U.S. DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Preliminary Cost-Benefit Analysis

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

Table of Contents

I. Introduction

The Food Safety and Inspection Service (FSIS) has tentatively determined that *Salmonella* at levels of 1 colony forming unit (CFU) per gram or higher is an adulterant in breaded stuffed not-ready-to-eat (NRTE) chicken products within the meaning of the Poultry Products Inspection Act (PPIA). If the determination is finalized, the Agency intends to carry out verification procedures, including sampling and testing of the chicken component prior to stuffing and breading, to ensure producing establishments control *Salmonella* in these products. Breaded stuffed NRTE 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 is proposing to implement routine testing for *Salmonella* in the chicken component for these products, and if finalized, would allow industry time to implement possible changes to their food safety systems. This cost-benefit analysis (CBA) quantifies and explains the potential costs and benefits associated with this policy. Should this policy be finalized, all establishments producing NRTE breaded stuffed chicken products would be subject to FSIS *Salmonella* verification sampling of the chicken component before it is used in a NRTE breaded stuffed chicken product and would incur costs associated with holding the chicken component product until FSIS *Salmonella* test results are available. FSIS also assumes that all establishments impacted by this proposed new

[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".

policy would incur costs from reassessing their Hazard Analysis and Critical Control Point (HACCP) plan and would choose to implement a *Salmonella* sampling and testing program.[2]

In response to the proposed new policy, some establishments may make additional changes to their production processes to control for *Salmonella*. These changes may include applying interventions, training, product reformulation and label changes, and subsequent HACCP plan validation. FSIS is not requiring establishments to make these additional changes to their processes. Establishments would only incur these additional costs if it were in their economic best interest. FSIS is requesting comments on all the potential actions establishments may take in response to the proposed policy. FSIS will update this CBA with the final *Federal Register* determination based on comments or data received in response to this proposal.

When FSIS implements its NRTE breaded stuffed chicken product sampling and testing program, the Agency would incur costs associated with *Salmonella* verification procedures, including sampling and testing. FSIS would also prioritize a Public Health Risk Evaluation (PHRE) for any establishment that produces a NRTE breaded stuffed chicken product that contains a chicken component that received a *Salmonella* positive sample at 1 CFU/ gram or higher.[3] FSIS will use PHRE results to determine if a Food Safety Assessment (FSA)[4] is warranted.

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[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."

[3] 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.

[4] 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.

If finalized, FSIS expects that this proposed new policy, including FSIS sampling and testing, would lead to a reduction in illnesses and hospitalizations caused by *Salmonella* in NRTE breaded stuffed chicken products, benefiting consumers. The proposed new policy is also expected to reduce the number of outbreak-related recalls because NRTE breaded stuffed chicken products would no longer contain chicken components with *Salmonella* levels of 1 CFU/ gram or higher.

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 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.[5] 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 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 degrees Fahrenheit 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

[5] 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.

cases, 12 hospitalizations; and approximately 59.3 thousand pounds of the affected product recalled.[6,7,8]

In light of the 2021 and the 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 human illnesses associated with NRTE breaded stuffed chicken products contaminated with *Salmonella*. Therefore, FSIS is proposing to declare that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/ gram or higher are adulterated within the meaning of the PPIA.[9] FSIS intends to implement verification procedures, including sampling and testing of 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's 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

[6] 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

[7] 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

[8] 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

[9] 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 Proposed Determination and Request for Comments for more detailed discussion of the rationale and support for the proposed determination, available at: https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/salmonella-not-ready-eat-breaded-stuffed

shows that labeling adjustments are not sufficient to prevent outbreaks in these products. The proposed policy would 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 proposed new policy.[10]

Baseline

FSIS identified establishments producing NRTE breaded stuffed chicken products from FSIS' Public Health Information System (PHIS) data.[11] According to this 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 would be impacted by the proposed new policy.

FSIS cross-referenced these establishments to 2017-2021 production data from PHIS, which show that the number of establishments producing these products increased from five in 2017 to six in 2018-21, table 1. However, annual total industry production of NRTE breaded stuffed chicken products decreased over this period from over 191 million pounds in 2017 to less than 60 million pounds in 2021. This sharp decline in production indicates that establishments may already be moving away from producing NRTE breaded stuffed chicken products.

[10] 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.

[11] FSIS, Public Health Information System database, accessed 07/28/2022.

Table 1. Production Volume of NRTE breaded stuffed chicken products (2017-2021)		
Year	**Establishments**	**Pounds of Production (millions)**
2017	**5**	191.14
2018	**6**	165.26
2019	**6**	56.10
2020	**6**	59.46
2021	**6**	53.90

Production of NRTE breaded stuffed chicken products is concentrated among a limited number of high-volume establishments. 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.[12] Preliminary research shows that some of these establishments are affiliated with larger companies.[13] In this CBA, FSIS has categorized these establishments by their production volume 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

[12] 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.

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

2021, the three high-volume establishments accounted for 99.8 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 indicates that all six establishments produce other types of products. In 2021, 33 percent of the total production in these establishments came from other products. At the three low-volume establishments, nearly 90 percent of production came from other products. These other products include RTE poultry, raw ground chicken, and raw intact chicken.

III. Industry Costs

As a result of the proposed new policy, all establishments that continue to produce NRTE breaded stuffed chicken products would need to conduct a one-time HACCP plan reassessment. These establishments would also have to hold chicken components that are intended to be used to manufacture NRTE breaded stuffed chicken products sampled by FSIS pending negative test results.[14] As such, establishments would incur costs associated with a HACCP plan reassessment and to store product while FSIS conducts sampling and testing. Establishments whose chicken components receive a *Salmonella* positive result at levels of 1 CFU/ gram or higher must ensure that the chicken components represented by the sampled lot are diverted to a use other than NRTE breaded stuffed chicken products. For example, such lots could be diverted for use in a fully cooked poultry product or for use in another raw poultry product, such as ground chicken in which consumer preparation is more likely to mitigate the risk.[15] FSIS conservatively assumes

[14] 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.

[15] 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.

that all six establishments would choose to incur costs to implement establishment-conducted *Salmonella* sampling and testing programs.

FSIS expects some establishments to incur additional costs if they elect to change their production processes in response to this proposed new policy. These changes should control the prevalence of *Salmonella*. Some examples of what establishments may do in response to any final policy resulting from this proposal include applying interventions, training employees, reformulating products, subsequent label changes, and validating their HACCP plans.

While FSIS does not yet have data on all the actions establishments would take or on the *Salmonella* positive rates for these products, this CBA includes cost estimates for measures FSIS assumes establishments would implement in response to the proposed policy. Specifically, HACCP reassessment, cold storage, and developing, validating, implementing an establishment-conducted *Salmonella* sampling program. Further, the CBA provides an overview of other potential costs on a per establishment basis. We will update this CBA with the final *Federal Register* determination, should more data on industry responses to the Agency's verification program becomes available.

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, cold storage costs, and establishment-conducted sampling and testing cost.[16] The 2015 RTI report categorizes large and small establishments by

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

volume of production. FSIS used data from the Bureau of Labor Statistics (BLS) to update the costs in this report from 2015 to 2021 dollars.

A. HACCP Plan Reassessment and Validation

If the proposed policy is finalized, the Agency would require all establishments producing these products to reassess their HACCP plans to determine whether *Salmonella* is a hazard reasonably likely to occur.[17] Establishments would be able to lower costs by coordinating this HACCP plan reassessment with their otherwise required annual reassessment.[18]

Some establishments may choose to make changes to their production processes in response to this proposed new policy and their HACCP plan reassessment. Establishments that choose to make changes would 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 2021 average hourly wage for a production employee was $15.39.[19] FSIS applied a factor of two to the hourly wage rate to account for employee benefits and overhead, making the total estimated compensation rate $30.78 per hour.

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[17] 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' proposed determination that *Salmonella* at levels of 1 colony forming unit (CFU)/gram or higher is an adulterant in NRTE breaded stuffed chicken products would be such a change.

[18] 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."

[19] Mean hourly wage estimate of $15.39 obtained from the Bureau of Labor Statistics, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 51-3023 Production Occupations. https://www.bls.gov/oes/current/oes513023.htm.

The total one-time estimated establishment cost for the three low-volume establishments to reassess their HACCP plan is $2,770 (3 × $30.78 × 30), with a range from $1,385 (3 × $30.78 × 15) to $4,155 (3 × $30.78 × 45).[20] For the three high-volume establishments, the estimated medium cost is $5,540, with a range from $2,770 to $8,311. The estimated medium one-time HACCP reassessment cost for all six establishments combined is $8,311, and ranges from $4,155 to $12,466.[21] Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $1,106, table 2.

Table 2. HACCP Plan Reassessment Costs Estimate (2021$)

Establishment Size	Number	Low	Medium	High
Low-Volume	3	$1,385	$2,770	$4,155
High-Volume	3	$2,770	$5,540	$8,311
Combined	6	$4,155	$8,311	$12,466
Annualized[1]	6	$553	$1,106	$1,659

[1] Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

2. HACCP Plan Validation Costs

An establishment may make changes in response to this proposed 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.[22] The 2015 RTI report estimated it would take a small establishment longer to complete a HACCP plan validation. The 2021 hourly compensation rate for a food scientist was $80.92, which includes a wage of $40.46 and a

[20] Numbers are rounded to the nearest dollar.
[21] Numbers may not add up to totals due to rounding.
[22] 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.

benefits and overhead factor of two.[23] The Agency does not have information on how establishments would respond to this proposed new policy. 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 $32,368 ($80.92 × 400), ranging from $16,184 to $48,552. For a high-volume establishment, the estimated cost is $25,894, ranging from $12,947 to $38,842. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $4,307 for a low-volume establishment and $3,446 for a high-volume establishment.

B. Training Costs

If FSIS finalizes this proposed policy, FSIS expects that establishments that choose to make changes to their HACCP system would 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 would train one employee per shift, with low-volume establishments operating one shift per day and high-volume establishments operating two shifts per day.[24] FSIS assumes that the one-time training would take one to three hours.[25] The 2021 hourly compensation (wages, and a benefits and overhead factor of two) for a QC manager is $113.24[26] and $30.78 for a production employee. The one-time training cost would be $288 (($113.24 + $30.78) × 2 hours × 1 shift) at a low-volume

[23] Mean hourly wage estimate of $40.46 obtained from the Bureau of Labor Statistics, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19-1012 Food Scientists & Technologists. https://www.bls.gov/oes/current/oes191012.htm.
[24] RTI, *Costs of Food Safety Investments,* 2015, 2-5 Standard Assumptions Used for Cost Calculations by Establishment Size and Species.
[25] RTI, *Costs of Food Safety Investments,* 2015, Table 4-4. Training Costs for Management and Production Employees. Annual Refresher Training Hours.
[26] Mean hourly wage estimate of $56.62 obtained from the Bureau of Labor Statistics, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 11-3051 Management Occupations. https://www.bls.gov/oes/current/oes113051.htm.

establishment and $576 (($113.24 + $30.78) × 2 hours × 2 shift) at a high-volume establishment.[27]

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 47.3 percent and applied it to the one-time training costs previously calculated.[28] These recurring costs would begin the year after establishments choose to make changes to their HACCP plans. The recuring training cost would be $136 ($288 × 47.3 percent) at a low-volume establishment and $272 ($576 × 47.3 percent) at a high-volume establishment.[29] FSIS does not have information on how establishments would respond to this proposed new policy. However, if establishments choose to conduct additional training, the estimated per establishment costs are $156 for a low-volume establishment and $313 for a high-volume establishment, annualized at the 7 percent discount rate over 10 years. [30]

C. Cold Storage Costs

FSIS assumes that industry would incur costs for holding product while waiting for FSIS sampling and testing results. If FSIS finalizes its proposed routine *Salmonella* verification testing program for the chicken component intended for use in NRTE breaded stuffed chicken products, establishments that produce these products would need to control and maintain the integrity of

[27] Numbers may not add up to totals due to rounding.
[28] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. January 2022. Released Wednesday, March 9, 2022. Table 16. Annual total separations rate by industry and region, not seasonally adjusted. 2021 annual total labor separations rate for nondurable goods industry, available at: https://www.bls.gov/news.release/archives/jolts_03092022.pdf.
[29] Numbers may not add up to totals due to rounding.
[30] Numbers may not add up to totals due to rounding.

the sampled chicken component lot pending the availability of test results. For a conservative estimate, FSIS assumed that establishments would maintain control of the chicken component, represented as a sampled lot, by storing all product pending FSIS *Salmonella* test results. FSIS estimates that initial screening tests would require industry to hold all product for 2 days and product that screens positive will be held for an additional 2 to 4 days to get the confirmed test results.[31] Based on the average FSIS *Salmonella* sampling results for comminuted chicken, 28.59 percent of products initially test positive, while 71.41 percent initially test negative for the pathogen.[32] In 2021, the total production of NRTE breaded stuffed chicken products was 53.9 million pounds, 53.8 million pounds from high-volume establishments and 0.1 million pounds from low-volume establishments.[33] Therefore, FSIS estimates that 38.49 million pounds of chicken component (53.9 million × 71.41 percent) will be held for two days, and 15.41 million pounds (53.9 million × 28.59 percent) will be held for 4 to 6 days. FSIS used the 2015 RTI report to estimate the cost of cold storage[34] and adjusted for inflation to 2021 dollars.[35] Based on this, FSIS estimates the cold storage cost for chicken components intended for use in NRTE breaded stuffed chicken products at 0.0023 cents per pound per day. The total annual industry

[31] 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.

[32] In this CBA, FSIS is using the average *Salmonella* Results for Collection Dates Between 5/13/2021 and 5/13/2022 for sampling program HC_CH_COM01: Ground and Other Chicken (not Mechanically Separated)-Comminuted as a proxy for the percent positive rates in NRTE breaded stuffed chicken products. The actual percent positive rates for NRTE breaded stuffed chicken could be higher or lower.

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

[34] 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. FSIS assumes establishments would refrigerate these products.

[35] The costs were inflated, by using the 2021 BLS Consumer Price Index (CPI) data. Moving, storage, freight expense in U.S. city average, all urban consumers, not seasonally adjusted (Series ID CUUR0000SEHP03).

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 $354,282,[36] with a range of $318,841 to $389,723, table 3.

Table 3. Industry Cold Storage Annual Cost Estimate[1,2] (Refrigerated Product)

Establishment Type	Number	Low	Medium	High
Low-Volume	3	$625	$694	$763
High-Volume	3	$318,216	$353,588	$388,960
Combined	6	$318,841	$354,282	$389,723
Annualized[1]	6	$318,841	$354,282	$389,723

[1] Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.
[2] Low, medium, and high estimates assume product that initially tests positive is held for 4, 5, or 6 days respectively.

D. Establishment Sampling Plan Development, Validation, and Implementation

In response to the proposed new policy, FSIS assumes all six establishments would likely incur costs to develop, validate, and implement a sampling plan for the 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 false positive *Salmonella* results. FSIS assumes the establishment's sampling plan would include one sample of the chicken component per lot. FSIS assumes that the high-volume establishments already conduct some *Salmonella* chicken component sampling and testing. However, FSIS assumes these establishments would reassess their existing sampling plan and may increase their sampling to one sample per lot. FSIS is

[36] Cold storage cost: (38.5 million pounds that initially test negative for *Salmonella* × $0.0023 daily storage costs × 2 days) + (15.4 million pounds that initially test positive for *Salmonella* × $0.0023 storage costs × 5 days) = $354,282. Numbers may not sum to totals due to rounding.

requesting comments on these assumptions. FSIS assumes the lot size at high-volume or low-volume establishments would be 10,000 or 1,000 pounds, respectively

1. Sampling Plan Development

Using the 2015 RTI report, FSIS estimates it would cost $7,479 (with a range of $3,740 to $11,218) for a low-volume establishment to develop a sampling plan with a consultant.[37] These costs are inflated to 2021 dollars using the Consumer Price Index.[38]

The estimated medium one-time sampling plan development costs for the three low-volume establishments is $22,437 [($7,479 × 3)], and ranges from $11,219 to $33,653.[39] Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annualized cost of $2,986, table 4.

Table 4. Sampling Plan Development Costs for Low-Volume Establishments (2021$)

Establishment				
Type	**Number**	**Low**	**Medium**	**High**
Low-Volume	3	$11,219	$22,437	$33,653
One-Time Costs	3	$11,219	$22,437	$33,653
Annualized[1]	3	$1,493	$2,986	$4,478

[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

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

[37] RTI, *Costs of Food Safety Investments*, 2015, Costs of Sampling Plan Development, Validation, and Reassessment Table 4-3.
[38] The costs were inflated, by using the 2021 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.
[39] Numbers may not sum due to rounding

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 1800 hours, to complete a sampling plan validation. As mentioned above, the 2021 hourly compensation rate for a food scientist was $80.92. Thus, the medium cost to validate a sampling plan at the three low-volume establishments is $291,312 ($80.92 × 1,200 × 3).

FSIS assumes high-volume establishments would reassess an existing *Salmonella* sampling plan for their chicken component in response to the proposed policy and increase sampling to one sample per lot. The estimated cost for a consultant to reassess a high-volume establishment sampling plan in 2021 dollars is $6,860, ranging from $3,430 to $10,289.[40] In addition to the consultant costs, it would 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 plan at the three high-volume establishments is $991,620 (($6,860 consultant costs × 3) + ($80.92 × 4,000 × 3)).[41] The estimated medium one-time sampling plan validation and reassessment costs for all six establishments is $1.28 million, and ranges from $641,466 to $1.9 million. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $170,711, table 5.

Table 5. Sampling Plan Validation and Reassessment Costs, (2021$)

Establishment Type	Number	Low	Medium	High
Low-Volume Validation	3	$145,656	$291,312	$436,968
High-Volume Reassessment	3	$495,810	$991,620	$1,487,427
Combined	6	$641,466	$1,282,932	$1,924,395
Annualized [1]	6	$85,355	$170,711	$256,066

[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

[40] 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.
[41] Numbers rounded to the nearest dollar.

3. Sampling Plan One-Time and Recurring Training

Once establishments have a validated or reassessed their sampling plans, they will train their current employees to collect samples. FSIS assumes that a QC manager would initially train two employees per shift, which includes training a relief employee. 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 $1,144 (with a range of $572 to $1,715) in 2021 dollars.[42] As mentioned above, the 2021 hourly compensation was $113.24 for a QC manager and $30.78 for a production employee. Thus, the medium cost to train employees to sample at the three low-volume establishments is $16,018 [($1,144 × 3) + (($113.24 + (2 × $30.78)) × 24) × 3]. The medium cost at the three high-volume establishments is $28,603 [($1,144 × 3) + (($113.24 + (2 × $30.78)) × (24 × 2)) × 3]. The total one-time sampling training cost for all six establishments is $44,621, and ranges from $22,310 to $66,925. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $5,937, table 6.

Table 6. One-time Initial Sampling Training Costs, (2021$)

Establishment				
Type	**Number**	**Low**	**Medium**	**High**
Low-Volume	3	$8,009	$16,018	$24,023
High-Volume	3	$14,302	$28,603	$42,902
Combined	6	$22,310	$44,621	$66,925
Annualized[1]	6	$2,969	$5,937	$8,905

[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

[42] 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.

Establishments would 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 47.3 percent and applied it to the one-time sampling training costs previously calculated.[43] The total sampling training cost due to employee turnover for all six establishments is $21,105 ($44,621 × 47.3%), and ranges from $10,553 to $31,656. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $18,297, table 7.

Table 7. Recurring Sampling Training Costs due to Employee Turnover, (2021$)

Establishment Type	Number	Low	Medium	High
Low-Volume	3	$3,788	$7,576	$11,363
High-Volume	3	$6,765	$13,529	$20,293
Combined	6	$10,553	$21,105	$31,656
Annualized[1]	6	$9,149	$18,297	$27,444

[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

Establishments would also accrue annual employee refresher training costs. This analysis assumes each establishment would provide refresher training for one QC manager and two production employees per shift, with hourly compensation of $113.24 and $30.78, respectively. The refresher training sessions would occur once a year and take two hours, ranging from one to three hours.[44] Under these assumptions, the medium cost for recuring training at the three low-

[43] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. January 2022. Released Wednesday, March 9, 2022. Table 16. Annual total separations rate by industry and region, not seasonally adjusted. 2021 annual total labor separations rate for nondurable goods industry, available at: https://www.bls.gov/news.release/archives/jolts_03092022.pdf.

[44] 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.

volume establishments is $1,049 [($113.24 + ($30.78 × 2)) × 2 × 1 × 3]. The medium cost at the three high-volume establishments is $2,098 [($113.24 + (30.78 × 2)) × 2 × 2 × 3]. The total refresher training cost for all six establishments is $3,146, and ranges from $1,573 to $4,720. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $2,728, table 8. These costs are likely an overestimate because only 52.7 percent of employees would receive the refresher training.[45]

Table 8. Annual Refresher Training Costs, (2021$)

Establishment Type	Number	Low	Medium	High
Low-Volume	3	$524	$1,049	$1,573
High-Volume	3	$1,049	$2,098	$3,146
Combined	6	$1,573	$3,146	$4,720
Annualized[1]	6	$1,364	$2,728	$4,092

[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.

The total sampling training cost, including initial, turnover, and refresher training for all six establishments is $68,872, and ranges from $34,437 to $103,301. Annualizing these costs over 10 years, assuming a 7 percent discount rate, arrives at a medium annual cost of $26,962, table 9.

[45] US Department of Labor, Bureau of Labor Statistics News Release. Job Openings and Labor Turnover. January 2022. Released Wednesday, March 9, 2022. Table 16. Annual total separations rate by industry and region, not seasonally adjusted. 2021 annual total labor separations rate for nondurable goods industry, available at: https://www.bls.gov/news.release/archives/jolts_03092022.pdf. The labor turnover rate is 47.3; thus, these employees will receive the initial training each year and the remaining 52.7 percent of employees (100 percent-47.3 percent) will receive the refresher training.

Table 9. Total Sampling Training Costs, (2021$)				
Establishment				
Type	Number	Low	Medium	High
Low-Volume	3	$12,321	$24,642	$36,960
High-Volume	3	$22,115	$44,230	$66,341
Combined	6	$34,437	$68,872	$103,301
Annualized[1]	6	$13,482	$26,962	$40,441
[1]Costs annualized at a discount rate of 7% over 10 years. Numbers in table may not sum to totals due to rounding.				

4. Sampling Implementation Costs

After training employees, establishments would begin collecting chicken component samples. FSIS assumes high-volume establishments would sample every 10,000 pounds and low-volume establishments would sample every 1,000 pounds. Using these assumptions and 2021 production volumes for NRTE breaded stuffed chicken products, the three low-volume establishments would sample a total of 106 lots annually and the three high-volume establishment would sample a total of 5,380 lots annually.

As mentioned above, FSIS estimates that the establishment's sampling plan would include one sample of the chicken component, per lot. Using information available to FSIS, FSIS assumes that high-volume establishments already conduct some testing of their chicken components but would still have labor, lost product, and testing cost associated with increasing their chicken component testing. FSIS seeks comments on this assumption. Low-volume establishments would also have labor, lost product, and testing costs associated with sampling their chicken component.

FSIS assumes it takes a production employee 17.5 minutes per sample, 15 minutes to collect the sample and 2.5 minutes to complete the associated recordkeeping.[46] The labor cost to collect one sample is $8.98 (17.5 minutes ÷ 60 minutes × $30.78). The labor cost for all three low-volume establishments to collect samples is $952 ($8.98 × 106 annual lots × 1 samples per lot) and for the three high-volume establishments it is $48,312 ($8.98 × 5,380 annual lots × 1 sample per lot) for a total annual cost of $49,264, table 10.

Table 10. Labor Costs for Sampling and Recordkeeping	
Low Volume	$952
High Volume	$48,312
Recurring Cost (2021$)[1]	$49,264
[1]Numbers in table may not sum to totals due to rounding.	

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. FSIS is requesting comments on this assumption. In 2021 dollars, the medium estimate for a *Salmonella* screen test is $29, ranging from $20 to $37 per sample.[47] The *Salmonella* screen test cost for the three low-volume establishments is $3,074 ($29 × 106 annual lots) and for the three high-volume establishments it is $156,020 ($29 × 5,380 annual lots) for a total annual cost of $159,094 ranging from $109,720 to $202,982, table 11.

[46] 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

[47] The 2015 RTI *Costs of Food Safety Investments*, Table 5-1. Laboratory Testing Costs. Salmonella Screening. The cost was inflated using the 2021 BLS Employment Cost Index Total compensation for Private industry workers in Service-providing; management, professional, and related occupations (Series ID CIU201S000100000I).

Table 11. *Salmonella* Sample Testing Costs, (2021$)			
Establishment Type	**Low**	**Medium**	**High**
Low-Volume	$2,120	$3,074	$3,922
High-Volume	$107,600	$156,020	$199,060
Combined[1]	$109,720	$159,094	$202,982
[1]Numbers in table may not sum to totals due to rounding.			

Combined, the total sampling implementation costs, which includes labor costs for sampling and recordkeeping, and *Salmonella* sample testing costs are $208,358, with a range of $158,984 to $252,246, table 12. This equates to $37.98 per lot at low-volume and high-volume establishments.

Table 12. Total *Salmonella* Sampling Plan Implementation Costs (2021$)			
Establishment Type	**Low**	**Medium**	**High**
Low-Volume	$3,072	$4,026	$4,874
High-Volume	$155,912	$204,332	$247,372
Combined[1]	$158,984	$208,358	$252,246
[1]Numbers in table may not sum to totals due to rounding.			

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

FSIS assumes high-volume establishments would divert all their chicken components and low-volume establishments would discard all their chicken components positive for *Salmonella* at levels of 1 CFU/gram or higher. FSIS has enumerated a subset of comminuted chicken performance standards samples since 2015 and estimates that 2.88 percent of comminuted chicken products would be positive for *Salmonella* over 1 CFU/gram or higher limit.[48] Applying

[48] The percentage is derived from a preliminary analysis of FSIS' comminuted chicken verification sampling data based on 1,815 samples where *Salmonella* concentrations were estimated using the Most Probable Number technique. The analysis method is described in Williams, M.S., Ebel, E.D., Cao, Y., 2013. Fitting distributions to microbial contamination data collected with an unequal probability sampling design. Journal of Applied Microbiology 114, 152-160.

the 2.88 percent positive rate to an annual production of approximately 53.9 million pounds, an estimated 1.55 million pounds of chicken component would need to be diverted to a use other than NRTE breaded stuffed chicken products or destroyed (3,040 pounds for low-volume establishments and 1,549,382 pounds for high-volume establishments).[49] This is a conservative estimate because pounds of production for NRTE breaded stuffed chicken products includes other ingredients. The amount of chicken component 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 chicken components used in NRTE breaded stuffed chicken products in 2021 was about $3.45 per pound.[50] As such, discarded chicken components, i.e., those chicken components that are confirmed positive for *Salmonella* at 1 CFU per gram or higher, would lose $3.45 per pound. However, diverted chicken components maintain at least some of their market value. This analysis assumes that diverted chicken components would lose 2/3 of their market value, or $2.30 per pound, because their use may be limited.[51] FSIS estimates that industry would have an annual loss of approximately $3.57 million dollars ($3.56 million dollars for high-volume establishments (1,549,382 pounds × $2.30) and $0.01 million for low-volume establishments (3,040 pounds × $3.45)), table 13.

[49] 53,903,550 pounds × 2.88 percent = 1,552,422 pounds. Numbers may not add up due to rounding.
[50] This estimate is based on the 2021 average retail price of boneless chicken breast. U.S. Department of Labor, Bureau of Labor Statistics (BLS). Accessed on March 13, 2023: https://www.ers.usda.gov/webdocs/DataFiles/52160/cuts.xls?v=0

[51] 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.

Table 13. Lost Product Costs due to *Salmonella* Results at 1 CFU/gram or Higher, (2021$)			
	Establishment		Lost Product Value ($ million)
	Type	Number	
Low-Volume Destroyed Product		3	$0.01
High-Volume Diverted Product		3	$3.56
Combined [1]		6	$3.57
[1]Calculations may not sum to totals due to rounding.			

There also may be industry costs associated with Agency testing of product that screens positive for *Salmonella* but is not at the level of 1 CFU/gram or higher. This is because FSIS' screen testing can detect levels of *Salmonella* below the 1 CFU/gram limit. Upon a positive screen for *Salmonella*, FSIS would send the chicken component sample for confirmation and enumeration. At that time, FSIS would confirm the positive result if the sample tests positive for *Salmonella* at levels of 1 CFU/gram or higher. Although the industry can use chicken components that have tested positive for *Salmonella* but are below the 1 CFU/gram threshold in NRTE breaded stuffed chicken products, they may incur some costs associated with actions they take on those products that test positive for *Salmonella* but are below 1 CFU/gram. FSIS is requesting comment on the possible costs industry may incur on product that is screened positive for *Salmonella* but then found to be below the 1 CFU/gram threshold.

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[52] and requested in a 2016 National Chicken Council (NCC) petition.[53]

FSIS is not requiring establishments to reformulate or relabel their products as a result of this proposed new policy. However, some manufacturers could choose to reformulate their products and, subsequently, relabel. For example, an establishment may decide to reformulate their product 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 proposed new policy.[54]

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[52] 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)

[53] 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

[54] 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".

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 ready-to-eat based on information in the ingredients statement.[55] 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 $0.14 million per formula, a small establishment is approximately $2.02 million per formula, and a large establishment is approximately $5.05 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, $0.27 million for a small establishment, and $0.67 million for a large establishment. These costs 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.[56] FSIS inflated these costs to 2021 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

[55] 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.

[56] 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.

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 to appear NRTE, they would also likely have to relabel the product, which is estimated to cost $848 per label in 2021 dollars, or $113 annualized over ten years, assuming a 7 percent discount rate.[57] 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 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 chicken components 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 $4.33 million annually, table 14.

[57] 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.

Table 14. Total Industry Costs ($mil)			
Cost Component ($2021)	**Low Estimate**	**Medium Estimate**	**High Estimate**
HACCP Plan Reassessment[1]	$0.0006	$0.0011	$0.0017
Cold Storage	$0.32	$0.35	$0.39
Sampling Plan Development, Reassessment, Training and Implementation	$0.26	$0.41	$0.55
Lost Product	$3.57	$3.57	$3.57
Combined Annualized Costs[2]	$4.15	$4.33	$4.51

[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 proposed 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 is requesting comments on the frequency at which establishments would incur the costs listed in table 15 and on any other possible industry costs resulting from FSIS declaring NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 CFU/gram or higher adulterated.

Table 15. Potential Industry Costs, Annualized ($2021)[1]			
HACCP Plan Validation Per Establishment	**Low Estimate**	**Medium Estimate**	**High Estimate**
Small	$2,153	$4,307	$6,460
Large	$1,723	$3,446	$5,168
Training[2] Per Establishment			
Small	$78	$156	$234
Large	$156	$313	$469
Formula Change			
Very Small	$9,964	$18,837	$32,978
Small	$136,086	$268,562	$480,349
Large	$351,665	$671,745	$1,223,610
Label Change	$27	$113	$239
[1] All Costs annualized at a discount rate of 7% over 10 years. [2] Training Costs includes recurring training			

IV. Agency Costs

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 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 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. FSIS will update this CBA with the final *Federal Register* finalization of the determination once more data on the Agency's sampling plan becomes available.

Each establishment with a confirmed positive *Salmonella* test will be assigned follow-up samples that will be detailed in the NRTE breaded stuffed chicken sampling plan.[58] 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 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 2021 dollars, is about $5,400 per FSA.[59]

V. Benefits

If the proposed policy is finalized and FSIS carries 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 this proposed 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

[58] 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.

[59] 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 2021 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.

reduce illnesses. The Centers for Disease Control and Prevention (CDC) estimate *Salmonella* bacteria cause about 1.35 million infections, 26,500 hospitalizations, and 420 deaths in the United States every year.[60] 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.[61] 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 $4,352 per case in 2021 dollars.[62] 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 $0.57 million, which averages to $51,828 per outbreak. The CDC estimated that the number of actual cases may be higher than the number of reported cases for products for which there is only data for illnesses associated with reported outbreaks available, including NRTE breaded stuffed chicken products.[63] As such, the number of *Salmonella* cases associated with NRTE breaded stuffed chicken products is likely more widespread than these numbers indicate. Therefore, the estimated illness cost burden is likely an underestimate. FSIS requests comments on whether a multiplier

[60] CDC: https://www.cdc.gov/salmonella/index.html (last accessed on 12/7/2022).
[61] 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.
[62] The FSIS estimate for the cost of *Salmonella*-related illness ($4,352 per case, —2021 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.
[63] 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/

should be used to better estimate the illnesses associated with NRTE breaded stuffed chicken products, and if so, what is an appropriate multiplier.

Table 16. *Salmonella* Outbreaks in NRTE breaded stuffed chicken products Between 2006 and 2021[1,2]		
Year with Reported *Salmonella* Outbreaks[1]	Number of Outbreaks	Reported Cases of *Salmonella*
2006	1	3
2008[3]	2	54
2009	2	4
2013	1	3
2014	1	6
2015	2	20
2016	1	5
2021	1	36
Combined	**11**	**131**
Combined Illness Cost		**$570,112**
Average Illness Cost Per Outbreak		**$51,828**

[1]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.
[2]These outbreaks include reported state and national level outbreaks in these products during this period.
[3] While the second outbreak in 2008 spanned two years, 2008-2009, its occurrence and reported cases of Salmonella are included in 2008.

B. Industry Benefits

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, 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, etc.). The Agency also incurs costs for verifying that companies recalled and properly disposed of product.[64]

To estimate how much a recall could cost industry, FSIS used a 2011 report by the Grocery Manufacturers Association done in collaboration with Covington & Burling LLP and Ernst & Young, which surveyed 36 food, beverage, and consumer products companies that have faced a recall in the previous five years.[65] FSIS estimated the average cost of food recalls to companies to be approximately $25.8 million per recall. [66]

C. Total Benefits

From 2006 to 2021 (15 years), there were 11 documented outbreaks. The number of reported cases of *Salmonella* associated with these outbreaks ranged from 3 to 36, table 16. As detailed in the "Consumer Benefits" section, FSIS estimates the average corresponding cost of a single outbreak for NRTE breaded stuffed chicken is approximately $51,828. As detailed in the "Industry Benefits" section, FSIS estimates the average industry cost of a food recall is approximately $25.8 million. Therefore, preventing a single outbreak and outbreak-related recall would result in approximately $25.85 million in benefits ($51,828 + $25.8 million). FSIS uses this information to conduct a break-even analysis in the Summary of Costs and Benefits section.

[64] This includes inspectors' activities at the establishments, FSAs, recall effectiveness checks, and dissemination of information about recalls through press releases.
[65] 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.
[66] 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.

VI. Summary of Costs and Benefits

This proposed new policy is expected to cost industry at least $4.33 million annually, assuming a 7 percent discount rate over a ten-year period. These costs are associated with HACCP plan reassessments, holding chicken components in cold storage awaiting test results, and the costs associated with developing and implementing an establishment-conducted sampling program. To varying degrees, industry may also incur other costs associated with their individual responses to this policy. The Agency would incur costs associated with sampling and testing for S*almonella* and conducting FSAs. However, these costs are likely more than offset by consumer and industry benefits.

The benefit from reduced outbreak-related recalls depends on the number of recalls the proposed new policy prevents annually.[67] With a total estimated industry cost of $4.33 million, and the estimated quantified benefit of one prevented outbreak-related recall being $25.85 million, total benefits would exceed total costs if the proposed new policy prevents at least 1 outbreak-related recall every 5.96 years ($25.85 ÷ $4.33).[68] Although the proposed policy may not prevent every possible *Salmonella*-related outbreak or illness in these products, the benefits of the proposed policy may exceed the costs if the policy contributes to preventing at least 1 outbreak-related recall every 60 months.[69] Between 2006 and 2021 there was one outbreak every 16.4 months on average (15 years ÷ 11 outbreaks). Also, according to the CDC, reported cases

[67] 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.
[68] Numbers may not add up due to rounding.
[69] Numbers rounded to the nearest month.

from outbreaks only represent a fraction of actual cases; therefore, the health benefits associated with this proposed new policy are likely to be higher than estimated in this CBA.[70]

VIII. Potential Impact on Small Businesses

All three of the low-volume establishments that would be impacted by this proposed new policy are HACCP size small or very small.[71] FSIS expects the cost burden of this proposed new policy on low-volume establishments to be small. Nearly 90 percent of production at these three low-volume establishments is product other than NRTE breaded stuffed chicken products. These establishments would choose to incur costs based on their own economic rationale. In addition,

(1) if FSIS finalizes this new policy, FSIS intends to implement routine testing for *Salmonella* and would allow industry time to implement possible changes to food safety systems. A small business would have this time to prepare for changes, lowering the burden.

(2) FSIS assumes establishments needing monetary assistance with this proposed new policy would take advantage of the grants and financial options available to small establishments. More information on these loans and grants can be found on the FSIS website.[72]

[70] Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M., Roy, S. L. Griffin, P. M. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17(1), 7-15. https://doi.org/10.3201/eid1701.p11101.

[71] 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.

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