

U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Preliminary Cost-Benefit Analysis

Proposed Ground Beef and Beef Manufacturing Trimmings *Salmonella* Performance Standards

I. Introduction

FSIS is proposing *Salmonella* performance standards for ground beef and manufacturing trimmings (trim) producing establishments. Should these standards become final, the Agency would assess whether beef grinding and manufacturing trim establishments' processes meet the standards using a 52-week moving window of sampling results ending the last Saturday of the previous month. In response to the proposed pathogen reduction performance standards, establishments would likely make changes to their production process dependent on their level of production volume. For this reason, FSIS used the volume categories described in the 2019 Risk Assessment¹ to help predict the changes that establishments would most likely implement to meet the proposed performance standards.

The 2019 Risk Assessment describes the methodology for developing the proposed pathogen reduction performance standards for ground beef and manufacturing trim based on daily production volume thresholds. FSIS classified small and medium size grinding establishments that produce roughly less than 50,000 pounds of product per day as lower-volume grinding establishments. FSIS also classified small and medium size manufacturing trim establishments that produce roughly less than 50,000 pounds of product per day as lower-volume manufacturing trim establishments. These lower-volume establishments represent nine percent of ground beef production and six percent of manufacturing trim production and would not be subject to the proposed performance standards. FSIS may initiate follow-up sampling and/or conduct a Public Health Risk Evaluation (PHRE) or Food Safety Assessment (FSA) in these lower-volume establishments when there is evidence of high levels of *Salmonella* contamination.

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<http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES>

FSIS would conduct these activities in a way that is resource neutral and estimates no additional Agency costs. Recognizing that these establishments are sampled much less frequently than the higher-volume establishments, FSIS is requesting comments on this approach.

In the 2019 Risk Assessment, FSIS classified higher-volume establishments as producing greater than 50,000 pounds per day. These higher-volume establishments represent 91 percent of ground beef production and 96 percent of manufacturing trim production and would be subject to the proposed performance standards.

Higher-volume beef grinding establishments and manufacturing trim producing establishments that do not meet the proposed performance standard would be required to reassess their HACCP plan.² The establishments would need to reassess their HACCP plan for that product to determine whether the plan needs to be modified to address the hazard. Some establishments may choose to make changes to their production processes that need to be validated. To ensure a conservative cost estimate, FSIS assumed that all establishments that initially do not meet the proposed performance standards and choose to make changes would validate their HACCP plan. In addition, beef grinding establishments and manufacturing trim producing establishments that initially do not meet the proposed performance standards, would face decisions regarding corrective actions. The type of corrective actions, and the implementation of these actions, would ultimately be the choice of the individual company or establishment. Some establishments that initially do not meet the proposed standard but aspire to do so, would need to make changes to their production processes to lower the prevalence of *Salmonella*. For example, establishments may conduct *Salmonella* sampling, apply

² 9 CFR 417.4(a) (3) requires the establishment to conduct a HACCP re-assessment at least annually and “whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.”

antimicrobial interventions (including purchasing necessary capital equipment), and/or conduct training.

II. Establishments Affected by the Proposed Performance Standards

The proposed performance standards would affect higher-volume beef grinding establishments and manufacturing trim establishments. FSIS used its Public Health Information System (PHIS) to identify these establishments by volume category. Table 1 provides an itemization of establishments by product and volume processing size. The proposed performance standards would affect a total of 75 beef grinding establishments and 49 manufacturing trim establishments. FSIS plans to maintain the production volume categories as defined by FSIS sampling programs MT43³ and MT60⁴ to implement the proposed performance standards.

³ MT43 is the FSIS sampling program for raw ground beef products that are subject to FSIS sampling for *E. coli* O157:H7 and *Salmonella*. Raw ground beef products are described in the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)). Raw ground beef products include: ground or chopped beef or veal; hamburger; beef or veal patties; beef or veal patty mix; and similar ground beef or veal products made with added seasonings or ingredients.

https://www.fsis.usda.gov/wps/wcm/connect/50c9fb74-c0db-48cd-a682-b399ed6b70c0/29_IM_Raw_Beef_Prod_Sampling.pdf?MOD=AJPERES

⁴ MT60 is the FSIS sampling program for beef manufacturing trimmings sampled for *E. coli* O157:H7, other non-O157 STEC (Shiga Toxin-Producing *Escherichia coli*), and *Salmonella*. Beef manufacturing trimmings are trimmings produced from cattle (including veal) that are slaughtered onsite, that is, at the establishment where the MT60 sampling is occurring. Beef manufacturing trimmings includes trim of any size; or primal/subprimal cuts, like chucks, rounds, or shanks; or boneless beef of any size, in any packaging. The MT60 sampling project covers any trim that is used at the slaughter establishment for non-intact use, or is intended for raw non-intact use by other establishments. https://www.fsis.usda.gov/wps/wcm/connect/50c9fb74-c0db-48cd-a682-b399ed6b70c0/29_IM_Raw_Beef_Prod_Sampling.pdf?MOD=AJPERES

Table 1. Establishments Producing Ground Beef and Manufacturing Trim (PHIS)	
Beef Production	Greater than 50,000 pounds per day
Manufacturing Trim	49
Ground	75
Total	124

Using data from its PHIS system, FSIS produced a Risk Assessment that estimated the percentage of establishments, which would initially not meet the proposed performance standards, and the percentage of total product produced at those establishments. In the 2019 Risk Assessment, FSIS assumed that 50% of establishments initially not meeting the proposed performance standards would eventually make changes to meet the standards.⁵

i. Estimation of the Number of Establishments Likely to Meet the Proposed Performance Standards After Initially Not Meeting the Proposed Standards

FSIS used the following methodology to estimate the number of establishments that would initially not meet the proposed performance standards but would most likely meet the proposed standards after making changes to their processes.

- The number of higher-volume grinding establishments x failure rate⁶ x compliance rate:

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<http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES>

⁶ FSIS determined the failure rate using FSIS *Salmonella* testing data from beef establishments. The *Salmonella* testing in beef establishments began in 2014 when *Salmonella* and STEC pathogens were co-analyzed in samples collected under its MT43 (ground beef) and MT60 (manufacturing trim) programs. Please see the 2019 Risk Assessment for more detail on *Salmonella* Testing. [<http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES>].

$75 \times 18\% \times 50\% = 7$ higher-volume grinding establishments⁷.

- The number of higher-volume manufacturing trim establishments x failure rate x compliance rate:

$49 \times 20\% \times 50\% = 5$ higher-volume manufacturing trim establishments.

Table 2 contains the results of these calculations.

ii. Production Volume Calculation for Establishments Likely to Meet the Proposed Standards After Initially Not Meeting the Proposed Standards

FSIS used the following methodology to estimate the production volume for establishments that would initially not meet the proposed performance standards but would most likely meet the proposed standards after making changes to their processes. The pounds of production equals the number of establishments at the 50% compliance level multiplied by the average production volume at the grinding establishments. For example, FSIS calculated the pounds of production for beef grinding and manufacturing trim establishments as:

- For higher-volume grinding establishments as:

7×109.19 million pounds = 764.33 million pounds.

- For higher-volume manufacturing trim establishments as:

5×140.95 million pounds = 704.75 million pounds.

Table 2 contains the results of these calculations.

⁷ FSIS rounded all calculations regarding the number of establishments to the nearest whole number.

Table 2. Initial Share of Establishments and Production Volume (2019 Risk Assessment⁸)		
Metric	Ground Beef >50,000 per day	Manufacturing Trim >50,000 per day
Proposed performance standard ¹	2 <i>Salmonella</i> positives of 48 total samples	2 <i>Salmonella</i> positives of 48 total samples
Minimum number of samples to apply the proposed standard	48	48
Production volume share	91%	96%
Establishment share	6%	10%
Number of establishments initially not meeting the proposed standard	14	10
Number of establishments initially not meeting then meeting the proposed standard	7	5
Production volume for establishments likely to meet after initially not meeting the proposed standard	764.33 million pounds	704.75 million pounds
¹ The 2019 Risk Assessment defines the proposed performance standards as a maximum allowable number of <i>Salmonella</i> positive samples in a 52-week moving window ending the last Saturday of the previous month. FSIS is proposing performance standards to accomplish a reduction in <i>Salmonella</i> illnesses. The 2019 Risk Assessment contains these findings.		

FSIS would assess individual establishment performance using a “moving window” approach and then web-post individual establishments as either “meeting” or “not meeting” the proposed standards. Please see definitions below:

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.

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<http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES>

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.

The Agency's policy of web-posting establishments' process control performance has stimulated improvement in industry performance. FSIS data show that sharing this information provides an incentive for establishments to further reduce *Salmonella* levels, which is 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 broiler slaughter establishments that had been in Category 3 decreased by 66 percent.⁹

III. Current Practices of Antimicrobial Use and Sampling in Beef Grinding and Manufacturing Trim Establishments

FSIS used data from the 2013 Pathogen Controls in Beef Operations Summary Results survey (BOSR)¹⁰ for information on antimicrobial use and sampling and testing operations of

⁹ 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. (<https://www.fsis.usda.gov/wps/wcm/connect/55a6586e-d2d6-406a-b2b9-e5d83c110511/2014-0023.pdf?MOD=AJPERES>)

¹⁰ FSIS conducted a comprehensive survey of its field personnel, who are stationed in beef slaughtering and processing establishments. The survey was launched to FSIS personnel in a step-wise fashion starting May 6, 2013, and closed July 25, 2013. This data can be found in a final report titled 'Pathogen Controls in Beef Operations Summary Results' Available at <https://www.fsis.usda.gov/wps/wcm/connect/fe95af5f-3271-41af-b92b->

beef establishments. Relevant BOSR survey questions and responses are in Appendix A. The use of antimicrobials is an important intervention and would occur and be applied to trim before grinding and during trim production. FSIS used the BOSR to estimate the percentage of establishments that are using some type of antimicrobial intervention and to understand antimicrobial use in beef establishments. The BOSR showed that 83.4 percent of establishments do not apply any antimicrobials to trim.¹¹ FSIS found that Lactic Acid (LAA) was the most commonly used antimicrobial applied to trim.¹² LAA achieves large pathogen reductions in beef products, making it a good representative antimicrobial agent on which to base the cost estimate for antimicrobials. FSIS also used the BOSR to identify the establishments' actions for pathogen sampling and testing. As mentioned earlier, sampling and testing is another method establishments would use to verify whether they meet the proposed performance standards. FSIS found 30 percent of establishments sample for pathogens during trim production and 77 percent for ground product.¹³

IV. Expected Costs - Industry

The beef industry would incur costs to implement changes to meet the proposed performance standards. FSIS assumed that all establishments that do not meet the proposed standards would reassess their HACCP plan.

[68490fa87cab/beef-operations-summary-results.pdf?MOD=AJPERES](#). Please see Appendix A for the survey questions used to determine percentages.

¹¹ Please see Appendix A, "Calculation of Establishments not Applying Antimicrobials to Trim" for the calculation used to determine this percentage.

¹² Please see Appendix A for the survey questions used to determine most common antimicrobial.

¹³ Please see Appendix A for the survey questions used to determine percentages.

Higher-Volume Establishments

i. Cost for Antimicrobial Agents and Equipment for Higher-Volume Establishments

As a result of the proposed performance standards, higher-volume grinding establishments are not likely to apply additional interventions in the form of antimicrobials to processing steps because these higher-volume establishments have a high number of antimicrobial interventions in place. In contrast, higher-volume manufacturing trim establishments are likely to use additional antimicrobial interventions in seeking to meet the proposed performance standard. FSIS believes that higher-volume manufacturing trim establishments would add additional antimicrobials to their production process. Higher-volume manufacturing trim producing establishments would have costs for the additional equipment needed to apply antimicrobials as well as the additional antimicrobials used in application.

ii. Antimicrobial Costs for Higher-Volume Establishments

As a result of the proposed performance standards, FSIS estimated that the annual manufacturing trim production of higher-volume establishments of 704.75 million pounds would now receive additional antimicrobial solution; please see Table 3. FSIS calculated that the total annual cost for the additional antimicrobial solution would be \$147,998 (704.75 million pounds x \$0.00021¹⁴ cost per pound of antimicrobial solution).

¹⁴ Please see Appendix B for the calculation of antimicrobial cost.

Table 3. Antimicrobial Intervention Solution Cost Estimates¹ for Higher-Volume Establishments			
Establishment Size	Number of Establishments Initially Not Meeting the Proposed Standards then Meeting the Proposed Standards	Affected Annual Volume with Added Antimicrobial Solution (Million lbs.)	Primary Estimate
Higher-volume ground	N/A	N/A	N/A
Higher-volume manufacturing trim	5	704.75	\$147,998
Total	5	704.75	\$147,998
¹ Costs annualized at a discount rate of 7% over 10 years.			

iii. Equipment Costs for Antimicrobial Application for Higher-Volume Establishments

FSIS assumed that higher-volume manufacturing trim establishments already use antimicrobial interventions with equipment such as sprayers, bars, and nozzles. Because higher-volume manufacturing trim producing establishments have this equipment in place, FSIS believes these establishments would only need to add, on average, two sprayer bars with eight nozzles to their antimicrobial intervention system at a cost of approximately \$912¹⁵ per establishment. FSIS calculated the cost of this new antimicrobial equipment to be \$4,560.¹⁶

FSIS assumed that establishments would spend approximately 10 percent of their total equipment and installation costs annually in the form of operating, maintenance, and insurance

¹⁵ An industry expert noted that a higher-volume establishment would add 1-2 sprayer bars and 2-8 nozzles. FSIS used the higher estimates to be conservative. Spray.com priced Fulljet nozzles at \$50-\$55 in 2016. FSIS used the \$55 rate and multiplied that by 8 to get \$440 for the price of the nozzles. The estimate for 2 bars with 4 nozzles is \$471.55. The total equipment cost is (\$440+\$471.55=\$911.55).

¹⁶Five (5) higher-volume manufacturing trim establishments intending to meet the proposed standard after not meeting the proposed standard x \$912.

costs.¹⁷ Thus, the total annual recurring equipment cost for the higher-volume manufacturing trim establishments would be about \$456 (\$4,560 x 10%).

Establishment Size	Number of Establishments Initially Not Meeting the Proposed Standards then Meeting the Proposed Standards	Affected Annual Volume (Million lbs.)	Primary Estimate
Higher-volume ground	N/A	N/A	N/A
Higher-volume manufacturing trim	5	704.75	\$1,002
Total	5	704.75	\$1,002

¹Costs annualized at a discount rate of 7% over 10 years.

iv. Testing Cost for Higher-Volume Establishments Currently Sampling for Pathogens

FSIS assumed that most higher-volume establishments currently sample and test for some pathogens, but do not test for *Salmonella*.¹⁸ FSIS also assumed that higher-volume establishments currently testing for pathogens that initially do not meet the proposed performance standard and seek to meet the proposed standard, would begin *Salmonella* testing for their product. Of the seven higher-volume grinding establishments that would seek to meet the proposed performance standard, six establishments already sample and test for pathogens.¹⁹

¹⁷ Costs of Food Safety Investments Contract No. AG-3A94-B-13-0003 Order No. AG-3A94-K-14-0056 Final Report: https://ems-team.usda.gov/sites/fsis-oppd-pas/Surveys/Expert%20Illicitation--Food%20Safety%20Costs/AG-3A94-K-14-0056_Food%20Safety%20Costs_Final%20Report.pdf. Repair and Maintenance cost for antimicrobial equipment.

¹⁸ FSIS experts noted that most higher-volume establishments that are currently sampling do not test for *Salmonella*.

¹⁹ Results from the BOSR show that approximately 77% of all establishments currently test ground product for pathogens.

Of the five higher-volume manufacturing trim establishments that would likely seek to meet the proposed performance standard, two establishments already sample and test for pathogens.²⁰

Although these establishments are already sampling and testing for some pathogens, to be conservative, FSIS assumed that these establishments would implement new *Salmonella* testing to the samples they currently collect.

FSIS calculated the number of new *Salmonella* tests needed from the number of samples establishments currently collect by analyzing the number of lots establishments produce on average in a year. Establishments sample each lot, and FSIS estimated that 10,000 pounds are in one lot.²¹ FSIS estimated the annual number of samples using the following calculation:

((The average annual production volume in pounds x the number of establishments that already sample for pathogens) / pounds in one lot) x 1 test). Higher-volume grinding establishments that already sample would add roughly 65,515 new tests for *Salmonella* (((109.19 million pounds x 6)/10,000 pounds) x 1 test).²² Higher-volume manufacturing trim establishments that already sample would add roughly 28,190 new tests for *Salmonella* (((140.95 million pounds x 2)/10,000 pounds) x 1 test).

²⁰ The BOSR for all manufacturing trim establishments show that approximately 30% of establishments currently test trim product for pathogens.

²¹ An FSIS expert provided information that the average size of a production lot is 10,000 pounds.

²² This calculation varies slightly due to rounding.

v. Sampling and Testing Costs for Higher-Volume Establishments not Currently Sampling for Pathogens

In order to try to meet the proposed performance standards, higher-volume grinding establishments and higher-volume manufacturing trim establishments would most likely begin collecting samples for *Salmonella* testing. If the establishment does not currently collect any samples for pathogen testing, the establishment would likely begin collecting samples and would test them for *Salmonella*. Of the seven higher-volume grinding establishments that would seek to meet the proposed performance standard, FSIS estimated one establishment does not currently sample and test for pathogens. Of the five higher-volume manufacturing trim establishments that would seek to meet the proposed performance standard, three establishments do not currently sample and test for pathogens. The higher-volume establishments that do not sample and test for pathogens would have additional costs for sampling, which includes the lost product associated with the sample and the labor time needed for the collection of the sample as well as additional costs for *Salmonella* testing.

FSIS first estimated the number of new samples and new tests needed for these establishments by calculating the number of lots in a year that these establishments would start sampling, because establishments take samples once per lot. Based on the assumption that 10,000 pounds are in one lot, FSIS estimated the annual number of samples and new tests using the following calculation.²³

(The average annual production volume in pounds x the number of establishments that do not sample or test for pathogens) / pounds in one lot. Higher-volume grinding establishments would add roughly 10,919 new samples and tests for *Salmonella*.

²³ An FSIS expert provided information that the average size of a production lot is 10,000 pounds.

$((109.19 \text{ million pounds} \times 1) / 10,000 \text{ pounds per lot})$.

Higher-volume manufacturing trim establishments would add roughly 42,285 new samples and tests for *Salmonella*.

$((140.95 \text{ million pounds} \times 3) / 10,000 \text{ pounds per lot})$.

Higher-volume establishments that do not currently sample would also have to pay for a technician (\$8.00) to take one sample per lot. The cost for a technician to sample includes the following elements:

- Quality Technician hourly compensation rate: \$16.02²⁴
- Benefit rate²⁵ of 2 applied to the hourly compensation rate
- FSIS assumed a Quality Technician would take 15²⁶ minutes to sample one lot
 - Quality Technician compensation = Quality Technician hourly rate x Benefit rate x Quality Technician Time
 - Quality Technician compensation = \$16.02 x 2 x (15 minutes / 60 minutes in an hour) = \$8.01 per sample. FSIS rounded this figure to \$8.00 per sample.

Higher-volume establishments that do not currently sample would also incur a lost product cost. FSIS estimates that establishments would lose 0.72 pounds of product per

²⁴ Wage estimate of \$16.02 obtained from the Bureau of Labor Statistics, Occupational Employment and Wages, May 2016 19-4011 Agricultural and Food Science Technicians in the Animal Slaughtering and Process Industry (NAICS code 311600). <https://www.bls.gov/oes/current/oes194011.htm>

²⁵ To account for the additional costs establishments must pay employees for benefits such as paid leave, health insurance, and retirement and savings, FSIS applied a benefits factor of two.

²⁶ Please see Appendix A for the BOSR survey question used to estimate the time it would take to sample.

sample.²⁷ FSIS estimated the average wholesale price per pound of ground beef as \$1.72²⁸ and manufacturing trim as \$0.51 per pound.²⁹ Higher-volume grinding establishments that do not already sample would lose \$1.23 of product per sample. Higher-volume trim establishments that do not already sample would lose \$0.37 worth of product per sample.

vi. Estimated Contract Lab Cost for Higher-Volume Establishments

FSIS could not estimate the number of higher-volume establishments that would use an in-house lab and the number of establishments that would use contract labs. For this reason, and to be conservative, FSIS assumed the cost to test for *Salmonella* was the higher of the two costs, or the cost to test product in a contract lab. Both higher-volume grinding and manufacturing trim establishments that currently sample for pathogens and higher-volume grinding and manufacturing trim establishments that do not sample for pathogens would incur the contract lab testing cost of \$20.00 per test per lot.

vii. Total Cost for Sampling and Testing for Higher-Volume Establishments

FSIS estimated the total cost for new sampling and testing for *Salmonella*, as a result of the proposed performance standards, at establishments that currently sample for pathogens and at those that do not currently sample for pathogens using the following calculations:

- 1) The total testing cost for higher-volume grinding establishments currently sampling for pathogens is \$1.3 million (65,515 new tests x \$20 per test).

²⁷ FSIS assumed establishments would take sample sizes like MT43 and MT60 sampling of 325 grams. 325 grams=.72 pounds.

²⁸ <http://www.beefretail.org/wholesalepriceupdate.aspx> average price per pound for IMPS#136,137 for Ground. Price of the week ending December 15, 2017.

²⁹ <http://www.beefretail.org/wholesalepriceupdate.aspx> price per pound for IMPS#138 for 50% Trimmings Fresh. Price of the week ending December 15, 2017.

- 2) The total testing cost for higher-volume manufacturing trim establishments currently sampling for pathogens is \$563,800 (28,190 new tests x \$20 per test).
- 3) The total sampling and testing costs for higher-volume grinding establishments not currently sampling for pathogens = \$319,162 ((10,919 new tests x \$20 per test) + (10,919 x \$8 cost for the technician) + (10,919 new tests x \$1.23 loss product cost per pound)).
- 4) The total sampling and testing costs for higher-volume manufacturing trim establishments not currently sampling for pathogens = \$1.20 million ((42,285 new tests x \$20 per test) + (42,285 new tests x \$8 cost for the technician) + (42,285 x \$0.37 loss product cost per pound)).

Table 5. Product Sampling and Testing Cost Estimates¹ for Higher-Volume Establishments			
Establishment Size	Number of Establishments Initially Not Meeting the Proposed Standards then Meeting the Proposed Standards	Affected Annual Volume (Million lbs.)	Primary Estimate
Higher-volume ground	7	764	\$1,629,472
Higher-volume manufacturing trim	5	705	\$1,763,642
Total	12	1,469	\$3,393,114
¹ Costs annualized at a discount rate of 7% over 10 years.			

V. HACCP Re-assessment and Validation Cost

In order to ensure that their HACCP systems are functioning correctly, higher-volume manufacturing trim and grinding establishments that do not meet the proposed performance

standards would need to reassess their HACCP plans.³⁰ The establishment, to maintain an adequate HACCP system, may need to address the pathogen *Salmonella* in its HACCP plan, rather than through a prerequisite program such as Sanitation Standard Operating Procedures. Some establishments may choose to make changes to their production processes that need to be validated. To ensure a conservative cost estimate, FSIS assumed that all establishments that initially do not meet the proposed performance standards and choose to make changes, would validate their HACCP plan.

To estimate the cost of reassessing and validating a HACCP plan, FSIS used the Research Triangle Institute survey, *Costs of Food Safety Investments*,³¹ September 2015, which contains a range of costs for HACCP plan re-assessment and validation depending on the size of the establishment. The survey showed that the labor hours required for re-assessment from higher-volume establishments ranged from 30 hours to 90 hours and the labor hours required to validate a HACCP plan ranged from 160 hours to 480 hours. The survey presents total cost estimates for both re-assessment and validation. The range of total costs, updated to 2016 dollars, for re-assessment and validation per HACCP plan is between \$5,946 and \$17,838 for higher-volume establishments.

Table 6 displays the one-time HACCP plan re-assessment costs for all establishments not expected to meet the proposed performance standards. Table 6 also includes the validation costs for those establishments that FSIS expects would make changes to their HACCP systems to meet

³⁰ 9 CFR 417.4(a) (3) requires establishment to conduct a HACCP re-assessment at least annually and “whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.”

³¹ Viator, C. Et. Al. 2015. RTI International collected data on the cost of food safety investments for the production of meat and poultry products at the pre-harvest and slaughter and processing stages. This data was provided to FSIS in a final report titled ‘Costs of Food Safety Investments’ and was prepared by Catherine L. Viator, Mary K. Muth, and Jenna E. Brophy. The contract number is No. AG-3A94-B-13-0003. The order number is AG-3A94-K-14-0056. Available at <http://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>

the proposed performance standards. FSIS included validation costs for those establishments expected to make changes to more conservatively estimate the cost of the proposed performance standards. The 14 higher-volume grinding establishments that are not expected to meet the proposed performance standards would reassess their HACCP plans. Additionally, FSIS estimated 7 of the 14 higher-volume grinding establishments would validate their HACCP plans. FSIS also assumed 10 higher-volume manufacturing trim establishments would not meet the proposed performance standards and would reassess their HACCP plans and 5 of the 10 higher-volume manufacturing trim establishments would validate their HACCP plans.

Table 6. HACCP Plan Re-assessment and Validation Costs for Higher-Volume Establishments			
	Low Cost Estimate	Medium Cost Estimate	High Cost Estimate
Ground Producers	\$6,302	\$12,604	\$18,905
Trim Producers	\$4,479	\$8,959	\$13,438
Total Costs* Annualized ¹	\$10,781	\$21,562	\$32,344
*Numbers in table may not sum to totals due to rounding. ¹ Costs annualized at a discount rate of 7% over 10 years.			

FSIS predicts that in addition to costs associated with HACCP plan re-assessment and validation, establishments that choose to make changes to their HACCP system to meet the proposed performance standards would incur costs for employee training. FSIS assumed that a Quality Control (QC) Manager would perform training for re-assessment, and would take approximately one hour to complete training per shift. FSIS estimated that the mean hourly

wage rate of a QC Manager is approximately \$58.70.³² To account for the additional costs establishments must pay employees for benefits, FSIS applied a benefits factor of two to the hourly wage rate to estimate a total compensation rate of \$117.40 per hour.

Production employees might need to learn how to mix the antimicrobial solution, operate any new equipment, and perform any additional tasks associated with addressing pathogens in the establishment's HACCP plan rather than through a Sanitation Standard Operating Procedure or other prerequisite program. FSIS assumed that higher-volume establishments would operate with two shifts and train a production employee on each shift. Furthermore, FSIS assumed that the QC Manager would lead this training and it would take them approximately one hour. FSIS estimated the total hourly compensation rate of a production employee to be \$27.32.³³ Therefore, the one-time training cost would be approximately \$578.88³⁴ for higher-volume establishments. Establishments would realize these costs when they choose to implement the changes.

Establishments would also accrue additional costs due to employee turnover. As the production employees responsible for ensuring proper antimicrobial application leave over time, establishments would train new hires to replace them. To estimate annually recurring training costs, FSIS used a turnover rate of 29.5 percent³⁵ and applied it to the one-time training costs

³² Mean hourly wage estimate of \$58.70 obtained from the Bureau of Labor Statistics, May 2016 National Industry-Specific Occupational Employment and Wage Estimates for 11-1021 General and Operations Managers. <https://www.bls.gov/oes/current/oes111021.htm>

³³ Wage estimate of \$13.66 obtained from the Bureau of Labor Statistics, May 2016 National Industry-Specific Occupational Employment and Wage Estimates (see footnote 22), for the Processing Workers (Occupational Code 51-0000) in the Animal Slaughtering and Process Industry (NAICS code 311600). http://www.bls.gov/oes/current/naics4_311600.htm#11-0000. FSIS multiplied the wage rate by a benefits factor of 2, to obtain a total compensation rate of \$27.32 per hour. http://www.bls.gov/oes/current/naics4_311600.htm#11-0000

³⁴ Higher-volume 2 shift establishments: 2 production employees at \$27.32 + one QC manager for 2 hours at \$117.40 = \$289.44*2 to account for opportunity costs = \$578.88.

³⁵ Annual total separations rate for nondurable goods, Bureau of Labor Statistics Job Openings and Labor Turnover Survey, available at: <http://www.bls.gov/news.release/jolts.t16.htm>

previously calculated. Training due to labor turnover would cost approximately \$170.77 for higher-volume establishments annually.³⁶ These recurring costs would begin the year after establishments choose to make changes to their HACCP plans. Table 7 shows these cost estimates.

Table 7. Employee Training Costs for Higher-Volume Establishments				
Ground Producers	Total Number of Establishments	Total Number of Quality Control (QC) Managers	Total Number of Production Employees	Primary Estimate
One-time Training				\$539
Recurring Training				\$1,036
Total*	7	7	14	\$1,576
Trim Producers				
One-time Training				\$385
Recurring Training				\$740
Total	5	5	10	\$1,125
Total Costs Annualized ¹				\$2,701
*Numbers in table may not sum to totals due to rounding.				
¹ Costs annualized at a discount rate of 7% over 10 years.				

VI. Expected Total Cost – Agency

FSIS does not expect the Agency to incur any budgetary impacts because of the proposed performance standards. FSIS would implement the two major components of the proposed performance standards – product sampling/testing and follow-up actions –in such a way that they are resource neutral. Also, when there are high levels of *Salmonella* contamination in low

³⁶ Higher-volume: \$578.88 x turnover rate (.295)= \$170.77

volume establishments that are not subject to the performance standards, FSIS may conduct follow-up sampling and/or a PHRE or FSA, but in a way that is resource neutral. FSIS is not expanding the number of samples it would analyze. Since FSIS samples using a moving window, the number of samples FSIS would collect and analyze would remain the same, and FSIS would not need to invest in additional laboratory equipment or additional personnel.

The resources required for enforcement actions, namely PHREs, that may lead to Food Safety Assessments (FSAs) would also remain unchanged.

VII. Summary of Total Costs

Table 8. Total Industry Costs for Grinding and Manufacturing Trim Establishments Annualized¹			
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 Re-assessment	\$10,781	\$21,562	\$32,344
Employee Training	\$2,701	\$2,701	\$2,701
Total Costs*	\$3,555,596	\$3,566,377	\$3,577,159

*Numbers in table may not sum to totals due to rounding.
¹Costs annualized at a discount rate of 7% over 10 years.
²FSIS assumed that 50% of establishments that fail to meet the proposed standards would incur all the described costs, except for HACCP re-assessment. FSIS assumed 100% of establishments that fail to meet the proposed standards would reassess their HACCP plan.

VIII. Expected Benefits

As establishments make changes to their production processes and reduce the prevalence of *Salmonella* in raw ground beef and beef manufacturing trimmings products, public health

benefits would be realized in the form of averted illnesses. As discussed in the 2019 Risk Assessment, FSIS estimated the number of annual illnesses attributed to products under the proposed performance standards. FSIS then estimated the number of illnesses averted if 50 percent of the establishments that do not meet the proposed performance standards would make changes to their HACCP system to meet the proposed standards after one year. 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 9.

Table 9. Annual Illnesses Averted (2019 Risk Assessment)			
Product	Compliance Rate for Establishments Initially Not Meeting the Proposed Standards, but then Meeting the Proposed Standards Over 2 Years	<i>Averted Illnesses due to Salmonella</i>	Cost of Illness
Raw Ground Beef and Beef Manufacturing Trimmings	50%	8,900	\$29,265,796
		(2,000-20,000) (5 th -95 th percentile)	(\$6,576,583 - \$65,765,834)
¹ Cost of Illness annualized at a discount rate of 7% over 10 years occurring one year after establishments would begin making changes.			

FSIS used cost of illness estimates for *Salmonella* of \$3,793³⁷ per case to quantify the effect that these averted illnesses would have on the economy. FSIS assumed benefits would only accumulate once changes are in place in the establishment. After the proposed standards are finalized and once the first 52-week window ending the last Saturday of the previous month is complete, FSIS plans to begin web-posting for all eligible establishments, based on at least the minimum number of FSIS sampling results for *Salmonella*, whether the establishment is meeting or not meeting the pathogen reduction performance standards for the product.

FSIS calculated a range of estimates to reflect the uncertainty in the underlying foodborne illness distribution.³⁸ 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 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 the products purchased, returning or disposing of products identified by the recalls, and so on).

FSIS expects the proposed raw ground beef and manufacturing trimmings performance standards would lead to less 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 ground beef products and fewer illnesses, outbreaks and recalls.

³⁷ The FSIS estimate for the cost of *Salmonella* (\$3,793 per case, —2017 dollars) was developed using the USDA, Economic Research Service Cost Estimates of Foodborne Illness *Salmonella* (October 2014) updated for inflation. <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/>.

³⁸

<http://www.fsis.usda.gov/wps/wcm/connect/8a38566a-6d6c-4c96-85ce-41fd02050358/beef-ps-aug-2019.pdf?MOD=AJPERES>

IX. Summary of Net Benefits

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

Table 10. Summary of Estimated Net Benefits¹				
Compliance Rate for Establishments Initially Not Meeting the Proposed Standards, but then Meeting the Proposed Standards Over 2 Years	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
¹ All costs (savings) annualized at a discount rate of 7% over 10 years.				

X. Effect on Small Businesses

FSIS assumed the proposed performance standards would affect small businesses by using a volume metric of 50,000 pounds per day as a proxy to distinguish between large and small businesses. FSIS is requesting comments on this assumption. Because the proposed performance standards would only apply to higher-volume establishments producing more the 50,000 pounds of product per day, small and very small establishments would not be included in the proposed performance standards and would not incur costs as a result of the proposed performance standards.

Appendix A

FSIS used data from the [2013 Pathogen Controls in Beef Operations Summary Results](#) survey (BOSR) for information on the operations of beef establishments that produce beef trimmings and/or ground beef. FSIS used relevant survey questions and responses (see below) to calculate the number of establishments that use sampling and antimicrobial interventions. The BOSR included 482 respondents.

TrimINT5. Does the establishment apply any interventions to beef trimmings?			
Response	Frequency	Weighted Frequency	Weighted Percentage
Yes	65	232	22.19%
No	173	810	77.48%
No response	3	3	0.33%
Total	241	1045	100.00%

TrimINT6. Which interventions does the establishment apply to beef trimmings? If the establishment implements any of the following interventions to beef trimmings, when do they implement the intervention? (Select all that apply)									
Intervention	Interventions applied throughout the year			Varies by suppliers (i.e., purchase specifications)			N/A		
	Frequency	Weighted Frequency	Weighted Percentage	Frequency	Weighted Frequency	Weighted Percentage	Frequency	Weighted Frequency	Weighted Percentage
Lactic acid (LAA)	24	69	29.40%	1	1	0.52%	40	161	68.61%
Acetic Acid (AA)	1	1	0.45%				64	231	98.08%
Lauramide arginine ethyl ester (LAE)	1	10	4.17%				64	222	94.36%
Acidified sodium chloride (ASC)	8	50	21.17%	2	2	1.04%	55	180	76.33%
Hypobromous acid				1	1	0.46%	64	231	98.08%
Peroxyacetic acid (PAA) (trade names: Inspexx, Microtox, other)	26	55	23.22%	1	3	1.14%	38	174	74.17%

TrimINT7. Does the establishment apply interventions other than interventions mentioned in the previous question?			
Response	Frequency	Weighted Frequency	Weighted Percentage
Yes, specify (Responses not reported)	6	56	23.67%
No	59	176	74.87%
No response	3	3	1.46%
Total	68	235	100.00%

TST1. Does the establishment sample trim?			
Response	Frequency	Weighted Frequency	Weighted Percentage
Yes	120	388	30.32%
No	179	887	69.41%
No response	3	3	0.27%
Total	302	1278	100.00%

RGBST1. Does the establishment test raw ground beef?			
Response	Frequency	Weighted Frequency	Weighted Percentage
Yes	202	1040	76.77%
No	77	315	23.23%
Total	279	1355	100.00%

TST4. Approximately, how long does it take the establishment to collect a sample (e.g., all 60 pieces if the establishment uses N-60 method)?			
Method- Surface excision (similar to FSIS N-60 method)	Frequency	Weighted Frequency	Weighted Percentage
15 minutes or less	38	100	25.89%
30 minutes	22	82	21.15%
45 minutes	4	14	3.72%
1 hour	9	36.89477086	9.52%
1 hour 15 minutes	1	1	0.30%
1 hour 30 minutes	1	1.225	0.32%
1 hour 45 minutes	-	-	-
2 hours	1	10	2.53%
More than 2 hours	6	37	9.58%
N/A	35	90	23.21%

Calculation of Establishments not Applying Antimicrobials to Trim

To calculate the percent of establishments not applying antimicrobials to trim (such as before grinding), the following formula was used: $[1 - [\text{TrimINT5 yes (22.19\%)} \times \text{TrimINT7 no (74.87\%)}]$]. Since 22.19 percent of establishments apply interventions to trim and 74.87 percent of these establishments' intervention is some antimicrobial, this means 16.6 percent of establishments apply an antimicrobial as an intervention for trim, and the remaining 83.4 percent of establishments do not apply antimicrobials to trim before grinding.

Appendix B

FSIS used the price estimate adopted from a University of Georgia Food Science Extension Outreach Program experiment³⁹ to estimate the price of Lactic Acid per pound. The chart notes that the cost to spray Lactic Acid (LAA) per beef carcass is \$0.12800. FSIS estimated an average carcass weight of 755 pounds.⁴⁰ FSIS then divided the average carcass weight by the cost per carcass to get the cost per pound of \$0.000170 ($=\$0.12800/755$ pounds). The price was then inflated from 2005 to 2017 dollars using the Consumer Price Index to get the LAA cost per pound of \$0.00021.⁴¹

³⁹ https://www.fsis.usda.gov/wps/wcm/connect/2fc604e6-52d2-4638-91f9-9b5e6bd038df/New_Technology_C-28_C-29_Lactic-Peroxyacetic_Wash_FY2003.pdf?MOD=AJPERES

⁴⁰ <http://igrow.org/livestock/beef/how-much-meat-can-you-expect-from-a-fed-steer/>. The organization notes that a 1200-pound steer would yield 740 – 770 pound carcass or an average of 755 $= ((770+740)/2)$.

⁴¹ Annual CPI-All Urban Consumers (Current Series) Not Seasonally Adjusted: CUUR0000SA0 Annual (2005-2017). Price Change $= (CPI_{2017} - CPI_{2005}) / CPI_{2005}$ or 0.25509473 $= (245.12 - 195.3) / 195.3$
LAA price per pound adjusted for inflation = LAA cost per pound + (Price Change x LAA cost per pound) or
 $\$0.00021 = \$0.000170 + (0.25509473 \times \$0.000170)$.