U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Final Cost-Benefit Analysis

Salmonella in Certain Not Ready-To-Eat Breaded Stuffed Chicken Products

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I. Introduction

The Food Safety and Inspection Service (FSIS) has determined that *Salmonella* at levels of 1 colony forming unit (CFU) per gram (g) or higher is an adulterant in not-ready-to-eat (NRTE) breaded stuffed chicken products within the meaning of the Poultry Products Inspection Act (PPIA). The Agency intends to carry out verification procedures, including sampling and testing of the incoming chicken components for the NRTE breaded stuffed chicken products, to ensure producing establishments control *Salmonella* in these products. NRTE breaded stuffed chicken products contain raw, comminuted chicken breast meat or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading on the exterior of the product, which may impart an RTE appearance.[1] FSIS will implement routine testing for *Salmonella* in the incoming chicken components for these products. This cost-benefit analysis (CBA) quantifies and explains the potential costs and benefits associated with this policy. In the final policy, all establishments producing NRTE breaded stuffed chicken products will be subject to FSIS *Salmonella* verification sampling of the incoming chicken component before it is used in a NRTE breaded stuffed chicken product and are estimated to incur costs associated with holding the incoming chicken components until FSIS *Salmonella* test results are available. FSIS also assumes that all establishments impacted by this new policy will incur costs from reassessing their Hazard Analysis and Critical Control Point (HACCP) plan, will voluntarily choose to implement a *Salmonella* sampling and testing program, and incur costs associated with diverting or destroying product with *Salmonella* levels at or above 1 CFU/g.[2]

[1] FSIS Directive 5300.1, Revision 1. Managing the Establishment Profile in the Public Health Information System. (usda.gov), available at: https://www.fsis.usda.gov/policy/fsis-directives/5300.1. See attachment 2 "NRTE Breaded Stuffed Chicken Products that appear RTE".

[2] 9 CFR 417.4(a) (3) requires an 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."

After careful consideration of public comments, FSIS decided to modify the verification sampling location originally proposed from "collecting samples after the establishment completed all processes needed to prepare the chicken component to be stuffed and breaded," to "collecting samples on the raw incoming chicken components." Establishments with incoming chicken components that receive a *Salmonella* positive result at levels of 1 CFU/g or higher must ensure that the incoming chicken components represented by the sampled lot are not used in NRTE breaded stuffed chicken products. This change should provide establishments greater flexibility and reduce costs to industry.

In the preliminary CBA, FSIS provided estimates on the costs of HACCP reassessment, employee training, cold storage, establishment-led sampling, lost product, reformulating, and relabeling products. Based on information included in the public comments, switching the FSIS verification sampling location to the incoming chicken components will lead industry to primarily respond to the new policy by implementing establishment-led sampling for *Salmonella* and diverting or destroying incoming chicken components that receive a *Salmonella* positive result at levels of 1 CFU/g or higher. Therefore, the Agency maintained the costs in the total cost estimate and breakeven analysis consistent with the preliminary CBA with the updates described below. While FSIS has included cost estimates for other potential changes that establishments may choose to make on a per establishment basis, FSIS does not expect these changes will be commonly adopted due to the change in the FSIS sampling location and based on public comments. As such, these costs were not included in the total cost analysis.

When FSIS implements its NRTE breaded stuffed chicken product sampling and testing program, the Agency will incur costs associated with *Salmonella* verification procedures, including sampling and testing, however, FSIS will be able to shift existing resources as

necessary to implement the final determination. In the final determination, the Agency includes an estimated opportunity cost for the Agency to implement the new sampling program.[3] FSIS may also prioritize a Public Health Risk Evaluation (PHRE) for any establishment that produces a NRTE breaded stuffed chicken product that contains incoming chicken components that received a *Salmonella* positive sample at 1 CFU/ g or higher.[4] FSIS will use PHRE results to determine if a Food Safety Assessment (FSA) is warranted.[5]

FSIS expects that the new policy, including FSIS sampling and testing, will lead to a reduction in illnesses and hospitalizations caused by *Salmonella* in NRTE breaded stuffed chicken products, benefiting consumers. The Agency requested comments on the use of a multiplier to estimate the actual number of *Salmonella* illnesses associated with outbreaks in NRTE breaded stuffed chicken products. With input from the Centers for Disease Control and Prevention (CDC), the Agency updated the benefits section to include an under-reporting multiplier.[6] The new policy is also expected to reduce the number of outbreak-related recalls because NRTE breaded stuffed chicken products will no longer contain incoming chicken components with *Salmonella* at levels of 1 CFU/g or higher.

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[3] As noted by the Office of Management and Budget in the Circular No. A-4 published on November 9, 2023. Opportunity costs "is the cost attributable to a regulation if an agency will be performing enforcement activities or otherwise using resources in connection with that regulation, even if the agency's budget is not increasing." https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf. Accessed on 02/15/2024.

[4] The PHRE is an analysis of establishment performance based on "For-cause" and "Routine risk-based" criteria. FSIS Directive 5100.4 Revision 2 - Public Health Risk Evaluation Methodology (usda.gov), available at: https://www.fsis.usda.gov/policy/fsis-directives/5100.4.

[5] The purpose of an FSA is to conduct a risk-based, targeted review of establishment food safety systems to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements. FSIS Directive 5100.1 - Enforcement, Investigations And Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology (usda.gov), available at: https://www.fsis.usda.gov/policy/fsis-directives/5100.1.

[6] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States–major pathogens pdf icon [PDF – 9 pages]. Emerging Infectious Diseases. 2011;17(1):7-15: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/. The under-reporting multiplier of 25.5 for a group of other pathogens was used as a proxy for NRTE stuffed chicken products.

FSIS updated the estimated costs and benefits for the final policy from those published in the preliminary CBA from 2021 to 2022 dollars. Also, in response to public comments, FSIS updated the assumed lot size for FSIS and industry sampling, included a range of wages, updated the assumed type of employee that will conduct establishment-led sampling, and updated the assumptions used to estimate cold storage time and costs. Finally, this CBA includes updates to Section VII. Potential Impact on Small Business.

II. Need for a New Policy

NRTE breaded stuffed chicken products contain raw poultry and thus may contain pathogens, such as *Salmonella*. Some consumers may only reheat the product for aesthetic or palatability purposes rather than subject it to cooking sufficient to kill pathogenic bacteria, because NRTE breaded stuffed chicken products may appear fully cooked. NRTE breaded stuffed chicken products are also typically cooked from a frozen state, which increases the risk that they will not reach the internal temperature of 165˚ Fahrenheit (F) needed to destroy *Salmonella* organisms that may be in the product.

Since 1998, FSIS and public health partners have investigated 14 documented *Salmonella* outbreaks linked to NRTE breaded stuffed chicken products (for more details, see section VI. Benefits). In response to these outbreaks, the producing industry has made numerous changes to the labeling of NRTE breaded stuffed chicken products over time to inform consumers that these products are raw and to provide instructions on how to prepare them safely. Of the four most recent outbreaks, two occurred in 2015, the third occurred in 2016 and the fourth outbreak occurred in 2021. The two 2015 outbreaks had a combined total of 20 reported cases, 6

hospitalizations, and about 4.2 million pounds of product recalled.[7] The 2016 outbreak had five *Salmonella* cases associated with NRTE breaded stuffed chicken reported in Minnesota. In 2015-2016, FSIS held conference calls and worked directly with the establishments involved in the 2015 outbreaks to modify the product labeling to further emphasize that the product is raw and to ensure that the label included validated cooking instructions. Based on recommendations from FSIS, establishments re-validated the cooking instructions on the product labels to ensure that, when prepared as instructed, a NRTE breaded stuffed chicken product would reach an internal temperature needed to destroy *Salmonella* organisms on the interior of the product. FSIS also worked with industry to ensure that the product labels emphasized that these products were raw and should not be prepared in a microwave oven.

The 2021 outbreak occurred despite these changes. The labeling of the products associated with the 2021 outbreak stated that the product was raw on the front and back of the packaging and included statements and icons to signal that the product is raw and should not be cooked in a microwave oven. It also provided validated cooking instructions that included a "do not microwave" icon, as well as icons and instructions to cook the product in a conventional oven to an internal temperature of 165˚F as measured by a food thermometer. However, even with these labeling features, some of the cases reported that they did not follow the manufacturer's cooking instructions on the label. The 2021 outbreak included 36 reported cases,

[7] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Determination and Request for Comments. Docket No. FSIS-2022-0013, available at: https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/salmonella-not-ready-eat-breaded-stuffed.

12 hospitalizations; and approximately 59.3 thousand pounds of the affected product recalled.[8,9,10]

In light of the 2021 outbreak, and previous outbreaks associated with NRTE breaded stuffed chicken products, FSIS has concluded that measures that focus primarily on product labeling and consumer handling practices are unlikely to be effective in preventing all human illnesses associated with NRTE breaded stuffed chicken products contaminated with *Salmonella*. FSIS is declaring that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/g or higher are adulterated within the meaning of the PPIA.[11] FSIS will implement verification procedures, including sampling and testing of incoming chicken components intended for use in NRTE breaded stuffed chicken products, to ensure control of *Salmonella* at establishments producing NRTE breaded stuffed chicken products. FSIS' verification procedures may lead to producers allocating additional resources and using more effective methods to control for *Salmonella* in NRTE breaded stuffed chicken products. Previously, some producers may have chosen less costly methods to control for *Salmonella* because they believe proper handling of the product by consumers would mitigate the risks. However, the 2021 outbreak in NRTE breaded stuffed chicken products shows that labeling

[8] USDA, FSIS: *Salmonella* Enteritidis Outbreak Linked to Frozen, Raw, Breaded, Stuffed, Chicken Products; Outbreak Investigation After Action Review, Report 2021-07 at: https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/FSIS-After-Action-Review-2021-07.pdf

[9] CDC: *Salmonella* Outbreak Linked to Raw Frozen Breaded Stuffed Chicken Products (October 13, 2021) at: https://www.cdc.gov/salmonella/enteritidis-06-21/index.html

[10] Serenade Foods Recalls Frozen, Raw, Breaded, Stuffed Chicken Products Due to Possible *Salmonella* Contamination (August 9, 2021) at: https://www.fsis.usda.gov/recalls-alerts/serenade-foods-recalls-frozen-raw-breaded-stuffed-chicken-products-due-possible

[11] Under the PPIA, a poultry product is adulterated, among other circumstances, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health" (21 U.S.C 435(g)(1)). See Final Determination for more detailed discussion of the rationale and support for the final determination, available at: https://www.regulations.gov/docket/FSIS-2022-0013.

adjustments are not sufficient to prevent all outbreaks in these products because proper handling by consumers is not guaranteed. The policy is expected to cause industry to use more effective methods to control for *Salmonella* in NRTE breaded stuffed chicken products. Please refer to the published *Federal Register* notice for more information on the need for this new policy.[12]

Baseline

FSIS identified establishments producing NRTE breaded stuffed chicken products from FSIS' Public Health Information System (PHIS) data.[13] According to these data, there were six establishments producing NRTE breaded stuffed chicken products in 2022. The CBA assumes all six establishments that produce NRTE breaded stuffed chicken products will be impacted by the new policy.

FSIS cross-referenced these establishments to 2018-2022 production data from PHIS, table 1. However, annual total industry production of NRTE breaded stuffed chicken products decreased over this period from over 165 million pounds in 2018 to about 51 million pounds in 2022. This sharp decline in production indicates that establishments may be moving away from producing NRTE breaded stuffed chicken products.

Table 1. Production Volume of NRTE breaded stuffed chicken products (2018-2022)

Year	Establishments	Pounds of Production (millions)
2018	**6**	165.26
2019	**6**	56.10
2020	**6**	59.46
2021	**6**	53.90
2022	**6**	51.00

[12] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Final Determination. Docket No. FSIS-2022-0013, available at: https://www.regulations.gov/docket/FSIS-2022-0013.
[13] FSIS, Public Health Information System database, accessed 03/6/2023.

According to PHIS data, of the six establishments that produce NRTE breaded stuffed chicken products, two are HACCP size large, two are small, and two are very small.[14] However, production of NRTE breaded stuffed chicken products is concentrated among a limited number of high-volume establishments. Research shows that some of these establishments are affiliated with larger companies.[15] In this CBA, FSIS has categorized these establishments by their production volume of NRTE breaded stuffed chicken product because the HACCP size of an establishment does not indicate the volume of NRTE breaded stuffed chicken product produced. In this CBA, FSIS defines high-volume establishments as establishments that produce at least 1 million pounds of NRTE breaded stuffed chicken products annually and low-volume establishments as establishments that produce less than 1 million pounds annually. Using these categories, three establishments were classified as high-volume and three establishments as low-volume. Among the high-volume establishments, two are HACCP size large and one is HACCP size small. In the low-volume category, one establishment is HACCP size small, and two establishments are HACCP size very small. In 2022, the three high-volume establishments accounted for 99.3 percent of the production volume of NRTE breaded stuffed chicken products.

Establishments that produce NRTE breaded stuffed chicken products can produce a variety of FSIS-inspected and non-FSIS-inspected products. Agency data indicate that all six establishments produce other types of products. In 2022, 37 percent of the total production in these establishments was from other products. At two of the three low-volume establishments,

[14] Under the HACCP size definitions, large establishments have 500 or more employees, small establishments have between 10 and 499 employees, and very small establishments have less than 10 employees or less than $2.5 million in annual revenue. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 FR 38806, July 25, 1996, https://www.federalregister.gov/documents/1996/07/25/96-17837/pathogen-reduction-hazard-analysis-and-critical-control-point-haccp-systems.

[15] Based on FSIS data and public information, at least four of these establishments are affiliated with larger companies.

nearly 90 percent of production was from other products. These other products include RTE poultry, raw ground chicken, and raw intact chicken.

III. Industry Costs

As a result of the new policy, all establishments that continue to produce NRTE breaded stuffed chicken products will need to conduct a one-time HACCP plan reassessment. These establishments will also have to hold raw incoming chicken components that are intended to be used to manufacture NRTE breaded stuffed chicken products sampled by FSIS pending test results.[16] As such, establishments will incur costs associated with a HACCP plan reassessment and with storing product while FSIS conducts sampling and testing. Establishments whose incoming chicken components receive a *Salmonella* result at levels of 1 CFU/g or higher must ensure that the incoming chicken components represented by the sampled lot are not used in NRTE breaded stuffed chicken products. For example, such lots could be diverted for use in a fully cooked poultry product (at the same or another establishment) or for use in another raw poultry product, such as ground chicken in which consumer preparation is more likely to mitigate the risk.[17] FSIS assumes that all six establishments will choose to incur costs to implement establishment-conducted *Salmonella* sampling and testing programs, including lost value costs associated with diverting or destroying product with *Salmonella* levels at or above 1 CFU/g.

In the proposed determination, FSIS expected some establishments to incur additional costs if they elected to change their production processes in response to this new policy to

[16] Not Applying the Mark of Inspection Pending Certain Test Results, 77 FR 73401, December 10, 2012, https://www.federalregister.gov/documents/2012/12/10/2012-29516/not-applying-the-mark-of-inspection-pending-certain-test-results.

[17] 9 CFR 417.3 a (4) Corrective Actions. No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

control the prevalence of *Salmonella*. Some examples of what FSIS assumed establishments may have done included applying interventions, training employees, reformulating products, subsequent label changes, and validating their HACCP plans. In response to public comments, FSIS has changed the sampling location to incoming chicken components, which allows establishments more flexibility for complying with the final determination. FSIS expects industry to respond to the final determination by implementing establishment sampling and testing for *Salmonella* and diverting or destroying product that tests positive for *Salmonella* at 1 CFU/g or higher. Based on information provided in the public comments, the Agency does not expect establishments to make additional changes.

This CBA includes cost estimates for measures FSIS assumes establishments will implement in response to the new policy. Specifically, HACCP plan reassessment, cold storage, and developing, validating, and implementing an establishment-conducted *Salmonella* sampling program and diverting or destroying product at or over the 1 CFU/g limit. Further, the CBA provides an overview of other potential costs on a per establishment basis. Though the cost of implementing additional interventions is not included in the CBA, establishments will only adopt additional interventions if incurring the cost to implement the interventions is more beneficial than establishment sampling and testing, and subsequently diverting or destroying product. Any interventions used should offset the cost of diverted product already accounted for in the CBA.

FSIS used the costs detailed in the 2015 Research Triangle Institute (RTI) International *Costs of Food Safety Investments* (referred to as the "2015 RTI report" in this document) to estimate the HACCP reassessment cost, frozen cold storage costs, and establishment-conducted sampling and testing cost.[18] The 2015 RTI report categorizes large and small establishments by

[18] RTI *Costs of Food Safety Investments*. September 2015. Contract No. AG-3A94-B-13-0003

volume of production. FSIS used data from the U.S. Bureau of Labor Statistics (BLS) to update the costs in this report from 2015 to 2022 dollars.

A. HACCP Plan Reassessment and Validation

The policy will require all establishments producing these products to reassess their HACCP plans to determine whether *Salmonella* is a hazard reasonably likely to occur.[19] Establishments may be able to coordinate this HACCP plan reassessment with their otherwise required annual reassessments, which would lower costs.[20] Some establishments may choose to make changes to their production processes in response to this new policy and their HACCP plan reassessment. Establishments that choose to make changes will incur costs associated with validating their HACCP plans as well as any costs associated with the changes themselves.

1. HACCP Plan Reassessment Costs

The 2015 RTI report notes that it would take an experienced production employee at a small or low-volume establishment, on average, 30 hours, with a range of 15 to 45 hours, to complete a HACCP plan reassessment. For a large, or high-volume establishment, it would take 60 hours, with a range of 30 to 90 hours. The 2022 average hourly wage for a production employee was $16.94 ranging from $13.20 to $21.01.[21] FSIS applied a factor of two to the

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Order No. AG-3A94-K-14-0056.Revised Final Report. Prepared by Catherine L. Viator, Mary K. Muth, Jenna E. Brophy. RTI International. RTI Project Number 0214016.003.000.001 The full report is available here: https://www.fsis.usda.gov/sites/default/files/media_file/documents/Costs_of_Food_Safety_Investments_FSIS-2022-0013.pdf.

[19] 9 CFR 417.4(a) (3) requires establishments to conduct a HACCP reassessment at least annually and "whenever any changes occur that could affect the hazard analysis or alter the HACCP plan." FSIS' final determination that *Salmonella* at levels of 1 colony forming unit (CFU)/g or higher is an adulterant in NRTE breaded stuffed chicken products would be such a change.

[20] 9 CFR 417.4(a) (3) requires an 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."

[21] Median hourly wage estimate of $16.94 obtained from the Bureau of Labor Statistics, May 2022 National Industry-Specific Occupational Employment and Wage Estimates for 51-3023 Production Occupations. https://www.bls.gov/oes/current/oes513023.htm.

hourly wage rate to account for employee benefits and overhead, making the total estimated compensation rate $33.88 per hour at the median estimate, ranging from $26.40 to $42.02. The total one-time estimated establishment cost for the three low-volume establishments to reassess their HACCP plan is $3,049 (3 × $33.88 × 30), with a range from $1,188 (3 × $26.40 × 15) to $5,673 (3 × $42.02 × 45).[22] For the three high-volume establishments, the estimated medium cost is $6,098, with a range from $2,376 to $9,067. The estimated medium one-time HACCP reassessment cost for all six establishments combined is $9,148, and ranges from $3,564 to $14,739.[23] Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $1,217, table 2.

Table 2. HACCP Plan Reassessment Costs Estimate (2022$)

Establishment Size	Number	Low	Medium	High
Low-Volume	3	$1,188	$3,049	$5,673
High-Volume	3	$2,376	$6,098	$9,067
Combined	6	$3,564	$9,148	$14,739
Annualized[1]	6	$474	$1,217	$1,961

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

2. HACCP Plan Validation Costs

An establishment may make changes in response to this new policy, which could require a HACCP plan validation. The 2015 RTI report noted that it takes one food scientist at a small or low-volume establishment 400 hours, with a range of 200 to 600 hours, to complete a HACCP plan validation. For a large or high-volume establishment, it would take a food scientist 320 hours, with a range of 160 to 480 hours.[24] The 2015 RTI report estimated it would take a small establishment longer to complete a HACCP plan validation. The 2022 median hourly wage for a

[22] Numbers are rounded to the nearest dollar.
[23] Numbers may not add up to totals due to rounding.
[24] RTI, *Costs of Food Safety Investments,* 2015, Table 4-1. Costs of HACCP Plan Development, Validation, and Reassessment per HACCP Category: Small and Large Establishments.

food scientist was $38.39 ranging from $23.03 to $63.57.[25] Applying the benefits and overhead factor of two, the total hourly compensation rate for a food scientist is $76.78, ranging from $46.06 to $127.14. If a low-volume establishment decides to make changes to its production process, the associated HACCP plan validation cost per establishment would be an estimated $30,712 ($76.78 × 400), ranging from $9,212 to $76,284. For a high-volume establishment, the estimated cost is $24,570, ranging from $7,370 to $61,027. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $4,087 for a low-volume establishment and $3,269 for a high-volume establishment.

B. Training Costs

In response to the new policy, FSIS expects establishments that choose to make changes to their HACCP system will also incur employee training costs. For example, production employees may be trained on operating existing equipment associated with current establishment interventions. FSIS assumes that a quality control (QC) manager will train one employee per shift, with low-volume establishments operating one shift per day and high-volume establishments operating two shifts per day.[26] FSIS assumes that the one-time training would take one to three hours.[27] The 2022 median hourly compensation (wages, and a benefits and overhead factor of two) for a QC manager is $103.42[28] and $33.88 for a production employee. The one-time training cost would be $275 (($103.42 + $33.88) × 2 hours × 1 shift) at a low-

[25] Median hourly wage estimate of $38.39 obtained from the Bureau of Labor Statistics, May 2022 National Industry-Specific Occupational Employment and Wage Estimates for 19-1012 Food Scientists & Technologists. https://www.bls.gov/oes/current/oes191012.htm.
[26] RTI, *Costs of Food Safety Investments,* 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species.
[27] RTI, *Costs of Food Safety Investments,* 2015, Table 4-4. Training Costs for Management and Production Employees. Annual Refresher Training Hours.
[28] Median hourly wage estimate of $51.71, ranging from $32.56 to $85.80, obtained from the Bureau of Labor Statistics, May 2022 National Industry-Specific Occupational Employment and Wage Estimates for 11-3051 Management Occupations. https://www.bls.gov/oes/current/oes113051.htm.

volume establishment and $549 (($103.42 + $33.88) × 2 hours × 2 shift) at a high-volume establishment.[29]

Establishments would also accrue additional costs due to employee turnover. As the production employees responsible for applying interventions or other pathogen controls and related tasks leave over time, establishments would train new hires to replace them. To estimate annual recurring training costs, FSIS used a labor turnover rate of about 48.8 percent and applied it to the one-time training costs previously calculated.[30] These recurring costs would begin the year after establishments choose to make changes to their HACCP plans. The recurring training cost would be $134 ($275 × 48.8 percent) at a low-volume establishment and $268 ($549 × 48.8 percent) at a high-volume establishment.[31] If establishments choose to conduct additional training, the estimated per establishment costs are $153 for a low-volume establishment and $305 for a high-volume establishment, annualized at the 7 percent discount rate over 10 years.[32]

C. Cold Storage Costs

FSIS assumes that industry will incur costs for holding product while waiting for FSIS sampling and testing results. FSIS is planning to implement a routine FSIS *Salmonella* verification testing program for the incoming chicken components intended for use in NRTE breaded stuffed chicken products. Establishments that produce these products will need to control and maintain the integrity of the sampled lot pending the availability of test results. In the preliminary CBA, FSIS estimated that initial screening tests would require industry to have held all product for 2 days and product that screens positive would have been held for an additional 2

[29] Numbers may not add up to totals due to rounding.
[30] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. Annual total separations rate by industry and region, not seasonally adjusted. 2022 annual total labor separations rate for nondurable goods industry.
[31] Numbers may not add up to totals due to rounding.
[32] Numbers may not add up to totals due to rounding.

to 4 days to get the confirmed test results.[33] In the final determination, FSIS estimates all product sampled and tested by FSIS will be held for 2 days pending screening and enumeration results, and product with *Salmonella* levels at or above 1 CFU/g will be held for an additional 3 days for confirmation test results. This estimate may have a tendency toward overstating impacts because, while product is being held, establishments may choose to complete the production process using sampled product, provided they maintain control of any finished products and do not release them into commerce, pending acceptable test results.

In this final determination CBA, FSIS assumes the Agency might collect up to 5 samples per month from establishments producing NRTE breaded stuffed chicken.[34] This sampling frequency would reduce the amount of product FSIS assumed industry would hold in cold storage awaiting FSIS test results in the preliminary CBA. Under these assumptions, FSIS may collect up to 60 samples per year from establishments that produce NRTE breaded stuffed chicken for a total of 360 industry samples (60 annual samples × 6 establishments).

Industry may hold FSIS sampled product for 2 days waiting for screening and enumeration results and product that tests at or over 1 CFU/g may be held an additional 3 days.

Based on the average FSIS *Salmonella* sampling results for comminuted chicken, approximately 3 percent of total sampled product would have *Salmonella* levels of 1 CFU/g or

[33] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Final Determination. Docket No. FSIS-2022-0013, available at: https://www.regulations.gov/docket/FSIS-2022-0013.

[34] The number used in this CBA may differ from the actual number of samples the Agency will take in the future. For sampling plan development, the Agency will design sampling that takes into consideration the number of establishments producing NRTE breaded stuffed chicken, risk, production volumes, Agency resources, and other pertinent factors.

higher.[35,36] Thus, assuming the incoming chicken components intended for use in NRTE breaded stuffed chicken products has similar *Salmonella* positive rates as comminuted chicken, approximately 97 percent of FSIS sampled product may be held for 2 days and 3 percent of FSIS sampled product may be held a total of 5 days. In 2022, the total production of NRTE breaded stuffed chicken products was 51 million pounds, 50.6 million pounds from high-volume establishments and 0.4 million pounds from low-volume establishments.[37]

In response to public comments, FSIS now assumes that establishments would hold a day's worth of incoming chicken components when FSIS conducts sampling. FSIS estimates the average annual production per high volume establishment is 16.9 million pounds by dividing the 2022 total production at high-volume establishments by the three high-volume establishments (50.6 million pounds ÷ 3 high-volume establishments). Daily production at a high-volume establishment is about 61,328 pounds assuming the establishment operates 275 production days a year.[38] FSIS estimates the average annual production per low-volume establishment is 0.13 million pounds by dividing the 2022 total production at low-volume establishments by the three low volume establishments (0.4 million pounds ÷ 3 low-volume establishments). Daily

[35] Average Most Probable Number (MPN) *Salmonella* Results for Collection Dates Between 6/4/2015 to 3/9/2020 showed that 12.27 percent of positive *Salmonella* results for comminuted chicken are at or over the 1 CFU/g limit. To estimate the percent positive rate for incoming chicken components at or over the 1CFU/g limit, FSIS multiplied the percent positive rate of 27 percent by 12.27 percent. Thus, FSIS estimates 3.31 percent of total product sampled is at or over the 1 CFU/g limit and 96.69 percent would be below the 1 CFU/g limit.

[36] Average Most Probable Number (MPN) *Salmonella* Results for Collection Dates Between 6/4/2015 to 3/9/2020. MPN HC_CH_COM01: Ground and Other Chicken (not Mechanically Separated)-Comminuted results show that 3.31 percent of total product sampled is at or over 1 CFU/g and 96.69 would be below the 1 CFU/g limit.

[37] Pounds of production are rounded to the nearest whole number.

[38] RTI, Costs of Food Safety Investments, 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species. Pounds of production are rounded to the nearest whole number. Large Poultry establishments have 275 production days a year.

production at a low-volume establishment is about 668 pounds assuming the establishment operates 200 production days a year.[39]

Therefore, FSIS estimates that, annually, 10.8 million pounds of NRTE breaded stuffed incoming chicken components will be held for two days, and 0.37 million pounds will be held for 3 additional days.[40,41] FSIS used the 2015 RTI report to estimate the cost of cold storage[42] and adjusted for inflation to 2022 dollars.[43] In response to comments, FSIS used the estimate for frozen cold storage costs in the final CBA instead of refrigerated cold storage costs. Based on this, FSIS estimates the cold storage cost for the incoming chicken components intended for use in NRTE breaded stuffed chicken products at 0.005 cents per pound per day. The total annual industry cost for all six establishments to keep their product in cold storage while waiting for FSIS' sampling and testing results has a medium estimate of $115,287,[44] table 3.

Table 3. Industry Cold Storage Annual Cost Estimate[1] (Frozen Product)		
Establishment		**Medium**
Type	**Number**	
Low-Volume	3	$1,242
High-Volume	3	$114,045
Combined	6	$115,287
Annualized[1]	6	$115,287

[39] RTI, Costs of Food Safety Investments, 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species. Pounds of production are rounded to the nearest whole number. Small Poultry Establishments have 200 Production days a year.
[40] [(61,328 pounds × 3 high-volume establishment × 60 samples per establishment) + (668 pounds × 3 low-volume establishment)] × 96.69 percent below the 1 CFU/g limit.
[41] [(61,328 pounds × 3 high-volume establishment × 60 samples per establishment) + (668 pounds × 3 low-volume establishment)] × 3.31 percent below the 1 CFU/g limit.
[42] RTI, *Costs of Food Safety Investments*, 2015, Table 4-12. Storage Costs. For cold storage, the report assumes that the cost of creating and maintaining onsite storage would be equivalent to third-party, offsite cold storage. The establishment needs to ensure that the offsite cold storage facility is certified for food-grade products by USDA. Incoming product will already be cooled, so the storage facility would only need to maintain the product temperature. In the final determination, FSIS assumes establishments would store frozen products.
[43] The costs were inflated, by using the 2022 BLS Consumer Price Index (CPI) data. Moving, storage, freight expense in U.S. city average, all urban consumers, not seasonally adjusted (Series ID CUUR0000SEHP03).
[44] Cold storage cost: (10.8 million pounds that initially test negative for *Salmonella* × $0.005 daily storage costs × 2 days) + (0.37 million pounds that initially test positive over 1/CFU g for *Salmonella* × $0.005 storage costs × 3 days) = $115,287. Numbers may not sum to totals due to rounding.

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

D. Establishment Sampling Plan Development, Validation, and Implementation

In response to the new policy, FSIS assumes all six establishments would likely incur costs to develop, validate, and implement a sampling plan for the incoming chicken component for NRTE breaded stuffed chicken products. Implementation costs would include training, labor costs for collecting samples and recordkeeping, testing costs for analyzing the samples, and lost product costs associated with positive *Salmonella* results at or over the 1 CFU/g limit. FSIS assumes the establishment's sampling plan will include one sample of the incoming chicken component per lot. FSIS assumes that the high-volume establishments already conduct some *Salmonella* sampling and testing on incoming chicken components. However, FSIS assumes these establishments will reassess their existing sampling plan and may increase their sampling to one sample per lot. For the final determination, FSIS is updating the assumptions for industry-led sampling lots to a day's production. Establishments ultimately define their lot sizes, and the Agency is estimating the costs associated with industry's decisions. The Agency updated the estimated lot size for sampling to a day's production in response to public comments.

1. Sampling Plan Development

Using the 2015 RTI report, FSIS estimates it would cost $8,078 (with a range of $4,039 to $12,115) for a low-volume establishment to develop a sampling plan with a consultant.[45] These costs are inflated to 2022 dollars using the Consumer Price Index.[46] The estimated medium one-time sampling plan development costs for the three low-volume establishments is

[45] RTI, *Costs of Food Safety Investments*, 2015, Costs of Sampling Plan Development, Validation, and Reassessment Table 4-3.

[46] The costs were inflated, by using the 2022 BLS Consumer Price Index (CPI) All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted). Costs are rounded to the nearest dollar.

$24,233 (8,078 × 3), and ranges from $12,117 to $36,346.[47] Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annualized cost of $3,225, table 4.

Table 4. Sampling Plan Development Costs for Low-Volume Establishments (2022$)

Establishment				
Type	**Number**	**Low**	**Medium**	**High**
Low-Volume	3	$12,117	$24,233	$36,346
One-Time Costs	3	$12,117	$24,233	$36,346
Annualized[1]	3	$1,612	$3,225	$4,836

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

2. Sampling Plan Validation and Reassessment

After developing a sampling plan with a consultant, establishments would have to validate the sampling plan. The 2015 RTI report assumes low-volume establishments would validate their plan in-house, noting that it would take one food scientist at a low-volume establishment 1,200 hours, with a range of 600 to 1,800 hours, to complete a sampling plan validation. As mentioned above, the 2022 median hourly compensation rate for a food scientist was $76.78. Thus, the medium cost to validate a sampling plan at the three low-volume establishments is $276,408 ($76.78 × 1,200 × 3).

FSIS assumes high-volume establishments will reassess an existing *Salmonella* sampling plan for their incoming chicken components in response to the new policy and increase sampling to one sample per lot. The estimated cost for a consultant to reassess a high-volume establishment sampling plan in 2022 dollars is $7,408, ranging from $3,704 to $11,113.[48] In addition to the consultant costs, it will take a staff food scientist 4,000 hours, with a range of 2,000 to 6,000 hours, to validate a sampling plan. Thus, the medium cost to reassess a sampling

[47] Numbers may not sum due to rounding.
[48] We used the CPI for "All items in U.S. City average, all urban consumers" from the Bureau of Labor Statistics to adjust for inflation.

plan at the three high-volume establishments is $943,584 (($7,408 consultant costs × 3) + ($76.78× 4,000 × 3)).[49] The estimated medium one-time sampling plan validation and reassessment costs for all six establishments is $1.22 million, and ranges from $370,380 to $3.01 million. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $162,336, table 5.

Table 5. Sampling Plan Validation and Reassessment Costs, (2022$)				
Establishment Type	**Number**	**Low**	**Medium**	**High**
Low-Volume Validation	3	$82,908	$276,408	$686,556
High-Volume Reassessment	3	$287,472	$943,584	$2,321,859
Combined	6	$370,380	$1,219,992	$3,008,415
Annualized [1]	6	$49,284	$162,336	$400,309
[1]Costs annualized at a discount rate of 7% over 10 years.				

3. Sampling Plan One-Time and Recurring Training

Once establishments have validated or reassessed their sampling plans, they will train their current employees to collect samples. FSIS assumes that a QC manager will initially train two employees per shift, which includes training a relief employee. In the preliminary CBA, FSIS assumed that establishments would train a production employee to collect samples. In response to comments, FSIS now assumes that a food scientist or Quality Technician (QT) will take the samples. The 2015 RTI report notes that low-volume establishments operate one shift per day and high-volume establishments operate two shifts per day. In the report, the one-time training would take 24 hours (with a range of 12 to 36 hours) and a course fee of $1,235 (with a range of $618 to $1,853) in 2022 dollars.[50] As mentioned above, the 2022 hourly compensation

[49] Numbers rounded to the nearest dollar.
[50] We used the CPI for "All items in U.S. City average, all urban consumers" from the Bureau of Labor Statistics to adjust for inflation.

was $103.42 for a QC manager and $76.78 for a food scientist or QT. Thus, the medium cost to train employees to sample at the three low-volume establishments is $22,208 [($1,235 × 3) + (($103.42 + (2 × $76.78)) × 24) × 3]. The medium cost at the three high-volume establishments is $40,710 [($1,235 × 3) + (($103.42 + (2 × $76.78)) × (24 × 2)) × 3]. The total one-time sampling training cost for all six establishments is $62,918, and ranges from $20,690 to $149,103. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $8,372, table 6.

Table 6. One-time Initial Sampling Training Costs, (2022$)

Establishment				
Type	**Number**	**Low**	**Medium**	**High**
Low-Volume	3	$7,515	$22,208	$51,554
High-Volume	3	$13,175	$40,710	$97,549
Combined	6	$20,690	$62,918	$149,103
Annualized[1]	6	$2,753	$8,372	$19,840

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

Establishments will also accrue additional costs due to employee turnover. As production employees responsible for sampling leave over time, establishments would train new employees to replace them. To estimate annual recurring sampling training costs, FSIS used a labor turnover rate of about 49 percent and applied it to the one-time sampling training costs previously calculated.[51] The total sampling training cost due to employee turnover for all six establishments is $30,704 ($62,918 × 48.8%), and ranges from $10,097 to $72,762. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $26,618, table 7.

[51] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. 2022 Annual total separations rate by industry and region, not seasonally adjusted. 2022 annual total labor separations rate for nondurable goods industry.

Table 7. Recurring Sampling Training Costs due to Employee Turnover, (2022$)				
Establishment Type	Number	Low	Medium	High
Low-Volume	3	$3,667	$10,837	$25,158
High-Volume	3	$6,430	$19,867	$47,604
Combined	6	$10,097	$30,704	$72,762
Annualized[1]	6	$8,753	$26,618	$63,080
[1]Costs annualized at a discount rate of 7% over 10 years.				

Establishments will also accrue annual employee refresher training costs. This analysis assumes each establishment will provide refresher training for one QC manager and two QTs or food scientists per shift, with hourly compensation of $103.42 and $76.78, respectively. The CBA assumes the refresher training sessions will occur once a year and take two hours, ranging from one to three hours.[52] Under these assumptions, the medium cost for recurring training at the three low-volume establishments is $1,542 [($103.42 + ($76.78 × 2)) × 2 × 1 × 3]. The medium cost at the three high-volume establishments is $3,084 [($103.42 + ($76.78 × 2)) × 2 × 2 × 3]. The total refresher training cost for all six establishments is $4,626, and ranges from $1,415 to $11,499. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $4,010, table 8. These costs are likely an overestimate because only 51.2 percent of employees would receive the refresher training.[53]

Table 8. Annual Refresher Training Costs, (2022$)				
Establishment Type	Number	Low	Medium	High
Low-Volume	3	$472	$1,542	$3,833
High-Volume	3	$943	$3,084	$7,666

[52] The 2015 RTI *Costs of Food Safety Investments* report assumes that the annual refresher training would be conducted in the establishment or online; thus, there is no course material fee.
[53] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. 2022 annual total labor separations rate for nondurable goods industry. The labor turnover rate is 48.8; thus, these employees will receive the initial training each year and the remaining 51.2 percent of employees (100 percent-48.8 percent) will receive the refresher training.

Combined	6	$1,415	$4,626	$11,499
Annualized[1]	6	$1,227	$4,010	$9,969
[1]Costs annualized at a discount rate of 7% over 10 years.				

The total sampling training cost, including initial, turnover, and refresher training for all six establishments is $98,247, and ranges from $32,202 to $233,364. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $39,000, table 9.

Table 9. Total Sampling Training Costs, (2022$)

Establishment				
Type	**Number**	**Low**	**Medium**	**High**
Low-Volume	3	$11,653	$34,586	$80,545
High-Volume	3	$20,549	$63,661	$152,819
Combined	6	$32,202	$98,247	$233,364
Annualized[1]	6	$12,733	$39,000	$92,889
[1]Costs annualized at a discount rate of 7% over 10 years.				

4. Sampling Implementation Costs

After training employees, establishments would begin collecting incoming chicken component samples. FSIS assumes establishments would test a single sample every day of production. FSIS assumes high-volume establishments operate 275 production days a year and low-volume establishments operate 200 production days a year.[54, 55]

As mentioned above, FSIS estimates that the establishment's sampling plan would include one sample of the incoming chicken component per test. Using information available to FSIS, FSIS assumes that high-volume establishments already conduct some testing of their

[54] RTI, Costs of Food Safety Investments, 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species. Pounds of production are rounded to the nearest whole number. Large Poultry establishments have 275 production days a year.
[55] RTI, Costs of Food Safety Investments, 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species. Pounds of production are rounded to the nearest whole number. Small Poultry Establishments have 200 production days a year.

incoming chicken components but would still have labor, lost product, and testing cost associated with increasing their incoming chicken component testing. Low-volume establishments would also have labor, lost product, and testing costs associated with sampling their incoming chicken components.

FSIS assumes it takes a QT or food scientist 17.5 minutes per sample, 15 minutes to collect the sample and 2.5 minutes to complete the associated recordkeeping.[56] The labor cost to collect one sample is $22.40 (17.5 minutes ÷ 60 minutes × $76.78). The labor cost for all three low-volume establishments to collect samples is $13,440 ($22.40 × 200 annual samples × 3 low-volume establishments) and for the three high-volume establishments it is $18,480 ($22.40 × 275 annual samples × 3 high-volume establishments) for a total annual cost of $31,920 ranging from $19,152 to $52,853, table 10.

Table 10. Labor Costs for Sampling and Recordkeeping

Recurring Cost Estimate (2022$)	Low	Medium	High
Low Volume	$8,064	$13,440	$22,254
High Volume	$11,088	$18,480	$30,599
Recurring Cost (2022$)	$19,152	$31,920	$52,853

FSIS used data from the 2015 RTI report to estimate the cost to conduct a *Salmonella* screen test. FSIS assumed the cost for detecting *Salmonella* at levels of 1 CFU/g or higher would be similar to the cost to perform a screen test. In 2022 dollars, the medium estimate for a *Salmonella* screen test is $31, ranging from $21 to $39 per sample.[57] The *Salmonella* screen test

[56] Modernization of Poultry Slaughter Inspection-Final Rule. 79 FR 49565 Page: 49565-49637, August 21, 2014, https://www.federalregister.gov/documents/2014/08/21/2014-18526/modernization-of-poultry-slaughter-inspection

[57] The 2015 RTI *Costs of Food Safety Investments*, Table 5-1. Laboratory Testing Costs. Salmonella Screening. The cost was inflated using the 2022 BLS Employment Cost Index Total compensation for Private industry workers in Service-providing; management, professional, and related occupations (Series ID CIU201S000100000I).

cost for the three low-volume establishments is $18,600 ($31 × 200 annual lots × 3 low-volume establishments) and for the three high-volume establishments it is $25,575 ($31 × 275 annual lots × 3 high-volume establishments) for a total annual cost of $44,175 ranging from $29,925 to $55,575, table 11.

Table 11. *Salmonella* Sample Testing Costs, (2022$)			
Establishment Type	**Low**	**Medium**	**High**
Low-Volume	$12,600	$18,600	$23,400
High-Volume	$17,325	$25,575	$32,175
Combined[1]	$29,925	$44,175	$55,575

Combined, the total sampling implementation costs, which include labor costs for sampling and recordkeeping, and *Salmonella* sample testing costs are $76,095, with a range of $49,077 to $108,428, table 12. This equates to $53.40 per test at low-volume and high-volume establishments.

Table 12. Total *Salmonella* Sampling Plan Implementation Costs (2022$)			
Establishment Type	**Low**	**Medium**	**High**
Low-Volume	$20,664	$32,040	$45,654
High-Volume	$28,413	$44,055	$62,774
Combined[1]	$49,077	$76,095	$108,428

5. Lost and Diverted Product Costs Due to FSIS and Industry *Salmonella* Testing Results at Levels of 1 CFU/g or Higher

FSIS assumes establishments will either divert or discard any incoming chicken components intended for use in NRTE breaded stuffed chicken products found to have *Salmonella* levels at 1 CFU/g or higher, either by Agency or establishment sampling. This analysis assumes high-volume establishments will divert this material, while low volume establishments will discard this material. FSIS estimates 3.31 percent of total sampled product

would have *Salmonella* levels at 1 CFU/g or higher.[58] Applying the 3.31 percent positive rate to the 2022 annual production of NRTE breaded stuffed chicken, an estimated 1.7 million pounds of incoming chicken components would need to be diverted to a use other than NRTE breaded stuffed chicken products or destroyed (13,258 pounds for low-volume establishments and 1,674,728 pounds for high-volume establishments).[59] This estimate may have some tendency toward overstatement because pounds of production for NRTE breaded stuffed chicken products include other ingredients. The amount of incoming chicken components that would be diverted or destroyed would be less than the production volume of the NRTE breaded stuffed chicken products.

FSIS estimates the average retail price of incoming chicken components used in NRTE breaded stuffed chicken products in 2022 was about $4.32 per pound.[60] As such, discarded incoming chicken components, i.e., incoming chicken components that are confirmed positive for *Salmonella* at 1 CFU/g or higher, would lose $4.32 per pound. However, diverted incoming chicken components maintain at least some of their market value. This analysis assumes that diverted incoming chicken components would lose 2/3 of their market value, or $2.88 per pound, because their use may be limited.[61] FSIS estimates that industry would have an annual loss of approximately $4.89 million dollars ($4.83 million dollars for high-volume establishments

[58] Average Most Probable Number (MPN) *Salmonella* Results for Collection Dates Between 6/4/2015 to 3/9/2020 showed that 12.27 percent of positive *Salmonella* results for comminuted chicken are at or over the 1 CFU/g limit. To estimate the percent positive rate for incoming chicken components at or over the 1CFU/g limit, FSIS multiplied the percent positive rate of 27 percent by 12.27 percent. Thus, FSIS estimates 3.31 percent of total product sampled is at or over the 1 CFU/g limit and 96.69 percent would be below the 1 CFU/g limit.

[59] 50,996,550 million pounds × 3.31 percent = 1,687,986 pounds. Numbers may not add up due to rounding.

[60] This estimate is based on the 2022 average retail price of boneless chicken breast. U.S. Department of Labor, Bureau of Labor Statistics (BLS). Accessed on October 27, 2023: https://www.ers.usda.gov/webdocs/DataFiles/52160/cuts.xls?v=0

[61] Cost-Benefit Analysis for FSIS's Implementation of Its Non-O157 STEC Testing on Beef Manufacturing Trimmings and Expansion of Its Testing to Ground Beef and Ground Beef Components Other Than Beef Manufacturing Trimmings: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf.

(1,674,728 pounds × $2.88) and $0.057 million for low-volume establishments (13,258 pounds × $4.32)), table 13.[62]

Table 13. Lost Product Costs due to *Salmonella* Results at 1 CFU/g or Higher, (2022$)			
	Establishment	**Lost Product Value ($ million)**	
	Type	**Number**	
Low-Volume Destroyed Product		3	$0.057
High-Volume Diverted Product		3	$4.83
Combined [1]		6	$4.89
[1]Calculations may not sum to totals due to rounding.			

In the preliminary CBA, FSIS requested comments on the possible costs industry may incur from sampling chicken components of these products prior to stuffing and breading that screened positive for *Salmonella*, but then are found to be below the 1 CFU/g threshold. After considering the public comments, FSIS will collect samples on raw incoming chicken components. This new sampling location will provide industry greater flexibility and avoid potential costs from actions taken on product that is found to be positive for *Salmonella*, but below the 1 CFU/g threshold. As mentioned in the "Baseline" section, all six establishments producing NRTE breaded stuffed chicken product, produce other types of products with the same chicken components. As such, although industry can use incoming chicken components that have tested positive for *Salmonella* below the 1 CFU/g threshold in NRTE breaded stuffed chicken products, they may choose to repurpose this material for an alternative product. FSIS has already accounted for the cold storage costs that establishments would incur as a result of this

[62] Calculations may not sum to totals due to rounding.

final determination and any additional potential costs to produce an alternative product that uses the same chicken source material would be de minimis,

E. Reformulation and Relabeling Costs

In 2015-2016, FSIS worked directly with establishments that produced NRTE breaded stuffed chicken products to modify the product labeling to further emphasize that the product is raw and to ensure that the label included validated cooking instructions. Based on recommendations from FSIS, establishments re-validated the cooking instructions on the product label to ensure that, when prepared as instructed, an NRTE breaded stuffed chicken product would reach an internal temperature needed to destroy *Salmonella* organisms on the interior of the product. FSIS also worked with industry to ensure that the product labels emphasized that these products should not be prepared in a microwave oven. Thus, after the 2015 *Salmonella* outbreaks associated with NRTE breaded stuffed chicken products, FSIS reviewed the labels of these products. This review found that most manufacturers had voluntarily incorporated the labeling features recommended by the 2016 National Advisory Committee on Meat and Poultry Inspection (NACMPI) subcommittee[63] and requested in a 2016 National Chicken Council (NCC) petition.[64]

FSIS is not requiring establishments to reformulate or relabel their products as a result of this policy. However, some manufacturers could choose to reformulate their products and, subsequently, relabel. For example, an establishment may decide to reformulate their product to

[63] Subcommittee #2 Consideration of Mandatory Labeling Features for Certain Processed Not Ready to Eat Meat and Poultry Products (March 2016) (https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/NRTE-Labeling.pdf)

[64] National Chicken Council petition #16-03, "Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not Ready-to-Eat Stuffed Chicken Breast Products That Appear Ready-to-Eat" dated May 24, 2016 available at: https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-eat-stuffed-chicken-products

remove chicken skin as a component or so that the breading is no longer par-fried, such that the products may no longer appear RTE. This reformulation may also lead to the establishment relabeling this product to remove any ingredient associated with par-frying the products from the ingredients statement. Such products would no longer be classified as NRTE breaded stuffed chicken products in which the final product has been heat-treated only to set the batter or breading, which may impart a RTE appearance, and thus would not be subject to this new policy.[65]

Current data from Label Insight shows that there are approximately 119 unique labels (Universal Product Codes) with 96 unique formulas (recipes) with the term "Raw Stuffed Chicken" on the package and appear to be RTE based on information in the ingredients statement.[66] FSIS does not have information on how many establishments, if any, would choose to reformulate and subsequently relabel these products, but manufacturers would only choose to do so if it's in their best economic interest.

If an establishment were to reformulate its products, the one-time cost for a very small establishment is approximately $0.15 million per formula, a small establishment is approximately $2.08 million per formula, and a large establishment is approximately $5.19 million per formula. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $0.02 million for a very small establishment, $0.28 million

[65] NRTE breaded stuffed chicken products that appear RTE "contain raw, comminuted chicken breast meat or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading on the exterior of the product and impart an RTE appearance" FSIS Directive 5300.1, Revision 1. Managing the Establishment Profile in the Public Health Information System. (usda.gov), available at: https://www.fsis.usda.gov/policy/fsis-directives/5300.1. See attachment 2 "NRTE Breaded Stuffed Chicken Products that appear RTE".

[66] Label Insight, accessed May 11, 2022. Label Insight is a market research firm that collects data on over 80 percent of food, pet, and personal care products in the U.S. retail market. Data are collected mostly from web scraping and company submissions. See https://www.labelinsight.com/our-difference/ for more information.

for a small establishment, and $0.69 million for a large establishment. These cost estimates are derived from the 2014 *FDA Reformulation Cost Model*, which estimates the total reformulation cost per type of reformulation change, based on several factors.[67] FSIS inflated these costs to 2022 dollars. If a manufacturer chooses to reformulate, as described above, the reformulation type would be categorized as "a change in production process and ingredient change" by the model. The cost for this type of reformulation depends on the complexity of the food item (low, medium, or high), the company size (small, medium, or large), and the compliance time. The model defines NRTE breaded stuffed chicken products as "high-complexity" food items. The model also defines small businesses as having less than $1 million in annual sales, medium businesses as having between $1-$500 million in annual sales, and large businesses as having over $500 million in sales. For this analysis, FSIS assumes very small HACCP-sized establishments are small businesses, small HACCP-sized establishments are medium businesses, and large HACCP-sized establishments are large businesses. Since product reformulations are a business decision, FSIS used the longest compliance period for the cost estimate, which is 24 months for small and very small establishments and 36 months for large establishments.

If establishments choose to reformulate their products they would also likely have to relabel the product, which is estimated to cost $874 per label in 2022 dollars, or $116 annualized over ten years, assuming a 7 percent discount rate.[68] The total cost of a label change depends on the type of change (minor, major, or extensive) and whether the label can be coordinated with a planned change. If a manufacturer chooses to change a product's label following reformulation

[67] The model accounts for variations in food product complexity, company size, compliance period, and reformulation types and activities. RTI International, "Reformulation Cost Model," prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela Coglaiti, Shawn Karns, and Catherine Viator. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.

[68] RTI International, "2014 FDA Labeling Cost Model," Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.

so that their product appears NRTE, the label change would likely be a minor, coordinated change. Minor label changes are categorized as alterations that do not require the entire label to be redesigned, e.g., changing a single color or updating the ingredient list.

F. Summary of Industry Costs

All six establishments are likely to incur costs associated with HACCP plan reassessments, holding incoming chicken components, or finished product in cold storage pending FSIS test results from product sampled by FSIS, establishment conducted sampling and testing, and lost product value. Combined, these actions are expected to cost industry about $5.29 million annually, table 14.

Table 14. Total Industry Costs ($mil)

Cost Component ($2022)	Low Estimate	Medium Estimate	High Estimate
HACCP Plan Reassessment[1]	$0.0005	$0.0012	$0.0020
Cold Storage	$0.12	$0.12	$0.12
Sampling Plan Development, Reassessment, Training and Implementation	$0.11	$0.28	$0.61
Lost Product	$4.89	$4.89	$4.89
Combined Annualized Costs[2]	$5.12	$5.29	$5.61

[1] FSIS assumes all establishments producing NRTE breaded stuffed chicken products that appear RTE would reassess their HACCP plan.
[2]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

Establishments may also incur some additional costs associated with actions they choose to take in response to the new policy, such as HACCP plan validation, training, formula changes, process changes, and label changes. However, due to uncertainty about which establishments would take these actions in response to the new policy, these costs have not been estimated at the industry level, table 15. FSIS did not receive comments on the frequency at which establishments will incur the costs listed in table 15 or on any other possible industry costs resulting from FSIS declaring NRTE breaded stuffed chicken products that contain *Salmonella* at

levels of 1 CFU/g or higher adulterated. For those reasons, the potential costs listed in table 15 are not included in the breakeven analysis found in Section VI "Summary of Cost and Benefits" below.

Table 15. Potential Industry Costs, Annualized ($2022)[1]			
HACCP Plan Validation Per Establishment	**Low Estimate**	**Medium Estimate**	**High Estimate**
Small	$1,226	$4,087	$10,151
Large	$981	$3,269	$8,120
Training[2] Per Establishment			
Small	$51	$153	$356
Large	$101	$305	$713
Formula Change			
Very Small	$10,407	$19,410	$37,629
Small	$143,436	$276,995	$545,672
Large	$370,262	$690,485	$1,317,125
Label Change	$27	$116	$240
[1] All Costs annualized at a discount rate of 7% over 10 years. [2] Training Costs includes recurring training			

IV. Agency Costs

FSIS will be able to shift existing resources as necessary to implement the final determination. Agency costs associated with verification procedures to ensure control for *Salmonella* in NRTE breaded stuffed chicken products include: (1) cost to FSIS laboratories for analyzing samples collected by FSIS personnel for *Salmonella* testing in incoming chicken components intended for use in NRTE breaded stuffed chicken products, (2) cost to conduct follow-up sampling and testing, and (3) cost to conduct for-cause Food Safety Assessments (FSAs). FSIS will use screening and confirmation testing to analyze the incoming chicken components for *Salmonella*. The estimated cost per test for samples that screen negative is

$14.00, which includes sampling and screening costs; while the cost for samples that screen positive and need to get a confirming test is $217, which includes sampling, screening, confirmation, characterization, and enumeration costs. As described in "Section C. Cold Storage Cost" and given the assumptions in this CBA, the Agency may collect an estimated 360 samples annually at establishments producing NRTE breaded stuffed chicken products. This would have an opportunity cost to the Agency of approximately $24,771 or $0.02 million a year, assuming a 27 percent screen positive rate [(360 × 27% × $217) + (360 × 73% × $14)].[69,70] The Agency will assign follow-up sampling as needed. [71] For perspective, in Fiscal Year 2024, the Agency planned 90,154 samples for all sampling programs.[72] The NRTE stuffed chicken sampling program would represent less than half a percent of the total sampling allocation for the Agency. Thus, the Agency will be able to implement the final determination with existing resources.

FSIS will prioritize a PHRE for any NRTE breaded stuffed chicken establishment that received a *Salmonella* positive sample. FSIS would use the results of the PHRE to determine the

[69] As noted by the Office of Management and Budget in the Circular No. A-4 published on November 9, 2023. Opportunity costs "is the cost attributable to a regulation if an agency will be performing enforcement activities or otherwise using resources in connection with that regulation, even if the agency's budget is not increasing.," https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.. Accessed on 02/15/2024.

[70] Average Most Probable Number (MPN) *Salmonella* Results for Collection Dates Between 6/4/2015 to 3/9/2020 showed that the percent positive rate for comminuted chicken of 27 percent. FSIS used this rate as a proxy for incoming chicken components for NRTE breaded stuffed chicken. Thus, FSIS estimates that Agency costs would be based on the positive rates of the incoming chicken components source material.

[71] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Proposed Determination and Request for Comments. Docket No. FSIS-2022-0013, available at: https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/salmonella-not-ready-eat-breaded-stuffed.

[72] USDA Food Safety and Inspection Service. Annual Sampling Plan. FY 2024. https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-Annual-Sampling-Plan-FY2024.pdf. Accessed on 02/14/2024.

need for an FSA. The Agency estimated that the average cost to conduct a for-cause FSA in 2016 was about $4,800, which, inflated to 2022 dollars, is about $5,853 per FSA.[73]

V. Benefits

Once the new policy is implemented, FSIS will carry out verification procedures to ensure the control of *Salmonella* in NRTE breaded stuffed chicken products, consumers would benefit from reduced cases of *salmonellosis* and industry would benefit from a reduction in costs associated with outbreaks and outbreak-associated recalls.

A. Consumer Benefits

One benefit from the new policy is the likely reduction of illnesses and hospitalizations caused by *Salmonella* in NRTE breaded stuffed chicken products. The overall purpose of FSIS inspection and sampling is to verify that establishments maintain process control within their production processes and adhere to Agency regulations, policies, and performance standards, which FSIS believes can help protect the public from foodborne illnesses caused by these products. In addition, establishments' actions, such as HACCP plan reassessment, would improve the establishments' overall control of *Salmonella* and further reduce illnesses. The CDC estimate *Salmonella* bacteria cause about 1.35 million infections, 26,500 hospitalizations, and 420 deaths in the United States every year.[74] From 1998 to 2021, FSIS and public health partners investigated 14 *Salmonella* outbreaks linked to NRTE breaded stuffed chicken products. After FSIS issued guidance in 2006, there were 11 outbreaks and 131 confirmed cases, table 16.[75]

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[73] Based on the FSIS Office of the Chief Financial Officer (OCFO) preliminary analysis of the average cost per FSA under the new FSA methodology, FY 2016. The costs were inflated, by using the 2022 BLS Consumer Price Index (CPI) All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted). Costs are rounded to the nearest hundreds.

[74] CDC: https://www.cdc.gov/salmonella/index.html (last accessed on 12/7/2022).

[75] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Final Determination and Request for Comments. Docket No. FSIS-2022-0013, available at: https://www.regulations.gov/docket/FSIS-2022-0013.

Confirmed cases are cases that were reported to physicians and other health-care providers and confirmed through laboratory testing. FSIS used the reported cases of *Salmonella* associated with the 11 outbreaks between 2006 and 2021 to calculate the illness cost burden per outbreak. The USDA Economic Research Service has estimated that *Salmonella* has an illness cost burden of $4,682 per case in 2022 dollars.[76] As such, the 131 reported cases of *Salmonella* associated with the 11 NRTE breaded stuffed chicken product outbreaks had an illness cost burden of about $0.61 million, which averages to $55,758 per outbreak. Scallan et. al indicate that the actual number of illnesses may be higher than the number of reported illnesses for cases where only data for illnesses associated with reported outbreaks are available. They estimated an underreporting multiplier of 25.5.[77] Since the number of salmonellosis caused by NRTE breaded stuffed chicken products is only available from reported outbreak data, FSIS applied this underreporting multiplier to the number of reported illnesses from outbreak data. The estimated number of *Salmonella* illnesses adjusted by the underreporting multiplier is 3,341, which had an estimated illness cost burden of about $15.6 million, or $1.42 million, on average, per outbreak (table 16).

Table 16. *Salmonella* Outbreaks in NRTE breaded stuffed chicken products Between 2006 and 2021[1,2]

Reported *Salmonella* Outbreaks[1]	Reported Cases of *Salmonella*	Cases of *Salmonella* Accounted for Under-reporting[3]
2006	3	77
2008	7	179

[76] The FSIS estimate for the cost of *Salmonella*-related illness $4,682 per case, (2022 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/. The cost model accounts for medical costs (including hospitalizations), premature death and productivity loss.

[77] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States–major pathogens pdf icon [PDF – 9 pages]. Emerging Infectious Diseases. 2011;17(1):7-15: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/

2008-2009	47	1,199
2009	2	51
2009	2	51
2013	3	77
2014	6	153
2015	5	128
2015	15	383
2016	5	128
2021	36	918
Total for the 11 Outbreaks	**131**	**3,341**
Combined Illness Cost	$613,342	$15,642,562
Average Illness Cost Per Outbreak	$55,758	$1,422,051

[1] Food Safety and Inspection Service, USDA. *Salmonella* in Not Ready-To-Eat Breaded Stuffed Chicken Products. Proposed Determination. Docket No. FSIS-2022-0013, available at: https://www.regulations.gov/docket/FSIS-2022-0013.
[2] These outbreaks include reported state and national level outbreaks in these products during this period.
[3] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States–major pathogens pdf icon [PDF – 9 pages]. Emerging Infectious Diseases. 2011;17(1):7-15: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/

B. Costs avoided from prevented outbreak-related recalls

Any recall may have a significant impact on industry, consumers, and the Government. The negative impacts of recalls on industry include the loss of sales revenue, the cost to dispose of recalled products, 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). The Agency also incurs costs for verifying that companies recalled and properly disposed of product.[78] While some establishments may invest in food safety measures that would minimize the risk of *Salmonella* illnesses, others may not implement

[78] This includes inspectors' activities at the establishments, FSAs, recall effectiveness checks, and dissemination of information about recalls through press releases.

sufficient controls, but are still able to sell their products at the same price point in the marketplace. This results in an inefficient market with limited information and reduces producers' incentives for controlling for the pathogen as establishments may experience pressure to underinvest in food safety measures to maintain cost competitiveness.[79] This results in an increased risk of *Salmonella* illnesses, and, in consequence, there is an increased risk of outbreaks and outbreak-related recalls for establishments. In the absence of an efficient market, regulation could be an effective tool to improve food safety.[80]

To estimate how much a recall could cost industry, FSIS used a 2011 report by the Grocery Manufacturers Association (GMA) done in collaboration with Covington & Burling LLP and Ernst & Young, which surveyed 36 food, beverage, and consumer products companies, of which approximately 58 percent had been impacted by a recall in the previous five years.[81] The recall cost estimate in the GMA report includes lost profits from business interruption, recall execution cost, liability cost, and financial loss from reputation damage, and does not include the cost of illnesses and deaths. FSIS estimated the average cost of food recalls to companies to be approximately $25.8 million per recall in 2011 dollars, inflated to $33.57 million in 2022 dollars.[82,83]

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[79] Roberts, T. *Food Safety Economics: Incentives for a Safer Food Supply*. 2018, Springer International Publishing, p. 46. https://doi.org/10.1007/978-3-319-92138-9

[80] Starbird, S.A., 2005. Moral hazard, inspection policy, and food safety. American Journal of Agricultural Economics, 87(1), pp.15-27. https://www.jstor.org/stable/3697988.

[81] Grocery Manufacturers Association (GMA), *Capturing Recall Costs: Measuring and Recovering the Losses,* 2011, https://www.gma.maxx.matrixdev.net/forms/store/ProductFormPublic/capturing-recall-costs. Note that GMA became Consumer Brands Association in January 2020.

[82] Cost-Benefit Analysis for FSIS's Implementation of Its Non-O157 STEC Testing on Beef Manufacturing Trimmings and Expansion of Its Testing to Ground Beef and Ground Beef Components Other Than Beef Manufacturing Trimmings: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf.

[83] The costs were inflated, by using the 2022 BLS Consumer Price Index (CPI) All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted). Costs are rounded to the nearest dollar.

C. Total Benefits

From 2006 to 2021 (15 years), there were 11 documented outbreaks. The number of reported cases of *Salmonella* per outbreak ranged from 2 to 47 and applying the under-reporting multiplier, the estimated number of cases ranges from 51 to 1,199. As detailed in the "Consumer Benefits" section, FSIS estimates the average cost of illnesses of a single outbreak for NRTE breaded stuffed chicken, adjusted for underreporting, to be approximately $1.42 million. As detailed in the "Costs avoided from prevented outbreak-related recalls" section, FSIS estimates that the average industry cost of a food recall is approximately $33.57 million. Therefore, preventing a single outbreak and outbreak-related recall would result in approximately $34.99 million in benefits ($1.42 million + $33.57 million). FSIS uses this information to conduct a break-even analysis in the Summary of Costs and Benefits section.

VI. Summary of Costs and Benefits

The estimated total cost for this policy is $5.31 million: $5.29 million in costs to industry and $0.02 million in opportunity costs for FSIS, assuming a 7 percent discount rate over a 10-year period. Industry costs are associated with HACCP plan reassessments, holding incoming chicken components in cold storage awaiting test results, the costs associated with developing and implementing an establishment-conducted sampling program and lost product value. To varying degrees, industry may also incur other costs associated with their individual responses to this policy, including applying interventions, training, product reformulation and label changes, and subsequent HACCP plan validation. However, based on public comments, establishments are not expected to make these changes. If establishments were to implement these changes, then we would expect both additional costs and benefits. The Agency would incur costs associated

with sampling and testing for S*almonella* and conducting FSAs; thus, the Agency may have an opportunity cost of $0.02 million annually.

The estimated benefits for this policy are derived from preventing outbreak-related recalls.[84] Each prevented outbreak-related recall has an estimated benefit of $34.99 million ($1.42 million in health benefits + $33.57 million in industry benefits). Between 2006 and 2021 there was one outbreak every 1.36 years on average (15 years ÷ 11 outbreaks). Total benefits will exceed total costs if the new policy prevents at least 1 outbreak-related recall every 6.6 years ($34.99 million ÷ $5.31 million).[85] Though the policy may not prevent every possible outbreak-related recall, the Agency expects it will prevent at least 1 every 6.6 years.

Without this policy, there is a higher risk of *Salmonella* illnesses from NRTE breaded stuffed chicken products. When only considering health benefits, the policy would break-even if 1,134 illnesses were avoided annually ($5.31 million ÷ $4,682).[86] The smallest number of cases associated with an outbreak in NRTE breaded stuffed chicken products occurred in 2009, with 2 reported cases, which represents 51 cases and a cost burden of $0.24 million, when applying the under-reporting multiplier of 25.5.[87] The largest number of reported cases associated with outbreaks occurred between 2008-2009, with 47 reported cases, which represents 1,199 estimated cases and a cost burden of $5.6 million, when applying the under-reporting

[84] Though each reported outbreak between 2006 and 2021 did not result in a recall, FSIS assumes there is a risk of recall with each possible *Salmonella* outbreak.
[85] Numbers may not add up due to rounding.
[86] Number rounded to the nearest whole number.
[87] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States–major pathogens pdf icon [PDF – 9 pages]. Emerging Infectious Diseases. 2011;17(1):7-15: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375761/.

multiplier.[88,89] Despite proper labeling, the most recent outbreak in 2021 occurred, with 36 reported cases, which represents 918 estimated cases and a cost burden of $4.3 million, when applying the under-reporting multiplier. In the final determination, FSIS is declaring NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 CFU/g or higher adulterated. FSIS intends to carry out verification procedures, including sampling and testing of the raw incoming chicken components used to produce NRTE breaded stuffed chicken products prior to stuffing and breading. This determination, and the associated FSIS verification procedures, should decrease the number of illnesses associated with *Salmonella* in NRTE breaded stuffed chicken products.

VII. Potential Impact on Small Businesses

Establishments subject to this final determination are classified in the 311615 Poultry Processing sector of the North American Industry Classification System (NAICS).[90] The Small Business Administration (SBA) size standard for small businesses in this section is 1,250 employees.[91] This NAICS sector includes establishments "primarily engaged in (1) slaughtering poultry and small game and/or (2) preparing processed poultry and small game meat and meat byproducts."[92] As a result, the NAICS sector includes establishments that produce products

[88] Food Safety and Inspection Service, USDA. Salmonella in Not Ready-To-Eat Breaded Stuffed Chicken Products. Final Determination. Docket No. FSIS-2022-0013, available at: https://www.regulations.gov/docket/FSIS-2022-0013.

[89] The FSIS estimate for the cost of Salmonella-related illness $4,682 per case, (2022 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/. The cost model accounts for medical costs (including hospitalizations), premature death and productivity loss. Numbers may not calculate due to rounding.

[90] U.S. Census Bureau, "North American Industry Classification System– 2022 NAICS Definition: 311615 Poultry Processing January. 3, 2024, https://www.census.gov/naics/?input=311615&year=2022&details=311615.

[91] SBA, Table of size standards, October 25, 2023, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

[92] U.S. Census Bureau, "North American Industry Classification System– 2022 NAICS Definition: 311615 Poultry Processing January. 3, 2024, https://www.census.gov/naics/?input=311615&year=2022&details=311615.

beyond the scope of this final determination. FSIS has typically classified establishments in three HACCP size categories based on employment counts and annual sales: large establishments have over 500 employees, small establishments have between 10 and 499 employees, and very small establishments have less than 10 employees or less than $2.5 million in annual sales.[93] All three of the low-volume establishments that would be impacted by this new policy are HACCP size small or very small. These categories, however, do not necessarily capture the variability in production volumes between regulated establishments. For this reason, FSIS also classified establishments based on production volumes of NRTE breaded stuffed chicken products subject to this final determination. In this CBA, FSIS defines high-volume establishments as establishments that produce at least 1 million pounds of NRTE breaded stuffed chicken products annually and low-volume establishments as establishments that produce less than 1 million pounds annually.

FSIS expects the cost burden of this new policy on low-volume establishments to be small because the estimated costs are a small percentage of revenue from these NRTE breaded stuffed chicken products. The final determination CBA estimated total industry annual cost for low-volume establishments at $0.14 million, annualized over 10 years assuming a 7 percent discount rate, or $0.05 million on average for each establishment.[94] In 2022, these three low-volume establishments produced a combined total of 0.4 million pounds of NRTE breaded stuffed chicken products which, assuming a retail price of $8.10 per pound, is estimated to result in $3.2 million in revenue, or $1.1 million on average for each establishment.[95] Under these

[93] 61 FR 38806
[94] Numbers may not add up due to rounding.
[95] This estimate is based on the average price of 39 NRTE breaded stuffed chicken products in the 2020 Information Resources, Inc (IRI) retail scanner data, adjusted for inflation to 2022 dollars using the. BLS, "Consumer Price Index for Chicken in U.S. city average, all urban consumers, not seasonally adjusted," accessed March 19, 2024.

assumptions, the final determination's estimated costs are less than 4.2 percent of the estimated revenue from NRTE breaded stuffed chicken products produced at these three establishments. As mentioned above, establishments are not required to develop and implement their own sampling programs in response to this determination. If establishments chose to avoid these voluntary costs, the final determination is estimated to cost low-volume establishments $0.08 million, annualized over 10 years assuming a 7 percent discount rate, or $0.03 million on average for each establishment.[96] This cost would represent about 1.9 percent of estimated revenue from NRTE breaded stuffed chicken products produced at these three establishments. In addition, nearly 90 percent of production at two of the three low-volume establishments is product other than NRTE breaded stuffed chicken products. Thus, the impact of this final determination would represent a smaller percentage of these establishments' overall total revenue.

This CBA includes costs that establishment may not incur and which if avoided would lessen the cost-burden on small businesses. The highest cost component for the low-volume establishments is establishment sampling, plan development, and implementation, which the final determination does not require. Establishments will choose to incur these costs if they determine that it is in their economic interest. Further, once the policy is implemented, FSIS does not intend to begin the FSIS sampling and verification testing discussed in the final determination until 12 months after the date of publication in the *Federal Register*. A small business would have this time to prepare for changes, lowering the burden. Finally, establishments needing monetary assistance with this new policy may be able to take advantage

The analysis, findings, and conclusions expressed in this report should not be attributed to IRI. IRI gathers data by scanners in supermarkets, drugstores, and mass merchandisers and maintains a panel of consumer households that record purchases at outlets by scanning UPC codes on the products purchased. Numbers may not add up due to rounding.

[96] Numbers may not add up due to rounding.

of the grants and financial options available to small establishments, reducing potential burden. More information on these loans and grants can be found on the FSIS website.[97]

[97] Grants and Financial Options, USDA FSIS https://www.fsis.usda.gov/inspection/apply-grant-inspection/grants-financial-options.