pork is a continuing public health concern. The changes described below will apply to most of the pork consumed in the United States and will likely improve FSIS' ability to detect *Salmonella* by focusing increased sampling on the largest establishments that produce the greatest amount of product. Also discussed below, FSIS has developed performance standards that will likely lead establishments producing raw pork products to strengthen their own *Salmonella* control measures. Such changes at establishments will likely have a positive impact on public health.

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

---

[12]Available at https://www.cdc.gov/salmonella/pork-08-15/index.html.
[13]FSIS Recall 110-2015; available at Kapowsin Meats Recalls Pork Product Due To Possible Salmonella Contamination | Food Safety and Inspection Service (usda.gov).
[14]Available at Kapowsin Meats Inc. Recalls Pork Products Due To Possible Salmonella Contamination | Food Safety and Inspection Service (usda.gov).
[15]Available at https://www.cdc.gov/norsdashboard/.

Campylobacter pathogen reduction performance standards (81 FR 7285). FSIS stated that the moving window would be 52 weeks and that the Agency 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.[16] FSIS intends to use this moving window approach for pork establishments that produce raw comminuted pork and/or raw intact or non-intact pork cuts that will be subject to the new *Salmonella* performance standards.

In preparation for the implementation of the new performance standards, FSIS has begun *Salmonella* sampling in all pork establishments that produce greater than 1,000 pounds of raw comminuted pork and greater than 1,000 pounds of raw intact or non-intact pork cuts per day.[17] FSIS currently assigns samples five times per month in pork establishments producing greater than 6,000 pounds per day of raw comminuted pork and/or greater than 50,000 pounds per day of raw intact or non-intact pork cuts. FSIS samples less frequently in the lower-volume establishments.

FSIS will use the results of this sampling to gain additional information on the prevalence of *Salmonella* in these products and to make sure the data continue to support the

[16]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.
[17]FSIS Notice 41-19, Raw Pork Products Sampling Program; Oct. 28, 2019.

standards. FSIS ensures that result information is made available to establishments. Note that FSIS does not recognize *Salmonella* in raw pork products as a pathogen that would ordinarily render the product injurious to health, and thus an adulterant within the meaning of 21 U.S.C. 601(m)(1). As such, currently and when new standards are in place, individual *Salmonella* sample results will not result in regulatory control actions.

Illness Reduction Goals

As explained above, FSIS has committed, with its public health partners, to a 25-percent reduction in annual cases of salmonellosis. Using published results,[18] FSIS estimates a median of about 122,000 annual cases of salmonellosis associated with the consumption of raw pork contaminated with *Salmonella*. FSIS estimates that approximately 34,000 of these illnesses are associated with raw comminuted pork and 88,000 of these illnesses are associated with raw intact or non-intact pork cuts. Thus, to meet the 25-percent reduction goal, there would need to be about 8,300 and 21,600 fewer annual *Salmonella* illnesses from raw comminuted pork and raw intact or non-intact pork cuts, respectively.

Pathogen Reduction Performance Standards

With the goal of reducing *Salmonella* in raw pork products, the Agency is proposing two new pathogen reduction performance standards - one for *Salmonella* in raw comminuted pork and

[18]Scallan, et al, 2011; IFSAC 2019.

another for *Salmonella* in raw intact or non-intact pork cuts.[19]

Sampling evidence suggests that these two pork product classes differ with respect to *Salmonella* contamination occurrence. The prevalence of *Salmonella* in raw comminuted is about 30% while the combined percent positive for raw intact or non-intact pork cuts is about nine percent. Therefore, FSIS is proposing separate performance standards for each of these product classes.

The modeling methods for developing the proposed pathogen reduction performance standards and predictions for the public health effect of those standards are described in FSIS' Public Health Effects of Performance Standards for raw Comminuted Pork and raw Pork Cuts (2020 Pork Risk Assessment)(cite when posts).

Because the pork product industry is relatively concentrated by production volume, that is, a relatively small number of establishments produce most of the raw pork, FSIS developed pathogen reduction performance standards for each of the above product classes based on an average daily production volume threshold. The proposed performance standards would be applicable to establishments producing greater than 6,000 pounds per day in the case of raw comminuted pork and/or greater than 50,000 pounds per day in the case of raw intact and/or non-intact pork cuts. This approach would account for approximately

[19]Data collected during Phase 2 of the RPPESP showed the percentage of positive samples for raw comminuted pork, intact pork cuts, and non-intact cuts was 16.4, 9.4, and 6.3, respectively. However, FSIS found no significant difference in the percentage of positive samples from intact pork cuts and non-intact pork cuts, so the two product classes were combined into a single product class. The percentage of *Salmonella*-positive samples for the combined product class was 8.7%.

96 percent of raw comminuted pork and 91 percent of raw intact and non-intact pork cuts produced annually. And as further explained in the 2020 Pork Risk Assessment, the approach would also focus Agency resources on that part of the pork industry where *Salmonella* contamination is most clustered.

FSIS intends to collect and analyze 52 samples per year for each establishment subject to the performance standards. Analyzing this number of samples would provide strong evidence that an establishment is meeting the performance standard.

FSIS has opted at this time not to propose pathogen reduction performance standards in lower-volume establishments (i.e., those producing less than or equal to 6,000 pounds per day of raw comminuted pork and/or less than or equal to 50,000 pounds per day of raw intact or non-intact pork cuts). A summary of the new performance standards is provided in Table 1.

Table 1. New performance standards for *Salmonella* in raw comminuted (ground) pork and raw intact or non-intact pork cuts

Product (Establishment Volume (pounds/day))	Maximum number of allowable positive samples	Minimum number of samples needed to assess establishment performance*
Raw Comminuted Pork (>6,000)	13 of 52	52
Raw Intact or Non-Intact Pork Cuts (>50,000)	6 of 52	52

*Any establishment with more than the maximum number of allowable positive samples for that product class in a 52-week window would be categorized as *Category 3* even when less than the minimum number of samples (52) are collected/analyzed.

Raw Comminuted Pork

For raw comminuted pork, FSIS is proposing a pathogen

reduction performance standard for *Salmonella* of 13 allowable positives out of 52 samples. This standard would be applied to establishments producing greater than 6,000 pounds of raw comminuted pork per day (approximately 10 percent of establishments that produce this product class, 138 establishments). As mentioned above, FSIS would continue to assign samples five times per month in all establishments producing greater than 6,000 pounds of eligible product per day with the intention of collecting and analyzing 52 samples in a 52-week window.

FSIS predicts that approximately 44 percent of establishments (about 61 establishments) would initially not meet this performance standard. Once implemented, if about half (45%) of the establishments producing greater than 6,000 pounds of raw comminuted pork 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 8,300 (95% uncertainty interval: 3,600 – 16,300).

Raw Intact or Non-intact Pork Cuts

For both raw intact and non-intact pork cuts, FSIS is proposing a single pathogen reduction performance standard for *Salmonella* of 6 allowable positives out of 52 samples in a 52-week window. This standard would be applied to establishments producing greater than 50,000 pounds of these products per day

(approximately 4 percent of establishments producing this product class, 38 establishments). Approximately 39 percent of these establishments (about 15 establishments) are predicted to initially not meet this performance standard (i.e., would be categorized as *Category 3*). Once implemented, if about half (45%) of the establishments producing greater than 50,000 pounds of raw intact or non-intact pork cuts 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 21,600 (95% uncertainty interval: 10,000 – 40,000).

Specifics of the 52-week Window Approach and Categorizing Establishments

As stated, the performance standard is intended to apply to 52 samples in a 52-week window. If FSIS analyzes more than 52 samples in a 52-week window, the most recent 52 sample results in that 52-week window would be used to categorize the establishment. Although unlikely, there may be rare occasions when fewer than 52 samples are analyzed in these establishments within a 52-week window. If fewer than 52 samples are analyzed, the establishment's status would be reported as "N/A," provided the establishment has fewer than the minimum number of allowable *Salmonella* positives for that product class in that window. Any establishment with more than the minimum number of allowable *Salmonella* positives for that product class in a 52-week window

would be categorized as *Category 3* (outlined below), regardless of the number of samples collected/analyzed in that window.

Web-posting Establishment Performance

Should FSIS move forward with finalizing the proposed pathogen reduction performance standards for *Salmonella* in raw comminuted pork and raw intact or non-intact pork cuts, FSIS would announce the final standards and the sample dates FSIS will use to assess whether establishments meet the standards in a subsequent **Federal Register** notice. About one year after FSIS starts assessing whether establishments meet the standards, FSIS would determine individual establishment performance based on the last 52 FSIS *Salmonella* sample results and then report on the FSIS website the category of each establishment subject to the performance standard using the following criteria:

- **Category 1:** Establishments with 50% or less of the allowable number of positive *Salmonella* sample results for that product class during the most recent 52-week window, based on the last 52 FSIS *Salmonella* sample results.
- **Category 2:** Establishments with greater than 50% but not more than the allowable number of positive *Salmonella* sample results for that product class during the most recent 52-week window, based on the last 52 FSIS *Salmonella* sample results.
- **Category 3:** Establishments with more than the allowable number of positive *Salmonella* sample results for that product class during the most recent 52-week window, based on the last 52 FSIS *Salmonella* sample results.

During the period after FSIS begins to make performance assessments based on the proposed standards, and before the performance standards are implemented, FSIS intends to make available monthly aggregate information relative to status (i.e., *Category 1, Category 2, or Category 3*) 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 comminuted pork and raw intact or non-intact pork cuts.

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 reasonably likely to occur (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)).

When a pork 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 conduct follow-up sampling after the establishment is categorized as *Category 3* to verify the adequacy of corrective actions taken by the establishment. 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 standard. Follow-up sampling for establishments that do not meet the raw comminuted pork and/or raw pork cuts 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.[20]

In addition, FSIS may conduct a Public Health Risk Evaluation (PHRE), a decision-making process that is used by Agency enforcement and investigation personnel, for any pork establishment that a) does not meet a *Salmonella* pathogen reduction performance standard; b) has produced products with repetitive *Salmonella* serotypes of public health concern[21] or repetitive antibiotic-resistant *Salmonella;* and/or c) has

[20]See also FSIS Notice 17-19, Follow-up Sampling in Raw Poultry Establishments Not Meeting Salmonella Performance Standards; June 4, 2019.
[21]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.

Salmonella whole-genome sequencing (WGS) matching those found in recent outbreaks or epidemiologically linked to illnesses (see FSIS Directive 5100.4 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)[22] at the establishment.

As explained above, and also consistent with existing FSIS practices,[23] after notifying a pork establishment that it is in *Category 3* (has not met a pathogen reduction performance standard), FSIS would conduct an assessment of the establishment's HACCP plan and Sanitation SOPs, 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 pork 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' follow-up and routine sampling and in some

[22]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.

[23]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 7288).

cases from the results of a PHRE or 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 less than or equal to 6,000 pounds per day of raw comminuted pork and/or less than or equal to 50,000 pounds per day of raw intact or non-intact pork cuts would not be subject to the proposed performance standards, FSIS may initiate follow-up sampling and/or conduct a PHRE or a FSA in these establishments when there is evidence of a high level of *Salmonella* contamination and for any of the reasons listed above, other than failing to meet the performance standard.

Establishments producing less than or equal to 1,000 pounds per day would not be sampled and are not eligible for performance standards. However, recognizing that establishments producing greater than 1,000 pounds per day but less than or equal to 6,000 pounds per day of raw comminuted pork, and greater than 1,000 pounds per day but less than or equal to 50,000 pounds per day of raw intact or non-intact pork cuts, would not be subject to the proposed performance standards, FSIS would continue the current sampling program discussed above to

monitor this population of lower volume establishments.[24] FSIS would sample and test product from these establishments at a yearly rate that would allow the Agency to determine whether there has been a significant change in *Salmonella* prevalence at these establishments by +/- 5 percent. FSIS would review changes in prevalence over time in aggregate for this population of establishments and determine whether it is improving. If not, FSIS may increase sampling at that volume class in order to assess what is happening at the establishment level.

As previously announced in a 2012 **Federal Register** notice on Agency verification procedures, if any livestock establishment produces product associated with a *Salmonella* illness outbreak identified through epidemiological and/or traceback investigations, FSIS likely will consider the product to be adulterated under 21 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).

[24] FSIS Notice 41-19, Raw Pork Products Sampling Program; Oct. 28, 2019.

FSIS monitors relevant databases (e.g., those maintained by the CDC and the National Institutes of Health) for clinical isolates[25] 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, so as to focus its 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 comminuted pork and raw intact or non-intact pork cuts. The full analysis is published on the FSIS website as supporting documentation to this notice ([insert link]). FSIS is seeking comment on the information and assumptions used in the cost-benefit analysis. A summary of the analysis follows.

Industry Costs

FSIS predicts that approximately 44 percent of the medium and higher-volume raw comminuted pork establishments (about 61 establishments) and 39 percent of the higher-volume intact or

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

non-intact pork cuts establishments (about 15 establishments) would not initially meet the standards. Establishments meeting the performance standards would not have any cost associated with these standards. In order to ensure their HACCP systems are functioning correctly, establishments not meeting the performance standards would incur cost associated with a HACCP plan reassessment and possibly with an Agency Food Safety Assessment (FSA), the associated primary industry costs being $18,203 and $1,361, respectively, annualized at the 7 percent discount rate over 10 years.

Establishments that initially do not meet the proposed standards but aspire to do so, would incur additional cost. For those establishments initially not meeting the performance standards, FSIS assumes approximately 45 percent would start making changes after one year and eventually would meet the standards in two years by making changes to their production process. Based on available information, FSIS expects that these establishments would most likely add antimicrobial interventions and equipment to their production process to meet the performance standard, with an associated primary cost of $1,236,391, annualized at the 7 percent discount rate over 10 years. These establishments may also add *Salmonella* testing to their existing sampling program or start *Salmonella* sampling and testing, with an associated primary cost of $122,451, annualized at the 7 percent discount rate over 10 years. These establishments would also likely validate their HACCP plans,

and/or conduct training, with an associated total primary industry cost of $114,903 and $11,097, annualized at the 7 percent discount rate over 10 years, respectively.

Total industry cost ranges from $1,163,796 to $1,842,518, with a primary estimate of $1,504,406, annualized at the 7 percent discount rate over 10 years, table 2. The majority of these costs are associated with antimicrobial equipment maintenance and labor incurred by establishments that initially do not meet the performance standards but attempt to meet the standards. Establishments that meet the performance standards would incur minimal cost associated with lost product due to FSIS *Salmonella* sampling.

Agency Costs

The raw comminuted pork and raw intact or non-intact performance standards would require FSIS sampling, which would incur Agency cost for follow-up sampling. FSIS estimates that total sampling for the performance standards, including follow-up sampling and lower-volume sampling, would be 12,232 samples. However, in 2021 FSIS planned for 8,640 raw comminuted pork *Salmonella* samples and 2,400 raw intact or non-intact pork cuts samples for a total of 11,040 samples[26] for the Raw Pork Sampling Program.[27] The raw comminuted pork and raw intact or non-intact performance standards would replace the Raw Pork Sampling

[26]FSIS Annual Sampling Plan FY2021: Table A3: FY 2020 and FY 2021 Sample Numbers for Raw Pork; available at https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/fsis-annual-sampling-plan-fy2021.pdf.

[27]FSIS Notice: Raw Pork Parts Sampling Program; available athttps://www.fsis.usda.gov/wps/wcm/connect/e2176090-7257-4d6e-9964-e9b8a512d8b5/41-19.pdf?MOD=AJPERES.

Program, leading to a net increase of 1,192 samples, which are attributed to follow-up sampling. The primary cost estimate for the additional 1,192 follow-up samples is $81,508, annualized at the 7 percent discount rate over ten years.

FSIS would also incur costs from PHREs and FSAs. Pork establishments that do not meet the *Salmonella* pathogen reduction performance standards would be prioritized for a PHRE. A portion of the establishments that receive a PHRE would also have an FSA.[28] The combined PHRE and FSA primary cost estimate is $20,988, annualized at the 7 percent over 10 years.

The total Agency cost for follow-up sampling, PHREs and FSAs ranges from $0.06 million to $0.18 million, with a primary estimate of $0.10 million, annualized at the 7 percent over 10 years, table 2.

Public Health Benefits

As pork establishments subject to the proposed performance standards make changes to their production processes and reduce the prevalence of *Salmonella* in raw comminuted pork and intact or non-intact pork cuts, public health benefits would be realized in the form of averted illnesses. The Agency's policy of web-posting establishments' process control performance may stimulate improvement in industry performance. FSIS data show that sharing this information provides an incentive for establishments to further reduce *Salmonella* levels, which is

[28]EIAO Public Health Risk Evaluation (PHRE) methodology Implementation of FSIS Directive 5100.4 (September 2016) report. The FSA cost estimate includes travel cost to the establishment.

necessary to reduce foodborne illness due to salmonellosis and protect consumers. For instance, in the poultry industry, after the Agency's announcement in 2006 that it was considering posting the names of broiler and turkey slaughter establishments with their respective performance standard categories based on Salmonella verification testing, the number of broiler slaughter establishments that had been in Category 3 decreased by 55 percent.[29] As discussed in the 2020 Risk Assessment, FSIS estimated the annual *Salmonella* foodborne illnesses associated with pork products. FSIS then estimated the number of annual illnesses attributed to products subject to the updated or new performance standards. Finally, FSIS estimated the number of illnesses averted if 45 percent of the establishments that do not initially 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 2020 Risk Assessment. The estimated public health benefits from the illnesses averted because of the proposed *Salmonella* pork performance standards ranges from $49.09 million to $203.24 million, with a primary

[29]FSIS defined the following categories for broiler and turkey slaughter establishments in 2006: Category 1: Consistent Process Control: Establishments that have achieved 50 percent or less of the *Salmonella* maximum allowable percent positive during all completed 52-week moving windows over the last 3 months. Category 2. Variable Process Control: Establishments that meet the Salmonella maximum allowable percent positive for all completed 52-week moving windows but have results greater than 50 percent of the maximum allowable percent positive during any completed 52-week moving window over the last 3 months. Category 3. Highly Variable Process Control: Establishments that have exceeded the Salmonella maximum allowable percent positive during any completed 52-week moving window over the last 3 months. Changes to the *Salmonella* and Campylobacter Verification Testing Program, Federal Register, Vol 80, No. 16, January 26, 2015. Docket No. FSIS-2014-0023.

estimate of $107.94 million, annualized at the 7 percent discount rate over 10 years, table 2.

Industry Benefits

FSIS expects that industry would benefit from reduced outbreak-related recalls. The negative impacts of recalls on industry include the loss of sales revenue, the loss of consumer confidence and consumers shifting away from meat products.[30] Recalls negatively impact consumers by creating anxiety and time-consuming inconveniences (e.g., looking for recall information, checking the products purchased, returning or disposing of products identified by the recalls, and so on). FSIS expects the proposed raw comminuted pork and intact or non-intact pork cuts performance standards would lead to fewer contaminated products, because of industry actions taken to reduce *Salmonella* in these products to meet the proposed performance standards. The reduction in *Salmonella* would result in less exposure to *Salmonella* for consumers that eat pork products and fewer illnesses, outbreaks, and recalls.

Summary of Net Benefits

Table 2 displays the total costs and benefits expected from the implementation of the performance standards for raw comminuted pork and raw intact or non-intact pork cuts establishments. There would be 138 establishments subject to the

[30]Marsh, T.L., T.C. Schroeder, J. Mintert. (2004). Impacts of Meat Product Recalls on Consumer Demand in the USA. Applied Economics. 36(9):897-909. URL accessed on July 1, 2020; available at http://ses.wsu.edu/publication/impacts-of-meat-product-recalls-on-consumer-demand-in-the-usa/.

raw comminuted pork performance standard and 38 establishments subject to the intact or non-intact pork cuts performance standard. These establishments represent 96 and 91 percent of total production volume, respectively. The proposed performance standards would lead to industry cost for these establishments and FSIS would incur Agency cost implementing these standards. Benefits would occur once establishments who initially do not meet the standard make changes to meet the performance standards. The net benefits are the public health benefits minus the industry and agency cost. The estimated net benefits associated with the proposed *Salmonella* pork performance standards range from $47.87 million to $201.22 million, with a primary estimate of $106.33 million, annualized at the 7 percent discount rate over 10 years, table 2.

Table 2. Summary of Estimated Net Benefits[1]

Compliance Rate[2]	Cost/Benefit Component	Low Estimate ($mil)	Primary Estimate ($mil)	High Estimate ($mil)
	Industry Costs	$1.16	$1.50	$1.84
	Agency Cost	$0.06	$0.10	$0.18
	Public Health Benefits	$49.09	$107.94	$203.24
45%	Net Benefits[3]	$47.87	$106.33	$201.22

[1]All costs (savings) annualized at a discount rate of 7 percent over 10 years. Numbers in table may not sum to totals due to rounding.
[2]Compliance rate for establishments initially not meeting the proposed standards, but then meeting the proposed standards over 2 years.
[3]Numbers in the table may not sum to totals due to rounding.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and

institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400

Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

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: https://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 e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at https://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.

Paul Kiecker,

Administrator.

[FR Doc. 2022-03301 Filed: 2/15/2022 8:45 am; Publication Date: 2/16/2022]