DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS–2023–0028]

RIN 0583–AD96

Salmonella Framework for Raw Poultry Products

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Proposed rule and Proposed Determination.

SUMMARY: FSIS is announcing its proposed determination that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products contaminated with certain *Salmonella* levels and serotypes are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). The proposed determination would establish final product standards based on these *Salmonella* levels and serotypes and would prevent raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products that contain *Salmonella* at the levels and serotypes that would render them adulterated from entering commerce. FSIS is also proposing to revise the regulations that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation to clarify that these procedures must include a microbial monitoring program (MMP) that incorporates statistical process control (SPC) monitoring methods, to require sampling at rehang instead of pre-chill, and to require that all establishments conduct paired sampling at rehang and post-chill.

DATES: Comments on this proposal must be received on or before October 7, 2024.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to: *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2023–0028. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: Go to the Federal eRulemaking Portal at *https://www.regulations.gov* for access to the rulemaking docket, including any background documents and the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023. For in-person access to background documents or comments received, call (202) 720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS, USDA; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Executive Summary

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled. In support of this mission, FSIS established a *Salmonella* verification testing program in 1996 as part of the ''Pathogen Reduction; Hazard Analysis and Critical Control Point Systems'' (PR/HACCP) final rule (61 FR 38805). Among other things, the PR/HACCP final rule established *Salmonella* pathogen reduction performance standards for raw product to allow FSIS to verify whether establishments have effective process controls to address *Salmonella.* The current performance standards for young chicken and turkey carcasses, raw chicken parts, and comminuted chicken and turkey products are represented as a fraction of the maximum number of allowable *Salmonella*-positive results over a targeted number of samples collected and analyzed in a 52-week moving window. FSIS categorizes establishments based on the *Salmonella* verification sampling results and posts the performance categorization of all establishments subject to the performance standards on the FSIS website. FSIS uses *Salmonella* performance standard categorization as a basis to prioritize in-depth evaluations of failing establishments' food safety systems, including their HACCP plan and sanitation Standard Operating Procedures (SOPs).

While the results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing the proportion of poultry products contaminated with *Salmonella,* these measures have yet to have an observable impact on human illness rates. The estimated rate of human *Salmonella* infections from all sources has remained consistent over the last two decades, with over 1.3 million illnesses estimated in the United States each year. Additionally, while current *Salmonella* performance standards are designed to achieve the Department of Health and Human Services' Healthy People Initiative [1] targets for foodborne illness reduction, the 2010 and 2020 Healthy People targets for a reduction in *Salmonella* infections from all sources were not met. The Healthy People 2030 target is to reduce *Salmonella* infections from all sources to a national case rate of no more than 11.5 per 100,000 consumers per year. To reach this 2030 target, *Salmonella* illnesses must be reduced by 25 percent.

Poultry is among the leading sources of *Salmonella* foodborne illness acquired domestically in the United States.[2] Therefore, on October 19, 2021, FSIS announced that it was mobilizing a stronger, and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products. In the

[1] Launched by the U.S. Department of Health and Human Services (HHS) in 1980, the Healthy People Initiative sets out to create widely accessible plans to help organizations, communities and individuals improve public health. Each decade, HHS releases new goals after evaluating the successes and areas of growth from the previous ten years. They monitor the progress toward Healthy People's objectives using high-quality data and feedback., the HHS benchmark continues to focus on reducing poultry-based *Salmonella* infections by 25 percent, a goal that has not been reached over the last decade. The Healthy People 2030 objectives were released on August 18, 2020.

[2] Interagency Food Safety Analytics Collaboration (FSAC). Foodborne illness source attribution estimates for 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States. GA and DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. 2022. Available at: *https://www.cdc.gov/ifsac/php/annual-reports/?CDC_AAref_Val=https://www.cdc.gov/foodsafety/ifsac/annual-reports.html.*

announcement, FSIS stated that it had initiated several activities designed to gather data and information to inform and support future actions related to this new effort. FSIS charged the National Committee on Microbiological Criteria for Food (NACMCF) to provide guidance on the types of microbiological criteria the Agency might use to better prevent *Salmonella* infections associated with poultry products. The Agency also conducted a risk profile for pathogenic *Salmonella* subtypes in poultry and developed two quantitative risk assessments —one for *Salmonella* in chicken and one for *Salmonella* in turkey. Additionally, FSIS conducted an exploratory sampling program for young chicken carcasses to generate microbial data to help inform future policies and added quantification to its *Salmonella* testing program.

In addition to initiating these activities, on October 17, 2022, FSIS shared with stakeholders a draft regulatory framework that the Agency was considering for a new strategy to control *Salmonella* in poultry products and announced that FSIS would be hosting a virtual public meeting on November 3, 2022, to discuss the framework. The three components under consideration in the draft framework included:

Component One. Requiring that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving and requiring that incoming flocks be tested for *Salmonella* before entering an establishment.

Component Two. Enhancing establishment process control monitoring and FSIS verification.

Component Three. Implementing an enforceable final product standard that would define whether certain raw poultry products contaminated with certain levels and/or serotypes of *Salmonella* are adulterated.

The draft framework under consideration also addressed cross-cutting issues associated with testing for *Salmonella,* considerations for small and very small establishments, and data sharing. At the November 2022 public meeting, stakeholders presented oral comments on the three separate components of the draft framework and the cross-cutting issues. Stakeholders also had an opportunity to submit written comments to FSIS by December 16, 2022.

After carefully evaluating the written comments and other stakeholder input provided on the October 2022 draft framework, along with new studies and information that have become available since the Agency made the October 2022 draft framework available to the public, FSIS is proposing a new regulatory framework targeted at reducing *Salmonella* illnesses associated with poultry products. The proposed regulatory framework reflects the draft framework with some modifications.

First, consistent with Component Three of the October 2022 draft framework, FSIS is proposing final product standards that would define whether certain raw poultry products contaminated with certain *Salmonella* levels and serotypes are adulterated as defined in the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*). Specifically, FSIS has tentatively determined that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if they contain any type of *Salmonella* at or above 10 colony forming units/per milliliter or gram (10 cfu/mL(g)) in analytical portion (*i.e.,* mL of rinsate or gram of product) and contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that commodity. The proposed *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, and comminuted chicken are Enteritidis, Typhimurium, and I 4,[5],12:i:-, and for raw comminuted turkey are Hadar, Typhimurium, and Muenchen. These are the most highly virulent *Salmonella* serotypes associated with these products identified in the FSIS chicken and turkey risk assessments.

The *Salmonella* serotypes of public health significance will likely change over time as the serotypes commonly associated with human illnesses change. FSIS would continue to track annual targets for reducing the proportion of poultry samples that contain *Salmonella* serotypes of public health significance as well as data on rates for additional serotypes commonly associated with human illness to inform future revisions to the *Salmonella* serotypes of public health significance. Should FSIS finalize the proposed final product standards, the Agency intends to further evaluate and, if necessary, refine these standards as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available. If FSIS finalizes the proposed final product standards, the Agency intends to re-evaluate the serotypes of public health concern every 3–5 years at a minimum and whenever new information on *Salmonella* serotypes associated with human illness become available. When evaluating the serotypes, FSIS would consider, among other things, outbreak illness data, foodborne illness surveillance data, product testing data, and animal testing data. FSIS would publicly announce any modifications to the final products standards in the **Federal Register**. FSIS requests comments on this proposed timeline for re-evaluating serotypes of public health concern.

Should FSIS finalize these proposed standards, the Agency intends to conduct a routine sampling and verification testing program for *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey in which the Agency would collect samples of raw final products and analyze them for *Salmonella* levels and serotypes to determine whether the final product is adulterated. Under the proposed *Salmonella* verification testing program, FSIS intends to only collect and analyze samples of the final raw poultry products produced by an establishment, *i.e.,* chicken carcasses to be shipped in commerce as whole chickens, chicken parts to be shipped in commerce as chicken parts, comminuted chicken to be shipped in commerce as comminuted chicken products, and comminuted turkey to be shipped in commerce as comminuted turkey products. Under this proposed determination, chicken parts subject to the final product standards would include legs, thighs, breasts, wings, quarters, and halves.

When FSIS tests a product sample for adulterants, establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, if FSIS finalizes its proposed routine *Salmonella* verification testing program for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, establishments that produce these raw products would need to control and maintain the integrity of the sampled lot pending the availability of test results. If test results detect *Salmonella* at a level of 10 cfu/mL(g) or higher and at least one *Salmonella* serotype of public health significance, FSIS would consider products represented by the sampled lots to be adulterated and would issue a non-compliance record (NR). Therefore, all products in the lot represented by the sample would be prohibited from entering commerce. If any product from the lot represented by the product samples has entered and remains available in commerce, FSIS would request that the producing establishment recall the implicated products. Depending on the circumstances, in addition to issuing an NR, FSIS could take other appropriate

enforcement action as authorized in 9 CFR part 500 because the establishment would have produced and shipped adulterated product. Such actions may include immediately suspending inspection or issuing a Notice of Intended Enforcement (NOIE).

As FSIS implements the final product standards verification sampling program, the Agency has tentatively decided to phase out all current *Salmonella* performance standards for poultry. Thus, when the proposed final product verification sampling program is fully implemented, FSIS has tentatively decided that it would no longer use *Salmonella* sampling results to categorize establishments that produce poultry products and would no longer publish these establishments' performance standards categories on the FSIS website. The Agency is requesting comments on this issue.

Consistent with Component Two of the initial proposed framework, FSIS is proposing to revise the regulations in 9 CFR 381.65(g) and (h) that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation and maintain records documenting those procedures. FSIS is proposing to amend these regulations to establish new requirements pertaining to how establishments monitor and document whether their processes for preventing microbial contamination are in control. The proposed revisions are intended to clarify existing regulatory requirements related to process control monitoring in 9 CFR 381.65(g) and (h).

Under this proposal, establishments would be required to incorporate statistical process control (SPC) monitoring principles into their microbial monitoring programs (MMPs). The proposed revisions would require that establishments use only validated and fit for purpose microbial sampling and analysis procedures, generate and record statistically meaningful microbial monitoring data, set benchmarks by which to evaluate microbial monitoring data, and otherwise define the statistical methods the establishment will use to evaluate the recorded data against the predefined limits. To offset the costs associated with this proposal, eligible very small (VS) and very low volume (VLV) establishments would have access to laboratory services provided by FSIS at no charge to analyze the establishments' microbial monitoring samples for them.

FSIS is further proposing to revise the regulations to ensure that establishments comply with the corrective action provisions required under HACCP as they apply to the establishment's MMP. FSIS is proposing to specifically require establishments to, at a minimum, implement written corrective actions, including a root cause assessment, when microbial monitoring results deviate from the predefined criteria in the MMP, the other process control monitoring results, or the process control determination made for the entire HACCP system.

FSIS has developed new guidance to help establishments meet the proposed updated sampling and analysis requirements under 9 CFR 381.65(g). The new guidance includes a SPC sampling plan based on paired sampling for Aerobic Count (AC) at the rehang and post-chill locations, with a one-sided process control statistical model that charts and calculates against minimum monitoring criteria at the minimum required frequency. Establishments that incorporate the guidance into their MMPs would not be required to provide FSIS with additional scientific or technical information to support their chosen statistical methods. FSIS also is proposing to make available to all poultry slaughter establishments an electronic spreadsheet file that is pre-programmed to calculate the monitoring measures for the guidance sampling plan as results are entered.

In addition, FSIS is proposing to amend the recordkeeping requirements under 9 CFR 381.65(h) to require that establishments submit their microbial monitoring sampling results to FSIS electronically. FSIS is developing a web portal that will allow external partners to securely upload sampling information and submit it to FSIS electronically in a machine-readable format.[3] Should FSIS finalize this proposal, the Agency would provide a template that establishments could use to record and submit their monthly results. Establishments that use the template to record the microbial monitoring results may upload their completed template into the portal or they may enter the information manually into the portal. Establishments that do not use the template provided by FSIS to record their results would need to manually enter microbial sampling data into the portal to submit the monthly data.

Under Component One of the October 2022 draft framework, FSIS considered whether it should require poultry slaughter establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. This approach would require the flock to meet a predetermined target level for *Salmonella* at receiving.

FSIS considered the available scientific research as well as input from the NACMCF and concluded that, at this time, the research does not support the use of a threshold for test results at the receiving step to reduce or eliminate *Salmonella* from raw poultry products. In addition, FSIS received several comments from small poultry processors and producers and trade associations representing the meat and poultry industries that expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers and processors. The comments also stated that requiring that establishments determine that *Salmonella* is a hazard reasonably likely to occur at receiving is inconsistent with HACCP principles. While FSIS has decided at this time not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an establishment, the Agency is focusing on a non-regulatory approach for reducing the *Salmonella* load on incoming birds. The Agency intends to provide updated guidance on pre-harvest interventions and practices for preventing or reducing *Salmonella* colonization of live birds. The Agency also will continue to explore and develop strategies for industry to address *Salmonella* contamination risk at receiving.

Costs and Benefits of the Proposed Rule and Proposed Determination

FSIS estimates this proposal would have a net benefit of $4.1 million per year, ranging from $1.1 million to $6.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, as discussed below (Table 1). This proposal is estimated to cost industry $16.4 million per year, ranging from $3.3 to $32.3 million. The main cost component in this proposal is the requirement that establishments subject to FSIS verification sampling for adulterants maintain control of sampled product pending test results. This cost is likely an overestimate as discussed below. Industry may also incur costs associated with HACCP plan

[3] In a format that provides a digital representation of data or information that can be imported and read into a computer system for further processing.

reassessments and changes to process control requirements.

FSIS estimates this proposal would result in benefits to society of $20.5 million per year, ranging from $4.4 million to $39.0 million. The majority of the benefits are derived from prevented illnesses of $12.9 million per year, ranging from $0.3 to $28.7 million. FSIS also estimated avoided costs from a reduction in the risk of outbreak-related recalls for industry. Additional industry actions in response to this proposal may lead to additional benefits.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Description	Total (million $)		
	Low	Medium	High
Costs:			
Costs associated with the proposed rule:			
Statistical Process Control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total costs	3.31	16.43	32.25
Benefits and Avoided Costs:			
Prevented illnesses from consumption of chicken products	0.09	4.35	15.11
Prevented illnesses from consumption of comminuted turkey	0.19	8.58	13.55
Prevented outbreak-related recalls	4.16	7.56	10.34
Total benefits	4.45	20.49	39.00
Net benefits	1.14	4.06	6.75

Note: All costs and benefits are annualized over 10 years at a 7 percent discount rate. Numbers in table may not sum to totals due to rounding.

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I. Background

A. Salmonella in Poultry and Human Illnesses

1. Salmonella Illnesses Attributed to Poultry

Salmonella in poultry is a significant food safety and public health concern. The Centers for Disease Control and Prevention (CDC) estimates that non-typhoidal *Salmonella* from all sources is responsible for over 1.3 million illnesses, 26,500 hospitalized, and 420 deaths each year in the United States.[4] From this overall number, FSIS estimates that there are 125,115 chicken-associated and 42,669 turkey-associated foodborne *Salmonella* illnesses per year. These values are

[4] Collier SA, Deng L, Adam EA, et al. Estimate of Burden and Direct Healthcare Cost of Infectious Waterborne Disease in the United States. Emerging Infectious Diseases. 2021;27(1):140–149. *https://doi.org/10.3201%2Feid2701.190676.*

calculated as the product of the total number of CDC FoodNet cases per year (7,600),[5] the share of these cases that are foodborne (66 percent) [6] and of domestic origin (89 percent),[7] and the under-diagnosis multiplier for *Salmonella* (24.3),[8] then dividing by the FoodNet catchment area (15 percent).[9] Finally, this number is multiplied by the portion the Interagency Food Safety Analytics Collaboration (IFSAC) estimates is attributable to chicken (17.3 percent) or turkey (5.9 percent).[10] Uncertainty remains in the FSIS estimation of chicken- and turkey-associated foodborne *Salmonella* illnesses per year. These illness estimates are subject to the same limitations encountered with other illness estimates.[11] Nevertheless, FSIS believes these are the best available estimates.

Salmonella illnesses associated with poultry also represent a considerable economic burden, particularly when accounting for not just the direct medical costs, but also productivity losses, lost life expectancy, chronic illness, and other associated pain and suffering. A recent study estimates that the economic costs of *Salmonella* illnesses in the United States associated with chicken is $2.8 billion annually.[12]

2. Salmonella Performance Standards for Poultry

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled. In support of this mission, FSIS began its *Salmonella* verification testing program with the PR/HACCP final rule, published on July 25, 1996 (61 FR 38806). Among other things, the PR/HACCP final rule established *Salmonella* pathogen reduction performance standards for establishments that slaughter selected classes of food animals and/or that produce selected classes of raw ground products.[13] The purpose of the *Salmonella* performance standards for raw product is to allow FSIS to verify whether establishments have effective process controls to address *Salmonella.* Since publishing the PR/HACCP final rule, FSIS has updated the performance standards for poultry products through a series of **Federal Register** notices.[14]

FSIS has established *Salmonella* performance standards for young chicken and turkey carcasses, raw chicken parts, and comminuted chicken and turkey products. The current performance standards are expressed as a fraction of the maximum number of allowable *Salmonella*-positive results over a targeted number of samples collected and analyzed in a 52-week moving window (see Table 2). FSIS categorizes establishments based on the *Salmonella* verification sampling results and posts the categorization of all establishments subject to the performance standards on the FSIS website.[15] [16] In addition, FSIS schedules follow-up verification sampling, a Public Health Risk Evaluation (PHRE),[17]

[5] Collins JP, Shah HJ, Weller DL, et al. Preliminary Incidence and Trends of Infections Caused by Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2021. MMWR Morb Mortal Wkly Rep 2022;71:1260–1264. DOI: *https://doi.org/10.15585/mmwr.mm7140a2. Note: the most recent annual FoodNet report was used for the total estimated FoodNet cases annually.*

[6] Beshearse E, Bruce BB, Nane GF, Cooke RM, Aspinall W, Hald T, et al. Attribution of Illnesses Transmitted by Food and Water to Comprehensive Transmission Pathways Using Structured Expert Judgment, United, States. Emerg Infect Dis. 2021;27(1):182–195. *https://doi.org/10.3201/eid2701.200316.* Note: This article represented a recent appraisal of the foodborne share of all *Salmonella* illnesses.

[7] 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. Emerg Infect Dis. 2011 Jan;17(1):7–15. doi: 10.3201/eid1701.p11101. PMID: 21192848; PMCID: PMC3375761. Note: This article outlines the general approach to estimating the burden of domestic foodborne illnesses. It provides an estimate for share of foodborne illnesses associated with foreign travel (11%) that was supported in the more recent Collins et al. (2022) article referenced above.

[8] Ebel, E.D., Williams, M.S., & Schlosser, W.D. (2012). Parametric distributions of underdiagnosis parameters used to estimate annual burden of illness for five foodborne pathogens. J Food Prot, 75, 775–778. *https://doi.org/10.4315/0362-028X.JFP-11-345.* Note: This article estimated parametric distributions for uncertainty about the under-diagnosis multiplier based on the Scallan et al. (2011) model assumptions.

[9] Scallan et al. (2011).

[10] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States. GA and DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. 2022. Annually, IFSAC releases a report that estimates foodborne illness source attribution for major commodity groups, including *Salmonella* in poultry products. At the time this proposal was developed, the 2019 IFSAC attribution estimates were the most recent data available. IFSAC released a new annual report in November 2023, which includes attribution estimates for 2020. In the 2023 report, IFSAC estimated that 18.6 percent of *Salmonella* illnesses are attributed to chicken products and 5.5 percent to turkey products, for a total 24.1 percent attributed to poultry products. FSIS intends to incorporate the 2023 report attribution estimates if this rule becomes final.

[11] Illness estimates from any risk assessment model are limited by uncertainty, simply because they are models. As explained by Food and Agriculture Organization of the World Health Organization (FAO/WHO), ''uncertainty is a property of the methodology and data used. Assessments with different methodologies and data will have different levels of uncertainty regarding their outputs. An understanding of uncertainty is important because it provides insight into how the lack of knowledge can affect decisions.'' *See* FAO/WHO *Microbiological Risk Assessment Guidance for Food (MRA 36)* at 206. FAO/WHO goes on to say, ''It is the risk managers' role to decide if the uncertainty of a risk assessment output allows for a decision to be made or not.'' *Id.* FSIS fully explored uncertainty in its risk assessment models to allow risk managers to make a fully informed decision. Full details are on pages 116–128 of the chicken risk assessment and pages 94–99 of the turkey risk assessment. The code for these analyses has also been provided.

[12] Scharff R.L. Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses. Journal of Food Protection. 2020; 83(6): 959–967.

[13] When FSIS initially implemented the *Salmonella* performance standards, the regulations authorized FSIS to suspend inspection if an establishment failed to take the corrective actions necessary to comply with the performance standards, or if an establishment failed to meet the standards on the third consecutive series of FSIS-conducted tests for that product. However, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc.* v. *USDA,* 275 F.3d 432 (5th Cir. 2001). In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the *Salmonella* performance standards. Since that time, FSIS has used *Salmonella* failures as a basis to conduct an in-depth evaluation of the establishment's food safety systems, including its HACCP plan and sanitation SOPs.

[14] See *Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection* (71 FR 9772, Feb 27, 2006); *New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule* (76 FR 15282, Mar 21, 2011); *New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule* (81 FR 7285, Feb 11, 2016); *Changes to the Salmonella and Campylobacter Verification Testing Program: Revised Categorization and Follow-Up Sampling Procedures* (83 FR 56046, Nov 9, 2018).

[15] *Salmonella* Categorization of Individual Establishments for Poultry Products at: *https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/salmonella-verification-testing-program-monthly.*

[16] The category definitions under verification sampling are as follows:

- Category 1: Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52- week moving window;
- Category2: Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recently completed 52-week moving window; and
- Category 3: Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

[17] 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*).

and possibly a Food Safety Assessment (FSA) [18] for establishments that do not meet the pathogen reduction performance standards. If, after 90 days, an establishment has not been able to regain process control, as determined from FSIS' follow-up sampling and from the results of the PHRE or FSA, and the establishment has not taken corrective actions, FSIS may take enforcement actions, such as by issuing a NOIE or by suspending inspection, under the conditions and according to the procedures described in 9 CFR part 500 (81 FR 7285, 7289). FSIS does not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a performance standard.

TABLE 2—SALMONELLA PERFORMANCE STANDARDS FOR POULTRY PRODUCTS

Product	Performance standard *	Maximum acceptable percent positive	Minimum number of samples to assess process control
Broiler Carcasses	5 of 51	9.8	11
Turkey Carcasses	4 of 56	7.1	14
Comminuted Chicken	13 of 52	25.0	10
Comminuted Turkey	7 of 52	13.5	10
Chicken Parts	8 of 52	15.4	10

* The performance standard is represented as a fraction of the maximum allowable positives over the target number of samples collected and analyzed in a 52-week window.

3. Salmonella Performance Standards and Illnesses

The current *Salmonella* performance standards are based on risk assessments [19] and are designed to achieve the Healthy People targets for foodborne illness reduction. When FSIS implemented the performance standards, the Agency expected that there would be an observed reduction in *Salmonella* illnesses rates because a smaller proportion of certain raw poultry products would likely be contaminated with *Salmonella* than had been the case without standards (81 FR 7285). The results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing *Salmonella* contamination in poultry.[20] [21] [22] However, these measures have yet to have an observable impact on *Salmonella* illnesses. With respect to foodborne illness reduction goals, the Healthy People 2020 objectives had aimed to reduce the annual number of foodborne illnesses caused by *Salmonella* from 15.0 per 100,000 population in 2006–2008 [23]. However, the CDC estimated that in 2019, Americans experienced 17.1 per 100,000 population *Salmonella* illnesses.[24] This represents an increase of 14 percent from the 2006–2008 baseline. As discussed below, there are likely several reasons why the reduction in *Salmonella* contamination in poultry products has not resulted in an observable impact on *Salmonella* illnesses.

With respect to *Salmonella* illnesses associated with chicken and turkey, one study found that the proportion of outbreaks associated with these commodities was essentially unchanged from 1998–2017 and that both the proportion of outbreaks and number of outbreaks associated with chicken remained essentially constant.[25] During that period, the per capita annual consumption for pork, beef, and turkey all declined between 9 percent and 22 percent, while annual consumption of chicken increased by 15 percent.

The overall findings of another study indicated declining trends in illness due to *Salmonella* serotypes associated with poultry and increasing trends in illness due to *Salmonella* serotypes not associated with poultry.[26] However, illness attribution was not an objective of the analysis. Thus, the observed illness declines may have been caused by reduced risk in non-poultry sources that have poultry-like serotype profiles.

The Healthy People 2030 target is to reduce the *Salmonella* illness national case rate of 15.3 per 100,000 population in 2016–2018 by 25 percent, or to no more than 11.5 per 100,000 population per year.[27] Thus, to reach the 2030 target, illnesses must be reduced by 25 percent. Although this target is for *Salmonella* illnesses from all sources, FSIS has adopted the same target for foodborne illnesses linked to FSIS-regulated products and aims to reduce these *Salmonella* illnesses by 25 percent. To move closer to achieving this target, FSIS has determined that it will need to adopt a new approach to more effectively reduce foodborne illness associated with FSIS-regulated products, starting with poultry as one of the leading food sources.

[18] 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—Food Safety Assessment Methodology (*usda.gov*).

[19] Ebel, E.D., Williams, M.S., Golden, N.J., Marks, H.M., 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. Food Control 28, 250–257; Williams, M.S., Ebel, E.D., Vose, D., 2011. Framework for microbial food-safety risk assessments amenable to Bayesian modeling. Risk Analysis 31, 548–565.

[20] Ebel E.D., Williams M.S., and Schlosser W.D. (2017). Estimating the Type II error of detecting changes in foodborne illness via public health surveillance. *Microbial Risk Analysis* 7: 1–7. *https://doi.org/10.1016/j.mran.2017.10.001.*

[21] Ebel, ED and Williams MS (2020). Assessing the effectiveness of revised performance standards for Salmonella contamination of comminuted poultry. *Microbial Risk Analysis* 14:100076. *https://doi.org/10.1016/j.mran.2019.05.002.*

[22] Williams MS, Ebel ED, Golden NJ, Saini G, Nyirabahiizi E, and Clinch N (2022). Assessing the effectiveness of performance standards for Salmonella contamination of chicken parts. *International Journal of Food Microbiology* 378: 109801. *https://doi.org/10.1016/j.ijfoodmicro.2022.109801.*

[23] HHS Office of Disease Prevention and Health Promotion archive. Healthy People 2020 at: *https://wayback.archive-it.org/5774/20220414163116/https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives.*

[24] Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food—Foodborne Disease Active Surveillance Network, 10 U.S. Sites, 2016–2019, MMWR Morb Mortal Wkly Rep 202;69:509–514. Available at: *https://www.cdc.gov/mmwr/volumes/69/wr/mm6917a1.htm#T1_down.*

[25] Williams, M.S., & Ebel, E.D. (2022). Temporal changes in the proportion of *Salmonella* outbreaks associated with 12 food commodity groups in the United States. *Epidemiology and infection, 150,* e126. *https://doi.org/10.1017/S0950268822001042.*

[26] Powell M.R. (2023). Trends in reported illnesses due to poultry-and nonpoultry associated Salmonella serotypes; United States 1996–2019. *Risk Analysis. https://doi.org/10.1111/risa.14181.*

[27] HHS Office of Disease Prevention and Health Promotion archive. Healthy People 2030 at: *https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-Salmonella-fs-04/data?group=None&state=United+States&from=2016&to=2018&populations=&tab=data-table#data-table.*

B. Consideration of Need for a New Framework To Control Salmonella in Poultry

1. Petitions and Initial Stakeholder Input

Consumer advocacy organizations and other stakeholders have noted that the Healthy People *Salmonella* reduction targets have not been met and have submitted petitions and letters to FSIS requesting that the Agency revise its current approach for reducing *Salmonella* illnesses associated with poultry. For example, in January 2020, Marler Clark LLP submitted a petition on behalf of several individuals and consumer advocacy organizations requesting FSIS to issue an interpretive rule to declare 31 *Salmonella* serotypes that have been associated with foodborne illness outbreaks to be adulterants of all meat and poultry products.[28] According to the petition, such action is needed to protect the health and welfare of consumers by encouraging the meat and poultry industry to engage in more effective oversight measures and create and implement effective preventative measures.

In May 2022, FSIS denied the petition without prejudice, citing a lack of sufficient data available to support the sweeping actions requested in the petition. In the response, FSIS agreed that an updated *Salmonella* strategy is necessary to reduce *Salmonella* illnesses associated with poultry and described how FSIS was working towards gathering data and information necessary to support a revised strategy.[29]

On January 25, 2021, the Center for Science in the Public Interest (CSPI) and other consumer advocacy organizations petitioned FSIS to establish enforceable standards targeting *Salmonella* types of greatest public health concern and all *Campylobacter*[30] in poultry.[31] Referencing the Healthy People reduction goals, the petition asserted that FSIS' current performance standards have not been effective in reducing *Salmonella* illnesses because they aim to reduce the prevalence of all *Salmonella* rather than prioritizing control efforts for the *Salmonella* serotypes most likely to make people sick. The petition laid out several suggestions for standards that FSIS could use to address *Salmonella* in poultry. The petition recommended that FSIS work with stakeholders and other public health agencies to establish enforceable final product standards to target *Salmonella* serotypes of greatest public health concern with an aim to eliminate these strains from poultry products over time. The petition also suggested that FSIS consider revising the current prevalence-based *Salmonella* performance standard to provide for quantitative testing and add *Salmonella* levels to the performance standards criteria to better ensure that when *Salmonella* is present on a product, it is present at low levels less likely to cause human illness. The petition asserted that FSIS is authorized to deem poultry products that contain virulent *Salmonella* strains and that contain pathogen levels above a set threshold to be adulterated under the PPIA because more virulent serotypes and certain levels of *Salmonella* are more likely to render poultry products injurious to health as defined in 21 U.S.C. 453(g)(1).

The 2021 CSPI petition also requested that FSIS initiate rulemaking to require that poultry establishments identify and control foodborne hazards within their supply chains, including *Salmonella.* The petition stated that supply chain interventions may include targeted vaccines developed for specific *Salmonella* serotypes and purchasing chicks from suppliers certified to be free of priority serotypes. The petition asserted that FSIS is authorized to require supply chain controls through the current HACCP regulations, which direct establishments to address, as appropriate, hazards both introduced in the establishment and introduced outside the establishment, including food safety hazards that occur before entry into the establishment (9 CFR 417.2). The petition also asserted that FSIS has authority to verify the effectiveness of supply chain controls under the PPIA's antemortem inspection authority, which requires FSIS to conduct an antemortem inspection in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under the PPIA ''where and to the extent considered . . . necessary,'' ''[f]or the purpose of preventing the entry into or flow or movement in commerce of . . . any poultry product which is capable of use as human food and is adulterated'' (21 U.S.C. 455(a)). FSIS has not yet responded to the 2021 CSPI petition but has considered the issues raised in developing this proposal.

In September 2021, FSIS received a letter from the Food Safety Coalition (FSC), a coalition of several food safety leaders, public health and consumer advocates, scientists, and members of the food industry. Like the CSPI petition, the FSC letter noted that although FSIS' current prevalence-based pathogen reduction performance standards have led to reduced occurrence of *Salmonella* contamination in poultry products, the Healthy People 2020 goals set by the Department of Health and Human Services in 2010 for lowering *Salmonella* and *Campylobacter* illness rates were not being met. The FSC letter stated that the likely reason is that FSIS' current *Salmonella* performance standards do not effectively target the particular types of *Salmonella* and products containing *Salmonella* levels that pose the greatest risks of illness. The letter stated that a new approach is needed to achieve the new Healthy People 2030 *Salmonella* illness rate target and presented several suggested changes to help reduce the rates of foodborne illness. The proposed changes recommended by the FSC included establishing modernized enforceable pathogen standards that ''invite innovation,'' as well as modernizing the HACCP framework to address risk reduction across the full production process, including defining the responsibility of poultry processors to consider pre-harvest practices and interventions in their HACCP plans.[32]

2. FSIS Announces New Salmonella Effort

After considering the available data on *Salmonella* illnesses associated with poultry as well as the initial stakeholder input discussed above, on October 19, 2021, FSIS announced that it was mobilizing a stronger, and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products.[33] In the

[28] Marler Clark LLP petition # 20–01 ''Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of *Salmonella enteritica* subspecies to be Adulterants'' dated January 19, 2020. Available at: *https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes.*

[29] FSIS Final Response to Petition #20–01, May 31, 2022. Available at: *https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes.*

[30] While the CSPI requested that FSIS take actions related to both *Salmonella* and Campylobacter, FSIS is currently focusing on re-evaluating its approach to prevent *Salmonella* illnesses associated with poultry.

[31] CSPI petition #21–01, ''Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls'' (January 25, 2021) at: *https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest.*

[32] Food Safety Coalition Letter, September 2, 2021. Available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry.*

[33] USDA Press Release, ''USDA Launches New Effort to Reduce *Salmonella* Illnesses Linked to

announcement, FSIS explained that the Agency would be initiating several key activities to gather the data and information necessary to support future action and move closer to the national target of a 25 percent reduction in *Salmonella* illnesses. The announcement also stated that FSIS intended to seek stakeholder feedback on specific *Salmonella* control and measurement strategies as well as using data to determine if there are other approaches to reduce *Salmonella.* The announcement noted that the effort would leverage USDA's strong research capabilities and highlighted that FSIS would ask the National Advisory Committee for Microbiological Criteria in Foods (NACMCF) to advise the Agency on how it can build on the latest science to improve its approach to *Salmonella* control. The announcement emphasized that FSIS would work closely with stakeholders on informing and implementing key activities of this framework.

Following this announcement, the Coalition for Poultry Safety Reform, a multistakeholder coalition that includes individuals and organizations representing consumers, victims of foodborne illness, food safety scientists, food safety officials, and members of the poultry industry, submitted a letter to the USDA Deputy Under Secretary for Food Safety in 2022 expressing support for a new effort to address *Salmonella.* The letter requested that FSIS focus its efforts on developing new regulatory standards related to *Salmonella* covering both products and supply chains and that these standards be informed by a risk assessment based on existing data.[34] The letter recommended that FSIS adopt enforceable product standards aimed at reducing risk of illness and develop and conduct a risk assessment to understand illness reduction benefits of various product standards.

3. Activities Initiated To Support a New Salmonella Framework

After FSIS announced its new initiative to reduce *Salmonella* illnesses associated with poultry products, the Agency initiated several activities designed to gather data and information to inform and support future actions related to this new effort.

National Advisory Committee Charge. On October 20, 2021, FSIS announced a public meeting of NACMCF from November 17, 2021, to November 19, 2021, to discuss, among other things, a new charge focused on enhancing *Salmonella* control in poultry products.[35] Specifically, FSIS charged the NACMF Subcommittee on Enhancing *Salmonella* Control in Poultry Products to provide guidance on the overarching risk management question: What types of microbiological criteria (*e.g., Salmonella* performance standards) might FSIS use to encourage reductions in *Salmonella* in poultry products so that they are more effective in preventing human *Salmonella* infections associated with these products? [36] FSIS also requested that the Subcommittee provide guidance on nine additional specific risk management questions. On April 25, 2022, NACMCF held a Subcommittee meeting for the workgroups addressing each of the questions in FSIS' charge to provide an update to the entire Subcommittee on their progress and to look at the overall timeline for completing the work of the Subcommittee.[37] On November 15, 2022, NACMCF held a virtual public meeting to discuss and vote on the Subcommittee's report on *Enhancing Salmonella Control in Poultry Products,* which had been posted to the FSIS website on November 1, 2022.[38] NACMCF adopted the final report pending finalization with consideration given to oral comments provided at the virtual public meeting and written comments submitted as directed in a **Federal Register** notice announcing the public meeting.[39] The comment period for the NACMCF report was scheduled to close on November 15, 2022, but was extended to December 30, 2022, to provide 60 days for public review.[40] After considering the public comments, NACMCF finalized its report on March 13, 2023. The final report ''Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products'' (referred to as the 2023 NACMCF report in this document) is available to the public on the FSIS website at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

Pilot Projects. In December 2021, FSIS announced in its *Constituent Update* that the Agency was inviting poultry slaughter and processing establishments to submit proposals for pilot projects that will test different control strategies for *Salmonella* contamination in poultry products.[41] The announcement explained that pilot projects would last for a defined period, during which establishments would experiment with new or existing pathogen control and measurement strategies and share data collected during the pilots with FSIS. The announcement included instructions on how interested establishments could submit proposals for pilots to FSIS. FSIS intended to analyze the data generated under the pilots to determine whether it supports changes to FSIS' existing *Salmonella* control strategies.

Since March 2023, FSIS has granted pilot projects to 9 establishments to examine the merits and logistics of excluding *Salmonella* poultry vaccine strains from the FSIS *Salmonella* performance categorization calculations. After evaluating the data collected under these pilots, on March 1, 2024, FSIS announced that beginning April 1, 2024, it intends to exclude current commercial vaccine subtypes confirmed in FSIS raw poultry samples from the calculation used to categorize establishments under the raw poultry *Salmonella* performance standards.[42] This action is intended to remove barriers to the use of vaccination as an important pre-harvest intervention to

Poultry'' (October 19, 2021) at: *https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry.*

[34] Coalition for Poultry Safety Reform Letter, February 2, 2022. Available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry.*

[35] National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMF) Public Meeting —November 2021. Available at: *https://www.fsis.usda.gov/news-events/events-meetings/national-advisory-committee-microbiological-criteria-foods-nacmcf-2.*

[36] 2021–2023 National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMF); FSIS Charge: Enhancing *Salmonella* Control in Poultry Products Available at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

[37] NACMCF FSIS Charge: Enhancing *Salmonella* Control in Poultry, April 25, 2022. Available at: *https://www.fsis.usda.gov/news-events/events-meetings/national-advisory-committee-microbiological-criteria-foods-nacmcf-fsis.*

[38] Public Meeting; National Advisory Committee on Microbiological Criteria for Food, Nov 15, 2022. Available at: *https://www.fsis.usda.gov/news-events/events-meetings/public-meeting-national-advisory-committee-microbiological-criteria.*

[39] Public Meeting National Advisory Committee on Microbiological Criteria for Food (87 FR 64001). Available at: *https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices/public-meeting-national-advisory.*

[40] FSIS Constituent Update—Nov 10, 2022: *Deadline Extended to Comment on NACMCF Document.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-november-10-2022.*

[41] FSIS Constituent Update—Dec 3, 2021: *FSIS Seeking Proposals for Pilot Projects to Control Salmonella in Poultry Slaughter and Processing Establishments.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-december-3-2021.*

[42] FSIS Constituent Update—March 1, 2024: *FSIS Intends to Exclude Vaccine Strains from the FSIS Salmonella Performance Categorization* at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-march-1-2024.*

control *Salmonella* in poultry. A summary report of the data from these pilots is posted on the Pilot Projects: *Salmonella* Control Strategies page of the FSIS website at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot.*

On September 23, 2023, FSIS granted a pilot to 2 establishments to examine the merits of using preharvest results to optimize establishment interventions.[43] The data generated under the pilot will be shared with and analyzed by FSIS to determine whether it supports changes to FSIS' *Salmonella* control strategies.

Research and Science Roundtable. On February 15, 2022, FSIS held a research and science roundtable on *Salmonella* in poultry.[44] The intent of the roundtable was to convene research scientists to discuss the scientific support for various potential components of a revised strategy for *Salmonella* control in poultry. Among the topics discussed at the roundtable were: research on surveillance and risk assessments to evaluate the public health impact of the presence of *Salmonella* serotypes of concern and levels of contamination at production; research on *Salmonella* serotype dynamics in poultry production; research to identify pre-harvest food safety challenges and solutions; research modeling and correlation analysis work on pre-harvest in poultry; research on interventions to control *Salmonella* in preharvest and postharvest poultry production; and research in the area of microbial biomapping of indicators and pathogenic loads throughout the processing chain and using pre-harvest and post-harvest quantification data to develop SPC programs. The presentations on these topics and other materials associated with the research roundtable are available to the public on the FSIS website at: *https://www.fsis.usda.gov/news-events/events-meetings/Salmonella-poultry-research-and-science-roundtable.*

Exploratory Sampling Program and New Salmonella Quantification System. In April 2022, FSIS initiated an exploratory program that expanded young chicken carcass sampling at establishments subject to the young chicken carcass performance standard.[45] The purpose of the exploratory sampling program was to generate microbial data to inform the Agency's effort to reduce *Salmonella* illnesses attributable to poultry. Under the program, in addition to the FSIS *Salmonella* verification sample already collected at post-chill, FSIS inspection program personnel (IPP) began collecting a second carcass sample at rehang from the same flock. In addition, FSIS IPP were instructed to collect the regularly scheduled National Antibiotic Resistance Monitoring System (NARMS) cecal samples from the same flock as the rehang and post-chill samples. The samples collected under the exploratory sampling program were initially analyzed for the presence of *Salmonella* and AC. FSIS IPP also completed a questionnaire at the time they collected exploratory samples to collect data on pre-harvest and slaughter interventions applied to the same flocks. A report on the exploratory sampling results is available at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

In August 2022, FSIS announced that FSIS laboratories would begin using new technology to quantify *Salmonella* in raw poultry rinses and updated the exploratory sampling program for young chickens to quantify confirmed *Salmonella* positive rehang and post-chill carcass results using the new quantification system.[46] These analyses were in addition to the whole genome sequencing (WGS) that FSIS had already been performing on confirmed *Salmonella*-positive post-chill carcass samples.

On January 30, 2023, FSIS added *Salmonella* quantification testing and AC indicator analyses to chicken part rinsates.[47] FSIS added these two analyses to comminuted chicken testing on February 27, 2023, and to comminuted turkey on April 3, 2023. *Salmonella* quantification is a significant step in updating the diagnostic capabilities of FSIS' food testing laboratories. The data generated from the new quantification system along with the data collected from the young chicken carcass exploratory sampling program were used to help inform the policies discussed in this document, including the quantitative microbial risk assessments to evaluate *Salmonella* in raw poultry discussed below. The data generated from the quantification system have also been added to FSIS' quarterly dataset release and are available at: *https://www.fsis.usda.gov/science-data/data-sets-visualizations/laboratory-sampling-data*.

Risk Profile. In May 2022, FSIS initiated a risk profile for *Salmonella* subtypes in poultry linked to foodborne illness. FSIS developed the risk profile to provide information on whether certain serotypes or subtypes of *Salmonella* should be considered as adulterants in specific poultry products within the meaning of the PPIA (21 U.S.C. 453(g)). The risk profile involved a comprehensive systematic review of literature and supporting data designed to provide responses to the following six risk management questions:

1. What *Salmonella* serotypes or subtypes are linked to foodborne illness or outbreaks from consuming specific raw or not-ready-to-eat chicken or turkey products?
2. Are these *Salmonella* serotypes or subtypes of concern present in live chickens, live turkeys, and poultry products?
3. Can exposure to a small number of these *Salmonella* serotypes or subtypes of concern result in foodborne illness?
4. Can exposure to these *Salmonella* serotypes or subtypes of concern cause severe, debilitating health outcomes?
5. How can these *Salmonella* serotypes or subtypes of concern be differentiated from other *Salmonella* subtypes?
6. Would ordinary consumer handling or preparation practices affect exposure to *Salmonella* serotypes or subtypes of concern?

The risk profile was submitted for independent peer-review [48] and updated in response to peer review comments. The results of the risk profile and how they were used to inform specific measures proposed in this document are discussed below. The final *Risk Profile for Pathogenic Salmonella in Poultry* (referred to as the 2023 risk profile in

[43] Pilot Projects: *Salmonella* control strategies. Current *Salmonella* Pilot Participants available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot.*

[44] *Salmonella* in Poultry: Research and Science Roundtable. Available at: *https://www.fsis.usda.gov/news-events/events-meetings/Salmonella-poultry-research-and-science-roundtable.*

[45] FSIS Constituent Update—April 22, 2022: *FSIS Expands Salmonella Sampling for Young Chicken Carcasses.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-22-2022.*

[46] FSIS Constituent Update—Aug 5, 2022: *FSIS to include Salmonella Quantification in all Poultry Rinse Samples.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-august-5-2022-0.* FSIS Notice 44–22, *Revised Young Chicken Exploratory Sampling Program,* Aug 11, 2022.

[47] FSIS Constituent Update—Feb 3, 2023: FSIS to Expand *Salmonella* Enumeration and Aerobic Count Indicator Testing to Other Poultry Products. Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-february-3-2023.* Notice 83–23, *New Sampling Instructions and Testing for Chicken Parts and NRTE Comminuted Poultry,* Feb 3, 2023. Available at: *https://www.fsis.usda.gov/policy/fsis-notice/08-23.*

[48] *Peer Review Plan: Risk Profile for Salmonella Subtypes in Poultry Products Linked to Foodborne Illness (usda.gov).*

this document) is available at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

Risk Assessments FSIS Developed to Inform Rulemaking. FSIS conducted two new quantitative microbial risk assessments, one for *Salmonella* in chicken and one for *Salmonella* in turkey, to inform the Agency's new framework for reducing *Salmonella* attributed to poultry consumed in the United States. FSIS expanded on this work through a Cooperative Agreement (FSIS–02152022) with the University of Maryland's Joint Institute for Food Safety and Applied Nutrition (UMD–JIFSAN), in partnership with EpiX Analytics, to differentiate *Salmonella* serotypes by virulence using advanced bioinformatics (*i.e.,* machine learning) to evaluate genomic data.[49] The risk assessments address the following risk management questions:

1. What is the public health impact (change in illnesses, hospitalizations, and deaths) achieved by eliminating at receiving a proportion of chicken (or turkey) contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?

2. What is the public health impact (change in illnesses, hospitalizations, and deaths) achieved by eliminating final product contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?

3. What is the public health impact of monitoring/enforcing process control from rehang to post-chill? Monitoring could include analytes such as *Enterobacteriaceae Count* (EB), AC, or other indicator organisms, analysis could include presence/absence or levels and the monitoring could also include variability of actual result versus expected result, log reduction, absolute sample result, or other individual establishment specific criteria.

4. What is the public health impact of implementing combinations of the risk management options listed above?

The risk assessments were submitted for independent peer-review [50] and updated in response to peer review comments. The risk assessments, and the manner in which the results were used to inform specific measures proposed in this document, are discussed below. The final *Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products* and *Quantitative Risk Assessment for Salmonella in Raw Turkey and Raw Turkey Products* (referred to as the 2023 risk assessments in this document) are available at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

4. Initial Measures Implemented To Address Salmonella Illnesses Associated With Consumption of Poultry Products

After FSIS announced its new *Salmonella* initiative in October 2021, in addition to initiating the activities to gather data to inform and support a new *Salmonella* Framework discussed above, the Agency implemented some initial measures to support this effort.

Salmonella Key Performance Indicator. As part of USDA's strategic and performance planning process for fiscal years (FY) 2022–2026, FSIS established a new ''key performance indicator'' (KPI) targeted to reduce the proportion of poultry samples with *Salmonella* serotypes commonly associated with human illnesses.[51] This KPI is a measure that is used to evaluate FSIS' progress towards reaching its objectives and goals identified in both Agency and USDA strategic plans and will serve as a metric for success for the USDA FY 2022–2026 Strategic Plan. FSIS analyzed historical Agency sampling data, in addition to FoodNet Fast data from the CDC, to determine the top three *Salmonella* serotypes commonly associated with human illness for this measure. The analysis found that these serotypes are Infantis, Enteritidis, and Typhimurium. FSIS will use annual targets to track progress toward reducing the proportion of poultry samples with the KPI serotypes and is seeking a 2 percent reduction each year, with the goal of achieving a 10 percent reduction by FY 2026. KPI serotypes are useful for strategic and performance planning purposes, and these may differ from the serotypes of public health significance (which will likely change over time as the serotypes commonly associated with human illnesses change).

Final Determination. On August 1, 2022, FSIS announced that it would be declaring *Salmonella* as an adulterant in breaded and stuffed not-ready-to-eat (NRTE) chicken products (also referred to as ''NRTE breaded stuffed chicken products'').[52] These products contain raw, comminuted chicken breast meat, trim, 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.[53] Although the labeling of NRTE breaded stuffed chicken products has undergone significant changes over time to better inform consumers that the products are raw and to provide instructions on how to prepare them safely, these products continue to be associated with *Salmonella* illness outbreaks. Based on information from *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products and information from research on consumer handling practices with respect to these products, FSIS concluded that labeling that informs consumers that these products are raw and how to prepare them safely fails to sufficiently protect consumers from illness.

On April 28, 2023, FSIS published a proposed determination to declare that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu per gram or higher are adulterated within the meaning of the PPIA (88 FR 26249). FSIS also proposed to carry out verification procedures, including sampling and testing of the chicken component of NRTE breaded stuffed chicken products prior to stuffing and breading, to ensure producing establishments control *Salmonella* in these products. The comment period for the proposed determination was scheduled to close on June 27, 2023, but was extended to August 11, 2023, in response to requests from members of the regulated industry.[54]

[49] FSIS Constituent Update—July 1, 2022: *FSIS Announces Cooperative Agreement on Salmonella Risk Assessments.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-1-2022. Salmonella* Risk Assessments and Risk Management Questions at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-Salmonella-poultry/Salmonella-1.*

[50] Peer Review Plan: Quantitative Microbial Risk Assessment of Salmonella in Chicken Products available at: *https://www.fsis.usda.gov/sites/default/files/media__file/documents/FSIS__Salmonella__Peer__Review__Plan__Chicken.pdf.*Peer Review Plan: Quantitative Microbial Risk Assessment of Salmonella in Turkey Products available at: *https://www.fsis.usda.gov/sites/default/files/media__file/documents/FSIS__Salmonella__Peer__Review__Plan__Turkey.pdf.*

[51] FY2022–2024 Food Safety Key Performance Indicator. Available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-Salmonella-poultry/Salmonella-0#:~:text=FY2022–2026FoodSafetyKeyPerformanceIndicatorA,theUSDAFiscalYear28FY292022–2026StrategicPlan.*

[52] *Salmonella* as an Adulterant in Breaded Stuffed Raw Chicken Products (Aug 1, 2022). Available at: *https://www.usda.gov/media/press-releases/2022/08/01/usda-announces-action-declare-Salmonella-adulterant-breaded-stuffed.*

[53] FSIS Directive 5300.1, Revision 1. Managing the Establishment Profile in the Public Health Information System. (usda.gov). See attachment 2 ''NRTE Stuffed Chicken Products that appear RTE.''

[54] FSIS Constituent Update—July 21, 2023: *FSIS Extends Comment Period on Proposed Determination: Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products.* Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-21-*

Continued

FSIS received 3,386 comments on the proposed determination. After careful consideration of the comments, on May 1, 2024, FSIS finalized the determination as proposed, with one change (89 FR 35033). Instead of collecting samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce a final NRTE breaded stuffed chicken product, as was proposed, FSIS will collect verification samples on the raw incoming chicken components. This change was intended to provide greater flexibility and reduce costs to industry.

As noted above, NRTE breaded stuffed chicken products are adulterated if they contain *Salmonella* at 1 cfu/g or higher, regardless of the *Salmonella* serotype. FSIS adopted this approach for NRTE breaded stuffed chicken products because these products present a unique public health risk. Unlike raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, NRTE breaded stuffed chicken products may have a cooked appearance, are thicker in diameter than many other poultry products, contain multiple ingredients, and are typically cooked from a frozen state. In addition, outbreak data cited in the NRTE breaded stuffed chicken proposal indicate that these products have been consistently and disproportionately associated with *Salmonella* illness outbreaks over the years. As FSIS acknowledged in the NRTE breaded stuffed chicken proposed and final determination, although not all *Salmonella* serotypes are equally likely to cause illness, all serotypes have the ability to invade, replicate, and survive in human host cells, resulting in potentially serious disease. Thus, because of the unique public health risk associated with NRTE breaded stuffed chicken products, FSIS determined that these products are adulterated if they contain any *Salmonella* stereotypes at or above 1 cfu/g.

C. Public Meeting on Salmonella Framework Under Consideration and Public Comments

1. Public Meeting and Proposed Framework

On October 17, 2022, FSIS published a **Federal Register** notice announcing that it was hosting a virtual public meeting on November 3, 2022, to discuss a regulatory framework that the Agency was considering for a new strategy to control *Salmonella* in poultry products and more effectively reduce foodborne *Salmonella* infections linked to these products (*87 FR 62784*). In the notice, FSIS shared the key elements of the framework under consideration and stated that the Agency was soliciting comments from stakeholders on all elements of the draft framework, both at the public meeting and in written comments submitted in response to the **Federal Register** notice, before moving forward with any proposed changes to regulations or other actions. The Agency also made a document outlining the regulatory framework under consideration available to the public before the public meeting by publishing it on the FSIS website.[55]

The three components under consideration in the draft framework included:

1. Requiring that incoming flocks be tested for *Salmonella* before entering an establishment;

2. Enhancing establishment process control monitoring and FSIS verification; and

3. Implementing an enforceable final product standard.

The framework under consideration also addressed cross-cutting issues associated with testing for *Salmonella,* considerations for small and VS establishments, and data sharing. FSIS specifically requested comments on factors the Agency should consider relative to the approaches outlined in each of the components, how each component can be strengthened, and where are there gaps in the framework. FSIS also requested comments on relevant scientific evidence or examples of how the components may be implemented or the impacts they may have on human *Salmonella* illnesses.

At the November 3, 2022, public meeting, stakeholders presented oral comments to FSIS panels comprised of FSIS leadership and experts on the three separate components of the framework and the cross-cutting issues. The primary purpose of the panels was to listen to stakeholder input and ask clarifying questions as needed.[56] In addition to the oral comments presented at the public meeting, FSIS also provided an opportunity for the public to submit written comments on the framework. The comment period for submitted written comments was scheduled to close on November 16, 2022, but was extended to December 16, 2022, to allow stakeholders sufficient time to take into consideration the discussion at the November 3, 2022, public meeting.[57] A summary of the general issues raised by the public comments is discussed below.

2. Public Comments on the Proposed Framework

During the comment period for the proposed framework, FSIS received 1,034 comments. Seven hundred seventy-three comments were identical or similar comment letters from individuals in support of the proposed framework, and 75 were identical or similar comment letters from individuals opposed to the proposed framework. One consumer advocacy organization submitted a comment letter with a spreadsheet containing 4,916 names in support of the framework. Another consumer advocacy organization submitted a comment letter with a spreadsheet containing 3,487 names in support of the framework. FSIS also received 149 unique comments from individuals, most in opposition to the proposed framework. In addition to the individual comments and form letters, FSIS received approximately 35 separate comment letters from trade associations representing the meat and poultry industries, consumer advocacy organizations, animal welfare advocacy organizations, small poultry growers and processors, organizations that support independent family farmers, a large meat producer, a trade association representing the veterinary profession, a State Department of Agriculture, an organic/sustainable agriculture organization, a biotech company representative, a meat scientist, and academics. The general issues raised on each of the components under consideration in the framework and on the cross-cutting issues are described below.

Comments on Component One. Component One of the draft framework considered whether FSIS should require slaughter establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. Under this approach, the flock would be required to meet a predetermined target for *Salmonella* at

2023#:~:text=FSISisextendingthecommentperiodonthe,FSISextendedthedeadlineuntilJuly272023.

[55] Proposed Regulatory Framework to *Salmonella* Illnesses Attributable to Poultry. Available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-Salmonella-poultry/proposed.*

[56] A transcript of the public meeting and other related materials are available to the public on the FSIS website at: *https://www.fsis.usda.gov/news-events/events-meetings/public-meeting-reducing-Salmonella-poultry.*

[57] FSIS Constituent Update—Oct 28, 20222: FSIS Extends Public Meeting and Comment Period on Proposed *Salmonella* Framework. Available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-october-28-2022-1.*

receiving, which may be industry-wide or establishment-specific. The establishment would be required to demonstrate that its subsequent process will be effective in reducing *Salmonella* so that the product meets the final product standard under consideration in Component Three.

Comments from individuals, consumer advocacy organizations, and animal welfare advocacy organizations expressed general support for the measures under consideration in Component One. A consumer advocacy organization commented that requiring incoming flocks be tested for *Salmonella* would provide incentives for producers to adopt effective pre-harvest measures and for establishments to take action to further reduce food safety risks from flocks failing the incoming *Salmonella* target, such as slaughtering more contaminated flocks at the end of the day.

Comments from small poultry processors and producers, organizations representing small poultry producers and independent family farmers, and trade associations representing the meat and poultry industries expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers. An organization representing small poultry producers and several individual comments stated that requiring that flocks be tested for *Salmonella* before they enter an establishment would add delays and costs that small operators cannot afford.

Several comments, including comments from trade associations representing the meat and poultry industries and organizations that support independent family farmers, asserted that FSIS lacks legal authority to require the measures under consideration in Component One, particularly the requirements that incoming flocks be tested for *Salmonella.* The commenters stated that FSIS' authority under the PPIA begins at the official establishment and does not extend to the farm. The commenters also asserted that Component One conflicts with HACCP principles in that under HACCP, establishments, not FSIS, are responsible for making decisions on how to execute their food safety system.

Comments from trade associations representing the meat and poultry industries asserted that FSIS had presented no data to demonstrate that an incoming *Salmonella* threshold or limit is necessary for an establishment to maintain process control and sufficiently reduce *Salmonella* during processing. They also stated that FSIS did not explain how on-farm sampling several weeks before a flock is processed correlates to actual incoming *Salmonella* loads or provide data to show that reducing incoming loads would have any public health impact. The commenters noted that many producers and processors currently employ interventions aimed at reducing *Salmonella* on farms and suggested that FSIS consider other measures to incentivize pre-harvest controls without requiring testing, such as encouraging establishments to consider *Salmonella* a hazard reasonably likely to occur and providing guidance for addressing *Salmonella* pre-harvest. Some of the commenters that opposed Component One suggested removing this component entirely.

Comments on Component Two. The measures under consideration in Component Two of the proposed framework would build on HACCP regulations, which provide a prevention-based approach to food safety. To ensure pathogen control throughout slaughter and processing operations, Component Two would modify the existing requirements for microbial organism testing for process control in 9 CFR 381.65(g) and establish additional parameters to better define the required analysis of the data. Establishments would be required to test for indicator organisms (*e.g.,* AC or EB) at rehang and post-chill and would be required to use a standardized statistical approach to process control. FSIS would consider production volume when determining the frequency that establishments must collect samples.

FSIS received several comments in support of the measures under consideration in Component Two from consumer advocacy organizations and academia. These commenters generally agreed with the proposal but recommended that FSIS consider additional measures, such as requiring establishments to test more broadly for indicator organisms and/or requiring testing at more sampling points. These commenters also recommended that FSIS work with stakeholders to develop the SPC approach after conducting research to determine the best points predictive of end product *Salmonella* levels and tailor the SPC for differences in processors' equipment and plant layouts.

Trade associations representing the meat and poultry industries, a State Department of Agriculture, and an organic/sustainable agriculture organization expressed concerns about some of the measures under consideration in Component Two. The commenters asserted that there is a lack of necessary data to support creating a rigid SPC framework for all establishments. An organic/sustainable agriculture organization requested that small producers be exempt from this component. A trade association representing the meat and poultry industry suggested that FSIS consider conducting verification sampling at specific locations and allow establishments to develop their own sampling plans. An association representing small and VS poultry establishments stated that the Component Two measures under consideration will be costly and will not reduce *Salmonella.*

Comments on Component Three. Component Three of the draft framework under consideration would implement an enforceable final product standard to prevent raw poultry products with certain levels and/or types of *Salmonella* contamination from entering the stream of commerce. FSIS would establish the standard by classifying certain *Salmonella* levels and/or serotypes as adulterants in raw poultry and take action against poultry products that exceed the final product standard.

Consumer advocacy organizations, coalitions promoting food safety, and individuals with expertise in food and meat science generally supported Component Three and recommended that FSIS prioritize developing and implementing Component Three. According to these commenters, it is the most critical part of the framework. These commenters recommended an enforceable approach to combatting *Salmonella.* The commenters stated that such an approach would provide much greater safety to consumers by preventing highly contaminated product from reaching store shelves and would motivate industry to adequately control *Salmonella* because of the direct financial cost of losing product that does not meet the final standard.

Some of the comments in support of Component Three requested that FSIS provide increased transparency and data regarding how the product standards under consideration would look. One consumer advocacy organization emphasized that FSIS should use scientifically sound risk assessments in determining final product standards. A consumer advocacy organization recommended establishing separate standards for different poultry products and stated that, for chicken, the standard could be based on FSIS' KPI serotypes Enteritidis, Infantis, and Typhimurium, and that for turkey, the standard could be based on serotypes Reading, Infantis, and Typhimurium. A

consumer advocacy organization stated that FSIS should set stricter standards for certain products if the risk assessment identifies higher risk poultry products and that the risk assessments would determine whether the final product standards should be based on *Salmonella* enumeration, serotypes, or a combination of both.

Comments from trade associations representing the meat and poultry industries, trade associations representing small poultry processors and family farmers, a state government entity, and both large and small businesses associated with poultry production did not support the establishment of enforceable final product standards. These comments opposed considering *Salmonella* to be an adulterant in raw poultry. Many of the commenters stated that FSIS has historically not considered *Salmonella* as an adulterant in raw poultry because: (1) *Salmonella* is not an ''added substance'' and (2) *Salmonella* is not present in levels that render chicken or turkey injurious to health because customary poultry cooking practices destroy *Salmonella.* The commenters stated that FSIS has not provided any new information to support a change in this interpretation. Comments from these trade associations and a state government entity also stated that FSIS' comparison of *Salmonella* in raw poultry to *Escherichia coli* (E. *c*oli) in non-intact beef is not relevant, given that the two are very different in how they occur in products and how they are destroyed through cooking.

On the other hand, comments from consumer advocacy organizations stated that *Salmonella* may be considered as an ''added substance'' because it is not found in the muscle tissue of healthy animals but rather is deposited through cross-contamination during slaughter and processing. The commenters asserted that regardless of whether FSIS considers certain *Salmonella* levels or serotypes most associated with human illness to be an ''added substance,'' they are adulterants because they ''ordinarily render'' contaminated poultry products injurious to health.

Commenters that opposed Component Three expressed concern about the delay that would result from a national verification testing program. A trade association representing the chicken industry argued that the extra time required for poultry producers to hold their product pending FSIS' *Salmonella* testing results will significantly decrease the number of poultry products that can safely reach store shelves. An organization representing small poultry producers and processors stated that waiting for acceptable test results would particularly affect small producers who may not have the capability to hold poultry for a long period of time.

Some commenters recommended alternatives to Component Three that the commenters believed would more effectively reduce *Salmonella* infection rates from poultry. For example, a large company that processes poultry recommended that, instead of developing new final product standards based on product adulteration, FSIS update the current performance standards to include a new metric based on a quantification target that measures beyond the prevalence of *Salmonella,* which the commenter said would work well within a current or an updated HACCP system.

Many comments opposed to Component Three asserted that the proposed measures under consideration lacked information on the data and methods that would be used to establish the final product standards. A trade association representing the chicken industry questioned whether FSIS had sufficient laboratory space needed to sample different product lots for *Salmonella* levels or serotypes. An organization representing independent family farmers recommended that, instead of establishing final product standards, FSIS should identify the *Salmonella* strains that cause most illnesses and target those strains specifically rather than providing more general product standards. The 75 similar comment letters that opposed the framework stated that FSIS should remove Component Three from the framework until the Agency provides a clear statement of the levels and/or strains of *Salmonella* that would define the final product standards.

Comments on other issues raised. In addition to comments about the above Components, there were comments raised about the framework in general. Among these comments were write-in campaigns that expressed general support for the proposed framework. A trade association representing the chicken industry argued that the proposed framework under consideration is not necessary because FSIS' existing framework for addressing *Salmonella* control has been working. A trade association representing the poultry industry commented that there is a need for consumer research and education regarding safe handling of poultry. Some comments expressed concern that adopting the framework would lead to an increase in food waste.

Comments on data sharing. FSIS received five comments regarding the need to share data. An academic suggested FSIS work with stakeholders to facilitate sharing of industry data that would provide additional insights into the sampling points that would be most predictive of process control. Trade associations representing the poultry industry urged FSIS to create a pathway for companies to share confidential proprietary data with the Agency and indicated it would be necessary to ensure that data is shared only with FSIS. A sustainable agriculture organization emphasized the need for an enhanced ability to share information among agencies, the academic community, and industry.

3. Additional Stakeholder Input

In addition to the November 2022 public meeting, FSIS also participated in technical meetings with representatives from the poultry industry, consumer advocacy organizations, academia, and other stakeholders to further discuss aspects of the proposed *Salmonella* ramework. These technical meetings were organized and hosted by the regulated industry. The first technical meeting was held on March 21, 2023. Among the topics discussed were differences in production practices and *Salmonella* control strategies between chicken and turkeys, review of ongoing risk assessments, pre-harvest control risk management measures, creating, implementing, and reacting to statistical process control measures, and *Salmonella* quantification methods. A second technical meeting was held on April 12, 2023. Among the topics discussed at that meeting were incentivizing use of pre-harvest interventions, how statistical process control is used in the poultry industry and educational needs, and addressing lot size and microbiological independence, and a review of the key differences between beef and poultry. FSIS officials also held a virtual meeting with small and VS establishment owners in February 2023 to seek input on the *Salmonella* Framework under consideration.[58]

4. Overview of Modifications to the Proposed *Salmonella* Framework

FSIS has carefully evaluated the written comments and other stakeholder input provided on the proposed *Salmonella* Framework, along with new studies and information that have become available since the Agency made the information about the framework under consideration

[58] Officials' Calendar of Meetings (Feb 2023) at: *https://www.fsis.usda.gov/news-events/events-meetings/officials-calendar-meetings.*

available to the public in November 2022. Based on this evaluation, FSIS has decided to modify some of the measures it had been considering as part of the *Salmonella* Framework and is proposing these modified measures in this document. FSIS requests comments on all measures proposed in this document. If, after the close of the comment period, the Agency determines that some portions of the modified *Salmonella* Framework can be finalized sooner than others, FSIS will finalize those portions separately from the others so as not to delay regulatory action on this important public health initiative.

The proposed modified framework components are discussed in more detail under separate headings in this document. The headings for the proposed modified framework correspond to the component headings used for the draft framework that FSIS presented to the public, *i.e.,* Component One, Component Two, Component Three. The components are discussed in this proposal in an order that emphasizes the most significant proposed changes first. Therefore, the discussion begins with Component Three: Final Product Standards, followed by Component Two: Enhanced Establishment Process Control Monitoring, and finally Component One: Pre-Harvest Measures.

Following is a general summary of the modifications.

Component Three Modifications. Consistent with Component Three of the draft framework that was under consideration, FSIS is proposing enforceable final product standards to prevent raw poultry products with certain levels and *Salmonella* serotypes from entering commerce. Under this proposal, FSIS has tentatively determined that certain raw poultry products that contain *Salmonella* in an amount that exceeds a specified level and that contain any detectable level of certain *Salmonella* serotypes are adulterated as defined in the PPIA. The proposed final product standards are as follows:

- *Chicken carcasses and chicken parts: Salmonella* at or above 10 cfu per milliliter of rinsate collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.,* Enteritidis, Typhimurium, and I 4,[5],12:i:-);
- *Comminuted chicken: Salmonella* at or above 10 cfu per gram of product collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.,* Enteritidis, Typhimurium, and I 4,[5],12:i:-);
- *Comminuted turkey: Salmonella* at or above 10 cfu per gram of product collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.,* Hadar, Typhimurium, and Muenchen).

FSIS is also proposing that the Agency would routinely collect samples of raw final products subject to the proposed standards and analyze them for *Salmonella* levels and serotypes to determine whether the product is adulterated.

Component Two Modifications. To ensure that poultry slaughter establishments are effectively controlling *Salmonella* throughout their operations, FSIS is proposing to revise the current regulations in 9 CFR 381.65(g) that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation. FSIS is proposing to revise these regulations to clarify that these procedures must include an MMP that incorporates SPC monitoring methods. These proposed amendments would also specify that the pre-chill sampling location is at rehang and specify the use of appropriate microbial organisms for monitoring process control. In addition, VS and VLV establishments operating under Traditional Inspection [59] would have to test at both rehang and post-chill, instead of at post-chill only, although some of these establishments would have the option to use laboratory services provided by FSIS to analyze their monitoring samples. FSIS has developed proposed guidance to help establishments meet the proposed sampling and analysis requirements. Under this proposal, the guidance would be considered as a ''safe harbor'' in that establishments that follow the guidance will have met the proposed MMP requirements in 9 CFR 381.65(g). FSIS is also proposing to amend the recordkeeping requirements in 9 CFR 381.65(h) to require that establishments submit their microbial monitoring results to the Agency electronically.

Component One Modifications. Based on the need for additional research and due to implementation challenges, FSIS has decided, at this time, not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an establishment. FSIS, however, will focus on achieving the goal of Component One—reduce the amount and type of *Salmonella* contamination that enters the establishment—through non-regulatory strategies. These include actively encouraging the wider use of modified-live vaccines, which have been demonstrated to have a very effective role in mitigating the hazard associated with specific *Salmonella* serotypes, while reducing the entire load of similar serogroup *Salmonella* through cross-protection. FSIS is also working with the Animal and Plant Health Inspection Service (APHIS) to explore ways to expand the National Poultry Improvement Program (NPIP), which has been effective in reducing the prevalence of particular *Salmonella* serotypes.

The Agency will continue to explore and develop strategies for addressing *Salmonella* contamination risk at receiving. FSIS also intends to revise its existing compliance guideline on *Controlling Salmonella in Raw Poultry* [60] to provide effective guidance on pre-harvest interventions and practices for preventing or reducing *Salmonella* colonization of live birds.

5. Severability

While the three components in this proposal support a comprehensive approach to controlling *Salmonella* in poultry, they are each separate actions that could operate independently of each other to address *Salmonella* illnesses associated with poultry products. Therefore, the following portions of this proposal are mutually severable from each other: The proposed determination that would establish final product standards for certain raw poultry products proposed under Component Three; the proposed amendments to 9 CFR 381.65 (g) and (h) that would enhance process control monitoring in all poultry slaughter establishments under Component Two; and the proposed non-regulatory approach to address pre-harvest measures in Component One. Should FSIS finalize this proposal, if any of the above portions were to be set aside by a reviewing court, FSIS would intend for the remainder of this action to remain in effect.

These proposals are discussed in more detail below.

[59] Traditional Inspection is typically employed at smaller lower production volume establishments that eviscerate carcasses by hand (77 FR 4410).

[60] *FSIS Guideline for Controlling Salmonella in Raw Poultry* (July 2021). Available at: *https://www.fsis.usda.gov/guidelines/2021-0005.*

II. Component Three: Proposed Final Product Standards

A. Current Salmonella Performance Standards and Consideration of an Alternative Approach

As discussed above, although FSIS sampling data show that the occurrence of *Salmonella* in raw poultry products has decreased since FSIS implemented its prevalence-based *Salmonella* performance standards, there has not been a corresponding observed reduction in *Salmonella* illnesses in the United States. There are likely multiple reasons for the disconnect between the reduced *Salmonella* contamination in poultry products and continued illnesses. Individuals who become ill may be exposed to more virulent *Salmonella* strains or higher concentrations of *Salmonella,*[61] and, as noted above, consumption of poultry has increased.[62] Additionally, as discussed below, several consumer behavior research studies suggest that ordinary consumer cooking and preparation practices for many raw chicken and turkey products do not provide adequate assurance that these products will not be contaminated with *Salmonella* when consumed. Therefore, FSIS has decided to reconsider its current approach to *Salmonella* performance standards for poultry and has tentatively concluded that the Agency should adopt an alternative approach to more effectively reduce *Salmonella* illnesses associated with poultry products. This proposal addresses the disconnect between *Salmonella* contamination on poultry and human illnesses because it targets specific *Salmonella* serotypes more frequently associated with illness and limits the concentration of *Salmonella* permitted in certain raw poultry products.

FSIS' current *Salmonella* performance standards focus on reducing the prevalence of all *Salmonella* without considering differences in virulence among individual *Salmonella* serotypes, strains, and genotypes. Thus, the current standards do not focus on the types of *Salmonella* most likely to cause human illnesses. In addition, the current *Salmonella* performance standards consider only the presence or absence of *Salmonella* in the product, while the quantity of the pathogen may also have an impact on illness. Thus, the current performance standards do not distinguish between poultry products that are heavily contaminated and that contain the most virulent type of *Salmonella* from those that contain trace amounts of a *Salmonella* with types not typically associated with foodborne illnesses in the United States.

Additionally, and independently, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc.* v. *USDA,* 275 F.3d 432 (5th Cir. 2001). In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the *Salmonella* performance standards. Since that time, FSIS has used *Salmonella* performance standard failures as a basis to conduct an in-depth evaluation of the establishment's food safety systems, including its HACCP plan and sanitation SOPs. However, because *Salmonella* is not currently considered an adulterant in raw poultry, the Agency cannot withhold the mark of inspection or otherwise prevent products produced in an establishment that has failed the performance standards from entering commerce based solely on the establishment's performance standard results (75 FR 27288, 27293–4). This proposal, on the other hand, would set an enforceable final product standard that prevents raw poultry products with certain levels and types of *Salmonella* contamination, which would be classified as adulterants, from entering the stream of commerce.

When FSIS initially established the pathogen reduction *Salmonella* performance standards in 1996, the Agency noted that, except for *E. coli* O157:H7, FSIS had not taken the position that some amount of a pathogen necessarily renders a raw meat or poultry product unsafe and legally adulterated (*61 FR 38806,* 38835). At the time, the Agency believed that it was constrained by the lack of a scientific basis for determining the levels at which specific pathogens do or do not present a safety hazard, and it also relied in part on the fact that proper cooking kills pathogens on raw product (*60 FR 6774,* 6799). Therefore, the initial pathogen reduction performance standards were based on a statistical evaluation of the prevalence of bacteria in each establishment's products, measured against the nationwide prevalence of the bacteria in the same products (61 FR 38806, 38836). The *Salmonella* performance standards were and still are not used to determine whether specific product lots are legally adulterated. However, when FSIS established the initial performance standards, the Agency made clear that ''as more research is done and more data become available, and as more sophisticated techniques are developed for quantitative risk assessment for microbiological agents, it may be possible and appropriate to develop performance standards that use a different approach'' (61 FR 38806, 38836).

Since FSIS implemented the *Salmonella* performance standards, the Agency has evaluated whether certain types of *Salmonella* should be considered as adulterants in raw meat and poultry in response to petitions submitted to the Agency in 2011, 2014, and 2022. For example, in response to two petitions submitted by CSPI in 2011 and 2014, FSIS evaluated whether certain antibiotic-resistant (ABR) *Salmonella* serotypes could be considered as adulterants in raw meat and raw poultry products under the Federal Meat Inspection Act (FMIA) and PPIA. The 2011 petition asked FSIS to declare four strains of ABR *Salmonella* as adulterants when found in ground meats and poultry.[63] FSIS denied the 2011 petition without prejudice on July 31, 2014. In its response, FSIS explained that the data available at that time ''did not support giving the four strains of ABR *Salmonella* identified in the petition a different status as an adulterant in raw ground beef and raw ground poultry than *Salmonella* strains that are susceptible to antibiotics.'' [64] The response stated that additional data on the characteristics of ABR *Salmonella* are needed to determine whether certain strains could qualify as adulterants under the FMIA and PPIA.

[61] *FSIS Risk Profile for Pathogenic Salmonella in Poultry* (2023); FAO/WHO (Food and Agriculture Organization/World Health Organization) ''*Microbiological Risk Assessment Series 3: Hazard Characterization for Pathogens in Food and Water*''. Geneva, Rome: World Health Organization, Food and Agricultural Organization of the United Nations; 2003; Cheng, RA, Eade CR, and Wiedmann M (2019). Embracing Diversity: Differences in Virulence Mechanisms, Disease Severity, and Host Adaptations Contribute to the Success of Nontyphoidal *Salmonella* as a Foodborne Pathogen. Frontiers in Microbiology, Volume 10 at: *https://doi.org/10.3389/fmicb.2019.01368;* Teunis, Peter FM (2022).Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae. Epidemics 41: 100653. *https://doi.org/10.1016/j.epidem.2022.100653.*

[62] Williams, M.S., & Ebel, E.D. (2022). Temporal changes in the proportion of *Salmonella* outbreaks associated with 12 food commodity groups in the United States. *Epidemiology and infection, 150,* e126. *https://doi.org/10.1017/S0950268822001042.*

[63] CSPI petition #11–06 (May 25, 2011), ''Petition for an Interpretive Rule Declaring Specific Strains of Antibiotic Resistant *Salmonella* to be Adulterants Withing the Meaning or 21 U.S.C. 601(m)(1) and (2)(a) and 21 U.S.C. 453(g)(1) and (2)(a).'' FSIS final response (July 31, 2014) at: *https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest-0.*

[64] FSIS final response to petition #11–06, p. 1.

The response also noted that because the Agency's denial was without prejudice, the petitioner was not precluded from submitting a revised petition that includes additional information to support the requested action.

The CSPI 2014 petition was a refiling of the 2011 petition and asked that FSIS declare certain strains of ABR *Salmonella* as adulterants in all meat and poultry products based on evidence attained since 2011 that, according to the petition, demonstrates both ground and intact poultry products are associated with outbreaks from ABR *Salmonella*.[65] Based on the data available at the time, FSIS denied the 2014 petition without prejudice on February 7, 2018. In its response to the petition, the Agency concluded that, with respect to its status as an adulterant, ''*Salmonella* does not appear to present the same issues as [*E. coli* O157:H7], regardless of whether it is resistant or susceptible to antibiotics.'' [66] Therefore, the Agency stated that it ''had no basis to conclude that either ABR-*Salmonella* or non-ABR *Salmonella* would render injurious to health what consumers consider to be properly cooked meat or poultry.'' [67]

As discussed above, FSIS also considered whether certain *Salmonella* serotypes should be considered as adulterants in all meat and poultry products in response to the January 2020 petition submitted by Marler Clark LLP requesting FSIS to declare 31 *Salmonella* serotypes that have been associated with foodborne illness outbreaks to be adulterants of all meat and poultry products.[68] As noted above, FSIS denied the petition without prejudice. However, in its response, the Agency explained that it believes that an updated *Salmonella* strategy is necessary to reduce *Salmonella* illnesses associated with poultry products and that FSIS had initiated several activities designed to gather data and information to inform and support future actions related to *Salmonella* in poultry. These activities were discussed in the *Background* section of this document.

Since FSIS denied the 2020 Marler petition, many of the activities that were initiated to inform an updated *Salmonella* strategy have generated new studies and information that FSIS has determined support a revised approach on the use of standards to address *Salmonella* in final raw poultry products. For example, after FSIS issued the 2020 Marler petition denial, the Agency completed its chicken carcass exploratory sampling program, NACMCF issued its final 2023 report, FSIS completed the peer-reviewed 2023 risk profile as well as the peer-reviewed 2023 risk assessments for chicken and turkey. The Agency also held the November 3, 2022, public meeting and received written and oral stakeholder input on the proposed *Salmonella* Framework that the Agency was considering.

As part of Component Three of the draft *Salmonella* Framework, FSIS stated that it was assessing whether certain levels and/or types of *Salmonella* on raw poultry present an elevated risk of causing human illness such that they should be considered adulterants. To evaluate the status of *Salmonella* in raw poultry under the PPIA, FSIS has considered stakeholder input received in response to the draft *Salmonella* Framework together with the available scientific information on *Salmonella* in poultry, including recommendations in the 2023 NACMCF report, the findings of the 2023 risk profile, and the results of the 2023 quantitative risk assessments for *Salmonella* in chicken and turkey. Additionally, because FSIS has relied in part on ordinary consumer cooking practices to determine the status of pathogens as adulterants in raw products, the Agency also considered the available consumer behavior research to evaluate whether ordinary consumer cooking and handling practices are able to consistently mitigate the risk associated with certain raw poultry products contaminated with certain levels and/or types of *Salmonella*. Based on its evaluation of scientific evidence, the Agency has tentatively concluded that there are certain raw poultry products and *Salmonella* levels and serotype pairs that have characteristics that distinguish them from other raw products contaminated with *Salmonella*. FSIS has also tentatively determined that, based on its evaluation of available scientific evidence, *Salmonella,* when present in these specific products at the specified levels and serotypes, should be considered as an adulterant.

Accordingly, FSIS is proposing final product standards that would define whether certain raw poultry products contaminated with certain *Salmonella* levels and serotypes are adulterants as defined in the PPIA. Specifically, FSIS had tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if they contain *Salmonella* at or above 10 cfu/per milliliter or gram (10 cfu/mL(g)) in analytical portion (*i.e.,* mL of rinsate or gram of product) and contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that product. The *Salmonella* serotypes of public health significance identified for chicken carcasses, chicken parts, and comminuted chicken are Enteritidis, Typhimurium, and I 4,[5],12:i:- and for comminuted turkey are Hadar, Typhimurium, and Muenchen. As discussed below, these serotypes were the three most highly virulent serotypes associated with a commodity identified in the 2023 risk assessments. The *Salmonella* serotypes of public health significance will likely change over time as the serotypes commonly associated with human illnesses change. FSIS will continue to track annual targets for reducing the proportion of poultry samples that contain *Salmonella* serotypes of public health significance, as well as data on rates for serotypes commonly associated with human illness to inform future revisions to the *Salmonella* serotypes of public health significance. FSIS would publicly announce and request comments on any changes to the serotypes of public health significance in the **Federal Register**. Additionally, should FSIS finalize the proposed final product standards, the Agency intends to further evaluate and, if necessary, refine these standards as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available. As discussed above, if FSIS finalizes the proposed final product standards, the Agency intends to re-evaluate the serotypes of public health concern every 3–5 years at a minimum and whenever new information on *Salmonella* serotypes associated with human illness become available.

Under this proposed determination, chicken parts subject to the final product standards would include legs, breasts, wings, thighs, quarters, and halves. FSIS is not proposing final product standards for turkey carcasses or parts because historically there have been very few *Salmonella*-positive detections in turkey carcasses. Additionally, the Agency does not

[65] CSPI petition #14–01 (October 1, 2014), ''Request for an Interpretive Rule Declaring Certain Antibiotic-Resistant Strains of *Salmonella* to be Adulterants'' and FSIS final response (February 7, 2018) at: *https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains.*

[66] FSIS final response to petition #14–06, p. 6.

[67] FSIS final response to petition #14–06, p. 7.

[68] Marler Clark LLP petition # 20–01 ''Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of *Salmonella enteritica* subspecies to be Adulterants'' dated January 19, 2020. Available at: *https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes.*

quantify *Salmonella* on turkey carcass sponge samples and has never had a *Salmonella* verification sampling program for turkey parts. Thus, it was not possible for the 2023 turkey risk assessment to assess the risk management questions for turkey parts or provide a robust assessment on final product standards for turkey carcasses that FSIS could use to inform the development of final product standards for these products.

The basis for the proposed final product standards and FSIS' proposed determination that products that contain the *Salmonella* levels and serotypes identified in the proposed final product standards are adulterated is discussed below.

B. Pathogens as Adulterants in Raw and Not-Ready-To Eat Meat and Poultry Products

Under the FMIA (21 U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C 451 *et seq.*), a meat or poultry product is adulterated if, among other circumstances, ''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 . . . if the quantity of such substance in or on such article does not ordinarily render it injurious to health'' (21 U.S.C. 601(m)(1); 21 U.S.C. 453(g)(1)). Meat and poultry products are also adulterated if they are ''unsound, unhealthful, unwholesome, or otherwise unfit for human food'' (21 U.S.C. 601(m)(3)); 21 U.S.C. 453(g)(3)).

Historically, most foodborne pathogens, including *Salmonella,* have not been considered as adulterants of raw and other NRTE meat and poultry products based on the assumption that ordinary cooking is generally sufficient to destroy the pathogens.[69] [70] One exception to date is *E. coli* O157:H:7 and certain non-O157 Shiga toxin-producing *Escherichia coli* (STEC) in raw, non-intact beef products and intact cuts that are to be further processed into non-intact products before being distributed for consumption. These pathogens are considered adulterants in these specific raw products because they render ''injurious to health'' what many consumers believe to be properly cooked non-intact beef products.[71] FSIS had also determined that when contaminated with these pathogens, raw, non-intact beef products are ''unhealthful, unwholesome, and otherwise unfit for human food.'' [72]

When FSIS determined that certain STEC are adulterants in non-intact raw beef products, the Agency identified characteristics associated with both the pathogen and the product that distinguish them from other raw products contaminated with other pathogens. Specially, FSIS considered that these STEC had been associated with illnesses and outbreaks, have a relatively low infectious dose, cause serious human illness, and can survive what many consumers consider to be ordinary preparation and cooking practices of non-intact beef products.

As discussed above, on May 1, 2024, FSIS published a final determination to declare that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu/g or higher are adulterated within the meaning of the PPIA.[73] In that determination, FSIS stated that while certain STEC have been the only pathogens to date that are considered adulterants in a raw product, certain other pathogens may also exhibit characteristics that would meet the standard to be considered as adulterants in a specific raw product. In the proposed determination, FSIS also stated that if the Agency became aware of evidence to show that a specific pathogen and product pair presents a significant public health risk, it would consider the factors it identified to distinguish certain STEC from other pathogens as adulterants in certain raw beef products to determine the pathogen's status as an adulterant, *i.e.,* pathogen serogroups or types associated with human illnesses; pathogen infectious dose; pathogen and serious human illnesses; and traditional or ordinary cooking practices. After applying these factors to *Salmonella* in NRTE breaded stuffed chicken products, FSIS decided to declare that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu/g or higher are adulterated within the meaning of the PPIA.

Specifically, FSIS determined that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 cfu/g or higher are adulterated under 21 U.S.C. 453 (g)(1) because, in these particular products, *Salmonella* is an added substance that may render them injurious to health (89 FR 35034–35035). FSIS also determined that *Salmonella* at 1 cfu/g in NRTE breaded stuffed chicken meets the more stringent ''ordinarily injurious to health'' standard for substances that are not added as provided in 21 U.S.C. 453(g)(1)) (89 FR 35035). Finally, FSIS determined that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 cfu/g or higher present a serious risk of causing *Salmonella* illnesses and that this elevated risk of illness makes them ''unhealthful, unwholesome, or otherwise unfit for human food'' as defined in 21 U.S.C. 453(g)(3) (89 FR 35037).

C. The Adulteration Standard for Raw Poultry Products

Consistent with its approach used to determine the status of certain STEC in certain raw beef products and to determine the status of *Salmonella* at certain levels in NRTE breaded stuffed chicken products, FSIS has evaluated the available information on *Salmonella* serotypes associated with human illnesses, the *Salmonella* infectious dose, the severity of human illnesses caused by *Salmonella,* and ordinary consumer preparation practices associated with these raw poultry products to assess the status of *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. Based on this evaluation, FSIS is proposing final product standards for levels and serotypes of *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS has also tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain the *Salmonella* levels and serotypes identified in the final product standard are adulterated as defined in the PPIA because they contain a poisonous or deleterious substance that renders them ''injurious to health'' as defined in 21 U.S.C. 453(g)(1). Additionally, FSIS has tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain the *Salmonella* levels and

[69] See proposed rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' February 4, 1993 (60 FR 6774 at 6798–6799) and final rule ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' July 25, 1996 (61 FR 38806 at 38835.) See also *Amer. Public Health Ass'n* v. *Butz,* 511 F.2d 331 (U.S. App. DC, 1974).

[70] When raw meat or poultry products are associated with an illness outbreak and contain pathogens that are not considered adulterants in those products, FSIS considers the product linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 453(g)(3) because the product is ''. . . unsound, unhealthful, unwholesome, or otherwise unfit for human food'' (77 FR 72681, 72689 (Dec. 6, 2012). Products that contain an adulterant are considered adulterated under 21 U.S.C. 601(m)(1) or 453(g)(1) even if they are not linked to an illness outbreak.

[71] See *Texas Food Industry Association* v. *Espy,* 870 F. Supp. 143 (1994).

[72] Shiga-Toxin Producing Escherichia coli in Certain Raw Beef Products (76 FR 58157, 58159).

[73] *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products; May 1, 2024 (89 FR 35033) at: *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-2022-0013F.pdf.*

serotypes identified in the final product standards are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them ''unhealthful, unwholesome, or otherwise unfit for human food.'' [74] The basis for this tentative determination is discussed below.

1. Pathogen Serogroups or Types Associated With Human Illness

Approximately 2,500 *Salmonella* serotypes have been identified,[75] though not all serotypes have been isolated from poultry. Most human infections have been epidemiologically linked to fewer than 100 serotypes. Almost all strains of *Salmonella* are pathogenic as they can invade, replicate and survive in human host cells, resulting in potentially fatal disease,[76] though not all are equally likely to cause illness. To evaluate which *Salmonella* serotypes are most likely to be associated with human illness, FSIS considered information from the 2023 NACMCF report, the 2023 risk profile, and the 2023 risk assessments.

NACMCF report. In the 2023 NACMCF report, the committee considered how foodborne illness surveillance data on human *Salmonella* illnesses, data from foodborne outbreaks associated with *Salmonella* in poultry, and data on *Salmonella* serotypes in poultry products can be used to identify the *Salmonella* serotypes of greatest public health concern associated with specific poultry products. The report stated that the relevant serotypes of greatest public health concern are those that are common causes of reported human illness, are present in poultry, and are transmitted through foods. The report noted that CDC surveillance provides data on the frequency of diagnosed illness caused by each serotype and that FSIS data from slaughterhouses and retail surveys can confirm the presence and frequency of serotypes in raw poultry. The report also concluded that outbreak investigations of foodborne salmonellosis can provide direct evidence that foodborne transmission of a particular serotype occurs.

The NACMCF report noted that several approaches have been used to attribute human salmonellosis to specific foods and sources. These include case-control studies, analysis of reported foodborne outbreaks, and most recently, source attribution based on WGS genotyping. The report concluded that attribution based on outbreak data and on genotype both give the greatest weight to data from the most recent years. NACMCF found that poultry is the leading source of human salmonellosis, based on both reported outbreaks and genotype-based attribution methods. The committee also stated that these data show that a small number of serotypes account for most poultry-associated salmonellosis led by Enteritidis, Typhimurium, I:4,5,12:i:-, Infantis, and Heidelberg, and even fewer serogroups: groups O:4 (formerly group B), O:7 (group C1), and O:9 (group D1).

Risk profile. In the 2023 risk profile, FSIS conducted a review of all information on *Salmonella* outbreaks reported in the CDC National Outbreak Reporting System (NORS), PubMed, and the web pages FSIS uses for maintaining records on outbreak investigations to determine which *Salmonella* serotypes or subtypes are linked to foodborne illnesses or outbreaks from consuming specific raw and NRTE chicken or turkey products. From these data sources, the risk profile identified 210 foodborne *Salmonella* outbreaks linked to poultry products between 1998 and 2020. Of these 210 foodborne *Salmonella* outbreaks, 84.8 percent (178/210) were linked to chicken products and 15.2 percent (32/210) to turkey products. Serotype information was available for 93.3 percent (196/210) of these outbreaks, including 2.4 percent (5/210) associated with multiple serotypes.

For the purposes of the risk profile, *Salmonella* subtypes associated with human illness outbreaks attributed to consuming chicken or turkey are referred to as ''subtypes of concern.'' The 196 outbreaks in which serotype information was available involved 32 subtypes of concern. Seventeen serotypes of concern were only linked to chicken products. One serotype of concern, Reading, was linked to a turkey product but not to chicken. There were 10 serotypes linked to both chicken and turkey products.

According to the data compiled for the risk profile, the 210 outbreaks include 7,018 illnesses, 1,202 hospitalizations, and 10 deaths attributed to poultry products. When considering outbreaks associated with either chicken or turkey products, nine serotypes accounted for 85 percent (5,794/7,018) of illnesses. Each of these subtypes caused 200 or more outbreak associated illnesses in chicken and/or turkey from 1998–2020. The top seven subtypes associated with chicken were Enteritidis, Heidelberg, Typhimurium, I 4,[5],12:i:-, Montevideo, Thompson, and Infantis. The top four subtypes associated with turkey were Enteritidis, Reading, Muenchen, and Heidelberg. The most common subtypes of concern associated with poultry products overall were Enteritidis, Heidelberg, Typhimurium, and I 4,[5],12:i:-.

Risk assessments. The chicken and turkey risk assessments leveraged FSIS' 2023 risk profile to identify *Salmonella* serotypes in chicken and turkey linked to foodborne illness and adopted the guidance on risk assessment recommendations from the 2023 NACMCF report. FSIS developed a probabilistic risk assessment model describing current *Salmonella* contamination in raw poultry products and the potential human exposure through consumption of servings derived from these raw products. Data from FSIS microbiological baseline studies, routine PR/HACCP sampling, and exploratory sampling programs were used to describe *Salmonella* in chicken carcasses, fabricated chicken parts, and comminuted chicken and turkey products. FSIS partnered with EpiX Analytics through a Cooperative Agreement with the University of Maryland to incorporate genomics into the risk assessment models developed by FSIS. FSIS selected the grouping of serotypes into two ''clusters'' (*i.e.,* ''higher virulence'' and ''lower virulence'') based on the virulence profiles, exposure in food, and foodborne epidemiological data and EpiX Analytics then derived two virulence-adjusted *Salmonella* dose-

[74] Under 21 U.S.C. 601(m)(3) of the FMIA and 21 U.S.C. 453(g)(3) of the PPIA, a meat or poultry product is adulterated ''if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.'' Historically, FSIS has interpreted the phrase ''is for any other reason unsound, unhealthful, or otherwise unfit for human food'' as providing a separate basis for adulteration than consists of ''any filthy, putrid, or decomposed substance.'' Thus, meat or poultry products that FSIS has determined are ''otherwise unfit for human food'' within the meaning of 21 U.S.C. 601(m)(3) and 21 U.S.C. 453(g)(3) do not also need to consist ''in whole or in part of any filthy, putrid, or decomposed substance.'' For example, when raw meat or poultry products are associated with an illness outbreak but contain pathogens that are not considered adulterants in raw products, FSIS has found products linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 21 U.S.C. 453(g)(3) because they are ''unsound, unhealthful, unwholesome or otherwise unfit for human food'' (77 FR 72689). FSIS has also determined that certain materials from cattle as well as the carcasses of non-ambulatory disabled cattle are adulterated because they present a sufficient risk of exposing humans to the bovine spongiform encephalopathy agent such as to render them ''unfit for human food'' under 21 U.S.C. 601(m)(3) (69 FR 1862).

[75] Brenner FW, Villar RG, Angulo FJ, Tauxe R, Swaminathan B. *Salmonella* nomenclature. J Clin Microbiol. 2000 Jul;38(7):2465–7. doi: 10.1128/JCM.38.7.2465–2467.2000. PMID: 10878026; PMCID: PMC86943.

[76] Shu-Kee Eng, Priyia Pusparajah, Nurul-Syakima Ab Mutalib, Hooi-Leng Ser, Kok-Gan Chan & Learn-Han Lee (2015) *Salmonella:* A review on pathogenesis, epidemiology and antibiotic resistance, Frontiers in Life Science, 8:3, 284–293, DOI: 10.1080/21553769.2015.1051243.

response models.[77] FSIS used these dose-response models in its quantitative risk assessment models for *Salmonella* in chicken and turkey. FSIS assessed public health benefits, in terms of annual illnesses prevented, by modeling the impact of removal of lots with *Salmonella* at or above a certain level or with certain serotypes and simulated the probability of illness per serving.

The analysis in the chicken risk assessment found the probability of illness from chicken contaminated with ''higher virulence'' serotypes exposures is 5.66 times larger than the probability of illness from chicken contaminated with ''lower virulence'' serotypes. In FSIS sampling, the average annual percentage of ''higher virulence'' serotypes is approximately 26 percent for chicken carcasses, 32 percent for comminuted chicken product, and 35 percent for chicken parts. The chicken risk assessment identified Enteritidis, Typhimurium, I 4,[5], 12:i:-, Hadar, and Litchfield as the five most frequent ''higher virulence'' serotypes in chicken. The chicken risk assessment identified Kentucky, Infantis, Schwarzengrund, Heidelberg, and Thompson as the five most frequent ''lower virulence'' serotypes in chicken.

The analysis in the turkey risk assessment found there are 49 different serotypes in comminuted turkey products, as compared to only 19 serotypes isolated on turkey carcasses in the Agency's pathogen reduction *Salmonella* sampling program. Reading and Hadar ranked as the top two in both carcasses and comminuted, comprising more than 30 percent of the serotype samples for each commodity. Hadar was also observed most often in the FSIS microbiological baseline studies for *Salmonella* in turkey [78] and appeared in the top ten CDC FoodNet annual summary from 2020.[79]

The turkey risk assessment identified Hadar, I 4,[5], 12:i: -, Muenchen Typhimurium, and Saintpaul as the five most frequent ''higher virulence'' serotypes in turkey. The turkey risk assessment identified Reading, Infantis, Schwarzengrund, Uganda, and Agona as the five most frequent ''lower virulence'' serotypes in turkey.

The list of serotypes of public health significance is highly important for this framework, as it determines whether products are adulterated as defined in the PPIA. FSIS recognizes that science constantly evolves and therefore our understanding of virulence and other factors will evolve over time.

The FSIS risk assessments utilized bioinformatic tools and methods for clustering *Salmonella* serotypes, and an optimized new dose-response model developed by EpiX Analytics. This model was genomically validated, and results corresponded with other standard bioinformatic techniques differentiating serotypes based on lineage features. Genomic virulence factors were used for the initial grouping of serotypes and the higher virulence serotypes of public health significance were validated by CDC illness outcome data and FSIS sampling data. FSIS did not rely solely on the genomic component of the risk assessment model to determine the list of serotypes of public health significance. FSIS developed a cohesive risk model that incorporates virulence factors, epidemiological outcomes, and frequency of exposure and conducted sensitivity and uncertainty analyses of the full model and the virulence component. FSIS requests comments on the full risk model and the uncertainty and sensitivity analyses, whether they are fit for the purpose of determining the serotypes of public health significance, and what model adjustments or other approaches FSIS should consider in the determination to adapt to evolving data, technology, and analytical methods.

FSIS recognizes that science consistently evolves, and therefore the Agency's understanding of virulence and other factors will evolve over time. Because the scientific understanding of virulence and other relevant factors evolves, FSIS is requesting comments on whether the EpiX Analytics serotype clustering and dose-response adjustment (*i.e.,* risk multiplier) used the best available data and genetic factors relevant to *Salmonella* risk and contamination in the United States poultry population. Additionally, FSIS is requesting comment on potential improvements to the serotype clustering robustness analysis and the risk multiplier sensitivity analysis.

Final product standards serotypes of public health significance. As noted above, as part of USDA's strategic and performance planning process for FY2022–2026, FSIS established a new KPI targeted to reduce the proportion of FSIS poultry samples with *Salmonella* serotypes commonly associated with human illnesses.[80] The KPI serotype list was determined using summary statistics, namely comparison of historical Agency sampling data for poultry products and CDC FoodNet data to determine the *Salmonella* serotypes commonly associated with human illness. It is important to note that the KPI is used as an internal performance measure for FSIS, which is not intended to assess industry performance, and, as such, was not externally peer reviewed. FSIS' analysis found that these serotypes are Infantis, Enteritidis, and Typhimurium. Thus, FSIS selected these serotypes as a KPI target for all raw poultry.

When developing the proposed final product standards, FSIS considered incorporating the KPI serotypes as the ''serotypes of public health significance'' as suggested by some of the comments on the initial draft *Salmonella* Framework. However, after evaluating the information on serotypes discussed above, FSIS concluded that, while the KPI serotypes are useful for strategic and performance planning purposes, the KPI was not a robust scientific tool by which to identify serotypes of public health concern as adulterants. Further, the KPI identified serotypes of public health concern for poultry as a whole, and not by individual product (*chicken* v. *turkey*). The KPI does not reflect the serotypes most commonly associated with illnesses from turkey, and the chicken risk assessment determined that Infantis is not a highly virulent serotype.

Therefore, instead of proposing serotypes of public health significance based solely on the KPI criteria, FSIS has decided that the proposed serotypes of public health significance should be based on a thorough review of multiple FSIS scientific analyses in this area, including the 2023 NACMCF report, the externally peer-reviewed 2023 risk profile, and the two externally peer-reviewed risk assessments. Based on consideration of these scientific efforts, these serotypes are Enteritidis, Typhimurium, and I 4,[5],12:i:- for chicken carcasses, chicken parts, and comminuted chicken, and Hadar, Typhimurium, and Muenchen for comminuted turkey. FSIS has determined that these serotypes more accurately reflect serotypes most likely

[77] Full details of the EpiX Analytics methodology are provided in Appendix A of the chicken Risk Assessment in the report entitled ''*Using genomics to identify nontyphoidal Salmonella serovars of concern and estimating dose-response models amenable to risk assessments in poultry.*''

[78] National Microbiological Baseline Data Collection Program: Young Turkey Survey available at: *https://www.fsis.usda.gov/node/1972*

[79] CDC FoodNet Reports available at: *https://www.cdc.gov/foodnet/reports/index.html.*

[80] FY2022–2024 Food Safety Key Performance Indicator. Available at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella-0#:~:text=FY%202022-2026%20Food%20Safety%20Key%20Performance%20Indicator%20A,the%20USDA%20Fiscal%20Year%20%28FY%29%202022-2026%20Strategic%20Plan.*

to cause illnesses because they are based on the same epidemiological evidence used in the risk profile and the 2023 NACMCF report, but pivotally also include analyses conducted in the risk assessments, which includes an additional analysis of virulence factors, epidemiological outcomes, and frequency of exposure.

The 2023 NACMCF report, the 2023 risk profile, and the Agency's KPI all identify Infantis as among the serotypes commonly associated with poultry-related illnesses, the scientific evidence does not support that the rising trend in Infantis illnesses is associated with chicken consumption. The emergence of Infantis in FSIS chicken sampling in 2016 did not correspond to a proportional increase in human Infantis illnesses, which have been on the rise in the United States since 2010.[81] Put another way, given the volume of chicken consumed by the American public—much of which is contaminated with Infantis—if it were a high-risk poultry serotype, we would predict more Infantis illnesses. Furthermore, the 2023 chicken risk assessment, which used published genomic methods,[82] also determined that Infantis is less virulent than many other serotypes with the exception of Kentucky. Additionally, the risk profile found that Infantis accounted for 2 percent of outbreaks identified in the CDC NORS, while I 4,[5],12:i:- accounted for 4.1 percent of those outbreaks.

However, FSIS is aware *Salmonella* Infantis remains of considerable concern in terms of potential severity of illness [83] and antimicrobial resistance, as can be observed in its routine inclusion in national lists of top serotypes by outbreak numbers and sporadic case counts.[84] CDC estimates that the serotypes of public health significance represent 66 percent of outbreaks and 68 percent of outbreak-associated illnesses in the past five years of outbreak data; including Infantis as a fourth serotype increases these figures to 75 percent and 79 percent, respectively.[85] Given the notable concern of the *Salmonella* Infantis REPJFX01 strain raised by the CDC and other public health experts, FSIS is requesting comment on the possible inclusion of Infantis as a serotype of public health significance. As discussed above, FSIS was not able to validate that chicken consumption is the major direct driver of the increased Infantis rates and is additionally asking for comment on scientific studies and data sources on this topic that are in line with regulatory evidence guidelines.

As research into *Salmonella* virulence factors and their gene functions continues to develop, clustering should be revisited to ensure reliability and consistency. FSIS took care to align the virulence modeling in the risk assessments with epidemiological and clinical patterns in surveillance data: however, current bioinformatics methods are based on the serotypes that have been the consistently highest illness causes (Enteriditis and Typhimurium) across time rather than the full genetic landscape of *Salmonella.* Furthermore, lower virulence serotypes can still outcompete higher virulence serotypes and pose public health risks. As noted above, the list of serotypes of public health significance is essential to this framework, as it determines whether products are adulterated as defined in the PPIA. FSIS requests comments on the initial proposed serotypes of public health significance and what scientific evidence and genetic *Salmonella* data sources beyond the most often studied serotypes should be considered, in addition to that already considered, in the identification of the most highly virulent serotypes identified in the risk assessments, which includes a thorough review of multiple FSIS efforts in this area, including the 2023 NACMCF report and the externally peer reviewed 2023 risk profile.

2. Dose Considerations

As summarized in the 2023 risk profile, although *Salmonella* data are limited, international and domestic outbreak investigations associated with a variety of food products have been used to estimate the relationship between the number of organisms consumed and the probability of illness. These estimates, and more broadly the emergence of dose-response modeling and quantitative risk assessment over the past 25 years, are all based on the concept that a single bacterium is all that is necessary to cause infection and/or illness, that is to say the single-hit model.[86] FSIS' evaluation and summarization of dose-response models, as well as analysis of outbreak data where estimates for the number of organisms consumed were available, demonstrate that the scientific consensus is that exposure to a small number of *Salmonella* organisms can result in foodborne illness.

In a study published in 2010 (the Teunis 2010 study), and included in the 2023 risk profile, using a dose-response model approach utilizing outbreak data, and accounting for variation among outbreaks represented by the data, the *Salmonella* median illness dose was 36 cfus (with 95 percent prediction interval of $0.69–1.26\times10^{7}$ cfu).[87] The median illness dose refers to the dose at which 50 percent of individuals in an exposed population will experience symptomatic illness. The median illness dose and its prediction interval reflect variability among outbreak strains and exposed populations and uncertainty about the dose-response relationship. Thus, it serves as a useful metric for comparing the pathogenicity of different serotypes. Additionally, the World Health Organization Food and Agriculture Organization of the United Nations developed a dose-response approach for risk assessments for *Salmonella.*[88] Also

[81] NACMCF final report ''Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella Control in Poultry Products'' (March 2023).

[82] Fenske GJ, Pouzou JG, Pouillot R, Taylor DD, Costard S, Zagmutt FJ. The genomic and epidemiological virulence patterns of Salmonella enterica serovars in the United States. PLoS One. 2023 Dec 5;18(12):e0294624. doi: 10.1371/journal.pone.0294624. PMID: 38051743; PMCID: PMC10697515.

[83] FSIS is aware only of results on Infantis severity of illness that reinforce it is not a high risk serotype: Brown AC, Chen JC, Watkins LK, et al. CTX–M–65 Extended-Spectrum β-Lactamase–Producing *Salmonella* enterica Serotype Infantis, United States. Emerging Infectious Diseases. 2018;24(12):2284–2291. doi:10.3201/eid2412.180500.

[84] Centers for Disease Control and Prevention (CDC). BEAM (Bacteria, Enterics, Amoeba, and Mycotics) Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services. *www.cdc.gov/ncezid/dfwed/BEAM-dashboard.html.* Accessed 06/07/2024.; Centers for Disease Control and Prevention (CDC). National Outbreak Reporting System Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. Last accessed 06/07/2024. Available from URL: *wwwn.cdc.gov/norsdashboard.;* Centers for Disease Control and Prevention (CDC). FoodNet Fast Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. Last accessed 06/07/2024. Available from URL: *https://www.cdc.gov/foodnet/foodnet-fast.html.*

[85] These estimates are based a CDC pilot analysis of data (CDC unpublished data) presented in 2023 to the National Advisory Committee on Microbiological Criteria for Foods. See: NACMCF final report ''Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products'' (March 13, 2023), available at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

[86] Teunis, P.F., & Havelaar, A.H. (2000). The Beta Poisson dose-response model is not a single-hit model. Risk analysis: an official publication of the Society for Risk Analysis, 20(4), 513–520. *https://doi.org/10.1111/0272-4332.204048.*

[87] Teunis P.F., et al., Dose-response modeling of *Salmonella* using outbreak data. *Int J Food Microbiol,* 2010. 144(2): p. 243–9; *https://doi.org/10.1016/j.ijfoodmicro.2010.09.026.*

[88] World Health Organization, Risk assessment of *Salmonella* in eggs and broiler chickens, March 25, 2002. Available at: *https://www.who.int/publications/i/item/9291562293.*

using outbreaks, the model estimated a 13 percent chance of becoming ill if ingesting an average dose of 100 organisms. Even at the level of 1 organism ingested, there was still a non-zero chance of illness (0.25 percent).

A study published after the 2023 FSIS risk profile was peer-reviewed revisited the 2010 Teunis study discussed above.[89] Using outbreak serotype data, and accounting for variation among outbreaks within a particular serotype, the median *Salmonella* dose predicted to result in 50 percent of exposed individuals becoming ill ($IllD_{50}$) was 3,360 cfu (95 percent range: 18–3.2×10^9), 1,500 cfu (38–8.8×10^7), and 1 cfu (0.69–1.0×10^6) for Enteritidis, Typhimurium and Infantis, respectively. For the same study, the median *Salmonella* dose predicted to result in 1 percent of exposed individuals becoming ill ($IllD_{01}$) was 0.6 cfu (95 percent range: 0.24–1.9), 9.9 cfu (0.32–57), and 0.07 cfu (0.01–2.0×10^4) for Enteritidis, Typhimurium and Infantis, respectively. These results describe that individuals exposed to small doses of *Salmonella* can experience symptomatic illness. Other *Salmonella* serotypes were also found to cause illness at small doses including Heidelberg ($IllD_{50}$=323 cfu and $IllD_{01}$=1 cfu) and Schwarzengrund ($IllD_{50}$=0.8 cfu and $IllD_{01}$=0.04 cfu).

Furthermore, the 2023 FSIS risk assessments developed two virulence-adjusted dose-response models (one for low virulence *Salmonella* serotypes, and another for high virulence *Salmonella* serotypes), which utilize the work described in the 2023 FSIS risk profile to poultry specific serotypes. The high virulence dose-response model (which includes the serotypes of public health significance) was estimated using outbreak data and employed a beta-Poisson model of infection for a given dose as outlined in the 2023 risk profile. Risk multipliers, derived from epidemiological outbreak data attributed to poultry sources, with consideration of prevalence in animal sources from FSIS poultry sampling programs, were then used to scale the relative risk of illness from exposures to each cluster. The probability of illness from consuming chicken containing high virulence *Salmonella* serotypes exposures is 5.66 times greater than the probability of illness from exposure to chicken products containing low virulence *Salmonella* serotypes. The dose-response findings of the 2023 risk assessment rely on the single-hit model, and the virulence adjusted dose-response models estimate of a 1 in 100 probability of illness at 1 cfu of high virulence *Salmonella* per serving and a 0.2 in 100 probability of illnesses at 1 cfu of low virulence *Salmonella* per serving. While the median illness is not attained by the low virulence *Salmonella* dose response model, the median illness dose described by the dose-response model for serotypes of public health significance is approximately 2000 cfu.

As summarized in the 2023 risk profile, five *Salmonella* foodborne outbreaks have shown that *Salmonella* can cause illness from exposure of 10 or fewer organisms per person.[90]Additionally, several outbreaks from a range of *Salmonella* serotypes in various food products have shown that exposure from 11 to 420 organisms per person can result in illness.[91] Thus, in these published studies, illnesses resulted from doses ranging from 1 to 420 *Salmonella* organisms per person.

The 2023 risk profile identified 32 *Salmonella* serotypes of concern linked to foodborne *Salmonella* outbreaks from chicken and turkey products. These identified serotypes of concern informed all subsequent risk management questions, including whether exposure to a small number of these serotypes result in foodborne illness. Because the *Salmonella* serotypes of public health significance identified in the final product standards are among the 32 *Salmonella* serotypes of concern identified in the risk profile and risk assessments, it is reasonable to conclude that the serotypes of public health significance in the final product standards all cause illness at a relatively low dose.

3. Severity of Illnesses

The 2023 risk profile found that exposure to the profile's *Salmonella* subtypes of concern, which include the final product standards serotypes of public health significance, can cause severe or debilitating human health outcomes. Although the symptoms of *Salmonella* infections are typically not reported to be as severe as some of those associated with STEC, *Salmonella* can cause bloody diarrhea, fever, abdominal cramps, nausea, and vomiting. In some instances, *Salmonella* enters the blood stream and makes its way to other areas of the body including, but not limited to, the heart, lung, bone, joints and the central nervous system.[92] This can result in severe illness requiring hospitalizations and even death, especially in vulnerable populations, such as very young, elderly, and immunocompromised individuals. Even when *Salmonella* is no longer detectable in the body, prior *Salmonella* illness has also been associated with an increased risk in colon cancer.[93] Also, the illness can cause debilitating, long-lasting conditions including inflammatory bowel disease, irritable bowel syndrome and reactive arthritis.

[89] Teunis P.F.M. Dose response for Salmonella Typhimurium and Enteritidis and other nontyphoid enteric salmonellae. *Epidemics* 41 (2022) 100653; *https://doi.org/10.1016/j.epidem.2022.100653.*

[90] Killalea, D., et al., International Epidemiological and Microbiological Study of Outbreak of *Salmonella* Agona Infection from a Ready to Eat Savoury Snack—I: England and Wales and the United States. 1996, British Medical Journal Publishing Group.; Shohat, T., et al., International Epidemiological and Microbiological Study of Outbreak of *Salmonella* Agona Infection from a Ready to Eat Savoury Snack—Ii: Israel. BMJ, 1996. 313(7065): p. 1107–1109.; D'aoust, J.Y. and J.Y.D. Aoust, Infective Dose of *Salmonella* Typhimurium in Cheddar Cheese. American Journal of Epidemiology, 1985. 122(4): p. 717–720.; D'aoust, J.Y., D.W. Warburton, and A.M. Sewell, *Salmonella* Typhimurium Phage-Type 10 from Cheddar Cheese Implicated in a Major Canadian Foodborne Outbreak. Journal of Food Protection, 1985. 48(12): p. 1062–1066.; Kapperud, G., et al., Outbreak of *Salmonella* Typhimurium Infection Traced to Contaminated Chocolate and Caused by a Strain Lacking the 60-Megadalton Virulence Plasmid. J Clin Microbiol, 1990. 28(12): p. 2597–601.; Hockin, J.C. et al., An International Outbreak of *Salmonella* Nima from Imported Chocolate. J Food Prot. 1989. 52(1): p. 51–54.; Lehmacher, A., Bockemuhl, J., and Aleksic. S. Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. 1995. Epidemiol Infect. 115: p. 501–11.

[91] Kasuga F.et al., Archiving of food samples from restaurants and caterers—Quantitative profiling of outbreaks of foodborne *Salmonella* in Japan. Journal of Food Protection, 2004. 67: p. 2024–2032; Blaser, M.J., and Newman, L.S. A review of human salmonellosis: I. Infective dose. Rev Infect Dis., 1982.4: p.1096–106; Abe, K., N. et al., Prolonged incubation period of Salmonellosis associated with low bacterial doses. Journal of food protection, 2004. 67: p. 2735–2740; Hara-Kudo, Y. and K. Takatori, Contamination level and ingestion dose of foodborne pathogens associated with infections. Epidemiology and Infection, 2011. 139: p. 1505–1510; Hennessy T.W., et al., A national outbreak of *Salmonella* enteritidis infections from ice cream. N Engl J Med, 1996. 334(20): p. 1281–6; Hedberg C.W., et al., A multistate outbreak of *Salmonella* javiana and *Salmonella* oranienburg infections due to consumption of contaminated cheese. *JAMA,* 1992. 268(22): p. 3203–7; Todd, E.C., et al., Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 4. Infective doses and pathogen carriage. *J Food Prot,* 2004. 71: p. 2339–73; Scheil W., et al., A South Australian Mdbandaka outbreak investigation using a database to select controls. *Aust NZ J Public Health,* 1998. 22(5): p. 536–9; Tamber, S., E. Swist, and D. Oudit, Physicochemical and bacteriological characteristics of organic sprouted chia and flax seed powders implicated in a foodborne Salmonellosis outbreak. *Journal of Food Protection,* 2016. 79(5): p. 703–709.

[92] Batz, M.B., et al., Long-Term consequences of foodborne illness. *Infect Dis Clin North Am,* Sept 2013. 28(3) p. 599–661; Hohmann, E.L., Nontyphoidal Salmonellosis, *Clin Infect Dis,* Sept 2001. 32 p. 263–269; Heymann, D. Salmonellosis. Control of Communicable Disease Manual, 2021.

[93] Mughini-Gras, L. et al. Increased colon cancer risk after severe *Salmonella* infection. *PLoS ONE,* 2018. 13(1): p. 1–19, *https://doi.org/10.1371/journal.pone.0189721.*

Furthermore, a study that allows for a comparison of case-fatality proportions of both *Salmonella* and STEC O157 demonstrates a higher frequency of deaths among *Salmonella* cases than among STEC O157 cases.[94] The estimated annual domestic foodborne illnesses reported in the study were 1,027,561 and 63,153 for *Salmonella* and STEC O157, respectively. Annual deaths from domestic foodborne illnesses are 378 and 20 for *Salmonella* and STEC O157, respectively. Therefore, *Salmonella* deaths occur at a frequency of 4 per 10,000 illnesses, while STEC O157 deaths occur at a frequency of 3 per 10,000 illnesses.

4. Consumer Cooking Practices

As noted above, until recently, with the publication of the proposed determination on *Salmonella* in NRTE breaded stuffed chicken products, FSIS historically has not taken the position that certain *Salmonella* levels or serotypes render raw poultry products adulterated as defined in the PPIA. This position was based in part on the fact that proper cooking kills pathogens on raw product. However, as discussed below, several consumer behavior research studies suggest that ordinary consumer cooking and preparation practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey do not provide adequate assurance that these products will not be contaminated when consumed.

Consumer behavior research. FSIS recommends cooking poultry products until the center of the thickest part of the meat reaches a minimum internal temperature of 165 °F measured by using a thermometer to eliminate the presence of *Salmonella* and other foodborne pathogens.[95] However, although using a thermometer is the only reliable way to ensure that poultry is properly cooked, studies show that many consumers do not ordinarily use a thermometer to determine whether whole chicken, chicken parts, comminuted chicken, and comminuted turkey have reached an internal temperature sufficient to destroy *Salmonella.* Studies also show that many consumers that do use a thermometer do not always do so correctly.

In a study published in 2017, a web-enabled panel survey of U.S. adult grocery shoppers (n = 1,504) was conducted to describe consumers' handling and preparation practices for raw poultry.[96] The purpose of the study was to characterize consumer food thermometer use and barriers to use. The study found that of the 62 percent of the survey respondents who reported owning a food thermometer, thermometer usage was highest among those cooking whole turkeys (73.2 percent). Fewer respondents reported using a thermometer when cooking whole chickens (56.7 percent), chicken breasts or other parts (26.3%), and meatloaf or a similar dish containing ground chicken or turkey (22.8 percent). Reported thermometer use was lowest among respondents cooking patties made with ground chicken or turkey (11.7 percent).

Participants who reported owning a food thermometer identified various reasons for not using a thermometer the last time they cooked poultry at home. For all cuts of poultry, the most common reason reported for not using a thermometer was use of another method to determine that the product was properly cooked (49.8 to 61.5 percent of respondents). The next most common reason selected was that the respondent never thought to use a thermometer (27 to 37.6 percent of respondents), which the researcher concluded suggests that these respondents do not consider it very important to use a food thermometer.

Of the respondents that reported using another method instead of a food thermometer, most reported that they determined that poultry is properly cooked by using visual cues, *i.e.,* color, juice clarity, and cleanliness of probing utensil. Of the 61.5 percent of the respondents that reported using another method to determine that a whole turkey or chicken is properly cooked, 42.2 percent cut the food to check that it was no longer pink, 42.2 percent relied on cooking time, and 41 percent checked that the juices ran clear. Of the 56.1 percent of the respondents that reported using another method to determine that chicken and turkey parts were properly cooked, 67.6 percent cut the food to check that it was no longer pink, 46.2 percent relied on cooking time and 40 percent checked that the juices ran clear. And of the 49 percent of the respondents that reported using another method to determine whether ground chicken or turkey was properly cooked, 61.5 percent inserted a knife, toothpick, or other utensil to see if it came out clean, 55.4 percent relied on cooking time, and 21.0 percent cut the food to check that it was no longer pink.

In an observational study published in 2016, 101 participants were observed as they prepared poultry and egg items to determine whether they followed food safety guidelines.[97] The poultry items prepared for the study were a baked whole chicken breast and a pan-fried ground turkey patty. The study found that thermometer use for all products was low. Only 37 percent of participants used a thermometer to determine that a chicken breast was properly cooked, and only 22 percent used a thermometer to determine that a turkey patty was properly cooked. For the chicken breast, the most common method used to determine doneness was cutting into the chicken (50 percent), followed by color (33 percent) and thermometer use (33 percent). For the turkey patty, the most common indicator used was color (39 percent), followed by cutting into it (30 percent), using a thermometer (22 percent), and looking at the juices (18 percent). The study also found that the participants who used a food thermometer often would use other methods, such as cutting into them or observing the juices, to determine if the poultry items were properly cooked.

The study also highlighted the importance of correctly using a thermometer to determine that poultry is properly cooked. Of the study participants who used a thermometer, 36 percent did not use it correctly in the chicken breast, the turkey patty, or both. The study also found that there was no statistical difference between a participant who did and did not use a thermometer in achieving an end point temperature of at least 165 °F in both the chicken breast and the turkey patty. Seventy-eight percent of participants that used a thermometer to cook the chicken breast reached a final internal temperature above 165 °F, compared to 75 percent for those who did not use a thermometer. Seventy-seven percent of participants who used a thermometer to cook a turkey patty reached a final internal temperature of at least 165 °F, compared to 66 percent of participants who did not use a thermometer.

[94] Scallan, et al., 2011.

[95] FSIS *Safe Minimum Internal Temperature Chart.* 2020; Available at: *https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/safe-temperature-chart.*

[96] KM Kosa, et al. (2017). Barriers to Using a Food Thermometer When Cooking Poultry at Home: Results from a National Survey. Food Protection Trends, 37/2, 116–125, available at: *https://www.foodprotection.org/files/food-protection-trends/mar-apr-17-kosa.pdf.*

[97] Maughan, et al. (2016). Food Handling Behaviors Observed in Consumers When Cooking Poultry and Eggs. Journal of Food Protection, 79:6, 970–977, available at: *https://www.sciencedirect.com/science/article/pii/S0362028X22080814?via%3Dihub.*

In another observational study published in 2014,[98] 120 volunteers were observed as they prepared chicken and salad in their homes. The study participants chose the manner of chicken preparation. Three volunteers prepared whole chicken, and all others prepared chicken parts. The study found that the most common method of determining whether the chicken was properly cooked was appearance. In response to a questionnaire administered after meal preparation, the study participants stated that to determine whether chicken was properly cooked, they looked for white colored meat, absence of blood or pink spots, and firm meat. The study found that 40 percent of the chicken that the participants considered to be properly cooked registered a temperature below 165 °F.

In this study, fewer than 5 percent of the participants voluntarily used a thermometer to record chicken temperature during meal preparation. When asked by the researcher if they wanted to check the cooked chicken's temperature, 34 percent of the participants checked the internal temperature using either their own thermometer or the thermometer provided by the researcher. When chicken temperature was taken, the internal temperature of 60 percent of the cooked chicken registered 165 °F or above. However, 39 percent of households stopped cooking even though the internal temperature of the poultry registered below 165 °F.

A 2020 study used a randomized experimental design and direct observation of meal preparation to test the effectiveness of a USDA food safety video intervention for consumer thermometer use.[99] The study was conducted in test kitchen facilities in which cameras recorded participants' meal preparation from beginning to end. A total of 383 people participated in the study, 201 in the control group (the group that did not watch the food safety video) and 182 in the treatment group. Before preparing the meal, the treatment group watched a 3-minute USDA food safety video on the importance of using a food thermometer. Participants in the control and treatment groups were observed while cooking turkey burgers and preparing a salad to determine whether the participants used a thermometer to determine whether the turkey patties were properly cooked. Following meal preparation, all participants responded to a post observation interview about food handling behaviors.

Sixty-one percent of the control group participants and 63 percent of the treatment group participants reported owning a food thermometer, which is consistent with the percentage of the respondents that reported owning a food thermometer in the 2017 study discussed above (62 percent). During the meal preparation session, the control group used a thermometer to determine whether the turkey patties were properly cooked 34 percent of the time, while the treatment group used a thermometer 75 percent of the time. The control participants were also less likely to insert the thermometer into the side of the patty (23 percent), the recommended practice, than the treatment participants (52 percent). Of the participants that used a thermometer and for whom temperature data were available, the turkey patties were observed to reach an internal temperature of 165 °F 54 percent of the time for the control group and 73 percent of the time for the treatment group. Thus, while both the control and treatment groups were likely to own a food thermometer, the control group was much less likely to use a food thermometer, correctly place a thermometer, and cook patties to a safe internal temperature than the treatment group.

The study also addressed whether the participants used methods other than a thermometer to determine whether the turkey patty was properly cooked. The study found that 45 percent of all participants used a method other than a thermometer to determine that the turkey patty was done cooking. Among participants who did not use the thermometer and for whom usable data were available, 46 percent of control group participants and 29 percent of the treatment group participants relied on the firmness or texture of the patty to determine that it was properly cooked, and 4 percent in the control group and 16 percent in the treatment group relied on patty color. Twenty-five percent of control group and 42 percent of treatment group were observed using both firmness and color of the patty.

Thus, consumer research shows that, rather than using a thermometer to check the internal temperature of whole chicken, chicken parts, comminuted chicken products, and comminuted turkey products, many consumers ordinarily rely on visual and textural cues to determine that these products are properly cooked. However, because these subjective cues have not been correlated with safe internal cooking temperature, they are unreliable for gauging whether poultry products have reached an internal temperature sufficient to destroy *Salmonella* that may be present.[100] As noted above, a 2014 observational study found that 40 percent of the chicken that participants considered to be properly cooked based on subjective cues registered a temperature below 165 °F. The 2017 survey study discussed above also cited a published summary of food safety literature that concluded that 70 percent of chicken pieces visually judged by consumers as ''done'' had not reached a safe internal temperature.[101] A European study that assessed the effect of household cooking methods on the presence and numbers of *Salmonella* Typhimurium in different types of raw poultry products found that improper cooking produced inadequate heat treatments that did not fully eliminate *Salmonella* from the products even when the initial contamination levels were as low as 10 cfu/g.[102] Thus, based on its review of the available consumer research, FSIS has concluded that many consumers do not cook chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey thoroughly and therefore, ordinary consumer cooking practices associated with these products fail to provide adequate assurance that the products will not be contaminated when consumed.

Cross-Contamination. In addition to consumer behavior research that found that many consumers ordinarily rely on visual and textural cues to determine that raw chicken and turkey products are properly cooked, recent studies also found that there are other ordinary consumer practices that create conditions for *Salmonella* exposure from raw poultry regardless of whether the products are properly cooked. Consumer hand washing practices are

[98] Bruhn, C.M. (2014). Chicken preparation in the home: An observational study. *Food Protection Trends, 34*(5):318–330. Available at: *https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/1640787777/se-2.*

[99] Duong M, Shumaker ET, Cates SC, Shelley L, Goodson L, Bernstein C, Lavallee A, Kirchner M, Goulter R, Jaykus LA, Chapman B (2020). An Observational Study of Thermometer Use by Consumers When Preparing Ground Turkey Patties. *J Food Prot. 83*(7):1167–1174. Available at: *https://www.sciencedirect.com/science/article/pii/S0362028X2210339X.*

[100] M. Duong et. al (2020).

[101] Kosa, et al. (2017) citing CJ Byrd-Bredbenner et al. (2013.) Food safety in home kitchens: a synthesis of the literature. *Int. J. Environ Res Publ Hlth 10:*4060–4085.

[102] Roccato A, Uyttendaele M, Cibin V, Barrucci F, Cappa V, Zavagnin P, Longo A, Ricci A (2015). Survival of *Salmonella* Typhimurium in poultry-based meat preparations during grilling, frying and baking. *Int J Food Microbiol 197:*1–8. Available at: *https://www.sciencedirect.com/science/article/pii/S0168160514006011?via%3Dihub.*

one example of this cross-contamination concern.

A 2015 observational study of consumers handling raw poultry as part of an at-home meal preparation event found that hands were washed 12 percent of the time after handling raw poultry.[103] Of note, 100 percent of the same study group responded on a pre-observation questionnaire that they washed their hands before and after handling raw poultry. Further, a 2016 observational study found that, during the preparation and cooking process, 40 percent of participants correctly washed their hands after handling raw whole chicken carcasses, and 46 percent correctly washed their hands after handling the raw ground turkey product.[104]

Research shows that washing poultry can spread bacteria to kitchen surfaces and other foods.[105] Studies also show that washing or rinsing raw poultry is a pervasive consumer preparation practice that raises cross-contamination concerns. For example, a 2019 survey of food handling practices indicated that a lack of adherence to the recommended practice to not wash or rinse raw poultry may have widespread impact on two age groups more susceptible to contracting foodborne illness—young children and older adults.[106] The Web-based survey found that only 39 percent of parents of young children (aged 5 years or younger) and only 31 percent of older adults (aged 60 years or older) reported not rinsing or washing raw poultry. Further, in a 2014 study on observed consumer handling behavior, 120 participants were asked to prepare in their home kitchen a chicken product and a salad. Before the observation, the participants were asked to select and purchase the ingredients, including a raw chicken carcass or part. The study found that 45 percent of the participants washed the raw chicken at the start of preparation.[107]

Additional research indicates that food handling education on the recommendation to not wash or rinse raw poultry may have limited impact on consumer behavior. In 2016, a four-week intervention survey study exposed participants to an educational pilot program developed to raise awareness and influence consumers to not wash raw poultry.[108] The results indicated that, while the program improved both knowledge and behavior of participants toward not washing raw poultry, the majority of consumers that viewed and understood the material still reported washing or rinsing raw poultry after the intervention program concluded.[109] These studies indicate that cross-contamination events are common during poultry handling in home kitchens, and that consumers' knowledge of proper food handling is often not correlated to safe handling behaviors.

E. Risk per Serving, Salmonella Levels, and Proposed Determination

1. Final Product Standards Salmonella Level and Risk per Serving

Salmonella contamination and levels. The 2023 risk assessments include analyses of FSIS testing of chicken and turkey products that show that the proportion of raw chicken carcasses, chicken parts, comminuted chicken and comminuted turkey products contaminated with *Salmonella* is very low and that the levels are very low for contaminated products (Table 3).

TABLE 3—ESTIMATED AMOUNT OF TEST POSITIVE SAMPLES PER SALMONELLA THRESHOLD

	Chicken carcasses (%)	Chicken parts (%)	Comminuted chicken (%)	Comminuted turkey (%)
Tests *Salmonella* Negative	96.92	93.31	72.90	84.26
Tests *Salmonella* Positive	3.08	6.69	27.10	15.74
≥1 cfu/mL or /g	9	2	11	12
≥10 cfu/mL or /g	1	0.07	3	4
≥100 cfu/mL or /g	0.10	<0.01	1	1

Approximately 97 percent of chicken carcasses and 93 percent of chicken parts test negative for *Salmonella* (*i.e.,* results are below the 0.03 cfu/mL limit of detection (LOD)). Approximately 73 percent of comminuted chicken and 84 percent of comminuted turkey test results are below the 0.003 cfu/g LOD. Of the 3 percent of chicken carcasses that test positive for *Salmonella* at the end of production, only 1 percent have *Salmonella* levels at or above 10 cfu/mL, and 0.10 percent have *Salmonella* levels at or above 100 cfu/mL. Of the chicken parts that test positive for *Salmonella,* only 0.07 percent have levels at or above 10 cfu/mL, and less than 0.01 percent were found to have levels at or above 100 cfu/mL. Of the 27 percent of comminuted chicken products that test positive for *Salmonella,* only 3 percent have levels at or above 10 cfu/g, and 1 percent have levels at or above 100 cfu/g. Finally, of the 16 percent of comminuted turkey products that test positive for *Salmonella,* only 4 percent have levels at or above 10 cfu/g, and 1 percent have levels at or above 100 cfu/g. Thus, given that the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey have *Salmonella* at levels below 0.03 cfu/

[103] E Mazengia, et al. (2015). Direct Observational Study of the Risk of Cross-Contamination during Raw Poultry Handling: Practices in Private Homes. Food Protection Trends, 35/1, 8–23. Available at: *https://www.foodprotection.org/files/food-protection-trends/JAN-FEB-15-mazengia.pdf.*

[104] Maughan, et al. (2016). Food Handling Behaviors Observed in Consumers When Cooking Poultry and Eggs. Journal of Food Protection, 79/6, 970–977. Available at: *https://www.sciencedirect.com/science/article/pii/S0362028X22080814?via%3Dihub.* For the purposes of the study, proper hand washing was defined as washing hands with soap for a minimum of 20 seconds immediately after touching the raw product and without touching anything else.

[105] Food Safety Consumer Research Project: Meal Preparation Experiment Related to Poultry Washing Final Report (August 20, 2019). Available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/FSCRP_Year%2B2_Final_Aug2019.pdf.*

[106] Kosa, KM, et al. (2019). Older Adults and Parents of Young Children Have Different Handling Practices for Raw Poultry. Journal of Food Protection, 82(2), 200–206, available at: *https://pubmed.ncbi.nlm.nih.gov/30673351/.*

[107] Bruhn, C.M. (2014). Chicken Preparation in the Home: An Observational Study. Food Protection Trends, 34/5, 318–330, available at: *https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/1640787777/se-2.*

[108] Henley, S., et al. (2016). Don't Wash Your Chicken!: A Food Safety Education Campaign to Address a Common Food Mishandling Practice. Food Protection Trends, 36/1, 43–53, available at: *https://www.foodprotection.org/files/food-protection-trends/jan-feb-16-henley.pdf.*

[109] Twenty-five percent of consumers in the intervention group reported not washing whole raw poultry, compared to 20.1 percent of consumers in the control group. Sixteen-point-three percent of consumers in the intervention group reported not washing small cuts of raw poultry, compared to 9.8 percent of consumers in the control group.

mL(g), FSIS testing data shows that *Salmonella* levels at or above 10 cfu/mL(g) represent comparatively higher levels of contamination that are infrequently identified in these raw poultry products.

Risk per Serving. The risk assessments also quantify and compare the probability of illness associated with chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* levels at or above 10 cfu/mL(g) with the average level of contamination for these raw products. The risk assessments used two dose-response models to provide a description of risk of illness per serving for *Salmonella* from chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products, when combined with an attenuation distribution. This attenuation distribution describes the variety of activities that occur between FSIS sampling a final product lot and a consumer ingesting a serving from that lot. These activities include product mixing, transportation, and cooking—all of which can result in both *Salmonella* growth and die off.

A summary of probability of illness per serving for the main scenarios that were considered in the risk assessments is provided in Table 4. The average *Salmonella* level for product lots that test at or above each threshold level are provided, along with the average dose consumed, *i.e.,* the level after attenuation, and likelihood that consumers are exposed to such servings.

The model-derived baseline probability of illness for chicken carcasses is 0.2 illnesses per 100,000 servings, for chicken parts is 0.3 illnesses per 100,000 servings, and 2.5 illnesses per 100,000 servings for comminuted chicken, and 2.5 illnesses per 100,000 servings for comminuted turkey. Comparison of the threshold probability of illness to the baseline quantifies how much higher than average the risk per serving is for each scenario.

Table 4—Average characteristics (level, dose, and probability of illness by serocluster) of failing lots for *Salmonella* threshold level scenarios in FSIS-sampled products under consideration and the overall likelihood of consumer exposure. The serotypes of public health significance (Enteritidis, Typhimurium, and I 4,[5],12:i:- for chicken products and Hadar, Typhimurium and Muenchen for Comminuted turkey) are among the higher virulence Serotype Cluster

Salmonella THRESHOLD LEVEL SCENARIOS UNDER CONSIDERATION

[cfu/mL or g]

Measurement	Product type	0.003	0.033	1	10	100
Average level for failing lots (cfu/mL(g)).	Chicken Carcasses	0.48	1.65	16	97	682
	Chicken Parts	0.08	0.30	4	33	281
	Comminuted Chicken	17	37	163	582	2,572
	Comminuted Turkey	163	348	1,373	4,249	15,479
Average dose consumed for average failing lot (cfu/serving).	Chicken Carcasses	0.08	0.26	3	15	108
	Chicken Parts	0.01	0.05	0.67	5	45
	Comminuted Chicken	3	6	26	92	408
	Comminuted Turkey	26	55	218	673	2,453
Probability of illness per 100,000 servings*, high virulence.	Chicken Carcasses	23	54	224	612	1,598
	Chicken Parts	6	16	100	340	1,050
	Comminuted Chicken	235	363	800	1,486	2,849
	Comminuted Turkey	801	1,166	2,184	3,490	5,660
OR						
Probability of illness per 100,000 servings*, low virulence.	Chicken Carcasses	4	9	42	119	329
	Chicken Parts	1	3	18	64	211
	Comminuted Chicken	44	69	158	305	611
	Comminuted Turkey	158	235	460	761	1,287
Likelihood of consumer exposure to raw product at or above initial level.	Chicken Carcasses	11%	3%	0.27%	0.03%	<0.01%
	Chicken Parts	31%	7%	0.17%	<0.01%	<0.01%
	Comminuted Chicken	27%	13%	3%	0.79%	0.17%
	Comminuted Turkey	16%	7%	2%	0.60%	0.16%

* Given average initial level multiplied by attenuation distribution.

As illustrated in Table 4, the risk assessments found that the probability of illness for servings of raw chicken carcasses that are contaminated with *Salmonella* levels at or above 10 cfu/mL and contain a serotype of public health significance is 612 illnesses per 100,000 servings of raw chicken carcasses, while the average probability of illness is 0.3 illnesses per 100,000 servings; the great majority of which have levels far below 10 cfu/mL. Therefore, servings from production lots of raw chicken carcasses that test positive for *Salmonella* at levels of 10 cfu/mL or greater with a serotype of public health significance are 2,000-fold (*i.e.,* ~ 612/0.3) more likely to cause illness than the average across all chicken carcass servings. Thus, while there is a relatively low probability that individuals will be exposed to carcasses that contain *Salmonella* at 10 cfu/mL, if exposed, there is a much higher probability of illness, *i.e.,* 2,000-fold, when compared to exposure to the majority of servings from chicken carcasses.

For raw chicken parts, the risk assessment found that chicken parts servings that are contaminated with *Salmonella* levels at or above 10 cfu/mL at the end of production and contain a serotype of public health significance have a probability of illness of 340 illnesses per 100,000 servings, while the average probability of illness is 0.3 per 100,000 servings for all servings; the great majority of which have levels

much below 10 cfu/mL. Therefore, servings from production lots of raw chicken parts that test positive for *Salmonella* at levels at or above 10 cfu/mL with a serotype of public health significance are 1,100-fold (*i.e.,* ~340/0.3) more likely to cause illness than the average across all chicken parts servings. Thus, while there is a relatively low probability that consumers will be exposed to chicken parts that contain *Salmonella* at 10 cfu/mL, if exposed, there is a much higher probability of illness, *i.e.,* 1,100-fold, when compared to exposure to the majority of servings from raw chicken parts.

For raw comminuted chicken servings, the risk assessments found that products that are contaminated with at least 10 cfu/g of *Salmonella* at the end of production and contain a serotype of public health significance have a 1,500 per 100,000 servings probability of illness, while average probability of illness is 2.5 per 100,000 servings for all servings; the majority of which have levels below 10 cfu/g. Therefore, servings from production lots of comminuted chicken that test positive for *Salmonella* at or above 10 cfu/g with a serotype of public health significance are 590-fold (*i.e.,* ~1,500/2.5) more likely to cause illness than the average across all comminuted chicken servings. Thus, while there is a relatively low probably that consumers will be exposed to comminuted chicken that contains *Salmonella* at 10 cfu/g, if exposed, there is a much higher probability of illness, *i.e.,* 590-fold, when compared to the majority of servings of comminuted chicken.

For raw comminuted turkey servings, the risk assessments found that products that are contaminated with at least 10 cfu/g of *Salmonella* at the end of production and contain a serotype of public health significance have a 3,500 per 100,000 servings probability of illness, while the average probability of illness is 2.5 per 100,000 servings across all servings; the majority of which have levels below 10 cfu/g. Therefore, servings from production lots of comminuted turkey that test positive for *Salmonella* at or above 10 cfu/g with a serotype of public health significance are 1,400-fold (*i.e.,* ~3,500/2.5) more likely to cause illness than the average across all comminuted turkey servings. Thus, while there is a relatively low probability that consumers will be exposed to comminuted turkey that contains *Salmonella* at 10 cfu/g, if exposed, there is a much higher probability of illness, *i.e.,* 1,400-fold, when compared to the majority of servings of comminuted turkey.

Illnesses prevented. The risk assessments also predicted the total number of illnesses prevented annually for chicken carcasses, parts, and comminuted chicken and turkey for different *Salmonella* threshold levels—0.03 cfu/ml(g), 1 cfu/mL(g), 10 cfu/mL(g), and 100 cfu/mL(g) (Table 5). Uncertainty analyses were also run for the main scenarios under consideration. A threshold set at the *Salmonella* detection level for comminuted chicken and turkey (0.003 cfu/g) was not as effective as the higher threshold levels in Table 5 below. Therefore, an analysis evaluating the uncertainty around the predicted public health impact for a threshold of 0.003 cfu/g *Salmonella* in comminuted poultry was not evaluated in the risk assessments.

The resulting overlapping 95 percent credible intervals around the estimated number of illnesses prevented suggest that there is little meaningful difference in effectiveness between the threshold standards with respect to annual illnesses prevented. However, as discussed above, when compared with the majority of servings, chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* at 10 cfu/mL(g) or higher present a much higher probability of illness. Thus, based on the elevated probability of illness associated with raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey associated with *Salmonella* levels at or above 10 cfu/mL(g), FSIS is proposing 10 cfu/mL(g) as the *Salmonella* level for the proposed final product standards.

TABLE 5—ANNUAL ILLNESSES PREVENTED, MOST LIKELY

[95% Credible Interval]

Threshold level	Chicken carcasses	Chicken parts	Comminuted chicken	Comminuted turkey
0.03 cfu/mL(g)	4600 (2000, 7100)	7900 (3300, 12700)	1500 (800, 2200)	2500 (700, 4900)
1 cfu/mL(g)	2400 (700, 5000)	1400 (400, 3600)	1400 (600, 2100)	2300 (600, 4800)
10 cfu/mL(g)	1000 (200, 3100)	200 (40, 700)	1000 (400, 1900)	2000 (500, 4300)
100 cfu/mL(g)	200 (0, 1500)	20 (0, 100)	600 (200, 1500)	1400 (200, 3500)

2. Proposed Determination

After careful consideration of the information presented above, FSIS has concluded that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance present an unacceptable risk of illness based on their risk per serving. As discussed above, the 2023 risk assessments for chicken found that production lots of raw chicken carcasses and raw chicken parts contaminated with these *Salmonella* levels and serotypes are at least 1,000 times more likely than average to cause illness across all chicken parts and carcass servings, and that servings from production lots of comminuted chicken and turkey contaminated with *Salmonella* at these levels and serotypes are at least 590 times more likely than average to cause illness across all comminuted chicken and turkey servings.

Additionally, *Salmonella* has been associated with severe and debilitating human illness and available data suggest that the *Salmonella* infectious dose for the serotypes of public health concern is relatively low. Information from consumer behavior research shows that, rather than using a food thermometer to check the internal temperature of whole chicken, chicken parts, comminuted chicken products, and comminuted turkey products, many consumers ordinarily rely on visual and textural cues to determine that these products are properly cooked. Consumer research also shows that chicken that consumers considered to be properly cooked based on these subjective cues often had not reached an internal temperature sufficient to destroy *Salmonella* that may be present, and one study found that for certain poultry products, that application of inadequate heat treatments from improper cooking was unable to assure complete elimination of *Salmonella* even with a low initial contamination level of 10 cfu/g. Information from consumer behavior research also shows

that ordinary consumer handling associated with chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey creates conditions for *Salmonella* exposure from raw poultry through cross contamination.

Thus, because *Salmonella* can survive what many consumers consider to be ordinary cooking and handling practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, and because the 2023 risk assessments found that servings of these products that test positive for *Salmonella* at levels at or above 10 cfu/mL(g) and a serotype of public health significance are much more likely to cause illness when compared to the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings, FSIS has tentatively determined that, when contaminated with *Salmonella* at these levels and serotypes, these products are adulterated as defined in the PPIA. Specifically, FSIS has tentatively concluded that these products are adulterated as defined in 21 U.S.C. 453(g)(1) because their elevated risk of illness renders them ''injurious to health.'' FSIS has also tentatively concluded that they are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them ''unsound, unhealthful, unwholesome, or otherwise unfit for human food.''

The adulteration definition in 21 U.S.C. 453(g)(1) includes two separate standards for determining whether a product is adulterated. Under 21 U.S.C. 453(g)(1), if a substance is an ''added substance'' the product is adulterated if the substance ''may render'' the product injurious to health. If the substance is not added, the product is adulterated ''if the quantity of such substance in or on'' the product ''ordinarily'' renders it injurious to health.

As noted above, in response to the draft October 2022 *Salmonella* Framework, FSIS received comments on whether *Salmonella* should be considered as an ''added substance'' in raw poultry. Comments from consumer advocacy organizations asserted that *Salmonella* should be considered as an ''added substance'' because it is not normally present in the muscle tissue of healthy birds. The comments stated that while *Salmonella* is present in the gastrointestinal tract of live birds, it is an ''added substance'' in poultry products because it only makes its way onto to poultry muscle tissue through contamination that occurs during slaughter and processing, specifically during defeathering and evisceration. To support this position, the commenters referenced case law that provides that where some portion of toxic substance present in a food has been introduced by human intervention, the entirety of that substance present in the food will be treated as an ''added substance''.[110]

Comments from trade associations representing the meat and poultry industries asserted that *Salmonella* is not an ''added substance'' because it exists naturally in and on the live birds. The comments stated that *Salmonella* can exist in a chicken's skin, muscle tissue, and gut. A trade association representing the chicken industry cited references that, according to the comment, show that researchers have identified *Salmonella* in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle. The commenter also stated that literature shows correlations between *Salmonella* loads on the farm and in birds and at various processing steps, reinforcing that *Salmonella* enters the process via the chickens themselves. A comment from a trade association representing the meat and poultry industry stated that *Salmonella* can exist on the exterior of the animal, harbor in feather follicles, and travel from the gastrointestinal tract of poultry to the bloodstream, theoretically providing a pathway for *Salmonella* to be distributed throughout the bird.

In addition, the comments stated that the case law provides that to be ''added,'' a substance must not otherwise be present in the food and must be artificially introduced by a person.[111] According to the chicken industry trade association, the fact that *Salmonella* may be present in greater expected concentrations in some parts of a chicken than others does not make it an ''added substance'' in poultry muscle because, as with any microbe, naturally-occurring *Salmonella* can be spread through cross-contact during processing.

FSIS had traditionally viewed *Salmonella* as ''naturally occurring'' in food animals.[112] FSIS has previously rejected broad requests for it to declare that *Salmonella* is considered an ''added substance'' in all products,[113] however, FSIS has not previously determined whether certain circumstances, considering what current scientific data indicates about *Salmonella's* spread to or within products, may render *Salmonella* an ''added substance'' in the raw products covered by this proposed framework. Before taking a position on whether there are any circumstances in which *Salmonella* can be considered an ''added substance'' in raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, FSIS has decided to request additional comments on both the legal and factual aspects of this issue.

As noted above, under 21 U.S.C. 453(g)(1), there are two definitions for adulteration, depending on whether a substance in a poultry product is ''added'' or ''not added.'' However, the PPIA does not define the circumstances in which a substance in a poultry product is ''added'' within the meaning of the statute. Prior court decisions that address whether *Salmonella* is an adulterant in raw meat or poultry products have never directly considered whether and under what circumstances *Salmonella* may be considered an ''added substance'' under the PPIA.[114]

As noted above, some of the comments on the October 2022 draft *Salmonella* Framework asserted that *Salmonella* should be considered as an ''added substance'' in raw poultry based on the holding in *U.S.* v. *Anderson Seafoods*. The *Anderson Seafoods* case involved toxic levels of mercury in swordfish. The issue before the court was whether all mercury found in the swordfish should be considered as an ''added substance'' under the adulteration provisions of the FFDCA [115] when some mercury in swordfish occurs naturally and some is the result of man-made pollution. The court held that ''where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be

[110] See *United States* v. *Anderson Seafoods, Inc.,* 622 F.2d 157 (5th Cir. 1980); *Continental Seafoods, Inc.* v. *Schweiker,* 674 F.2d 38 (D.C. Cir. 1982).

[111] These commenters cite *United States* v. *Coca Cola,* 241 U.S. 265 (1915) and *United States* v. *Anderson Seafoods, Inc.* 622 F.2d 157, 160 (5th Cir. 1980).

[112] See FSIS Final Response to Marler Clark LLP petition # 20–01 ''Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of *Salmonella enteritica* subspecies to be Adulterants'' Available at: *https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes.*

[113] See FSIS Final Response to Marler Clark petition.

[114] See *American Public Health Association (APHA)* v. *Butz,* 511 F. 2d 331 (D.C. Cir. 1974); *Continental Seafoods, Inc.* v. *Schweiker,* 674 F.2d 38 (D.C. Cir. 1982); *Supreme Beef Processors, Inc.* v. *USDA,* 275 F.3d 432 (5th Cir. 2001).

[115] The adulteration definition in the FFDCA at issue in *Anderson Seafoods* is, in relevant parts, identical to the definition in the PPIA and provides that ''A food shall be deemed to be adulterated (a)(1) 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 food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health''(21 U.S.C. s 342(a)(1)).

treated as an added substance'' as defined in the statute.[116] Based on this holding, some comments asserted that *Salmonella* should be considered as an ''added substance'' in raw poultry because poultry muscle does not normally contain *Salmonella,* and *Salmonella* only makes its way onto to poultry muscle tissue through contamination that occurs during slaughter and processing.

As noted by the comments, *Salmonella* is present in the gastrointestinal tract of live birds, and there is evidence that extraintestinal *Salmonella* exist in poultry skin, livers, bones, and bone marrow before processing.[117] Most *Salmonella* contamination on carcasses is believed to result from leakage of ingesta during crop removal and from feces during evisceration, as well as aerosolization during picking.[118] [119] After poultry carcasses are scalded, the carcasses travel through a series of defeathering machines where their feathers are removed using mechanical pickers with rubber ''fingers.'' During the picking process, these rubber fingers not only can massage *Salmonella*-contaminated water remaining from the scalder into the carcass but can also inadvertently press on the abdomen of the carcass, pushing out fecal matter and ingesta, resulting in transfer of *Salmonella* to the carcass skin or to the machinery.[120] The 2023 risk profile identified studies that show that *Salmonella* can persist on processing equipment after cleaning and sanitation,[121] which increases the potential for cross-contamination.

Another step in the process in which *Salmonella* may be spread to or increased in poultry carcasses is evisceration. During evisceration, *Salmonella* that is present in the gastrointestinal tract may be transferred to the skin and other carcass surfaces due to rupture of the viscera when the carcass is opened.[122] Additionally, the 2023 risk profile found that although used as a control step, immersion chilling may be an opportunity for cross-contamination of broiler carcasses. For example, in one study, a lower incidence of *Salmonella* in air-chilled broilers compared to immersion-chilled broilers (18.7 percent to 24.7 percent positive carcasses) suggests that cross-contamination may be more prevalent for immersion-chilled broilers.[123]

In addition to processes that can contribute to *Salmonella* contamination on poultry carcasses during slaughter and processing, further processing of carcasses into other commodities may also add *Salmonella* to or increase *Salmonella* in finished poultry parts, such as wings, breasts, and thighs. FSIS sampling data show that further processed chicken parts have a higher incidence of *Salmonella* compared to carcasses.[124] This difference is likely because of cross contamination between positive and negative parts and carcasses during further processing.[125] [126] Further processing presents various opportunities in which *Salmonella* that is present in certain parts of the bird may be added to interior edible muscle where *Salmonella* is not ordinarily found. For example, *Salmonella* can be found in feather follicles in the skin.[127] [128] When the skin is cut, *Salmonella* can be exposed and spread during processing to previously uncontaminated product and/or increased in product with low levels of contamination.[129] In addition, *Salmonella*-negative raw poultry parts and comminuted poultry may become cross-contaminated by contact with *Salmonella*-contaminated equipment or when they are commingled with *Salmonella*-positive products, such as when they are collected in combo bins for further processing.[130] [131]

Comminuted products are those that are ground, mechanically separated, or hand- or mechanically deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Because of the nature of comminuted processes, *Salmonella* contamination in chicken skin and bone can spread throughout an entire batch or lot through cross-contamination. FSIS sampling data show that ground and other raw comminuted chicken products that were produced using either bone-in or skin-on source materials were more likely to be contaminated with *Salmonella* than those fabricated from deboned, skinless source materials.[132] *Salmonella*-contaminated equipment used to produce comminuted poultry may also contribute to *Salmonella* contamination in these products.

FSIS requests comments on whether the available science supports that some *Salmonella* in a raw poultry product is ''naturally occurring'' and some is ''added.'' FSIS also requests comments on whether, under the reasoning of *Anderson Seafoods* or another rationale, the Agency has authority to regulate *Salmonella* as an ''added substance'' if it can demonstrate that some *Salmonella* can be artificially

[116] *Anderson Seafoods,* 622 F.2d at 161.

[117] Rimet, C.S., et al. (2019). *Salmonella* Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat. Frontiers in Sustainable Food Systems 3(2). see also Jones-Ibarra, A.M., et al. (2019). *Salmonella* recovery from chicken bone marrow and cecal counts differ by pathogen challenge method. Poult Sci 98(9): 4104–4112. see also Cox, N.A., et al. (2007). Recovery of *Campylobacter* and *Salmonella* Serovars from the Spleen, Liver and Gallbladder, and Ceca of Six-and Eight-Week-Old Commercial Broilers. Journal of Applied Poultry Research 16(4): 477–480.

[118] National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. J Food Prot. 82(4):645–668.

[119] Singh M and Thippareddi H (2020). *Managing Microbiological Food Safety Risks in Poultry Processing.* White Paper for 3M Food Safety at: *https://berstlerllc.com/wp-content/uploads/2023/03/3M-Food-Safety-Poultry-Segment-Whitepaper.pdf.*

[120] Singh 2020.

[121] Obe, T., et al., *Prevalence of Salmonella Enterica on Poultry Processing Equipment after Completion of Sanitization Procedures.* Poultry Science, 2020. 99(9): p. 4539–4548. Veluz, G.A., S. Pitchiah, and C.Z. Alvarado, *Attachment of Salmonella Serovars and Listeria Monocytogenes to Stainless Steel and Plastic Conveyor Belts.* Poultry Science, 2012. 91(8): p. 2004–2010. Rothrock, M.J., Jr., et al., *The Characterization of Salmonella Enterica Serotypes Isolated from the Scalder Tank Water of a Commercial Poultry Processing Plant: Recovery of a Multidrug-Resistant Heidelberg Strain.* Poultry Science, 2015. 94(3): p. 467–472. Bailey, J.S., et al., *Sources and Movement of Salmonella through Integrated Poultry Operations: A Multistate Epidemiological Investigation.* Journal of Food Protection, 2001. 64(11): p. 1690–7.

[122] Singh (2020); National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. J Food Prot. 82(4):645–668.

[123] Smith, D.P., J.A. Cason, and M.E. Berrang, *Effect of Fecal Contamination and Cross Contamination on Numbers of Coliform, Escherichia coli, Campylobacter, and Salmonella on Immersion-Chilled Broiler Carcasses.* Journal of Food Protection, 2005. 68(7): p. 1340–1345.

[124] Sampling Results for FSIS-Regulated Products. Available at: *https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products.*

[125] FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) p. 59. Available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf.*

[126] Codex Guideline for the Control of Campylobacter and *Salmonella* in Chicken Meat at: *https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B78-2011%252FCXG_078e.pdf.*

[127] Kim J–W and Slavik MF. 1996. Cetylpyridinium Chloride (CPC) treatment on poultry skin to reduce attached *Salmonella.* J. Food Prot. 59: 322–326.

[128] Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of *Salmonella* in neck skin and bone of chickens. J Food Prot. 77(7): 1193–1197.

[129] FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 59–60.

[130] FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 59.

[131] Codex Guideline for the Control of Campylobacter and *Salmonella* in Chicken Meat.

[132] FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 65–66, Table 4 FSIS exploratory sampling test results, raw comminuted chicken by source material composition (6/1/13–6/30/15, 2,688 samples.

introduced into raw poultry products through processing procedures and other actions attributable to man.

As discussed above, consumer behavior research shows that *Salmonella* can survive what many consumers consider to be ordinary cooking and handling practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. In addition, the 2023 risk assessments, which modeled a broad distribution of consumer cooking behavior, found that servings of these products that test positive for *Salmonella* at levels at or above 10 cfu/mL(g) and a serotype of public health significance are much more likely to cause illness when compared to the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings. Thus, regardless of whether *Salmonella* is considered as an ''added substance,'' FSIS tentatively determines through this proposal that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* levels at or above 10 cfu/mL(g) and a serotype of public health significance are adulterated under 21 U.S.C. 453(g)(1) because when contaminated with these levels and serotypes of *Salmonella,* the high likelihood that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey will result in illnesses when compared to the average serving of these products ''ordinarily'' renders them injurious to health. Additionally, through this proposal, FSIS tentatively determines that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* levels and serotypes in the proposed final product standards are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them ''unsound, unhealthful, unwholesome, or otherwise unfit for human food.'' This tentative determination does not depend on the status of *Salmonella* as an ''added substance.''

FSIS requests comments on its proposed determination that, when contaminated with *Salmonella* at the levels and serotypes provided in the final products standards, chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated as defined in 21 U.S.C. 453(g)(1) and (3) and whether there are alternative bases for determining adulteration for these poultry products.

F. Proposed Policy Implementation

1. HACCP Reassessment

The HACCP system regulations require that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)). If finalized, FSIS' proposed determination that chicken carcasses, chicken parts, comminuted chicken and comminuted turkey that contain *Salmonella* levels of 10 cfu/mL(g) or higher and any detectable levels of a serotype of public health significance are adulterated would be such a change. Thus, if FSIS finalizes this proposed determination, all establishments that produce chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that will enter commerce would need to reassess their HACCP plans. Establishments that make changes to their production process because of their reassessment would also need to re-validate their HACCP plans. FSIS would issue instructions to IPP in establishments that produce these final products to verify that these establishments have completed their reassessment before the effective date of any final determination resulting from this proposal.

2. Proposed Implementation and Status of Laboratory Methods

Products subject to verification sampling. Should FSIS finalize these proposed standards, the Agency intends to conduct a routine sampling and verification testing program for *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey in which the Agency would collect samples of raw final products and analyze them for *Salmonella* levels and serotypes to determine whether the final product is adulterated. FSIS would collect the verification samples after the establishment has completed all validated antimicrobial interventions. Under the proposed *Salmonella* verification testing program, FSIS intends to only collect and analyze samples of the final poultry products produced by an establishment, *i.e.,* chicken carcasses to be shipped in commerce as whole chickens, chicken parts to be shipped in commerce as chicken parts, comminuted chicken to be shipped in commerce as comminuted chicken products, and comminuted turkey to be shipped in commerce as comminuted turkey products. Thus, under this proposal, if a chicken slaughter establishment uses carcasses processed in the establishment to produce other final products, such as chicken parts or comminuted chicken, FSIS would not collect whole carcass samples as part of the proposed verification sampling program. Likewise, chicken parts produced by an establishment that are intended for use in another final product produced by the establishment, such as comminuted chicken, would not be subject to FSIS verification sampling. FSIS also does not intend to collect samples of mechanically separated chicken or mechanically separated turkey under the proposed verification sampling program. However, final comminuted chicken and turkey products that contain mechanically separated chicken or turkey would be eligible for verification sampling.

The final product samples collected under the proposed verification sampling plan would be determined on an establishment basis. Thus, all raw final products produced by an establishment that are not intended to be further processed into a RTE product would be subject to verification sampling regardless of where the product is shipped. For example, FSIS would consider whole carcasses or parts to be final products subject to verification sampling if the establishment that produced the carcasses or parts ships them to another establishment for further processing into a raw parts or comminuted product. FSIS would not, however, collect verification samples from raw whole carcasses, parts, or comminuted products that are shipped to another establishment for cooking or to be further processed into a ready-to-eat product. If off-site interventions, such as high-pressure processing or irradiation, are applied to prevent or control *Salmonella,* FSIS would sample the product after the off-site intervention is applied.

Additionally, should FSIS finalize these proposed final product standards, the Agency intends to conduct testing for *Salmonella* of imported raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products in accordance with FSIS' import reinspection procedures.[133] Poultry imports represent a small fraction of the U.S. domestic poultry supply, accounting for less than 0.5

[133] FSIS Directive 9900.2, Import Reinspection of Meat, Poultry and Egg Products (Rev. 2)(Oct 12 2021). Available at: *https://www.fsis.usda.gov/policy/fsis-directives/9900.2.*

FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products (Nov 3, 2015). Available at: *https://www.fsis.usda.gov/policy/fsis-directives/9900.6.*

percent in 2021. Currently, FSIS samples and tests imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey for the presence of *Salmonella.* According to data from PHIS, in 2021, FSIS collected and analyzed about 850 samples of imported chicken and turkey products, which represented about 15.8 million pounds of product. These samples were mainly from chicken parts and carcasses, as imports of comminuted chicken and turkey are relatively low. While data on the volume of imported product with results at or above 10 cfu/mL(g) are not available, FSIS estimates this would be a relatively low volume of product.

Sample analysis. The detection and isolation methodology for *Salmonella* is described in MLG chapter 4.14, of the FSIS Microbiology Laboratory Guidebook.[134] Based on current FSIS methodologies, when sampling the chicken carcasses and parts under this proposed determination, FSIS would collect a rinsate sample from the establishment to analyze 30 mL per test for *Salmonella.* When sampling comminuted chicken or comminuted turkey, the Agency would collect 1 pound of the product from the establishment to analyze 325 g per test for *Salmonella.* Samples would be initially screened, post-enrichment, for the presence or absence of *Salmonella.* Samples that screen negative would be reported as ''negative.'' For samples that screen positive, FSIS would use selective and differential culture-based media and proteomics testing to confirm. In parallel, all screen positives will be analyzed for levels and targeted rapid serotype screening. A sample is considered confirmed positive for *Salmonella* after completion of confirmatory tests. Any chicken carcass, chicken parts, comminuted chicken, or comminuted turkey final product sample ''confirmed positive'' with *Salmonella* levels of 10 cfu/mL(g) or higher and screened positive for a serotype of public health significance would not be allowed to enter commerce. Any chicken carcass, chicken parts, comminuted chicken, or comminuted turkey final product sample that contains *Salmonella* levels of 10 cfu/mL(g) or higher and a serotype of public health significance would be considered adulterated.

Based on current testing methodologies, FSIS estimates that *Salmonella* screening results and quantification results would routinely be available 2 days after a sample is taken. For samples above the quantification threshold, an additional 3 days may be necessary for a confirmed positive or negative result. Currently, the routine procedure is to use WGS to determine *Salmonella* isolate sequence, serotypes, and antimicrobial resistance (AMR) profile, which require at least 14 days for result reporting. FSIS could use a non-routine molecular serotyping methodology to determine the serotype in a more time sensitive manner such that results would be available by *Salmonella* confirmation, 5 days after sample collection, if not sooner.

FSIS is proposing the combined quantification and serotype final product standards recognizing current efforts underway by ARS and private sector laboratories to develop rapid, reliable, *Salmonella* quantification and serotyping technologies. FSIS is actively working to explore technologies that may have the capability of WGS in determining serotype and reduce the current timeframe. All timeframes and methods are likely to change as FSIS continuously incorporates new laboratory technologies into its sampling verification program. Any final verification sampling plan resulting from this proposal would use testing methods that are validated and fit for purpose.

FSIS requests comments on available technologies and methods for of quantification and serotyping. If FSIS finalizes this proposed sampling plan, data gathered from the sampling plan would enable the Agency to gauge more precisely the hazard posed by certain *Salmonella* levels and serotypes in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS intends to further evaluate and, if necessary, refine the proposed status of *Salmonella* as an adulterant in these raw poultry products as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available.

Sampled Lot. When FSIS tests a product sample for adulterants, the Agency withholds its determination as to whether product is not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received (*77 FR 73401).* Under this policy, establishments and importers of record at official import inspection establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, if FSIS finalizes its proposed routine *Salmonella* verification testing program for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, establishments that produce these raw products and official import inspection establishments where these raw products are reinspected would need to control and maintain the integrity of the sampled lot pending the availability of test results.

Under any final verification sampling plan, FSIS IPP would give establishments and official import inspection establishments advance notice before IPP collect a product sample for *Salmonella* to give these entities enough time to control the sampled lot without altering the process that the sample represents. The sampled lot is the product represented by the sample collected and analyzed by FSIS. Establishments are responsible for providing a supportable basis for defining the sample lot. For sampling purposes, product lots should be defined such that they are microbiologically independent. Microbiological independence is documented by separation, *e.g.,* physical, temporal, or by sanitation intervention, that clearly delineates the end of one production lot and the beginning of the next. The microbiological results from one test are independent of prior or later lots. In other words, if a product sample tests positive for *Salmonella* at a level of 10 cfu/mL(g) or higher and contains a detectable level of at least one serotype of public health significance, products from other production lots should not be implicated, provided the establishment can support that the lots remain microbiologically independent.

Generally, FSIS recommends that establishments develop and implement in-plant sampling plans that define production lots or sub-lots that are microbiologically independent of other production lots or sub-lots. Production lots that are so identified may bear distinctive markings on the shipping cartons. FSIS has issued guidance to help establishments and official import inspection establishments comply with the Agency's policy that does not allow product that FSIS has tested for adulterants to enter commerce until test results become available.[135] In addition to providing guidance on adequate control measures that establishments and official import inspection establishments can implement for products tested for adulterants, the document also includes guidance on

[134] FSIS Microbiology Laboratory Guidebook available at: *https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook.*

[135] FSIS Compliance Guideline: Controlling Meat and Poultry Product Pending FSIS Test Results (2013) at: *https://www.fsis.usda.gov/guidelines/2013-0003.*

how to define a product lot in order to determine the amount of product that must be controlled pending test results. If FSIS finalizes the proposed new standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, FSIS would consider updating the guidance to cover *Salmonella* sampling of these raw poultry products.

As discussed above, establishments would be required to control the raw poultry products sampled by FSIS pending the test results. If test results detect *Salmonella* at a level of 10 cfu/mL(g) or higher and at least one *Salmonella* serotype of public health significance, FSIS would consider products represented by the sampled lots to be adulterated and would issue an NR. Additionally, all products in the lot represented by the sample would be prohibited from entering commerce. If any product from the lot represented by the product samples has entered commerce, FSIS would request that the producing establishment recall the implicated products. Depending on the circumstances, in addition to issuing an NR, FSIS could take other appropriate enforcement action as authorized in 9 CFR part 500 because the establishment would have produced and shipped adulterated product. Such actions may include immediately suspending inspection or issuing an NOIE.

For imported products tested at port of entry, if the product tests positive for *Salmonella* at 10 cfu/mL(g) or higher and any detectable level of a *Salmonella* serotype of public health significance and has not been held at the official import inspection establishment or at an off-site premises under adequate controls, FSIS would request that the importer of record recall the product. If the product has been held, the product will be refused entry. Product lots subsequently presented for import inspection from the same foreign country and establishment would be held at the official import inspection establishment pending results in accordance with FSIS' import reinspection procedures.[136] The FSIS Office of International Coordination would notify the program officials of the affected exporting country when a positive result is reported, so that they can determine whether the producing establishment has exported any other product from the same production lot to the United States. If the foreign establishment has properly defined the product lot on the basis of specific control factors, and accurately tracked the containerization of product produced under those controls, the establishment can reduce the likelihood that adulterated product will enter commerce and can more easily recover product if a sample is positive for *Salmonella* levels and serotypes that would render the product adulterated.

Proposed implementation. To mitigate the impact of regulatory changes on small and VS establishments, FSIS has typically used a phased approach for implementation to provide additional time for small and VS establishments to adjust their operations to comply with any new regulatory requirements. FSIS defines large, small, and VS establishments based on the number of establishment employees and, for VS establishments, annual sales.[137]

Should FSIS finalize the proposed final product standards, the Agency intends to use a phased approach to initiate verification sampling in establishments that produce raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. However, instead of implementing the Agency's verification sampling program based on the current large, small, and VS establishment size definitions, FSIS has tentatively decided to establish implementation dates based on annual number of birds slaughtered or, for establishments that do not conduct slaughter operations, production volume. The current small establishment size definition was established in the HACCP final rule and corresponded to the Small Business Administration's size standards for business entities at that time (61 FR 38819). However, because FSIS has applied these standards to individual establishments rather than business entities, establishments classified as ''small'' may have up to 500 employees. Thus, FSIS believes that a phased implementation based on production volume would be a more effective approach to mitigate the impact of this proposed determination on low and VLV establishments than the current establishment size definitions.

As FSIS implements the final product standards verification sampling program, the Agency has tentatively decided to phase out all current *Salmonella* performance standards for poultry. Thus, when the proposed final product verification sampling program is fully implemented, FSIS would no long use *Salmonella* sampling results to categorize poultry establishments and would no longer publish these establishments' performance standards categories on the FSIS website. FSIS evaluates and revises its sampling and testing programs each year. Any final verification sampling program resulting from this proposal would be sufficient to verify that establishments are meeting the final product standards.

The proposed production volume categories and proposed verification sampling implementation schedule are as follows.

TABLE 6—PROPOSED IMPLEMENTATION DATES

Establishment volume category	Implementation date
High	1 year after publication.
Medium	2 years after publication.
Low	3 years after publication.
Very Low	3 years after publication.

TABLE 7—PROPOSED VOLUME CATEGORIES CHICKEN PARTS

Volume category	Definition (annual production pounds)
High	Over 70,000,000.
Medium	Between 1,000,000 and 70,000,000.
Low	Less than 1,000,000.

TABLE 8—PROPOSED VOLUME CATEGORIES CHICKEN CARCASSES

Establishment volume category	Definition (birds slaughtered per year)
High	Over 10 million.
Medium	Between 1.1 and 10 million.
Low	Between 440,001 and < 1.1 million.
Very Low	No more than 440,000.

TABLE 9—PROPOSED VOLUME CATEGORIES COMMINUTED CHICKEN AND TURKEY

Volume category	Definition (daily production pounds)
High	Over 250,000.
Medium	Between 6,001 and 250,000.
Low	No more than 6,000.

FSIS requests comments on this proposed implementation approach and on the proposed establishment production volume categories. FSIS also requests comments on whether the Agency should phase out the current performance standards as the Agency implements the final product standards or if the Agency should retain the current performance standards and later determine if these standards are still

[136] FSIS Directive 9900.8, Meat, Poultry, and Egg Products Refused Entry into the United States (Dec. 1 2020). Available at: *https://www.fsis.usda.gov/policy/fsis-directives/9900.8.*

[137] Large establishments are establishments with 500 or more employees, small establishments are establishments with 10 or more employees but fewer than 500, and very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million.

needed when evaluating the effectiveness of the proposed final product standards.

FSIS also requests comments on whether the Agency should consider an alternative implementation approach that would focus its final product verification sampling on establishments that have a demonstrated lack of process control. Under such an approach, FSIS would establish a microbial process control standard based on a threshold or some other parameter and require that establishments conduct sampling at a frequency sufficient to demonstrate that they are meeting the process control standard. Establishments whose results exceed the process control standard would be required to conduct intensified sampling, including environmental sampling and sampling at multiple points in the process, to determine if the initial results were an outlier or if there are problems with the establishment's production process. If an establishment's intensified sampling results show that it is meeting the process control standard, the establishment would return to the standard sampling protocol. If the establishment continues to exceed the process control standard, it would be required to take corrective actions and continue to conduct intensified sampling. If the establishment exceeds the process control standard again, FSIS would collect and analyze final product samples for *Salmonella* levels and serotypes because, at this point, the establishment would have a record that demonstrates that there are problems with its production process. The establishment would be required to control product represented by the sampled lot pending FSIS' test results. Product that tests positive for *Salmonella* at or above 10 cfu/mL(g) and a *Salmonella* serotype of public health significance would be considered unfit for human food and would be prohibited from entering commerce. If the establishment released the product into commerce, the product would be subject to recall.

III. Component Two: Enhanced Establishment Process Control Monitoring

A. Background and Current Regulatory Requirements

Process control monitoring, in the context of poultry slaughter, consists of the programs and procedures an establishment implements to ensure its processes are operating as intended in preventing contamination (including contamination with enteric pathogens and fecal material) of poultry carcasses and parts throughout the slaughter and dressing process and to ensure that the resulting products meet applicable regulatory standards or definitions (79 FR 49565, 49602). Establishments must demonstrate that their process is in control by implementing verification procedures, collecting data, and developing and maintaining accurate records to demonstrate that their processes and procedures are performing as intended and as required (9 CFR 381.65(g) and (h) and 9 CFR part 417). An effective process control system entails an establishment responding effectively to re-establish control when its ongoing verification activities show that its processes are not producing the expected results. Effective process control monitoring procedures should lead to lower rates of pathogen contamination because establishments will discover deficiencies in processing sooner and more reliably than would be the case without effective process control monitoring procedures.

Contamination of poultry carcasses and parts by enteric pathogens and fecal material (*e.g., Salmonella* and *Campylobacter*) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP or other prerequisite program (79 FR 49565, 49613). To ensure that establishments that slaughter poultry implement appropriate measures to prevent carcasses from becoming contaminated with pathogens, and that both FSIS and establishments have the documentation to verify the effectiveness of these measures on an on-going basis, current regulations require, among other things, that all establishments that slaughter poultry other than ratites develop, implement, and maintain written procedures to prevent contamination of poultry carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation (9 CFR 381.65(g)). Establishments are required to incorporate their process control procedures into their HACCP plan, sanitation SOPs, or other prerequisite programs (collectively, ''the HACCP system'') and maintain daily records sufficient to document the implementation and monitoring of these procedures (9 CFR 381.65(g) and (h)).

Microbiological test results that represent levels of microbiological contamination at key steps in the slaughter process are necessary for establishments to provide comprehensive, objective evidence that they are effectively maintaining process control to prevent carcasses from becoming contaminated before and after they enter the chiller (79 FR 49565, 49602). At present, establishments conduct pre-chill testing to monitor how well an establishment is minimizing contamination on live birds coming to slaughter and on carcasses throughout the slaughter and dressing process, and post-chill testing to monitor how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions that were applied (79 FR 49565, 49566). FSIS also collects a verification sample at the post-chill location and tests for *Salmonella* and *Campylobacter.* In 2012, FSIS considered requiring a third establishment sampling location at rehang (*i.e.,* after picking and prior to evisceration) to monitor the incoming load of pathogens but concluded that it was unnecessary to impose the additional costs on industry (77 FR 4407, 4428).

Regulations at 9 CFR 381.65 (h) and 9 CFR 417.5 (a)(1) require establishments to document their procedures and results in records subject to Agency verification. At a minimum, these procedures must include sampling and analysis for microbial organisms at the pre- and post-chill location to monitor for process control, with an exception for VS and VLV establishments operating under the Traditional Inspection System (9 CFR 381.65 (g)(1)).[138] In 2014, FSIS stated that because these establishments are typically less automated and run slower line speeds than larger establishments operating under other inspection systems, they may require less complicated measures for maintaining and monitoring process control on an ongoing basis (79 FR 49565, 49603). Therefore, at present, they are required to collect and analyze samples for microbial organisms only at the post-chill location.

In addition to prescribing the sampling locations for monitoring process control, the regulations specify a minimum sampling frequency to ensure establishments can detect changes in processing or inconsistencies

[138] Very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million dollars (9 CFR 381.65(g)(1)(i)). Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squab (9 CFR 381.65(g)(1)(ii)). Traditional Inspection must be used for turkeys when neither the New Turkey Inspection System (NTI) nor the New Poultry Inspection System (NPIS) is used. For other classes of poultry, Traditional Inspection must be used when SIS, NELS, and the NPIS are not used (9 CFR 381.76(b)(1)(v)).

that may occur (79 FR 49565, 49604). At a minimum, for chickens, establishments are required to collect a pair of pre-and post-chill samples once per 22,000 processed carcasses, but at a minimum of once each week of operation, and for turkeys, ducks, geese, guineas, and squab, establishments are required to collect a pair of samples once per 3,000 processed carcasses but a minimum of once each week of operation (9 CFR 381.65(g)(2)(i)). To minimize the sampling costs to the lower volume establishments, VLV establishments must minimally collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, an establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan (9 CFR 381.65(g)(2)(ii)). All establishments are required to conduct testing at a frequency sufficient to detect a loss of process control soon after it occurs so that they can take the necessary corrective actions to prevent further product contamination (79 FR 49565, 49605). Therefore, regardless of the prescribed minimum sampling frequency, the establishment must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens and fecal contamination (9 CFR 381.65(g)(2)(iii)).

When FSIS updated its poultry inspection regulations in 2014 (79 FR 49565), it referenced data from FSIS' 2007–2008 Young Chicken Baseline survey (hereinafter, the ''baseline survey''), which found levels of detectable generic *E. coli* (GEC) on post-chill carcasses well below the performance criteria in the existing regulations.[139] The baseline survey found that over 60 percent of samples had non-detectable levels of GEC. Among 12 establishments from which 10 or more samples were analyzed, none had detectable levels of GEC. On the other hand, FSIS analyzed 22 samples from each of 2 of these establishments and found that all 44 samples had detectable AC measurements. FSIS also concluded that AC levels at rehang were more highly correlated with *Salmonella* than GEC levels which suggested that AC measurements might provide a better measure of process control.[140]

Despite the baseline survey findings, FSIS did not require that establishments use a specific microbial organism to monitor process control when it updated its regulations in 2014. Thus, at present, establishments decide which microbiological organisms will best help them to monitor the effectiveness of their process control procedures and may develop sampling plans to test carcasses for enteric pathogens, such as *Salmonella,* or another appropriate indicator organism. Because establishments must incorporate their microbiological sampling plan into their HACCP system, they are required to provide scientific or technical documentation to support the judgements made in designing their sampling plans, as required by 9 CFR 381.65 (h) and HACCP regulation 9 CFR 417.4(a).

B. Need To Enhance Establishment Process Control Monitoring

Based on NACMCF recommendations, an analysis of PHIS inspection results, sampling data, and the findings of the 2023 risk assessments, FSIS has determined that there is a need to enhance establishment process control monitoring. These recommendations and findings are discussed below and collectively support FSIS' conclusion that regulatory revision will improve establishments' ability to monitor microbiological process control; demonstrate the effectiveness of their measures to prevent carcasses from becoming contaminated; and ensure that both FSIS and establishments have the documentation necessary to verify the effectiveness of these measures on an on-going basis. These recommendations and findings have also prompted FSIS to evaluate the need for additional resources, services, and guidance to help establishments develop microbiological process control monitoring programs and comply with FSIS requirements.

1. NACMCF Charge and Recommendations

According to NACMCF, process control can be defined as maintaining the output of a process within a desired range based on stability and capability to meet specifications.[141] Process control is accomplished through six steps: (1) The output must be monitored and quantified with appropriate sampling and testing; (2) There must be predefined limits and targets traceable to acceptable specifications and the history of the process; (3) The monitoring results must be compared to the relevant process control limits; (4) There must be a predetermined plan of action (such as a corrective action plan) based on the size and frequency of deviation from relevant limits; (5) The proper action must be decided upon based on the observed deviation; and (6) the proper action must be promptly taken to adjust the process.[142]

In 2015, NACMCF provided microbiological limits for food categories that reflect process control and sanitary manufacturing conditions. These limits can help FSIS-regulated establishments develop systems for measuring SPC. SPC is an approach that uses statistical methods to monitor and control a process. A process is under statistical control when the output varies as expected within a statistical range. Process variability is caused by chance or assignable causes. Assignable causes can be linked to improperly adjusted or controlled machines, operator errors, or defective raw material. A process that is operating with assignable causes is out-of-control.[143] Process capability is defined as the degree by which SPC limits fall within specifications. If the process exceeds an upper or a lower specification limit, the product does not meet the specification even if it is operating without assignable causes and is in control. Process capability is traditionally measured using a process capability index (Cp). For example, USDA's Agricultural Marketing Service uses Cp to monitor process control of fat content meeting allowable upper and specification lower limits and a one-side calculated process capability to monitor process control of microbial detection levels meeting upper allowable limits in raw beef finished products as part of the National School Lunch Program.[144]

Using microbiological testing to monitor SPC presents some challenges. Some testing may result in a discrete (presence/absence or binary) result or a continuous measure such as a plate

[139] FSIS (2007). Young Chicken Survey (baseline) June 2007–June 2008. *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Young_Chicken_2007-2008.pdf.*

[140] Williams, M.S., et al. (2015). ''Industry-level changes in microbial contamination on market hog and broiler chicken carcasses between two locations in the slaughter process.'' *Food Control* 51: 361–370.

[141] Note that a process can be stable and not capable of meeting specifications, or an unstable process may produce product that meets specifications. NACMCF (2015). '' Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions, available at *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.*

[142] NACMCF (2018). ''Response to Questions Posed by the Department of Defense Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions.'' J Food Prot 83(1): 115–141.

[143] Montgomery, D.C. (2013). Introduction to Statistical Quality Control 7th edition, chapter 5.

[144] AMS National School Lunch Program, information available at: *https://www.fns.usda.gov/nslp.*

count. Binary results and plate counts are typically modeled using a binomial or Poisson probability distributions, and their log-transformed values usually follow a lognormal distribution from which the statistical mean and variance may be calculated and used for SPC analyses that assume a normal probability distribution. Count data may include zero results, either due to the absence of the organism, or presence at levels below or above the test's limits of quantitation (LOQ). The later result is referred to as a censored value. Data with censored results exceeding the number of zeros expected by the Poisson distribution may consist of a heterogeneous mixture in which the organism is completely absent from some portion of the product and present in another portion. Such results may follow a zero-inflated Poisson distribution. A variety of methods have been proposed to fit censored data to a probability distribution. The choice of method depends on the number of samples and the proportion with enumerated samples. A distribution function cannot be reliably fitted to a dataset where fewer than 20 percent of samples are enumerated,[145] which is an important consideration for using count data. Other considerations for SPC include sampling frequency and lot definition. With respect to frequency, counts are more robust than binary results, and indicators of process control are best obtained with higher frequency sampling. NACMCF recommended sampling frequency be capable of detecting the presence of expected assignable causes within the first 10 percent of their persistence time since disruptions occur for a finite period and not much is learned if the disruption is not detected or detected too late for corrective action. Product lot definition has implications both for determining the acceptability of a lot and for monitoring SPC. In general, the defined product lot should be produced under reasonably constant conditions so that a lot is a homogeneous volume of contemporaneous production for calculating the mean level and variability. For poultry slaughter and dressing, a homogeneous volume of contemporaneous production means that each lot should represent a cohort (flock) of birds raised, transported, slaughtered and processed over the same period and locations. Production lots with equivalent means may have different variabilities and therefore, SPC methods should evaluate variance both within and between production lots.

When a microbiological sampling program is properly designed and implemented, it can provide valuable information about an establishment's process control. A well-designed microbiological sampling program should clearly define the intended use of the testing program, organisms of concern that will be the target of testing, sampling units (flocks, houses at preharvest, carcasses or parts at post-harvest), sampling scheme, microbiologically independent lotting practices, sampling locations, procedures for sample collection and for maintaining sample integrity, testing method, method for evaluating test results, and actions taken based on test results.[146] Results charting is typically used to identify trends and for identifying exceptions to process control that could be due to assignable causes. For low frequency binary results, NACMCF recommended a g-chart based on mean time between events. For higher frequency binary results, a p-chart based on proportions is recommended, and for counts, mean and range charts can be used.

In 2019, NACMCF concluded that most carcass contamination results from leakage of ingesta during crop removal, from feces during evisceration, as well as aerosolization during picking.[147] The committee also advised, to best assess controls, each establishment should look at the whole food safety system from breeder farm through processing, so it is not overwhelmed by the incoming load. Evaluating the prevalence and concentration of *Salmonella* on carcasses and parts throughout the production process unique to each facility can help to identify pathogen reduction at each step in the process.

In its October 2021 charge to the NACMCF Subcommittee on Enhancing *Salmonella* Control in Poultry Products, FSIS noted there is a documented correlation between a reduction in the quantity of AC between carcasses and finished products and the occurrence of *Salmonella* in finished products for beef, pork, and poultry. The Agency specifically requested that the Subcommittee provide guidance on how this information might be used to set microbiological criteria to assess process (pathogen) control in poultry.[148]

In response to FSIS' request for guidance on setting microbiological criteria to assess process control in poultry, the 2023 NACMCF report discussed process control as a method of determining trends over time and how it is useful to determine the sources of variation within a process. It noted that ''indicator organisms such as *Enterobacteriaceae* (EB) or [AC] have been used by the industry as gauges of process control and to measure the microbial reduction from carcasses at slaughter to post-chill.'' The report stated that ''studies show conflicting and apparent weak correlation between indicators and either the presence or level of *Salmonella* post carcass wash.'' The report also stated that, in addition to published studies, ''unpublished data provided by the poultry industry and university researchers suggests that indicator bacteria have very limited predictive value for the prevalence of *Salmonella.*''

Although the report found that the available data show that in many cases there may not be a strong statistical correlation between the presence or amount of an indicator and the presence or amount of *Salmonella* at specific points during processing or in finished poultry products, the report concluded that, ''. . . a change in [AC] from an early sampling point on the slaughter line to a final sampling point on the processing line, as well as absolute levels at the final point, may provide useful information about the effectiveness of the process in maintaining hygienic conditions.'' Therefore, the report concluded, ''[AC] may be useful to indicate process control even though it is not a true indication of the presence, level, or virulence of *Salmonella.*''

2. PHIS Inspection Data

The purpose of 9 CFR 381.65(g) and (h) is to ensure that establishments implement appropriate measures to prevent carcasses from becoming contaminated throughout the slaughter and dressing operation. Establishments must design and implement a program that uses microbiological sampling and analysis to monitor their ability to maintain process control and produces the documentation needed for FSIS and the establishment to continuously verify the effectiveness of these measures on an on-going basis, *i.e.,* an MMP. Establishments must provide scientific and technical support to justify the design of their MMPs.

[145] Williams, M.S., et al. (2013). ''Sample size guidelines for fitting a lognormal probability distribution to censored most probable number data with a Markov chain Monte Carlo method.'' International Journal of Food Microbiology 165(2): 89–96.

[146] NACMCF (2019). ''Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry.'' Journal of Food Protection 82(4): 645–668.

[147] NACMCF (2019). ''Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry.'' Journal of Food Protection 82(4): 645–668.

[148] 2021–2023 NACMCF report: Question 5.

As discussed, SPC monitoring evaluates microbial data against predefined quantitative and qualitative specifications. SPC monitoring results that do not fall within the predefined specifications with assignable causes indicate a process is not capable or in control. An effective MMP must, therefore, define and support the quantitative and qualitative microbial monitoring criteria an establishment will use to gauge whether its process is in control and the corrective actions it will take when its microbial monitoring results are not within its predefined parameters. Specifically, the establishment MMP must incorporate three criteria—target change, quantitative consistency, and qualitative consistency standards. ''Target change'' refers to the expected change in quantified levels of microbial contamination detected between two monitoring points that supports the procedures' ability to control contamination as required in 9 CFR 381.65(g) and as expected by the establishment. ''Quantitative consistency'' is measured by how close individual sampling results are to defined target change parameters and how much variation is expected amongst the results over time. ''Qualitative consistency'' is measured by assessing whether MMP process control findings are consistent with other process control monitoring results representing the same procedures (*e.g.,* fecal zero tolerance monitoring). Consistency can also be qualitatively assessed as whether the MMP process control determination is consistent with the process control determination for the HACCP system overall, *i.e.,* if all HACCP monitoring intended to assess process control draws the same conclusion. An effective MMP also defines how an establishment will respond when performance is not as expected, such as the corrective actions it will take.

A recent analysis of PHIS inspection data identified issues with the design and implementation of establishment MMPs, including how establishments respond to MMP results.[149] FSIS analyses of the PHIS inspection verification data from February 17, 2015, through December 31, 2022, found that MMP noncompliance with 9 CFR 381.65(g) was most often associated with sampling frequency and the monitoring of results to ensure frequency compliance (49 percent). Specifically, NRs showed establishments did not plan or adjust their sampling plan minimum frequencies in accordance with the actual slaughter volume; failed to collect samples at the frequency planned, at the minimum frequency required, or to collect additional samples when collected samples could not be analyzed. These noncompliance issues indicate that establishments are not assessing or adjusting the sampling frequency procedures in their MMPs as necessary due to their failure to identify and document the absence of expected monitoring results. These noncompliance issues also show that establishments often fail to provide adequate justification for not evaluating and updating the sampling frequency procedures in their MMPs in response to monitoring results, IPP observations, or other relevant information indicating that their current sampling frequency is not adequate to monitor process control.

NRs also indicated establishments failed to identify monitoring criteria, monitoring deviations, or documented trends or—when identified—failed to perform any root cause assessment for the deviation or perform corrective actions (31 percent). Further, NRs show that establishments failed to implement their sample collection or laboratory analysis methods as written (12 percent). These findings indicate establishments are not adequately considering or utilizing the MMP monitoring of process control in their overall consideration of whether the procedures incorporated into the HACCP system are performing as expected and the HACCP system is overall controlling the hazard to the acceptable level as intended.

3. Exploratory Sampling Program Data

As noted above, from April to November 2022, FSIS implemented an exploratory sampling program [150] to generate microbial data to inform the Agency's effort to reduce *Salmonella* illnesses attributable to poultry. Under the program, rehang and post-chill rinsate samples were tested for *Salmonella,* AC, and EC, and beginning August 11, 2022, for *Salmonella* levels using a quantitative method adopted by FSIS laboratories.

Overall, FSIS analyzed 4,654 paired samples collected from 204 of the 272 establishments that slaughtered young chicken in Calendar Year 2022. Testing results indicated that 2,910 rehang and 232 post-chill samples were positive for *Salmonella.* Of these, 1,460 rehang and 121 post-chill samples were analyzed with the *Salmonella* quantitative method, and the results indicated that approximately 90 percent of rehang and 86 percent of post-chill samples were below the lower LOQ.[151] Further, out of the 4,654 paired samples, tests detected AC in 4,592 and EB in 4,580 of both the rehang and post-chill location samples. Of the pairs that detected the AC or EB at both locations, 69.2 percent of the pairs yielded a quantified value at both rehang and post-chill for AC; whereas only 15.9 percent yielded a quantified value for EB.[152]

Of the 3,177 paired samples with quantified levels of AC, 98.7 percent demonstrated a reduction in AC from rehang to post-chill; while only 1.29 percent of paired samples demonstrated an increase in AC.[153] Among the 180 establishments with 12 or more analyzed paired samples,[154] all 180 establishments had greater than 20 percent of samples with AC detectable above the lower LOQ at post-chill, and 25 percent had greater than 20 percent of samples with EB above the lower LOQ. *Salmonella* percent positive was reduced from rehang to post-chill by an average of 56.6 percent and AC quantified level was reduced an average of 2.93 $\log_{10}$ cfu/mL (74 percent reduction).

Based on these findings, FSIS concluded that microbial monitoring of EB or *Salmonella* is unlikely to yield the reliable quantified results necessary for an individual establishment to support SPC monitoring. There has been an observable decline in post-chill levels of organisms detected since the 2007–2008

[149] 7096 noncompliance records (NRs) citing 381.65(g) were issued between 2/17/2015 and 12/31/2022; 8 had incomplete descriptions and were not further analyzed. Each of the 7088 NRs were read by OFO analysts to determine if the microbial monitoring program was reviewed as part of the verification and if the establishment microbial monitoring program was documented to be the cause of observed noncompliance.

[150] FSIS Notice 44–22Revised Young Chicken Carcass Exploratory Sampling Program.

[151] The lower LoQ for the *Salmonella,* AC, and EC tests utilized by FSIS laboratories was 10 cfu/mL.

[152] Comparatively, FSIS's 2007–2008 baseline survey did not assess results as true pairs or when both rehang and post-chill yielded quantifiable results. This prior survey reported the 3,275 analyzed pairs had levels significantly lower at post-chill and quantifiable AC and EC was detected in 97.1 percent and 57.4 percent of post-chill samples, respectively. The average rehang and post-chill AC values reported 4.51 log AC and 2.43 Log AC and EC as 3.28 Log EC and 1.57 Log EC, respectively (average change 2.08 Log AC and 1.71 Log EC). *https://www.fsis.usda.gov/node/1973.*

[153] Because a distribution function cannot be reliably fitted to a dataset where fewer than 20 percent of the samples are above the LOQ, FSIS has only summarized results for quantitative AC, not *Salmonella* or EC. *See* Helsel, D. R. (2005). ''Nondetects and Data Analysis: Statistics for Censored Environmental Data.''

[154] FSIS had estimated at least 12 pairs would be necessary over the study period to evaluate an individual establishment's indicator organism performance and 180 of the 204-establishment sampled had at least 12 pairs analyzed.

Young Chicken Baseline Survey. The current data shows that AC is more likely to yield reliably detectable quantified microbial results compared to either EB or *Salmonella* for most establishments. Additionally, given all establishments sampled consistently demonstrated a qualitative decrease in levels of organisms detected between rehang and post-chill, FSIS has determined that assessing the quantified level of decrease achieved is more informative of individual establishment process control changes and trends than the qualitative criteria of whether a decrease occurred.

4. FSIS Risk Assessments

The 2023 risk assessments for *Salmonella* in chicken and turkey evaluated, among other things, the public health impact of monitoring and enforcing process control from rehang to post-chill.[155] For all young chicken establishments sampled during the 2022 exploratory sampling program, FSIS measured an average of 4.40 and 1.39 log AC per mL at rehang and post-chill locations, respectively, *i.e.,* an average reduction of 3.01 log AC per mL. Comparatively, the 2007–2008 baseline survey measured an average of 4.50 and 2.46 log AC per mL at rehang and post-chill locations, respectively, *i.e.,* an average log reduction of 2.04 log AC per mL. These data show that between 2008 and 2022, there were no decreases in incoming AC loads on chicken carcasses; however, during that time, establishments achieved an additional 1 log reduction in AC levels after slaughter and processing. Based on this current study it is reasonable to expect reductions of 3 logs in *Salmonella* between rehang and post-chill. The risk assessment found weak correlations between post-chill *Salmonella* prevalence and AC, either based on the AC reduction between rehang and post-chill, or the fraction of post-chill samples where AC is not observed. Ultimately, FSIS' recent chicken risk assessment concluded that a hypothetical AC reduction standard could achieve a 25 percent reduction in *Salmonella* illnesses attributed to chicken only if microbiological criteria based on 2.5–3.0 log reduction or no AC tests exceed 10 cfu/mL at the post-chill location. The risk assessment concluded that AC is only moderately correlated with the occurrence of *Salmonella* and thus an AC based standard would perform less well than a *Salmonella* standard.

In addition to identifying a decrease in the average level of log AC detected at post-chill between the 2007–2008 baseline survey and 2022 exploratory sampling program from 2.46 to 1.39 log AC per mL, respectively, the 2023 chicken risk assessment identified a decrease in the proportion of young chicken carcass post-chill AC results above the limit of detection (LOD), from 97.1 percent at baseline to 70.0 percent currently. EB followed a similar trend with 57.4 percent during the prior baseline to just 16.1 percent above the LOD currently.

The 2023 turkey risk assessment reported that the correlation between AC or EB and *Salmonella* prevalence is weak, and it was not possible to fully assess the public health impact of monitoring and enforcing process control from rehang to post-chill.

C. Proposals To Enhance Establishment Process Control Monitoring

FSIS is proposing to amend 9 CFR 381.65(g) and (h) to establish new requirements pertaining to how establishments monitor and document whether their processes for preventing microbial contamination throughout the slaughter and dressing operation are in control. The goal of the proposed amendments is to clarify existing regulatory requirements related to process control monitoring and recordkeeping in 9 CFR 381.65(g) and (h) and to better define requirements with respect to the type of microbial data that should be collected, how the data should be analyzed, the level of acceptable process control deviations, and how establishments should respond to process control deviations. The clarifications are also intended to promote the collection of more standardized data by establishments to facilitate data quality. If this proposed rule is finalized, FSIS intends to update relevant guidance to help establishments comply with new requirements.

1. SPC Monitoring

This proposed rule revises 9 CFR 381.65(g) to require establishments to incorporate SPC monitoring principles into their MMPs. As discussed, SPC monitoring uses statistical methods to compare quantitative results against predefined benchmarks and, thereby, determine whether a process is operating within expected parameters.[156]

The proposed revisions to 9 CFR 381.65(g) would therefore require establishments to use only validated microbial sampling and laboratory analysis procedures, generate and record statistically meaningful microbial monitoring data, set benchmarks by which to evaluate microbial monitoring data, and to otherwise define the statistical methods the establishment will use to evaluate the recorded data against the predefined limits. The MMP design should also be consistent with other process control monitoring procedures and the establishment's HACCP system. For example, if an establishment assesses process control independently by evisceration line for visible fecal contamination, the establishment's MMP for process control of procedures to prevent fecal contamination should also be separated by evisceration line.

Statistical Methods. There must be scientific and technical support to justify the design of a MMP, including the statistical methods an establishment will use. Specifically, the MMP must include documentation and data demonstrating the initial scientific basis, validation, and ongoing verification of the statistical methods, including whether the quantified monitoring data generated by the establishment's process is normally or not normally distributed and whether the statistical method is appropriate. In instances where the minimum sampling frequency requirements of 9 CFR 381.85(g)(2) do not generate ''statistically robust'' results, an establishment must either increase its sampling frequency to generate robust results or provide support to demonstrate that the minimum frequency of collection is, nonetheless, adequate to demonstrate whether its particular process is in control.

FSIS has developed a Lower Capability Process Index (CPL) Statistical Measurement Model (SMM) which fits parameters for normally distributed data. The CPL–SMM is available for review and comment on the FSIS website.[157] Under this proposal, the CPL–SMM would be considered a ''safe harbor,'' in that establishments that incorporate the CPL–SMM into their MMPs would not be required to provide FSIS with

[155] The risk assessments analyzed data from the 2022 Exploratory Project, 2007–2008 Young Chicken Baseline Survey, and the 2008–2009 Turkey Baseline Survey.

[156] NACMCF (2015). '' Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions, available at *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.*

[157] Statistical Process Control Monitoring Method Assessment and the FSIS Proposed Lower Capability Process Index (CPL) Statistical Measurement Model (SMM) available at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

additional scientific or technical information to support their chosen statistical methods.[158] Should FSIS finalize this proposal, the Agency would make available on its website an electronic file for download (*i.e.,* a spreadsheet) programmed to calculate the change achieved, CPL, and chart results as the establishment inputs each sampling result as it is received from the laboratory. FSIS will provide relevant instructions for adopting the ''safe harbor'' method in a future guidance document. An example of the electronic file that FSIS intends to provide is available for viewing and public comment at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

FSIS requests comments on its proposed CPL–SMM and the related electronic file. FSIS also requests input on any other statistical monitoring methods that FSIS should recognize as satisfying the requirements of 9 CFR 381.65(g) without further scientific support, including but not limited to methods for normally and non-normally distributed results, use with specific indicator organisms, and various analyzed results sample sizes. FSIS requests that commenters include the appropriate data necessary to support any proposed alternatives as these data may not have been available to FSIS at the time of this rulemaking.

Target Change and Quantitative Consistency Criteria. To effectively incorporate SPC monitoring into an MMP, establishments must define and support target change and quantitative consistency microbial monitoring criteria. ''Target change,'' in the context of microbial process control monitoring, is the expected change in quantified levels of microbial contamination detected between two sampling locations that supports a procedure's ability to control contamination as minimally required in 9 CFR 381.65(g) and as expected by the establishment. For an MMP, target change parameters must be appropriate for the microbial monitoring organism an establishment uses to monitor process control. At a minimum, establishment MMPs must define the minimum target change expected (lower specification limit). The minimal level target change approach sets a benchmark from which establishments can evaluate trends in microbial contamination during slaughter and dressing with other trends in slaughter performance data such as pathogen, feces and ingesta, and sanitary operations monitoring findings. Establishment MMPs may also define a maximum target change expected (upper specification limit).

AC and EB are routinely utilized to monitor poultry slaughter process control and are frequently reported in logarithmic format (log).[159] FSIS' review of current scientific support indicates that, when monitoring indicator organisms reported in log, establishments should strive for a minimum target change value of 1 log reduction and that a change between 0 and 1 log is not reliably detected in normally distributed data, particularly at the statistical power associated with the single pair minimum sampling frequencies prescribed in 9 CFR 381.65(g)(2).[160] The 2023 risk assessment also identified a moderate correlation with the detection of post-chill *Salmonella* when at least a 3 log AC change was observed.[161] Moreover, FSIS' exploratory sampling program observed an average 2.93 log AC reduction in establishments with at least 12 carcass pairs analyzed.

Based on these findings, the Agency would consider an establishment's target change criteria to meet the requirements in 9 CFR 381.65(g) when its MMP sets an expected reduction of at least 1.0 log in detected microbial levels between sampling locations.[162] Establishments may, of course, set more stringent target change criteria in their MMP than the minimum 1.0 log reduction without providing additional support to FSIS. MMPs that define an expected target change value of less than 1.0 log must include comprehensive scientific support to demonstrate that its target change criteria reflect a statistically reliable value for measuring process control and why its expected target change is less than changes identified in national baseline data (*e.g.,* 2 log or 3 log as above). Establishments that conduct microbial sampling and testing in more than two locations in the slaughter process may define different quantified values to be achieved between the various points but, minimally, the target change value for monitoring between each pair of points should meet the minimum requirement as appropriate for the microbial monitoring organism being monitored. Similarly, establishments monitoring more than one shift, evisceration line, or species/subclass of poultry may elect to define different quantified target change values expected providing they meet the same minimum requirements. In any event, establishments must use scientifically validated mathematical methods to calculate the change in levels detected between sampling locations. FSIS would consider a simple subtraction method (*e.g.,* Sampling Point-A *log* value—Sampling Point-B *log* value) to be scientifically valid.

MMPs must also define quantitative consistency criteria. As discussed, SPC monitoring includes assessing the variation of results as each result is reported and over time to identify and detect when procedures may not be functioning as intended to prevent the enteric pathogen and fecal contamination from being introduced at one or more points in the process. In statistical applications, 99 percent of results fall within 6 standard deviations of the mean, or 3 standard deviations on either side of the mean. For an MMP monitoring whether the minimum target change expected is met (lower specification), the detected change between the two points monitored is within 3 standard deviations less than the average change detected for all samples in the monitoring period.

The establishment MMP must define and support the acceptable quantitative consistency (statistical variation) expected among the changes detected over time. The quantitative consistency expected must not exceed 3 standard deviations lower than the mean and for the establishment to conclude microbial contamination variability was controlled (one-side for lower specification). That is, FSIS recognizes the MMP defined quantified value is minimally supported when the sample result is no more than 3 standard deviations below the mean. As with target change criteria, establishments are

[158] Establishments are to be aware that the proposed CPL–SMM reflects the *minimum* frequency prescribed in 9 CFR 381.65(g)(2), and the establishment may need to increase the frequency of collection to meet compliance with the requirement the frequency is adequate to monitor their ability maintain process control as required under 9 CFR 381.65(g)(2)(iii).

[159] Microbial organism levels are frequently transformed to base 10 logarithmic format (log) for statistical assessment unless the conversion would result in log ''0' censored data result.

[160] De Villena, J.F., et al. (2022). ''Bio-Mapping Indicators and Pathogen Loads in a Commercial Broiler Processing Facility Operating with High and Low Antimicrobial Intervention Levels.'' Foods 11(6): 775. Cano, C., et al. (2021). ''Application of Peroxyacetic Acid for Decontamination of Raw Poultry Products and Comparison to Other Commonly Used Chemical Antimicrobial Interventions: A Review.'' J Food Prot 84(10): 1772–1783. Brashears, M.M. and B.D. Chaves (2017). ''The diversity of beef safety: A global reason to strengthen our current systems.'' Meat Sci 132: 59–71.

[161] Quantitative Microbial Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[162] FSIS notes that all sample results in the exploratory CPL–SMM modeling datasets had AC reductions greater than 1 log (97.5 percent) and mean log AC reductions across the exploratory sampling period were greater than 1 for 98.7 percent of establishments.

encouraged to define quantitative consistency criteria at each point monitored and may also set quantitative consistency criteria specific to shift, line, or specific/subclass of poultry slaughtered, provided the consistency variation target limit meets the minimum requirements discussed herein. Establishment MMP monitoring criteria decisions for target change and quantitative consistency expected, and the actual values observed during monitoring, must also consider and support the establishment's MMP organism, location, and frequency decision rationale. Establishments must assess their results as ongoing validation data to maintain support for all MMP requirements.

Monitoring Period. As discussed, SPC involves an assessment of trends measured over time. As such, an establishment's MMP must define the period over which trends will be assessed, *i.e.,* the ''monitoring period.'' FSIS' assessment of exploratory sampling program and *Salmonella* Initiative Program [163] data found that the sample collection frequency impacts the monitoring period required to generate a statistically robust sample size and how quickly the entire sample size is replaced with new results, *i.e.,* the ''sample size turnover.'' Based on the assessment of these available data, FSIS has identified the monitoring periods necessary for establishments to adequately assess trends over time. Establishments that incorporate these monitoring periods into their MMPs would not be required to provide the Agency with additional scientific or technical support.

As shown in Table 10 below, FSIS recommends that establishment MMPs define the monitoring periods as follows by the minimum monitoring frequency (paired carcass collection) prescribed in 9 CFR 381.65(g): (1) Poultry establishments collecting samples at a frequency of once per 22,000 (chicken) or 3,000 (other species) head slaughtered, respectively, or greater, are to designate a monitoring period of 140 samples or 52 weeks, whichever is shortest; (2) any poultry establishments collecting at a weekly frequency are to designate a monitoring period of the 52 most current weeks; (3) and VLV poultry establishments collecting 13 samples annually are to designate their monitoring period as all of the samples available in the most recent 52 weeks or all the samples in the current period of operations if slaughter of the predominant species is seasonal and not continuous. All poultry slaughter establishments are required to assess for trends during their designated monitoring period, as well as compare the monitoring periods for the current 52 weeks against the prior 52 weeks. Further, those establishments that collect less than weekly are to also compare trends going back an additional 52 weeks (*i.e.,* compare the current 52 weeks against the prior 104 weeks). All poultry slaughter establishments must also identify the sample size turnover rate based on their intended frequency of collection and provide scientific support for how the establishment will consider the turnover in their assessment of process control trends over time.

TABLE 10—MONITORING PERIOD BY MINIMUM FREQUENCY RECOGNIZED BY FSIS WITHOUT FURTHER SUPPORT

Poultry species	Minimum monitoring frequency	Minimum monitoring period	Minimum trend over time period
Chicken	≥1 per 22,000 head	Period necessary to obtain 140 samples or 52 weeks, whichever is shorter.	Prior 52 weeks.
Turkey, Goose, Guinea, Duck, Squab	≥1 per 3,000 head.		
Any Poultry Species	Weekly	52 weeks.	
Any Poultry Species	13 per year	All samples in 52 weeks or the period of operations for year if seasonal operations.	Prior 104 weeks.

2. Microbial Monitoring Organism

FSIS is proposing to amend 9 CFR 381.65(g) to establish new criteria that an establishment must meet to demonstrate that its selection of microbial organism is fit for purpose. Specifically, FSIS is proposing that establishments analyze for microbial organisms that are quantifiably detectable in the establishment's slaughter process and that will generate microbial monitoring data that is adequate to monitor their ability to maintain process control for enteric pathogens. Under this proposal, the establishment's measured results at each sample location must yield statistically reliable quantified value results.

The Agency recognizes that in order to successfully analyze quantified data, at least 20 percent or more of the sample size results must be quantified; otherwise, the data will be skewed, *i.e.,* shifted above or below the true value.[164] Thus, to comply with the proposed revisions to 9 CFR 381.65(g), establishments would have to demonstrate and continuously validate that their chosen microbial monitoring organism generates a quantified value in at least 20 percent of the results reported at each monitored location. Results that are reported ''above the limit of quantification'' or ''below the limit of quantification'' or ''0'' when log transformed would not be considered as quantified results, nor would samples with results not analyzed by the establishment. The establishment would also have to demonstrate and continuously validate that for each sample monitoring location, the microbial organism can be quantified across the upper and lower levels that actually occur in the establishment's individual process.

The Agency would consider the use of AC to monitor process control to meet the proposed criteria discussed above. FSIS has evaluated the available published studies and data at the time of rulemaking and concluded that AC are the microbial organisms most likely to result in quantified results that are reliably detectable at rehang and post-chill. Available paired microbial data representing pathogens like *Salmonella* and indicator organisms other than AC do not meet the 20 percent minimum quantified detection recommended. Establishments that choose to use other indicator organisms like EB, total coliforms, or GEC to assess the minimum target level of change, equal to or greater than 1 log10, must support the estimated change in a statistically appropriate manner.

[163] FSIS Salmonella Initiative Program, details available at *https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and.*

[164] Helsel, D.R. (2005). ''Nondetects and Data Analysis: Statistics for Censored Environmental Data.''

Regardless of the microbial monitoring organism chosen, the proposed revisions would require establishments to demonstrate that their chosen sample collection method is appropriate for the product sampled, the microbial organism monitored, and the laboratory method used to analyze the samples. Moreover, the proposed revision would require establishments' microbial sampling results to be generated by validated laboratory analyses and methods. Current HACCP regulations also require ongoing verification of the establishment's microbial monitoring procedures including the methods and equipment used (9 CFR 417.4).

Establishments that adhere to the Agency's carcass rinse and sponge sample collection method [165] would not be required to provide additional support to justify their chosen method of organism collection. Further, establishments that document sample analyses by International Standards Organization (ISO) or USDA's Accredited Laboratory Program (ALP) accredited laboratories would not be required to provide the Agency with additional support to justify their use of laboratory analyses and methods. Nonetheless, all establishments would be required to demonstrate and continuously validate that their MMPs analysis method can detect the selected microbial monitoring organism at the levels intended, expected, and occurring at the monitored points in the process. FSIS requests comments on whether FSIS should require establishments to use ISO accredited or USDA ALP accredited laboratories to analyze their microbial monitoring samples.

In lieu of requiring the VS or VLV establishments that slaughter the predominate species of poultry under Traditional Inspection to utilize their own resources to meet compliance with the proposed revisions to 9 CFR 381.65(g), FSIS is proposing that such establishments have access to laboratory services provided by FSIS at no monetary cost for sample supplies, analyses, or shipment. Eligible establishments would be required to agree to terms of participation that would be publicly announced following the publication of any final rule resulting from this proposal. These terms would limit the use of laboratory microbial analyses service to eligible establishments that sample for AC, given more than 75 percent of the post-chill carcass samples analyzed as part of the recent FSIS exploratory sampling assessment were below the FSIS lower limit of detection for EB and nearly 85 percent of the enumerated post-chill *Salmonella* were below the level of quantification.[166] The terms would also address laboratory service logistics such as establishment sample collection and shipment methods, collection and shipment dates to assure laboratory analysis capacity, reporting of establishment results through PHIS and LIMS-Direct email, and that the establishment agree to incorporate the FSIS CPL–SMM into its MMP exactly as described in the *Statistical Process Control Monitoring Method Assessment and the FSIS Proposed Lower Capability Process Index (CPL) Statistical Measurement Model (SMM)* at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

3. Sampling Location

FSIS is proposing to revise the sampling location regulations at 9 CFR 381.65(g)(1) to require that establishments, at a minimum, collect and analyze samples for microbial organisms at the rehang and post-chill points in the process, as opposed to the pre-chill and post-chill locations. FSIS has determined that sampling at the rehang point in the process, *i.e.,* after picking and prior to evisceration, is likely to be more effective for monitoring process control, given the introduction of carcass contamination tends to occur at slaughter process steps at or just prior to the rehang location and evisceration [167] and pre-chill sampling often takes place after evisceration and some antimicrobial interventions have already occurred.[168] The FSIS 2023 chicken risk assessment and FSIS assessment of exploratory sampling program data reported that there has been an increase in the log AC reduction achieved between rehang and post-chill influenced mostly because the levels of indicator organisms detected post-chill have declined since the prior 2007–2008 baseline study. FSIS has observed that pre-chill samples collected after evisceration and after most interventions, and prior to the chiller, typically have lower levels of organisms detected than rehang samples collected prior to evisceration and fewer intervention steps.

Under this proposal, establishments would be required to identify and provide supporting rationale for the exact point where they intend to collect their rehang sample. Establishments would be permitted to collect a pre-chill sample at a location other than rehang if they provide supporting data to demonstrate that the alternative location is at least as effective as rehang sampling for monitoring their ability to maintain process control. However, one benefit of rehang sampling is that it allows establishments to assess the level of microbial contamination early in the slaughter process and, thereby, better understand the level of enteric pathogen hazard associated with flocks at receiving. Also, according to NACMCF, monitoring change in AC ''from an early sampling point on the slaughter line to the final sampling point on the processing line . . . may provide useful information about the effectiveness of the process in maintaining hygiene conditions.'' [169] Moreover, continuing to monitor at pre-chill, which tends to occur after establishments apply antimicrobial interventions, would make it more difficult for establishments to justify how the microbial monitoring data they generate validates that their established target change and quantitative consistency parameters are adequate to monitor process control. Thus, ideally, the exact point of an establishment's rehang sampling should be immediately after the early slaughter processing steps that are mostly likely to introduce microbial contamination and before the establishment's use of antimicrobial interventions. Establishments slaughtering poultry predominantly under religious exemptions that result in feet on, un-eviscerated carcasses, or otherwise are slaughtered at post-picking but prior to the evisceration rehang step are to collect samples at the point in the process that results in the greatest source of introduction of enteric pathogen and fecal contamination.

Finally, FSIS' proposed amendments to 9 CFR 381.65(g)(1) would require VS and VLV establishments operating under Traditional Inspection to—like all other establishments—collect and analyze microbial samples at rehang and

[165] FSIS Directive 10,250.1, Salmonella and Campylobacter Verification Program for Raw Poultry Products, *https://www.fsis.usda.gov/policy/fsis-directives/10250.1.*

[166] Quantitative Microbial Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[167] NACMCF (2019). ''Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry.'' Journal of Food Protection 82(4): 645–668.

[168] Exploratory Project questionnaire responses indicate that 51 percent of the establishments applied one or more interventions prior to rehang, whereas all but one establishment applied one or more interventions after rehang.

[169] 2021–2023 National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMCF); FSIS Charge: Enhancing *Salmonella* Control in Poultry Products Available at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

post-chill locations. These establishments are currently required to collect microbial samples at the post-chill point only. To offset the economic impact of this amendment, these establishments would be eligible to have access to laboratory services provided by FSIS at no cost as described and discussed above. The FSIS 2023 risk assessment and the Agency's assessment of the exploratory sampling program data both recognized that greater levels of detected microbial organisms were more likely to be observed in the smaller size and volume establishments than the larger establishments, although microbial levels detected at post-chill were overall lower than previously observed during the 2007–2008 baseline study. FSIS has concluded that post-chill samples representing only the end of the slaughter process does not provide the same level of MMP adequacy to monitor process control throughout the slaughter and dressing process as minimum two-point sampling. Microbial monitoring at both rehang and post-chill will help VS and VLV establishments operating under Traditional Inspection to assess levels of microbial contamination at a point closer to the start of the slaughter process and the effect that their anti-microbial intervention steps have in reducing such contamination.

4. Sample Collection Monitoring Frequency

As discussed, a recent FSIS review of PHIS inspection data found that MMP noncompliance issues were frequently associated with sampling frequency and that the noncompliant establishments were most often those that produced lower volumes of product. FSIS is proposing, therefore, to amend 9 CFR 381.65(g) to make it easier for establishments to understand and comply with minimum sampling frequency requirements. First, FSIS is proposing to update the sampling frequency regulations for VLV establishments, which currently require that such establishments collect and analyze 13 weekly samples starting on June 1 of each year. FSIS has concluded that the current requirement would not generate statistically robust process control monitoring data regardless of if the results are collected over 13 consecutive weeks or at other intervals throughout the year. FSIS has also concluded that the June 1 requirement makes it difficult for VLV establishments to demonstrate that their MMP is adequate to monitor process control without collecting additional samples at other times of the year, such as during the establishment's greatest seasonal production or the slaughter of poultry from growers associated with greater risks of increased microbial carcass contamination. As such, FSIS is proposing to revise 9 CFR 381.65(g)(2)(ii) to remove the June 1 requirement and otherwise give VLV establishments the flexibility to collect their 13 weekly samples in accordance with their slaughter operations throughout the year. The MMP decision making rationale for all establishments, regardless of annual slaughter volume, must support how the establishment will determine when the monitoring will be performed and how the specific carcass will be selected for sampling.

Second, to help all establishments better understand their minimum sampling frequency requirements and develop their sampling frequency procedures, FSIS is proposing to tie sampling frequency requirements to annual slaughter volumes, as opposed to weekly slaughter volumes. As discussed, FSIS review of NRs found that many establishments have trouble planning or adjusting their sampling frequency regime to comply with current regulations given actual weekly slaughter volumes tends to fluctuate irregularly. Moreover, FSIS reviewed current sampling frequency requirements relative to annual slaughter volumes and determined that they require many lower volume establishments to collect samples at a greater rate than larger establishments.[170] The proposed revisions, which are outlined in Table 11 and Table 12 below, would simplify proposed slaughter volume criteria cut points for VLV, low volume, and medium to high volume establishments and make it easier for establishments to adapt to fluctuating conditions. Specifically, FSIS is proposing that medium to large volume establishments slaughtering as their predominant species *more than* 1,100,000 chickens or 156,000 other poultry species annually be required to collect at a minimum frequency of one paired sample every 22,000 or 3,000 head slaughtered, respectively.[171] Further, FSIS is proposing that LV establishments that slaughter as their predominant species between 440,001 to 1,100,000 chickens or 60,001 to 156,000 other poultry species annually be required to collect a minimum of one paired sample a week, regardless of weekly fluctuations in their actual slaughter volume. Lastly, FSIS is proposing that VLV establishments be required to collect a minimum of 13 weekly paired samples per year. Those VLV establishments that plan to operate less than 13 weeks per year may collect their 13 annual samples on a less than weekly basis, assuming they can demonstrate that their sample frequency is effectively monitoring that they are maintaining process control throughout the year and during any periods of slaughter operations. Regardless of these *minimum* required frequencies, FSIS regulations would continue to mandate that all establishments collect samples at a frequency that is adequate for the establishment to monitor process control.

TABLE 11—PROPOSED REVISIONS TO 9 CFR 381.65(g)(2) MINIMUM SAMPLING FREQUENCY: CHICKEN

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Chicken	Very Low Volume	1–440,000	13 Weekly Pairs per Year.
Chicken	Low Volume	440,001–1,100,000	Weekly.
Chicken	Medium and High Volume	≥1,100,000	1 per 22,000.

[170] E.g., under current regulations, non-VLV establishments that slaughter less than 22,000 chickens per week (*i.e.,* between 440,001 to 1,144,000 head annually) are required to collect at least 1 sample weekly, resulting in a collection range of 1 sample per every 8,461 to 22,000 chickens (*i.e.,* a midpoint rate of 1 sample per every 15,231 head). This is a greater sampling rate than those larger volume establishments collecting a minimum of only one sample every 22,000 head.

[171] Under current regulations, these establishments collect 1 sample for every 22,000 chickens or 3000 other poultry species slaughtered. This is an annualized slaughter volume of 1,140,000 head of chicken or 156,000 other species. To simplify proposed slaughter volume criteria cut points, FSIS rounded 1,144,000 to the 1,100,000 identified in Table 11; an annual slaughter of 1,100,000 averages 21,153 head per week.

TABLE 12—PROPOSED REVISIONS TO 9 CFR 381.65(g)(2) MINIMUM SAMPLING FREQUENCY: TURKEY, GEESE, GUINEA, DUCK, SQUAB

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Turkey, geese, guineas, Ducks, Squab	Medium and High Volume	≥156,000	1 per 3,000.
Turkey, Geese, Guinea, Ducks, Squab	Low Volume	60,001–156,000	Weekly.
Turkey, Geese, Guinea, Ducks, Squab	Very Low Volume	1–60,000	13 Weekly Pairs per Year.

5. Corrective Actions

FSIS is proposing to amend 9 CFR 381.65(g) to further clarify that MMP monitoring results and documented corrective actions must be part of the pre-shipment review process required under 9 CFR 417.5(c). Current regulations at 9 CFR 381.65(g) require establishments to incorporate microbial monitoring procedures into their HACCP systems. Under 9 CFR 417, HACCP records must be maintained and continuously evaluated as part of the establishment's validation, ongoing verification, and reassessment process. Moreover, HACCP regulations at 9 CFR 417.3 and 417.5 specifically require establishments to identify, in writing, the corrective actions that they will take when a HACCP system procedure may have failed. This failure may be observed by either the establishment or FSIS and may include failure to implement or maintain a procedure, evidence that the outcome of a procedure was ineffective, or when monitoring identifies the defined allowable limits have not been met.

FSIS is proposing to revise the regulations to ensure that establishments comply with these corrective action provisions as they apply to the establishment's MMP. Specifically, FSIS is proposing to amend 9 CFR 381.65(g) to require establishments to, at a minimum, implement written corrective actions, including a root cause assessment, when microbial monitoring results deviate from predefined target change, quantitative consistency, or other criteria defined in the MMP.

FSIS is also proposing that establishments' MMPs define the corrective actions the establishment intends to take when its MMP results do not align with other process control monitoring conclusions or when its MMP results do not support the conclusion that its HACCP system is controlling hazards as intended. FSIS recognizes a qualitative analysis of MMP results is necessary, given that a process can be stable and not capable of meeting quantitative specifications or unstable yet produce product that meets quantitative specifications.[172] Thus, establishments will need to continually consider their MMP results in conjunction with all other process control monitoring efforts to qualitatively assess the overall ability of their procedures to maintain process control and function as intended. Establishments are to investigate and implement corrective actions when their MMP monitoring results do not align with the other process control monitoring conclusions. FSIS expects establishments to consider their MMP results as part of their total HACCP system validation and ongoing verification in the assessment of whether the procedures as required by 9 CFR 381.65(g) are controlling the biological hazard (enteric pathogens) as intended by the establishment's HACCP system. A slaughter establishment's HACCP system should clearly identify what process control procedures are monitored by the MMP, any other process control monitoring results reflecting the same procedures, a lot of products represented by this process control monitoring, and any other procedures intended to control the same hazard as the procedures required by 9 CFR 381.65(g). Establishment documented corrective actions to observed MMP deviations must demonstrate the establishment assessed the root cause of any deviation in target change, quantitative consistency, and qualitative consistency as described above.

6. Recordkeeping Requirements

FSIS is proposing to add a new paragraph (2) to 381.65(h) that would require establishments to electronically submit a copy of their microbial monitoring results to FSIS on a monthly basis. As part of the publication of any final requirements, FSIS would provide a template to each establishment for submitting monthly results. While FSIS inspectors would continue to review process control sampling data in establishments, the proposed change would allow FSIS headquarters personnel to evaluate national trends to determine the efficacy of the revised process control requirements in reducing final product contamination and to inform FSIS' decision-making concerning agency verification sampling.

As part of the *Salmonella* Framework effort, FSIS met with internal FSIS, industry, and other government official stakeholders to explore potential improvements to FSIS receipt of third-party data. FSIS, academic, and industry stakeholders expressed concern around the lack of options for nationally represented industry microbial data. FSIS has determined it could update its information technology systems to provide for both individual result and bulk result data uploads by third parties. FSIS would publish guidance regarding the electronic submission of data alongside any final rule resulting from this proposal. FSIS is developing a web portal that will allow external partners to securely upload their sampling information and submit the data to FSIS electronically in a machine-readable format. The proposed fields that would be uploaded into the portal are: a sample identification number, the establishment number, date, time, slaughter line number, location of sample collection (*e.g.,* rehang, post-chill), poultry species sampled, sample type (*e.g.,* rinsate, sponge), analyte (*e.g.,* AC, EB), analyte units (*e.g.,* cfu/mL), quantified analyte result, and text analyte result (*e.g.,* <Lower LOD, >Upper LOD). FSIS is seeking comments on the proposed data fields requested. Establishments would have the option of entering the information directly into the system or utilizing the FSIS provided spreadsheet file discussed above as a template to bulk upload the information. FSIS anticipates that most establishments would use the FSIS provided template as the HACCP MMP monitoring record to avoid duplication of monitoring results.

FSIS is also seeking comment on specific data use opportunities which could be pursued that would support FSIS investing additional resources into the technology systems necessary to

[172] NACMCF (2015). ''Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions, available at *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.*

blind the proprietary MMP result record copies for research, industry, academic, or other pursuits.

IV. Component One: Pre-Harvest Measures

A. Scientific Support and Public Comments

Under Component One of the October 2022 draft framework, FSIS indicated that it was considering whether it should require poultry slaughter establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. This component is grounded in the strong scientific support for use of pre-harvest interventions and management practices, in particular that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to *Salmonella.*

The results of the 2023 risk assessments underscore the potential public health benefit of requiring pre-harvest interventions and management practices to reduce *Salmonella* contamination on poultry. Within the risk assessments, risk management options for controlling *Salmonella* at the receiving step focused on chicken and turkey slaughter establishments and sample results at the rehang location as a proxy for sampling live birds at or before the receiving step.[173] The 2023 risk assessments estimated the impact of eliminating certain serotypes. Two options were modeled: in the first, rehang results were considered as a verification of pre-harvest *Salmonella* control strategies. More effective strategies mean lower rates of certain serotypes at rehang. For the second option, rehang testing results would be used to take actions, such as diverting positive flocks with higher virulence serotypes to a safe end point (*e.g.,* cook product from those flocks).

If rehang testing is considered as a verification of pre-harvest strategies, between 27,000 and 55,000 annual salmonellosis cases could be avoided if flocks that have higher virulence serotypes were not being processed for food. Alternatively, if rehang testing is used to identify and divert contaminated carcasses, about 36,000 cases could be avoided. However, to achieve these outcomes, flocks with a higher virulence serotype would be diverted to a safe end point (*e.g.,* for cooking at an official establishment), resulting in the diversion of 46,000 flocks. Further, the rehang step takes place during processing. Requiring processors to react to testing—with results not available to at least two days—is not feasible. co Currently, FSIS analyzes about 10,000 young chicken carcasses from rinsates collected at the post-chill location annually. By comparison, there are approximately 9.384 billion carcasses that are processed each year at approximately two hundred slaughter establishments. Therefore, currently, FSIS analyzes about one out of every million young chicken carcasses processed annually.

Testing results at or before the receiving step may have a substantial public health impact. However, the requirements associated with the first option (verification of pre-harvest *Salmonella* control strategies) would require substantial industry resources, and there is no guarantee that the poultry industry would implement such *Salmonella* control strategies, since the first option would not penalize establishments for having highly virulent serotypes at the rehang step. The second option (divert flocks that test positive to a safe endpoint) would require the same resources as the first option. However, FSIS is not proposing such a diversion requirement at this time.

FSIS does not have a routine sampling program at the rehang location, but the Agency evaluated such a program as part of the 2022 young chicken exploratory sampling program discussed above. Among 180 establishments sampled twelve or more times at the rehang location, *Salmonella* positive rates for young chicken carcasses ranged from 0 to 100 percent, and the 95 percent confidence interval ranged from 54.9 to 69.0 percent. Variability at the rehang location was also observed with AC and EB. Among 180 establishments with at least twelve analyzed sample pairs, the ACs average at the rehang location was 4.40 log cfu per mL (95 percent confidence 4.34 to 4.46 log cfu per mL) and EB average was 3.00 log cfu per mL (95 percent confidence 2.94 to 3.06 log CFU per mL).

Two recent NACMCF reports, one published in March 2019 and the March 2023 NACMF Final Report, support the important role pre-harvest measures play in controlling *Salmonella* in poultry.

2019 NACMCF Report. At a March 2017 NACMCF meeting, FSIS asked the committee to address the issue of how to reduce the prevalence of *Salmonella* on poultry throughout the farm-to-table continuum.[174] In March 2019, the committee's final report addressing the Agency's questions was published in the Journal of Food Protection.[175] Questions two, three, and six related to pre-harvest measures to control *Salmonella* in poultry. Question two asked where *Salmonella* resides inside and on the surface of poultry and how those populations of bacteria contribute to food contamination. The committee responded that most carcass contamination is believed to result from leakage of ingesta during crop removal and from feces during evisceration, as well as aerosolization during picking. In addition, *Salmonella* may be present in feather follicles and on the surface of broilers when they enter the slaughter establishment. Several preslaughter strategies to reduce the burden of *Salmonella* in flocks entering slaughter establishments have been shown to be effective, and data demonstrating a correlation between flock status of *Salmonella* and pre- and post-chill contamination have been reported. Control measures for *Salmonella* in poultry can be classified as those that target (i) exposure and colonization within an individual animal, (ii) transmission between parent flocks and progeny, and (iii) transmission between birds within a flock. The committee also noted that *Salmonella* vaccination is one breeder-level pre-harvest intervention that contributes to an overall reduction and/or elimination of specific *Salmonella* serotypes. The committee stated that the most effective vaccination strategy is to focus on vaccination of breeder flocks and reduce vertical transmission of *Salmonella.*

Question three asked whether removing flocks of highly *Salmonella*-contaminated birds entering the slaughter establishment can reduce foodborne illnesses in humans. The committee responded that it is logical to expect that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to that source of *Salmonella,* potentially resulting in reduced foodborne illness in humans.

[173] For chicken FSIS used rehang sample data collected during the FSIS young chicken carcass exploratory sampling program (April to November 2022). For turkey, FSIS modeled *Salmonella* at receiving using rehang sampling data from the 2008–2009 FSIS Young Turkey Carcass baseline study due to the absence of other data for the turkey industry.

[174] 2015–2017 NACMCF Charge, *Salmonella* Control Strategies in Poultry, available at: *https://www.fsis.usda.gov/news-events/publications/2015-2017-national-advisory-committee-microbiological-criteria-foods.*

[175] Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry (March 26, 2019), Journal of Food Safety, available at: *https://www.fsis.usda.gov/news-events/publications/2015-2017-national-advisory-committee-microbiological-criteria-foods.*

However, there was no consensus within the committee regarding the predictive ability of farm sampling and subsequent *Salmonella* contamination on neck skin at the end of processing. Given uncertainty about the impact of removing flocks of highly *Salmonella*-contaminated birds from slaughter, the committee recommended that process controls be validated to address a worst-case scenario for contamination of incoming birds and be continually operating at that level to address the potential risk from highly contaminated birds. The committee concluded that rather than establishing lot- or flock-specific thresholds, *Salmonella* management programs should be based on historical trend analyses of specific farms and transportation supplying birds to the slaughter process. Sampling birds immediately before entering the slaughter process would be ideal, but detection technology did not currently exist to provide the rapid detection needed for this scenario. Historical data might be used to build statistical models to predict the potential for elevated levels of *Salmonella* from a particular farm. In addition, monitoring of external factors, such as weather or seasonality, may help indicate the possibility of a higher-than-normal contamination level. Historical knowledge of process controls and facility capability can be used by a processor to determine whether process controls should be reassessed and validated to address predicted risks.

Question six asked the committee to identify the top three focus points, control measures, or best practices that would be compatible with industry-wide practices and could be addressed or implemented to achieve the highest rate of reductions of *Salmonella* product contamination and foodborne illness. The committee's response included the statement that prevention or elimination of *Salmonella* colonization, should be effective for reducing *Salmonella* in final product and contributing to public health improvements.

2023 NACMCF Report. In the 2023 NACMCF report, the committee addressed issues related to pre-harvest measures to control *Salmonella* in poultry.[176] For question two of the NACMCF charges, FSIS asked the committee what types of microbiological criteria could be established to encourage control of *Salmonella* at pre-harvest, and what industry data would provide evidence of control. As part of its response, the committee noted that vaccination programs have been incorporated on U.S. farms. The committee described such vaccination programs as an effective management practice for controlling *Salmonella* at pre-harvest and noted that vaccines are likely the only serotype-specific intervention strategies.

Together, the 2019 and 2023 NACMCF report responses related to pre-harvest measures support the use of these measures to control *Salmonella* in poultry. In the 2019 report, the committee concluded that preslaughter strategies to reduce the burden of *Salmonella* in flocks entering slaughter establishments are effective, and that data show a correlation between flock status of *Salmonella* and pre- and post-chill contamination. The 2019 report also indicated that it is probable that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to that source of *Salmonella,* potentially resulting in reduced foodborne illness in humans. In the 2023 report, the committee recommended that the Agency target for consideration conditions in houses, transport crates, and holding areas that harbor and transmit *Salmonella* by universal implementation of known and validated mitigation strategies. Of note, both final reports indicated uncertainty regarding whether current testing technology and data are available to design and broadly implement effective threshold requirements for segregating *Salmonella*-contaminated flocks at receiving.

As discussed above, FSIS received comments on Component One of the October 2022 draft *Salmonella* Framework that raised concerns related to costs, testing technology, and implementation challenges. Several comments from small poultry processors and producers and trade associations representing the meat and poultry industries that expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers and processors.

In light of these comments, FSIS has decided at this time not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an establishment. FSIS will actively seek evidence and best practices from the poultry industry. The Agency will revisit its strategy for using testing (including quantitation and deep serotyping) to minimize the risk of cross-contamination at processing when logistical challenges have been addressed and testing becomes more timely and affordable.

FSIS has decided, instead, for the time being, to focus on non-regulatory approaches to controlling *Salmonella* at preharvest and reducing the *Salmonella* load on birds at receiving. FSIS not proposing to enforce measures under Component One at this time. If the Agency decides to make any of the approaches discussed below mandatory, it will do so through future rulemaking.

B. Possible Approaches To Control Salmonella at Pre-Harvest

1. National Poultry Improvement Program

FSIS will explore whether existing or new certification programs under the National Poultry Improvement Program (''NPIP'' or the ''Plan'') could serve to verify and document producers' actions (such as use of *Salmonella* vaccines) to control *Salmonella,* including serotypes of public health significance.

Administered by APHIS, NPIP is a cooperative industry, state, and federal program initially established to improve poultry and poultry products and prevent and control poultry diseases.[177] The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. NPIP regulations in 9 CFR parts 145 and 146 contain requirements that must be observed by participating flocks, including testing and biosecurity measures. These measures are updated over time as the science and technology evolve and improve. Affiliated flock-owners participate in the Plan through an agreement with a participating hatchery. Participating hatcheries must be maintained in sanitary condition as outlined in the NPIP Program Standards and the U.S. Code of Federal Regulations and are subject to third party audit by an official state agency at least once every two years or a sufficient frequency to ensure compliance. NPIP programs are available for multiplier and primary breeding flocks for meat-type chicken and products (9 CFR part 145 subparts C and H), and turkey breeding flocks and products (9 CFR part 145 subpart D). These programs include biosecurity measures and may include testing for *Salmonella* or *Salmonella* serotype Enteritidis. The

[176] NACMCF final report ''Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products'' (March 13, 2023), available at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

[177] USDA Animal and Plant Health and Inspection Service (APHIS) National Poultry Improvement Plan information available at: *https://www.poultryimprovement.org/default.cfm.*

Plan's ''U.S. *Salmonella* Monitored Program'' is intended for primary breeders of meat type chickens to reduce the incidence of *Salmonella* organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. The Plan's ''U.S. S. Enteritidis Clean Program'' is intended for primary or multiplier breeders of meat-type chickens wishing to assure their customers that the chicks produced are certified free of *Salmonella* Enteritidis.

2. Vaccination

FSIS will more actively encourage the development, licensure, and use of poultry vaccines against *Salmonella* serotypes of public health concern, particularly live attenuated vaccines, and will provide sampling data and technical support, as appropriate, to industry and regulatory bodies to advance these goals.

Salmonella vaccination is one tool in a multifaceted approach to overall *Salmonella* reduction and/or elimination of specific *Salmonella* serotypes. Vaccines reduce the susceptibility of individual birds to *Salmonella* infection, transmission among breeding flocks, cross-contamination during meat bird production, contamination of poultry house environments, and transmission to subsequent flocks. Live attenuated vaccines are derived from a specific strain of a target organism (*i.e., Salmonella* Typhimurium), subunit vaccines containing protein or nucleic acid from the target organism, and autogenous inactivated vaccines against a cocktail of strains found in a local area. Vaccines may provide cross protection across serotypes. For example, the availability of a commercial live attenuated vaccine created from *Salmonella* Typhimurium corresponded to a profound decline in the incidence of both Typhimurium and a related serotype Heidelberg illnesses.[178] Attenuated strains can be designed to expose common antigens, therefore inducing cross-protective immunity against diverse Salmonella serotypes.[179] Although vaccines can be protective and limit horizontal transmission of infection within broiler flocks, they must be given multiple times to all birds in each flock and, therefore, present logistical and cost challenges that must be overcome.

FSIS will continue to collect data on the impact of vaccine use on FSIS verification testing through pilot projects. As noted above, since March 2023, FSIS has granted pilot projects to 9 establishments to examine the merits and logistics of excluding *Salmonella* poultry vaccine strains from the FSIS *Salmonella* performance categorization calculation. Modified live *Salmonella* vaccines are used to reduce *Salmonella* colonization in poultry. These vaccine strains are not foodborne pathogens, making them a valuable pre-harvest tool for controlling wild-type *Salmonella.* FSIS is able to identify vaccine strains isolated from raw poultry products through the use of whole genome sequencing.

FSIS examined *Salmonella* detection and serotype data from flocks vaccinated with a modified live *Salmonella* vaccine at pre- and post-intervention points in the participating slaughter establishments. These data show that vaccine strains can occasionally be found in raw poultry products even when the vaccine is used as directed on the label. After reviewing the data, FSIS concluded that its policy to count such strains as a positive result in performance categorization may discourage use of vaccination as a tool to control *Salmonella.* Therefore, on March 1, 2024, FSIS announced that beginning April 1, 2024, it intends to exclude current commercial vaccine subtypes confirmed in FSIS raw poultry samples from the calculation used to categorize establishments under the raw poultry *Salmonella* performance standards.[180] This action is intended to remove barriers to the use of vaccination as an important pre-harvest intervention to control *Salmonella* in poultry. A summary report of the data from these pilots is posted on the Pilot Projects: *Salmonella* Control Strategies page of the FSIS website at: *https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot.*

3. Supply Chain Control Programs

Establishments operating under HACCP regulations (*9 CFR part 417*) must perform a hazard analysis to identify food safety hazards that can occur before, during, and after entry into the establishment and to identify the preventive measures the establishment can apply to control those hazards. Establishments that identify hazards that occur before entry face the challenge of providing assurance that preventive measures are effectively applied. FSIS-inspected establishments operating under HACCP must document, validate, and verify the effectiveness of their hazard control(s). While not required to do so, establishments slaughtering poultry that have identified *Salmonella* as a hazard during the breeder and multiplier and production stages are encouraged by FSIS to use supply chain programs [181] to verify the effectiveness of their supplier's interventions, and the Agency will ramp up its efforts to assist any establishment that wants to implement a supply chain program.

4. Updated Pre-Harvest Guidance

FSIS intends to revise its existing guideline on *Controlling Salmonella in Raw Poultry* [182] to provide updated guidance on pre-harvest interventions and management practices for preventing and reducing *Salmonella* colonization in live birds. FSIS remains committed to identifying and developing strategies for addressing *Salmonella* contamination in the pre-harvest environment. Additionally, the Agency is working with the USDA's Agricultural Research Service (ARS) on a literature review of *Salmonella* presence in poultry at pre-harvest.

V. State Programs and Foreign Government Programs

States that have their own poultry inspection programs for poultry

[178] NACMCF Report: ''Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella Control in Poultry Products'' (Mar 2023). Available at: *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021.*

[179] Aehle, S. and R. Curtiss (2017). Chapter 14—Current and Future Perspectives on Development of Salmonella Vaccine Technologies. Producing Safe Eggs. S. C. Ricke and R. K. Gast. San Diego, Academic Press: 281–299; Hassan, J. O. and R. Curtiss Iii (1997). ''Efficacy of a live avirulent Salmonella typhimurium vaccine in preventing colonization and invasion of laying hens by Salmonella typhimurium and Salmonella enteritidis.'' Avian Dis 41(4): 783–791.

[180] FSIS Constituent Update—March 1, 2024: FSIS Intends to Exclude Vaccine Strains from the FSIS Salmonella Performance Categorization at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-march-1-2024.*

[181] One example of a supply chain program is a process verified program (PVP) administered by USDA's Agricultural Marketing Service (AMS). A PVP may include one or more agricultural processes or portions of processes where self-described process points are supported by a documented management system, and independently verified by a qualified AMS auditor. One PVP available to the poultry industry is the Quality System Assessment (QSA). The QSA provides companies that supply agricultural products and services the opportunity to assure customers of their ability to provide consistent quality products or services. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. USDA AMS Process Verified Program information available at: *https://www.ams.usda.gov/services/auditing/process-verified-programs.*

[182] FSIS *Guideline for Controlling Salmonella in Raw Poultry* (June 2021), available at: *https://www.fsis.usda.gov/guidelines/2021-0005.*

products produced and transported solely within the State are required to have mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the PPIA (21 U.S.C. 454(a)(1)). Therefore, if FSIS finalizes this proposed rule and determination, these States would need to develop sampling procedures and testing methods to detect *Salmonella* at or above 10 cfu/mL(g) in an analytical portion and *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products that are at least as sensitive as FSIS' procedures and testing methods for *Salmonella.* Additionally, these States would need to implement requirements for poultry slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation that are at least equal to FSIS' proposed revisions to the poultry regulations. FSIS will coordinate closely with States that maintain federally supported poultry inspection programs to ensure that this *Salmonella* Framework for raw poultry products is implemented in all intrastate establishments.

Foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitary, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 466). Thus, in evaluating a foreign country's poultry inspection system to determine the country's eligibility to export products to the United States, FSIS will consider whether the sampling procedures and testing methods that the country implements for detection of *Salmonella* at or above 10 cfu/mL(g) in an analytical portion and *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products are equivalent to FSIS' sampling procedures and testing methods. Additionally, FSIS will also evaluate whether the country's requirements for slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation are equivalent to FSIS' proposed revisions to the poultry regulations. FSIS will continue to use the existing equivalence process to ensure that foreign countries implement requirements, sampling procedures and testing methods equivalent to FSIS' proposed revisions to the poultry regulations and the sampling procedures and testing methods for *Salmonella* in raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products. FSIS intends to provide countries that export poultry products to the United States 3 years after publication of the final rule to submit adequate documentation to support that their poultry inspection system is equivalent to FSIS' inspection system. Thus, exporting countries would have a 3-year transition period in which they could continue to export poultry products to the United States while they implement measures to ensure that their poultry inspection system is equivalent to the U.S. system. FSIS would likely begin testing imported raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products to verify products are not adulterated one year after the final publication. FSIS will provide additional details on these issues in any final rule and determination resulting from this proposal.

VI. Executive Orders 12866, as Amended by 14094, and 13563

Executive Orders (E.O.) 12866, as amended by 14094, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule and proposed determination have been designated a ''significant'' regulatory action by the Office of Information and Regulatory Affairs under section 3(f) of E.O. 12866. Accordingly, the proposed rule and proposed determination have been reviewed by the Office of Management and Budget under E.O. 12866.

Regulatory Impact Analysis

FSIS is proposing to clarify certain process control requirements for poultry slaughter establishments and establish final product standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. This proposal is aimed at reducing *Salmonella* illnesses in the U.S. population.

FSIS is proposing to clarify current requirements for monitoring compliance with 9 CFR 381.65(g) for poultry slaughter establishments and to require poultry slaughter establishments to submit process control monitoring data electronically to FSIS. These establishments are currently required to monitor their processes to ensure they comply with FSIS regulations. FSIS is clarifying that MMPs need to be statistically based and is requiring that establishments collect samples specifically at rehang, or an alternative location if they submit and maintain supporting documentation. The proposed clarifications are estimated to have minimal economic impact on most establishments, while the potential effects on VLV and VS establishments operating under Traditional Inspection, as described in this analysis, would be potentially mitigated by the use of laboratory services provided by FSIS.

FSIS is also proposing to implement new standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that would enter commerce. Product subject to these standards, as described in the foregoing, would be subject to FSIS routine sampling and verification testing for *Salmonella.* Establishments subject to FSIS verification sampling would be required to maintain control of sampled product pending test results. Product lots that do not meet the standards would be considered adulterated and would be diverted from commerce. Establishments could divert adulterated product to be fully cooked at a federal establishment and then sent into commerce.

Finally, FSIS is encouraging establishments to consider including pre-harvest measures in their HACCP systems to address the hazard of *Salmonella* contamination prior to slaughter. The Agency is not requiring that establishments adopt pre-harvest measures; thus, any potential costs or benefits associated with those measures are especially challenging to analyze, and we request comment on relevant data and analytic methods of analysis.

Need for the Rule

This regulatory action is necessary because while the results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing the proportion of poultry products contaminated with *Salmonella,* these measures have yet to have an observable impact on overall human *Salmonella* illness rates (see the *Salmonella Performance Standards and Illnesses* section for more details). An estimated 23 percent of *Salmonella* illnesses are

attributed to poultry—17 percent to chicken products and 6 percent to turkey products—making poultry one of the leading sources of foodborne *Salmonella* illnesses in the United States.[183] Thus, a reduction in *Salmonella* illnesses associated with poultry consumption would be expected to have an impact on overall *Salmonella* illnesses. A 2015 analysis found that poultry consumption was more likely than any other animal protein to lead to *Salmonella* illnesses.[184] Additionally, a 2021 study observed that *Salmonella* outbreaks related to consumption of single ingredient poultry products were disproportionately higher than the estimated level of consumption of single ingredient poultry products.[185]

As part of this proposal for *Salmonella* in poultry, FSIS is proposing to clarify existing regulatory requirements related to process control monitoring and recordkeeping in 9 CFR 381.65(g) and (h) to better ensure that poultry slaughter establishments are effectively controlling *Salmonella* throughout their slaughter and dressing operations. FSIS is also proposing to declare that raw chicken carcasses, parts, and comminuted chicken and turkey that contain *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance are adulterated because the 2023 risk assessments found that servings contaminated with these *Salmonella* levels and serotypes are much more likely to cause illness than the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings (see the *Risk per Serving, Salmonella Levels, and Proposed Determination* section for more details). The 2023 risk assessments estimate that diverting products that contain these *Salmonella* levels and serotypes from commerce would prevent annual foodborne illnesses from *Salmonella* linked to poultry.[186] Moreover, the FSIS risk profile indicates that for certain *Salmonella* serotypes often linked to poultry products a small amount of *Salmonella* bacteria can cause illness.[187] It also noted that these serotypes caused hospitalization more frequently and led to invasive disease and death as well as debilitating human health outcomes.

FSIS is taking this regulatory action to protect public health and reduce the number of *Salmonella* illnesses linked to poultry products. If this proposal is finalized, it would protect consumers from consuming products that have a higher probability of illness and would incentivize producers implement food safety measures that would minimize the risk of *Salmonella* illnesses.

Baseline for Evaluation of Costs and Benefits

Poultry consumption has grown 13 percent over the past 10 years, with broiler meat accounting for 83 percent of the total consumption, while turkey accounts for about 16 percent. Poultry—mainly chicken—is the main source of animal protein across demographic groups and is consumed both at home and away from home.[188] Poultry products are available in multiple formulations, ranging from raw whole birds and parts to fully cooked, ready-to-eat products. In the United States, chicken breasts, legs, and wings are the most consumed chicken products.[189] Turkey consumption, in contrast, is mainly as whole turkey, deli meat, ground turkey, or turkey bacon. Ground turkey consumption has increased substantially in the last decade, mainly as consumers opt for this product as a substitute for ground beef.[190]

On average, U.S. poultry establishments slaughtered 9.5 billion birds annually between 2017 and 2021, which is approximately 49.4 billion pounds of poultry. Broiler and turkey meat accounted for 87 and 12 percent of this production, respectively.[191] The U.S. poultry supply is mainly comprised of domestically grown and processed poultry as imports represent a very small fraction of the total supply.[192] Federally inspected establishments produce the vast majority of U.S. commercial poultry supply.[193] Most federally inspected establishments that produce a high volume of product solely produce chicken or turkey products. Some establishments also slaughter other classes of poultry, such as duck and geese. While there are establishments that slaughter multiple species, they tend to produce a low volume of product.

[183] The Interagency Food Safety Analytics Collaboration (IFSAC), ''Foodborne illness source attribution estimates for 2019 for *Salmonella,* Escherichia coli O157, Listeria monocytogenes, and Campylobacter using multi-year outbreak surveillance data, United States,'' October 2021, *https://www.cdc.gov/ifsac/php/annual-reports/index.html.* Annually, IFSAC releases a report that estimates foodborne illness source attribution for major commodity groups, including *Salmonella* in poultry products. At the time this proposal was developed, the 2019 IFSAC attribution estimates were the most recent data available. IFSAC released a new annual report in November 2023, which includes attribution estimates for 2020. In the 2023 report, IFSAC estimated that 18.6 percent of *Salmonella* illnesses are attributed to chicken products and 5.5 percent to turkey products, for a total 24.1 percent attributed to poultry products. FSIS intends to incorporate the 2023 report attribution estimates if this proposal is finalized. IFSAC, ''Foodborne illness source attribution estimates for Salmonella, Escherichia coli O157, and Listeria monocytogenes—United States 2021,'' November 2023, *https://www.cdc.gov/ifsac/php/annual-reports/index.html.*

[184] The analysis estimated that the risk of getting sick from *Salmonella* from one serving of poultry products was 94, 97, and 87 percent larger than that for a serving of pork, beef, and lamb products, respectively. Hsi, D.J., Ebel, E.D., Williams, M.S., Golden, N.J. and Schlosser, W.D., 2015. Comparing foodborne illness risks among meat commodities in the United States, *Food Control,* 54, pp.353–359. *https://doi.org/10.1016/j.foodcont.2015.02.018.*

[185] The analysis observed that while chicken and turkey consumption represent roughly 0.6 and 0.2 percent of the U.S. daily diet, the share of outbreaks linked to these products is significantly higher: 2.1 and 1.5 percent, respectively. These estimates are for chicken and turkey consumed as single-ingredient foods. Richardson, L.C., Cole D., Hoekstra, R.M., Rajasingham, A., Johnson, S.D., Bruce, B.B., 2021. Foods Implicated in U.S. Outbreaks Differ from the Types Most Commonly Consumed. *Journal of Food Protection,* 84(5), pp.869–875. *https://doi.org/10.4315/JFP-20-293.*

[186] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023; USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[187] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[188] There is variability in poultry consumption among demographic groups. For example, poultry consumption is higher among the non-Hispanic Black population, followed by Hispanics and non-Hispanic Asians. Poultry also represents a substantial source of protein for children, with chicken being the main source of animal protein among them. USDA, ERS, ''Racial and Ethnic Diversification Will Likely Shape U.S. Food Demand and Diet Quality,'' by Diansheng Dong and Hayden Stewart, April 4, 2022, *https://www.ers.usda.gov/amber-waves/2022/april/racial-and-ethnic-diversification-will-likely-shape-u-s-food-demand-and-diet-quality/.*

[189] USDA, Economic Research Service (ERS), ''Chicken leads U.S. per person availability of meat over last decade,'' March 1, 2023, *https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=105929.*

[190] National Turkey Federation, ''Turkey by the Numbers,'' accessed June 20, 2021, *https://www.eatturkey.org/turkeystats/;* Agricultural Marketing Resource Center, ''Turkey Profile,'' January 2022, *https://www.agmrc.org/commodities-products/livestock-dairy-poultry/poultry/turkey-profile.*

[191] Other types of poultry (*e.g.,* duck) account for the remaining 1 percent.

[192] Imports of poultry products into the United States represented less than 0.5 percent of total U.S. poultry consumption in 2021. The United States is a net exporter of poultry to the world and is the second largest exporter globally, with exports representing about 16 percent of the total domestic production in 2021. USDA, Foreign Agricultural Service, ''Production, Supply and Distribution database,'' accessed May 11, 2023.

[193] USDA, National Agricultural Statistics Service, Surveys: Poultry Slaughter, October 19, 2020, *https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Poultry_Slaughter/index.php.*

Establishments Subject to the Current Salmonella Performance Standards and Proposed Final Product Standards

FSIS used 2021 Public Health Information System (PHIS) data to identify establishments under the current *Salmonella* performance standards that produce chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, as well as their production volumes.[194]

Chicken Carcasses

In 2021, there were a total of 188 establishments under FSIS verification sampling for chicken carcasses that slaughtered over 8.3 billion chickens. FSIS classified these establishments into one of four volume categories (Table 13). Of these, 142 establishments were high-volume establishments, 9 were medium-volume, 4 were low-volume, and 33 were VLV chicken slaughter establishments. The 142 high-volume establishments accounted for over 99.5 percent of the total head count slaughtered in 2021.

TABLE 13—CHICKEN CARCASSES: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS

[2021]

Establishment volume category	Definition (birds)	Number of establishments	Annual production (million birds)	Share of production (%)
High	10 million or more	142	8,270	99.52
Medium	More than 1.1 million and less than 10 million.	9	33	0.40
Low	More than 440,001 and less than 1.1 million.	4	2	0.03
Very Low [1]	No more than 440,000	33	4	0.05
Total		188	8,309	

[1] Very low-volume establishments are defined in 9 CFR 381.65g(1)(i).
Note: Numbers in table may not sum to totals due to rounding.

Chicken Parts

In 2021, there were 490 establishments under FSIS verification sampling that produced chicken legs, breasts, wings, halves, and/or quarters (Table 14). Of these, 484 establishments were subject to FSIS performance standards sampling for chicken legs, breasts, and wings. The proposal would apply to establishments that produce chicken legs, breasts, wings, thighs, halves, and quarters. In 2021, most of the establishments producing chicken halves and quarters also produced legs, breasts, and wings. FSIS sampling at these establishments would be adjusted to incorporate chicken halves and quarters samples, while maintaining the current sampling frequency. In 2021, six establishments produced chicken halves and quarters, but did not produce legs, breasts, or wings. These six establishments are currently sampled as part of FSIS' exploratory sampling program for chicken halves and quarters.

FSIS estimates that these establishments produced over 31.2 billion pounds of chicken parts in 2021. FSIS classified these establishments according to the volume categories the Agency used in the 2016 cost-benefit analysis in support of FSIS ''Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards.'' [195] In 2021, 154 of these establishments were high-volume, 209 were medium-volume, and 127 were low-volume establishments (Table 14). The 154 high-volume establishments accounted for roughly 90 percent of the production volume of chicken parts in 2021.

TABLE 14—CHICKEN PARTS: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (annual production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
.				
High	70 million or more	154	28,113	90.1
Medium	More than 1 million and less than 70 million.	209	3,055	9.8
Low	1 million or less	127	40	0.1
Total		490	31,208	

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Chicken

In 2021, there were 74 establishments under FSIS verification sampling for comminuted chicken (Table 15). FSIS estimates that these establishments produced about 2.3 billion pounds of comminuted chicken in 2021. Using the categories in the 2016 cost-benefit analysis, the Agency classified 35 establishments as medium-volume and 39 establishments as low-volume. The

[194] USDA, FSIS, Public Health Information System database, accessed January 2, 2023 and April 5, 2023. Certain establishments are currently excluded from *Salmonella* verification testing. 81 FR 7288. FSIS adjusted the estimates for chicken parts, comminuted chicken, and comminuted turkey to match slaughter totals in the analysis period.

[195] USDA, FSIS, ''Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards,'' Final Cost-Benefit Analysis, February 11, 2016, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.*

35 medium-volume establishments accounted for 97.2 percent of total production of comminuted chicken in 2021.

TABLE 15—COMMINUTED CHICKEN: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (daily production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
High	250,000 or more	0	0	0.0
Medium	More than 6,000 and less than 250,000	35	2,193	97.2
Low	Less than 6,000	39	63	2.8
Total		74	2,256	

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Turkey

In 2021, there were 48 establishments under FSIS verification sampling for comminuted turkey (Table 16). FSIS estimates that these establishments produced about 1.7 billion pounds of comminuted turkey in 2021. Using the categories in the 2016 cost-benefit analysis, the Agency classified 5 establishments as high-volume, 25 establishments as medium-volume, and 18 as low-volume establishments. The 5 high-volume establishments accounted for 54.2 percent of the total production in 2021, while medium-volume establishments accounted for 45.3 percent, and low-volume establishments accounted for less than 1 percent of the total.

TABLE 16—COMMINUTED TURKEY: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (daily production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
High	250,000 or more	5	917	54.2
Medium	More than 6,001 and less than 250,000	25	766	45.3
Low	Less than 6,000	18	8	0.5
Total		48	1,691	

Note: Numbers in table may not sum to totals due to rounding.

Salmonella on Poultry Products

Salmonella is a foodborne pathogen commonly attributed to consumption of contaminated products that can lead to serious illness and death. In the United States, it is estimated to cause over 1.35 million illnesses annually, including 26,500 hospitalizations and 420 deaths.[196] *Salmonella* is estimated to be the leading pathogen in terms of total cost of illnesses in the United States, with about 24 percent of the total cost.[197] A 2020 study estimated that the economic costs of *Salmonella* illnesses associated with chicken is $2.8 billion annually.[198] A 2021 Interagency Food Safety Analytics Collaboration report attributed roughly 23 percent of the total annual *Salmonella* illnesses to consumption of poultry products, mainly chicken (17 percent) and turkey (6 percent).[199] *Salmonella* outbreaks linked to poultry products have continued to occur over the last two decades. From 1998 to 2020, FSIS identified 210 foodborne *Salmonella* outbreaks linked to chicken or turkey (Figure 1).[200] Generally, chicken products were implicated in 84.8 percent (178 out of 210) of the outbreaks and turkey products were implicated in 15.2 percent (32 out of 210) of the outbreaks.[201]

[196] CDC, ''*Salmonella,*'' November 10, 2022. *https://www.cdc.gov/salmonella/index.html;* USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[197] USDA, ERS, ''Cost Estimates of Foodborne Illnesses,'' Total cost of foodborne illness estimates for 15 leading foodborne pathogens dataset, March 10, 2021, *https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx.*

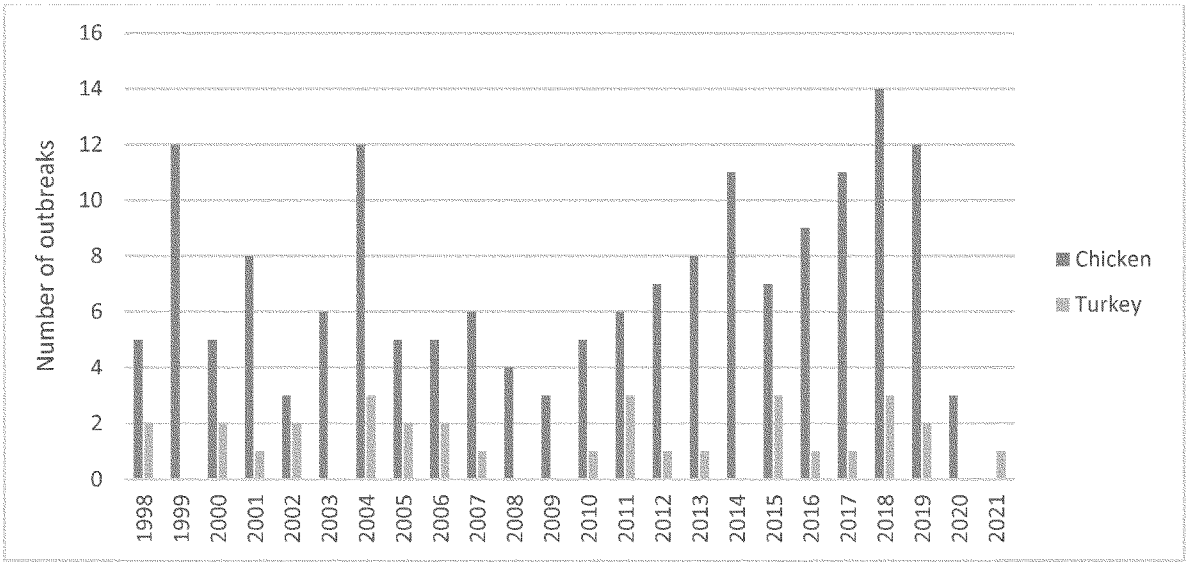
[198] USDA, FSIS, ''USDA Releases Proposed Regulatory Framework to Reduce *Salmonella* Infections Linked to Poultry Products,'' October 14, 2022, *https://www.fsis.usda.gov/news-events/news-press-releases/usda-releases-proposed-regulatory-framework-reduce-salmonella.* A cost of illness model that replaces the productivity loss estimates with a pain, suffering, and functional disability measure based on monetized quality-adjusted life year estimates indicates that the estimated annual cost of *Salmonella* illness was around $11.4 billion (ranging from $2.5 to $29.1 billion) in 2010 dollars. Scharff, R.L., 2012. Economic burden from health losses due to foodborne illness in the United States. *Journal of food protection,* 75(1), pp.123–131, DOI: 10.4315/0362–028X.JFP–11–058.

[199] The Interagency Food Safety Analytics Collaboration, ''Foodborne illness source attribution estimates for 2019 for *Salmonella,* Escherichia coli O157, Listeria monocytogenes, and Campylobacter using multi-year outbreak surveillance data, United States,'' October 2021, *https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf.*

[200] Chicken was considered the source of contamination on the outbreak linked to stuffed chicken products.

[201] CDC, National Outbreak Reporting System (NORS), NORS Dashboard, accessed April 2023, *https://wwwn.cdc.gov/norsdashboard/;USDA,* FSIS, ''Outbreak Investigations: Response May 10, 2023 *https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks/outbreak-investigations-response.*

Figure 1. Outbreaks with chicken and turkey as contaminated single ingredient from 1998 to 2020



In 2023, FSIS developed a risk profile that details current knowledge on *Salmonella* to inform Agency efforts. The risk profile identified 28 *Salmonella* serotypes (out of around 2,500 serotypes) and four serogroups which were attributed to human salmonellosis from consuming chicken and turkey products. The FSIS risk profile indicated that for at least some subtypes of concern a small amount (*i.e.,* low dose of *Salmonella* bacteria), can cause illness. The FSIS risk profile noted that certain serotypes caused hospitalization more frequently and also led to invasive disease and death. Some subtypes have also been found to cause debilitating human health outcomes. Among these outcomes are cancer, inflammatory bowel disease, irritable bowel syndrome, and reactive arthritis. The overall hospitalization rate for all *Salmonella* is about 2 percent and the fatality rate is about 0.04 percent. However, the hospitalization rate for these serotypes is nearly 23 percent and the fatality rate is about 0.5 percent.[202]

Salmonella is the main pathogen resulting in foodborne illness-related deaths and hospitalizations, as well as loss of quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). The CDC estimates that *Salmonella* accounts for about 11 percent of total cases of domestically acquired foodborne illness.[203] However, it disproportionately accounts for about 44 percent of deaths associated with domestic bacterial foodborne illness from major pathogens and 28 percent of the hospitalizations. It has also been estimated to lead to the highest amount of QALYs lost among 14 domestic foodborne bacterial, viral, and parasitic pathogens. *Salmonella* is also estimated to contribute to 32,900 lost DALYs, or about 30 percent of lost DALYs from seven leading foodborne pathogens.[204]

Potential Costs and Benefits of the Proposed Rule and Proposed Determination

FSIS estimates that this proposal would result in a reduction in *Salmonella* illnesses among consumers. Furthermore, for producers, the reduction in the risk of illness, and hence outbreaks, would result in a lower risk of having to recall product. Producers would, as a result avoid the costs associated with that reduction. While producers would respond to this proposal in a way that makes economic sense to them, FSIS estimated the quantified cost associated with this proposal as explained in more detail below.

This proposal would also benefit industry as FSIS would clarify process control requirements for poultry slaughter establishments, which would likely contribute to a reduction in *Salmonella* contamination. Further, the Agency would incentivize innovation and the adoption of safer scientific methods in poultry production.

In the following sections, this analysis presents potential costs and benefits generated over a range of assumptions that could accrue as a result of FSIS' action, if this rule is finalized. To implement this proposal, FSIS would adopt an implementation schedule that would allow medium-, low-, and very low-volume establishments additional flexibility. Specifically, medium-volume establishments would have two years after the proposal is finalized to comply with the proposed requirements, while low- and very low-volume establishments would have three years. High-volume establishments would be required to comply with these proposed requirements one year after this rule is finalized. The Agency incorporated this implementation schedule into the annualization of costs and benefits estimates in this analysis, which are presented after the one-time and recurring cost estimates for each requirement. FSIS annualized costs and benefits using a 7 percent discount rate over a period of 10 years. FSIS applied the share of production for each establishment category to derive the lost value and prevented illness estimates that correspond with the implementation schedule. FSIS is seeking comment on these assumptions.

[202] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[203] CDC, ''Burden of Foodborne Illness: Findings,'' November 5, 2018, *https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.*

[204] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

Potential Costs of the Proposed Rule and Proposed Determination

Costs Associated With the Proposed Rule

Statistical Process Control Costs

FSIS currently requires poultry slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens and fecal contamination throughout the entire slaughter operation and incorporate these procedures into their HACCP systems (9 CFR 381.65(g)). At a minimum, these procedures must include sampling and analysis for microbial organisms at pre-and post-chill to monitor their ability to maintain process control, with some exceptions for VS and VLV establishments operating under Traditional Inspection. The proposal specifies that establishments must collect the pre-chill sample at rehang (post-picking and pre-evisceration) and clarifies that its microbial organism monitoring practices must result in data suitable for monitoring process control. While many establishments already meet the proposed specifications, some establishments may change where they collect the pre-chill sample or change the microbial organism they test for. However, establishments may continue their current sampling location and microbial organism monitoring practices, or adopt an alternative location and organism, if they submit and maintain supporting documentation. The Agency is also providing guidance for establishments to develop their MMPs. FSIS assumes that most establishments would meet the proposed MMP requirements without having to make any changes that would result in costs, while some establishments would have to make minor changes in response to this proposal at de minimis costs. The Agency is seeking comments on these assumptions.

FSIS regulations currently require that VLV establishments collect process control monitoring samples minimally once per week for a minimum of 13 consecutive weeks per year, beginning the first week of June.[205] FSIS is proposing to eliminate the requirement that VLV establishments begin sample collection the first week in June, which would allow establishments to begin collecting samples throughout the year. FSIS estimates there is no cost associated with this revised requirement, while establishments may benefit from this flexibility.

FSIS estimates that 90 VLV and 2 VS poultry slaughter establishments operating under Traditional Inspection would likely need to make changes in response to the proposed process control requirements.[206] FSIS is proposing to revise 9 CFR 381.65g(1) such that all poultry slaughter establishments would be required to collect samples at the rehang and post-chill locations. Very small and VLV establishments operating under Traditional Inspection are currently required to collect samples only at post-chill. FSIS currently requires that VLV establishments minimally collect 13 weekly samples per year to monitor process control. If this rule is finalized, these establishments would be required to collect and analyze 13 additional samples per year. The number of additional samples for VS establishments operating under Traditional Inspection that are not VLV establishments depends on their production volume. FSIS assumed that these VS establishments currently collect 52 samples per year and, consequently, would collect an additional 52 samples per year. FSIS is seeking comment on these assumptions.

FSIS would reduce the burden this proposed increase in sampling places on VLV and VS establishments operating under Traditional Inspection by making laboratory services available to these establishments. Use of the laboratories provided by FSIS would enable these establishments to comply with the proposed minimum requirements for MMPs. Should these establishments elect not to use the laboratory services provided by FSIS, the Agency estimated the combined cost for these establishments to meet the proposed increase in sampling would be $48,412 annually (Table 17). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for these establishments to meet the proposed increase in sampling would be $35,950. This analysis assumed samples collected at these establishments are analyzed for AC, at a cost of $38 per sample.

TABLE 17—STATISTICAL PROCESS CONTROL COSTS

Establishments type	Number of establishments (2021)	Testing cost ($)
Very low-volume under Traditional Inspection	90	44,460
Very small under Traditional Inspection	2	3,952
Total	92	48,412
Annualized [1]		35,950

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

Electronic Data Submission

FSIS would require poultry slaughter establishments subject to 9 CFR 381.65(g) and (h) to electronically submit data generated as part of their process control monitoring. FSIS estimates that high- and medium-volume establishments already compile process control data electronically due to the large volume of their operations and the frequency of their sample collection and analysis. To mitigate the impact on low- and VLV establishments, should this rule become final, the Agency would develop and publish a template these establishments could use to record and submit their monthly results.

In 2021, there were 298 establishments that would have been subject to this change, of which 175 were high-volume, 15 medium-, 14 low-, and 94 very low-volume.[207]

[205] 9 CFR 381.65(g)(2)(ii).

[206] Very low-volume establishments are those that slaughter less than 440,000 chickens or 60,000 of any other poultry class annually. Very small establishments are those with less than 10 employees or under $2.5 million in annual sales. 9 CFR 381.65g(1)(i) and 9 CFR 381.65g(1)(ii).

[207] The 94 VLV establishments include the 90 establishments operating under Traditional Inspection, as well as four establishments not under Traditional Inspection.

Establishments that elect to use laboratory services provided by FSIS for their process control samples would meet this requirement and not incur additional costs. This analysis assumed that none of the eligible establishments would choose to use laboratories provided by FSIS and the Agency estimated the costs associated with this requirement for all eligible establishments. Consequently, there is a tendency toward overstatement in the cost to regulated establishments associated with this proposal.

FSIS assumed it would take a quality control (QC) manager 30 minutes (0.5 hours) once a month to submit these data. FSIS estimates that the average wage for a QC manager is $113.24, which includes an average hourly wage of $56.62 multiplied by a benefits and overhead factor of two.[208] Under these assumptions, the combined cost to industry is $202,473 (0.5 hours × 12 months × 298 establishments × $113.24) per year (Table 18), including $118,902 for high-volume establishments, $10,192 for medium-volume, $9,512 for low-volume, and $63,867 for VLV. Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for electronic data submissions is $182,228.

TABLE 18—ELECTRONIC DATA SUBMISSION COSTS

Establishment volume category	Cost ($)			
	Chicken	Turkey	All other classes	Total
High	97,839	19,024	2,038	118,902
Medium	8,153	679	1,359	10,192
Low	7,474	679	1,359	9,512
Very Low	55,714	7,474	679	63,867
Total	169,181	27,857	5,436	202,473
Annualized [1]				182,228

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

HACCP Plan Reassessment Costs [209]

The Agency assumed that every poultry slaughter establishment would reassess their HACCP plans and incur associated costs. This likely overestimates costs because not every establishment would reassess their HACCP plans. For chicken slaughter establishments that produce chicken carcasses subject to these proposed final product standards and are also subject to the proposed process control requirements, FSIS assumed they would only reassess their slaughter HACCP plan once. However, for establishments that produce multiple products subject to these final product standards, FSIS assumed they would reassess their HACCP plans for each of the products they produce that are affected by the proposed changes. However, establishments that have to reassess HACCP plans for multiple products would likely experience some economies of scope. Furthermore, establishments could coordinate reassessing their HACCP plans in response to this proposal with currently required annual reassessments.

FSIS estimates that the total cost to industry from reassessing HACCP plans as a result of this proposal is $1.39 million, ranging from $0.70 to $2.09 million (Table 19). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for HACCP plan reassessment is $0.18 million, ranging from $0.09 million to $0.26 million. High- and medium-volume establishments need an average of 60 hours (ranging from 30 to 90), while low and VLV establishments need an average of 30 hours (ranging from 15 to 45) to reassess a HACCP plan, according to the 2015 ''Costs of Food Safety Investments'' report. This report estimated costs for large and small establishments. FSIS assumed the large category would correspond with high- and medium-volume establishments, while the small category would correspond with low- and very low-volume establishments. FSIS used data from the U.S. Bureau of Labor Statistics to update the hourly wage for estimating these labor costs. Specifically, FSIS used the 2021 hourly wage for a production worker of $30.78, which includes an average hourly wage of $15.39 multiplied by a benefits and overhead factor of two.

TABLE 19—HACCP PLAN REASSESSMENT COSTS

Establishment volume category	Number of establishments	Cost (million $)		
		Low	Mid	High
High	333	0.31	0.61	0.92
Medium	279	0.26	0.52	0.77
Low	193	0.09	0.18	0.27
Very Low	91	0.04	0.08	0.13
Total		0.70	1.39	2.09
Annualized [1]		0.09	0.18	0.26

[1] Costs are annualized at a 7 percent discount rate over 10 years.

[208] 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/2021/may/oes113051.htm.*

[209] Note: For simplicity, this section includes HACCP reassessment costs associated with the proposed rule and proposed determination, as some establishments subject to the proposed rule are also subject to the proposed determination.

Note: Number of establishments is not additive as some establishments produce multiple products. Numbers in table may not sum to totals due to rounding.

Validation of HACCP Plans

If an establishment makes changes to their HACCP plan, they would also have to validate it, incurring associated costs. However, the Agency assumed few establishments would make changes to their MMPs and only those that make changes would need to validate their HACCP plans. Additionally, the Agency assumed that many establishments have already implemented *Salmonella* controls in response to the 2016 FSIS performance standards and will not need to make changes to their HACCP plan. The 2015 ''Costs of Food Safety Interventions'' report indicates that high- and medium-volume establishments would need an average of 320 labor hours, while low- or very low-volume establishments would need an average of 400 hours to validate a HACCP plan. The estimated cost for HACCP plan validation is $25,894 for a high or medium-volume establishment, on average, and for a low- or very low-volume establishment it is $32,368. FSIS used the 2021 hourly wage for a food scientist of $80.92, which includes an average hourly wage of $40.46 multiplied by a benefits and overhead factor of two, for this estimate.[210] FSIS did not include a total industry HACCP validation cost because FSIS does not have data on the number of establishments that will make changes to their plans in response to this proposal. FSIS is requesting comments to address this data gap.

Costs Associated With the Proposed Determination

Maintaining Control of Sampled Product Costs

FSIS is proposing that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with *Salmonella* levels at or above 10 cfu/mL(g) and one of the *Salmonella* serotypes of public health significance intended for consumption as final products would be adulterated. As proposed, FSIS inspected establishments would be required to maintain control of product sampled as part of FSIS verification sampling for adulterants. Any chicken carcass, parts, comminuted chicken, or comminuted turkey final products testing positive for *Salmonella* levels at 10 cfu/mL(g) or higher would not be allowed to enter commerce until the *Salmonella* serotype result is reported and no serotypes of public health significance are detected.

If this proposal is finalized, establishments would be required to prevent product sampled as part of FSIS verification sampling from entering commerce until a negative test result or one above the 10 cfu/mL(g) level but not containing a serotype of public health significance is received. FSIS does not require establishments to hold product at their physical location; thus, product can be stored off-site at an establishment's storage facility, or another private or public storage facility, pending test results. Product subject to FSIS verification sampling can also be diverted and processed into a product that is not subject to these final product standards (*i.e.,* fully cooked products) instead of being sent to cold storage.

FSIS anticipates that the Agency would provide establishments with final adulteration results five days after the sample is collected.[211] Results on a product's level of *Salmonella* would require industry to hold sampled lots for two days and results on the presence of a serotype of public health significance would take an additional three days. The Agency assumed that establishments would maintain control of product until final adulteration results are available. Establishments would be able to move product with test results at levels below 10 cfu/mL(g) into commerce, which would necessitate product to be under establishment's control for up to two days. The Agency assumed that establishments would decide to divert adulterated product after results on its adulteration status are available. This cost is described in the *Lost value to the industry costs* section.

To estimate the industry cost for holding product pending test results, FSIS used 2021 data from PHIS. FSIS assumed that establishments subject to these final product standards would maintain control of each sampled lot pending FSIS verification sampling results. Regulated establishments define their production lots according to their specific conditions and FSIS allows establishments to adjust their lot sizes if they provide scientific justification for defining lots.[212] Thus, FSIS used Agency data to approximate the amount of product subject to verification sampling. For chicken carcasses, the estimated lot size is 46,000 birds for high- and medium-volume establishments and 1,800 birds for low- and very low-volume establishments.[213] For establishments producing chicken parts, comminuted chicken, and comminuted turkey, the estimated lot sizes are (1) one hour, (2) one shift, and (3) one day of production. These estimated lot sizes, respectively, represent the low, medium, and high scenarios used for estimating the cost of maintaining control of product pending test results for chicken parts, comminuted chicken, and comminuted turkey in this analysis. FSIS is seeking comment on these assumptions.

Since FSIS is proposing to sample these products at the same rate as the current performance standards, the Agency used the number of samples collected in 2021 at establishments that would be subject to this proposal and the estimated lot sizes to approximate the volume of product that would be subject to the Agency's verification sampling program.[214]

FSIS used the per pound cost of cold storage as estimated in the 2015 ''Costs of Food Safety Investments'' report to monetize the cost to industry from holding product due to this proposal.[215]

[210] BLS, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19–1012 Food Scientists and Technologists, accessed April 13, 2023, *https://www.bls.gov/oes/2021/may/oes191012.htm.*

[211] While the Agency currently uses whole genome sequencing to determine the presence of *Salmonella* serotypes on product sampled by FSIS, the Agency would adopt an alternative approach that would lead to results on the presence of *Salmonella* serotypes in one to three days after screening.

[212] 77 FR 73401.

[213] Establishments that slaughter less than 1 million birds per year had flock sizes ranging from 100 to 3,500 birds. FSIS used the average, or 1,800 birds, to approximate the total sampled production at these establishments.

[214] FSIS collects up to five continuous samples per month at establishments producing young chicken and turkey carcasses, and raw chicken parts, comminuted chicken and turkey products. USDA, FSIS, ''*Salmonella* Verification Testing Program Monthly Posting,'' April 20, 2023, *https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/Salmonella-verification-testing-program-monthly.*

[215] 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 assumed product would be refrigerated. 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.*

FSIS updated this estimate to 2021 dollars by applying the growth in the ''Moving, storage, freight expense'' consumer price index.[216] The resulting cost of cold storage estimate, on a per pound, per day basis is $0.0023 in 2021 dollars. Establishments may already store product in their facilities or in an off-site location for a certain amount of time. However, the Agency assumed that all costs of storing product for the sampled lots are due to this proposal. FSIS is seeking comments on cold storage costs and availability at inspected establishments or off-site facilities.

Chicken Carcasses

FSIS estimated that in 2021 establishments subject to the performance standards produced 33.2 billion pounds of chicken carcasses. [217] The Agency estimated that about 11 percent of chicken carcasses are consumed as whole birds and, thus, final products subject to the proposal.[218] To account for uncertainty in this estimate, the Agency used 6, 11, and 16 percent as the low, medium, and high estimates of the volume of chicken carcasses subject to the proposal. FSIS estimated that in 2021 a total of 162.9 million pounds, ranging from 88.9 to 237.0 million, would have been sampled as part of these final product standards (Table 20).[219] There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 20—CHICKEN CARCASSES: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY

[2021]

Establishment volume category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	142	86.8	159.1	231.4
Medium	9	1.8	3.4	4.9
Low	4	0.04	0.1	0.1
Very Low	33	0.2	0.4	0.6
Total	188	88.9	162.9	237.0

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of sampled product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumes establishments would move into commerce product with test results below 10 cfu/mL(g) and would hold product at or above that level for an additional three days. FSIS estimated that 654,123 pounds of chicken carcasses would have test results at or above 10 cfu/mL, which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the total cost to industry of holding all sampled chicken carcasses pending test results at $0.75 million annually [(162.9 million × $0.0023 × 2) + (654,123 × $0.0023 × 3)], ranging from $0.41 to $1.09 million (Table 21). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding chicken carcasses pending test results is $0.75 million, ranging from $0.41 million to $1.09 million.

TABLE 21—CHICKEN CARCASSES: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Estimated cost (million $)		
	Low	Medium	High
High	0.40	0.73	1.07
Medium	0.01	0.02	0.02
Low	0.0002	0.0003	0.0005
Very low	0.0011	0.0020	0.0029
Total	0.41	0.75	1.09
Annualized [1]	0.41	0.75	1.09

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

[216] Bureau of Labor Statistics (BLS), Consumer Price Index (CPI), ''Moving, storage, freight expense in U.S. city average, all urban consumers, not seasonally adjusted,'' (Series ID CUUR0000SEHP03), accessed February 14, 2023. This CPI grew 37.5 percent from 2015 to 2021.

[217] (8.3 billion birds × 4 pounds). Dressed weights for chickens vary. For broilers, which is the main class of poultry slaughtered at FSIS inspected establishments, the 2023 chicken Risk Assessment used an average carcass weight was 4 pounds.

[218] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

Estimates from the National Chicken Council indicate that about 9 percent of broilers, the main chicken subclass produced in the United States, were marketed as whole birds in 2021. National Chicken Council (NCC), ''How Broilers are Marketed,'' accessed May 11, 2023, *https://www.nationalchickencouncil.org/statistic/how-broilers-are-marketed/.*

[219] This is the sum of the estimated sampled volume for all establishment categories. For each category, this volume is calculated as: number of establishments × average number of samples × lot size converted to pounds × estimated share of production intended as final product. For example, the medium estimate for high-volume establishments is 142 × 55 × (46,000 × 4) × 0.10. Calculations might not sum to totals due to rounding.

Chicken Parts

FSIS estimated that in 2021 establishments subject to the performance standards processed 31.2 billion pounds of chicken parts.[220] Raw chicken parts processed at FSIS regulated establishments can be sent into commerce as final products or further processed into a variety of preparations, including cooked products (*e.g.,* fully cooked chicken breasts). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of chicken parts would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimated that 2.6 billion pounds of chicken parts, ranging from 308 million to 5.5 billion, would have been sampled as part of these final product standards (Table 22).[221] There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 22—CHICKEN PARTS: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY

[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	154	286	2,433	5,153
Medium	209	21	181	325
Low	127	0	3	5
Total	490	308	2,617	5,483

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of sampled product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days product with results at or above that level. FSIS estimated that about 246,949 pounds of chicken parts would have test results at or above 10 cfu/mL(g), which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled chicken parts pending test results at $12.0 million annually [(2.6 billion × $0.0023 × 2) + (246,949 × $0.0023 × 3)], ranging from $1.4 to $25.1 million (Table 22). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding chicken parts pending test results is $11.88 million, ranging from $1.4 million to $24.9 million.

TABLE 23—CHICKEN PARTS: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million $)		
	Low	Medium	High
High	1.31	11.15	23.62
Medium	0.10	0.83	1.49
Low	0.00	0.02	0.02
Total	1.41	12.00	25.13
Annualized [1]	1.40	11.88	24.93

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

Comminuted Chicken

FSIS estimated that in 2021 establishments subject to the performance standards processed 2.3 billion pounds of comminuted chicken. Raw comminuted chicken processed at FSIS regulated establishments can be sent into commerce as final products or further processed into a variety of preparations, including cooked products (*e.g.,* fully cooked chicken nuggets). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of comminuted chicken would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimated that 264.19 million pounds, ranging from 26.1 to 427.65 million pounds of comminuted chicken, would have been sampled as part of these final product standards (Table 24).[222] There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

[220] The 2023 chicken risk assessment estimated that, of the total chicken slaughtered volume, about 83 percent is consumed as chicken parts. In 2021, total chicken slaughter volume was an estimated 37 billion pounds, 31.2 billion of which are estimated to be processed into chicken parts.

[221] FSIS calculated these estimates using average daily production volume and total number of samples in 2021 for each of the establishments producing chicken parts assuming lot sizes of one hour, one shift, and one day of production. FSIS multiplied this result by the share production intended as final product to obtain the low, medium, and high estimates.

[222] FSIS calculated these estimates using average daily production volume and total production days in 2021 for each of the establishments producing comminuted chicken and multiplying by the share production intended as final product.

TABLE 24—COMMINUTED CHICKEN: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY
[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	0	0	0	0
Medium	35	25.12	254.59	415.22
Low	39	1.02	9.59	12.43
Total	74	26.14	264.19	427.65

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of this product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days products with results at or above that level. FSIS estimated that about 5.0 million pounds of comminuted chicken would have test results at or above 10 cfu/mL(g), which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled comminuted chicken pending test results at $1.3 million annually (264.2 million × $0.0023 × 2) + (5.0 million × $0.0023 × 3)], ranging from $0.2 to $2.0 million (Table 25). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding comminuted chicken products pending test results is $1.1 million, ranging from $0.1 million to $1.7 million.

TABLE 25—COMMINUTED CHICKEN: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million $)		
	Low	Medium	High
High	0	0	0
Medium	0.15	1.20	1.94
Low	0.006	0.04	0.06
Total	0.15	1.25	1.99
Annualized [1]	0.13	1.07	1.72

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

Comminuted Turkey

FSIS estimated that in 2021 establishments subject to the performance standards processed 1.7 billion pounds of comminuted turkey. Raw comminuted turkey processed at FSIS regulated establishments can be sent into commerce as final products or further processed into preparations including cooked products (*e.g.,* fully cooked sausages). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of comminuted turkey would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimates that 156.7 million pounds, ranging from 18.4 to 330.4 million, would have been sampled as part of these final product standards (Table 26).[223] There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 26—COMMINUTED TURKEY: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY
[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	5	11.49	97.71	206.91
Medium	25	6.90	58.63	122.86
Low	18	0.04	0.36	0.65
Total	48	18.43	156.69	330.42

Note: Numbers in table may not sum to totals due to rounding.

[223] FSIS calculated these estimates using average daily production volume and total production days in 2021 for each of the establishments producing comminuted turkey and multiplying by the share production intended as final product.

This analysis assumed establishments would maintain control of this product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days product with results at or above that level. FSIS estimated that about 2.3 million pounds of comminuted turkey would have test results at or above 10 cfu/mL, which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled comminuted turkey pending test results at $0.7 million annually [(156.7 million × $0.0023 × 2) + (2.3 million × $0.0023 × 3)], ranging from $0.1 to $1.5 million (Table 27). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding comminuted turkey products pending test results is $0.70 million, ranging from $0.09 million to $1.45 million.

TABLE 27—COMMINUTED TURKEY: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million $)		
	Low	Medium	High
High	0.06	0.45	0.96
Medium	0.04	0.28	0.57
Low	0.0003	0.0017	0.0031
Total	0.10	0.73	1.53
Annualized [1]	0.09	0.70	1.45

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

Import Establishments Costs

FSIS conducts sampling activities at official import inspection establishments to verify that a foreign country's poultry inspection system is equivalent to the U.S. poultry inspection system. If this rule is finalized, FSIS would adapt its current *Salmonella* sampling program for imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. Import establishments would be required to maintain control of sampled product pending test results to verify that these products are not adulterated. Similar to domestic producers, FSIS assumed that official import inspection establishments would maintain control of sampled imported product lots for two days until results on the level of *Salmonella* are available. Sampled product with results below 10 CFU/mL(g) could be moved into commerce. If test results show *Salmonella* at or above 10 CFU/mL(g), FSIS assumed establishments would maintain control of these product lots for an additional one to three days, until the presence or absence of a serotype of public health significance is confirmed. Adulterated product would be diverted from U.S. commerce.

FSIS estimates the cost to import establishments for maintaining control of imported product subject to FSIS verification sampling for *Salmonella,* as described in this proposal, would be minimal. Poultry imports represent a small fraction of the U.S. domestic poultry supply, accounting for less than 0.5 percent in 2021.[224] In that year, only three countries exported raw chicken and turkey products to the United States: Canada, Chile, and Mexico.[225] Canada was the sole exporter of whole chicken carcasses, accounting for about 14 million pounds of chicken. Chile, in turn, was the main exporter of chicken parts (132 million pounds).[226]

Currently, FSIS samples and tests imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey for the presence of *Salmonella.* According to data from PHIS, in 2021, FSIS collected and analyzed about 850 samples of imported chicken and turkey products, which represented about 15.8 million pounds of product. These samples were mainly from chicken parts and carcasses, as imports of comminuted chicken and turkey are relatively low.

FSIS estimated the cost for these import establishments assuming that establishments would maintain control pending test results of all sampled product identified in 2021 data, which is likely an overestimate. The estimated cost for import establishments is $0.07 million per year (15.8 million pounds × 2 days × $0.0023). While data on the volume imported of product with results at or above 10 cfu/mL(g) are not available, FSIS estimates this would be a relatively low volume of product. In 2021, about 17 percent of imported poultry samples were positive for the presence of *Salmonella,* representing about 2.6 million pounds of product. This is likely a high estimate as countries would be required to implement measures to maintain equivalence with the U.S. poultry inspection system if this rule is finalized.

[224] USDA, Foreign Agricultural Service, ''Production, Supply and Distribution database,'' accessed May 11, 2023. Although U.S. import data does not directly correspond with the final product categories in this proposal, FSIS used available trade data to identify Harmonized Tariff Schedule (HTS) codes that would approximate imports of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS estimates that imports of chicken carcasses to the United States reached 13.7 million pounds in 2021 (HTS 0207.11 and 0207.12, Whole young chickens and Whole frozen chickens, respectively), while imports of chicken parts and comminuted chicken were 164 million pounds (HTS 0207.13 and 0207.14, Meat and edible offal of chickens, fresh or chilled and frozen, respectively). FSIS assumed that imports under HTS 0207.26 and 0207.27 (Meat and edible offal of turkeys, fresh or chilled and frozen, respectively) approximate imports of comminuted turkey, although this is likely an overestimate as this HTS code also includes turkey parts. Imports under HTS 0207.26 and 0207.27, combined, reached 74.3 million pounds in 2022. Imports under these HTS codes represent 0.5 percent of U.S. production of chicken carcasses, 0.04 percent of U.S. production of chicken parts and comminuted chicken, and 4 percent of imports of comminuted turkey. U.S. International Trade Commission DataWeb/U.S. Department of Commerce, accessed June 28, 2023.

[225] Three countries are eligible to export raw chicken and turkey products to the United States—Canada, Chile, and Poland,—while Mexico is eligible to export only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry to the United States. USDA, FSIS, ''Eligible Foreign Establishments,'' July 14, 2023, *https://www.fsis.usda.gov/inspection/import-export/import-export-library/eligible-foreign-establishments.*

[226] U.S. International Trade Commission DataWeb/U.S. Department of Commerce accessed June 28, 2023.

Total Costs to Industry From Maintaining Control of Sampled Product

FSIS estimated that the total cost to industry from complying with FSIS verification sampling requirements in this proposal is $14.47 million annually, ranging from $2.11 to $29.26 million (Table 28), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. As previously described, establishments are required to maintain control pending test results for product subject to FSIS verification sampling for adulterants. FSIS estimated that an average of 3.2 billion pounds of product per year would be subject to FSIS verification sampling. FSIS allows establishments to move product to an alternate location pending test results for an adulterant as long as they maintain control of the sampled product. Producers can also elect to divert sampled product into a product that is not subject to these standards (*i.e.,* fully cooked products), rather than maintaining control of it pending test results. Moreover, FSIS allows establishments to produce smaller representative product lots for FSIS verification sampling if they demonstrate that the lot presented is microbiologically independent from other production lots.[227] Thus, the cost for holding product pending test results is likely an overestimate. FSIS is seeking comments on these assumptions.

TABLE 28—SUMMARY OF COSTS TO INDUSTRY FROM MAINTAINING CONTROL OF SAMPLED PRODUCT

Product	Number of establishments [1]	Cost (million $) [2]		
		Low	Medium	High
Chicken carcasses	188	0.41	0.75	1.09
Chicken parts	490	1.40	11.88	24.93
Comminuted chicken	74	0.13	1.07	1.72
Subtotal for chicken products	752	1.94	13.71	27.74
Comminuted turkey	48	0.09	0.69	1.45
Import establishments	12	0.07	0.07	0.07
Total		2.11	14.47	29.26

[1] Establishments may produce more than one of the products subject to these final product standards.
[2] Costs are annualized at a 7 percent discount rate over 10 years.
Note: Numbers in table may not sum to totals due to rounding.

Lost Value to the Industry Costs

FSIS estimated the cost to industry from lost value resulting from diverting adulterated product subject to these final product standards. FSIS assumed that establishments would divert product after receiving final results showing a level of *Salmonella* at or above 10 cfu/mL(g) and the presence of a serotype of public health significance. As previously mentioned, FSIS laboratories would provide results on the level of *Salmonella* to establishments within two days from sample collection and results on the presence of a serotype of public health significance three days after initial results.

The 2023 risk assessments estimated that approximately 0.2 million pounds of chicken carcasses, 0.07 million pounds of chicken parts, 1.6 million pounds of comminuted chicken, and 0.6 million pounds of comminuted turkey per year would have *Salmonella* levels at or above 10 cfu/mL(g) and would contain a serotype of public health significance (Table 29). This represents less than 0.1 percent of estimated production for each of the product categories.

TABLE 29—TOTAL PRODUCTION, VOLUME OVER 10 cfu/mL(g) AND CONTAINING A SEROTYPE OF PUBLIC HEALTH SIGNIFICANCE, AND SHARE OF PRODUCTION BY PRODUCT

Product	Total production (million pounds)	Volume over 10 cfu/mL(g) and containing a serotype of public health significance (million pounds)	Share of production (%)
Chicken carcasses	33,238	0.2	0.000005
Chicken parts	31,208	0.07	0.000002
Comminuted chicken	2,256	1.6	0.000691
Comminuted turkey	1,691	0.6	0.000336

Note: Numbers in table may not sum to totals due to rounding.

To estimate the cost to industry of this lost value as a result of this proposal, FSIS applied the per pound retail price of select poultry products to the estimated volume of lost product. FSIS used data from 2017 to 2021 and used a range in these prices to account for variability and uncertainty: the lowest retail price in the five-year period as the minimum, the highest as the maximum, and the five-year average as the medium estimate. For chicken carcasses, FSIS used the retail price for whole fresh chicken while for chicken parts the Agency used the retail price for chicken breasts (Table 30). Because data for the five-year period for comminuted or ground chicken were not readily available, FSIS used the retail price for chicken legs as a proxy. For comminuted turkey, FSIS used data for whole frozen turkeys as data for the five-year period for comminuted or ground turkey were not available.

[227] 77 FR 73402.

TABLE 30—RETAIL PRICES FOR SELECT COMMODITIES

Product	Price source	Price per pound ($)		
		Low	Medium	High
Chicken carcasses	Whole fresh chicken [a]	1.36	1.51	1.75
Chicken parts	Chicken breasts [b]	2.90	3.19	3.72
Comminuted chicken	Chicken legs [c]	1.32	1.50	1.73
Comminuted turkey	Whole frozen turkey [d]	0.80	0.99	1.23

[a] U.S. Bureau of Labor Statistics (BLS), Chicken, fresh, whole, per lb. (453.6 gm) in U.S. city average, average price, not seasonally adjusted [APU0000706111], , accessed July 6, 2023, *https://data.bls.gov/timeseries/APU0000706111?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.*

[b] BLS, Chicken breast, boneless, per lb. (453.6 gm) [APU0000FF1101], accessed July 6, 2023; *https://data.bls.gov/timeseries/APU0000FF1101?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.*

[c] BLS, Chicken legs, bone-in, per lb. (453.6 gm) in U.S. city average, average price, not seasonally adjusted [APU0000706212], accessed July 6, 2023, *https://data.bls.gov/timeseries/APU0000706212?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.*

[d] USDA, Economic Research Service, Turkey Sector: Background & Statistics: Price Statistics, April 18, 2023, *https://www.ers.usda.gov/newsroom/trending-topics/turkey-sector-background-statistics.*

Previous FSIS analyses assumed that diverted product would lose 66 percent of its value.[228] As product under these final product standards are raw materials that can be diverted to a variety of fully cooked preparations, the Agency used a range to estimate the cost of lost value to the industry. Specifically, FSIS used 34, 50, and 66 percent as the low, medium, and high estimates. FSIS estimated that the cost to industry from diverting product is $1.7 million annually, with a range of $1.0 to $2.6 million (Table 31). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for lost value of products subject to this proposal is $1.5 million, ranging from $0.9 million to $2.4 million.

TABLE 31—LOST VALUE TO THE INDUSTRY COSTS, MILLION $

Product	Low	Medium	High
Chicken carcasses	0.1	0.1	0.2
Chicken parts	0.1	0.1	0.2
Comminuted chicken	0.7	1.2	1.8
Comminuted turkey	0.2	0.3	0.5
Total	1.0	1.7	2.6
Annualized [1]	0.9	1.5	2.4

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

Microbiological Sampling Plan Reassessment Costs

Establishments subject to these proposed final product standards may incur costs associated with reassessing their sampling plans. Current performance standards focus on the presence or absence of *Salmonella* in certain poultry products. However, the proposed standards would make product adulterated if it contains *Salmonella* at or above 10 cfu/mL(g) and has at least one of the serotypes of public health significance. To estimate a cost associated with this requirement, FSIS assumed a portion of establishments would reassess their microbiological sampling plans. Consistent with the estimates in the previous cost-benefit analysis for the 2016 performance standards, FSIS estimated the cost of reassessing a sampling plan for 30, 40, and 50 percent of the establishments subject to this proposal.[229] FSIS included all volume categories in these estimates. However, as previously noted in the cost-benefit analysis for the 2016 performance standards, FSIS does not expect low and VLV establishments to have an internal sampling plan.[230] FSIS assumed that these establishments would opt to not incur the expense of developing a sampling plan as sampling does not directly contribute to pathogen reduction. The Agency is seeking comments on this assumption.

FSIS estimated that the total cost to industry from reassessing their sampling plans is $0.3 million, ranging from $0.1 to $0.6 million (Table 32). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for microbiological sampling plan reassessment is $0.04 million, ranging from $0.02 million to $0.08 million. High- and medium-volume establishments need an average of 40 hours (ranging from 20 to 60), while low- and very low-volume establishments need an average of 20 hours (ranging from 10 to 30) to reassess a sampling plan, according to the 2017 *Costs of Food Safety Investments in the Meat and Poultry Slaughter*

[228] USDA, FSIS, ''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,'' June 2020, *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-0157-STEC-Testing-CBA-June-2020.pdf;* USDA, FSIS, ''*Salmonella* in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products,'' Preliminary Cost-Benefit Analysis, April 2023, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Stuffed_Chicken_CBA_FSIS-2022-0013.pdf.*

[229] USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.*

[230] USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.*

Industries.[231] This publication estimated costs for large and small establishments. FSIS assumed the large category would correspond with high- and medium-volume establishments, while the small category would correspond with low- and very low-volume establishments. FSIS used data from the U.S. Bureau of Labor Statistics to update the hourly wage for estimating these labor costs. Specifically, FSIS used the 2021 hourly wage for a production worker of $30.78, which includes an average hourly wage of $15.39 multiplied by a benefits and overhead factor of two.

TABLE 32—MICROBIOLOGICAL SAMPLING PLAN REASSESSMENT COSTS

Establishment volume category	Number of establishments	Cost (thousand $)		
		Low	Medium	High
High	302	0.06	0.15	0.28
Medium	276	0.05	0.14	0.25
Low	190	0.02	0.05	0.08
Very Low	91	0.003	0.007	0.014
Total		0.13	0.34	0.63
Annualized [1]		0.02	0.04	0.08

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

Validation of Microbiological Sampling Plans

If an establishment makes changes to their microbiological sampling plans in response to this proposal, they would incur costs associated with validating these changes. The 2015 ''Costs of Food Safety Interventions'' report indicates that high- and medium-volume establishments would need an average of 960 labor hours for validation of a microbiological sampling plan and 1,200 labor hours for low- and very low-volume establishments. On a per plan basis, the cost for validation of a microbiological sampling plan for a high- or medium-volume establishment is $77,683, on average, while for low- or very low-volume establishments, the average cost is $97,104. FSIS used the 2021 hourly wage for a food scientist of $80.92, which includes an average hourly wage of $40.46 multiplied by a benefits and overhead factor of 2.[232] FSIS did not include an estimate of total industry validation costs for microbiological sampling plans because FSIS does not have data on the number of establishments that would make changes to their plans in response to this proposal. FSIS is requesting comments to address this data gap.

Corrective Actions

FSIS would require establishments that do not meet the final product standards to take corrective actions. These corrective actions would be aimed at removing adulterated product from market and making changes to prevent production of adulterated product in the future. Interventions available to the poultry industry include antimicrobial agents, new equipment, and employee practices. FSIS does not have information on the types or frequency of corrective actions establishments may take in response to not meeting the final products standards, and the Agency is seeking comments on the potential costs associated with these.

Summary of Costs to Industry From This Proposed Rule and Proposed Determination

FSIS estimated the main cost to industry to comply with this proposal is $16.4 million annually, with a range of $3.3 to $32.3 million (Table 33), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The principal component of this cost is the requirement that establishments must maintain control of product subject to FSIS verification sampling for adulterants pending test results. The cost estimate associated with this requirement is likely an overestimate as it is possible that establishments' current practices and procedures would allow them to maintain control of a lower volume of product. Additionally, all timeframes and methods for *Salmonella* testing are likely to change as FSIS continuously incorporates new laboratory technologies into its sampling verification program. FSIS is seeking comment on these estimates. FSIS estimated that the total costs to establishments from reassessing HACCP and microbiological sampling plans, combined, is $0.22 million ($0.18 + $0.04 million). The estimated cost associated with the proposed statistical process control requirements is $0.04 million, which is likely an overestimate as certain establishments would be able to mitigate the cost by using laboratory services provided by FSIS, as previously described. To varying degrees, industry may also incur other costs associated with their individual responses to this proposal. The Agency estimated that this total cost represents less than 1 percent of the total industry's revenue in 2021. In 2021, the estimated total sales value for broilers and turkeys, on a live basis, was $37.4 billion, with a five-year average between 2017 and 2021 of $33.5 billion.[233] This value increased to $57.5 billion in 2022. For the poultry processing industry, the

[231] Viator CL, Muth MK, Brophy JE, Noyes G. Costs of Food Safety Investments in the Meat and Poultry Slaughter Industries. J Food Sci. 2017 Feb;82(2):260–269. doi: 10.1111/1750–3841.13597. Epub 2017 Jan 24. PMID: 28117890. FSIS derived the labor hours from the total costs presented on table 5 and the wage rate for production occupations on table 2. BLS, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19–1012 Food Scientists and Technologists, accessed April 13, 2023, *https://www.bls.gov/oes/current/oes191012.htm.*

[232] Viator CL, Muth MK, Brophy JE, Noyes G. Costs of Food Safety Investments in the Meat and Poultry Slaughter Industries. J Food Sci. 2017 Feb;82(2):260–269. doi: 10.1111/1750–3841.13597. Epub 2017 Jan 24. PMID: 28117890. FSIS derived the labor hours from the total costs presented on table 5 and the wage rate for production occupations on table 2. BLS, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19–1012 Food Scientists and Technologists, accessed April 13, 2023, *https://www.bls.gov/oes/current/oes191012.htm.*

[233] USDA, ERS, ''Poultry Sector at a Glance'' June 1, 2023, *https://www.ers.usda.gov/topics/animal-products/poultry-eggs/sector-at-a-glance/;* USDA, National Agricultural Statistics Service, ''Poultry—Production and Value: 2022 Summary,'' April 2023, *https://downloads.usda.library.cornell.edu/usda-esmis/files/m039k491c/wm119387d/5138kw352/plva0423.pdf.*

total 2021 revenue was $77 billion, according to U.S. Census data.[234]

TABLE 33—SUMMARY OF INDUSTRY COSTS

Cost descriptions	Cost (million $)		
	Low	Medium	High
Costs associated with the proposed rule:			
Statistical process control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total [1]	3.31	16.43	32.25

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

FSIS estimates industry would incur annual costs in response to this rule. Table 34 includes the expected undiscounted annual costs of this proposal assuming the implementation schedule over a 10-year period.

TABLE 34—SUMMARY OF ANNUAL COSTS OVER 10 YEARS

Year	Low	Medium	High
1	2,342,792	13,490,291	27,612,367
2	3,330,215	16,984,639	33,483,179
3	3,250,382	16,788,952	33,160,044
4	3,099,498	16,471,425	32,667,872
5	3,099,498	16,469,009	32,667,872
6	3,099,498	16,466,751	32,667,872
7	3,099,498	16,464,641	32,667,872
8	3,099,498	16,462,668	32,667,872
9	3,099,498	16,460,825	32,667,872
10	3,099,498	16,459,102	32,667,872

Costs to FSIS

FSIS does not anticipate the proposal, including using laboratory services provided by FSIS for analyzing process control samples for VS and VLV establishments under Traditional Inspection, as well as conducting verification sampling for the final product standards, will increase Agency costs. The Agency would adapt its current sampling for *Salmonella* on poultry products to conduct verification sampling for the new final product standards and would be able to shift existing resources as necessary to implement this proposal if finalized. FSIS currently enumerates samples collected as part of FSIS verification sampling for *Salmonella.* Consequently, if this proposal is finalized, the only additional cost to FSIS would be to incorporate serotype testing on *Salmonella* positive samples. The Agency estimates analyzing these tests would require 520 labor hours, or $0.03 million, per year to analyze results, with additional hours, including data management, procurement, result review and authorization, as needed.[235]

Costs related to follow-up sampling and conducting FSAs are not expected to increase. The Agency would conduct follow up sampling and a PHRE for any establishments that does not meet the final product standards. FSIS would use the results of the PHRE to determine the need for an FSA. FSIS currently conducts follow up sampling and PHREs on establishments that do not meet the current *Salmonella* performance standards. For instance, in 2022, FSIS conducted 30 FSAs at category three establishments. 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.[236]

Potential Benefits and Avoided Costs From the Proposed Rule and Proposed Determination

Prevented Salmonella Illnesses

FSIS is proposing to declare *Salmonella* at or above 10 cfu/mL(g) and containing a serotype of public health significance an adulterant on chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that would enter commerce. The 2023 risk assessments provide a range of data on the public health impacts achieved by reducing

[234] Sales, value of shipments, or revenue for the Poultry processing industry, as defined in the North American Industry Classification System code 311615. U.S. Census Bureau, Annual Survey of Manufacturers: Summary Statistics for Industry Groups and Industries in the U.S.: 2018–2021 (NAICS 311615), accessed on April 11, 2023.

[235] FSIS used the 2024 base salary of a GS–12 step 1 full time employee of $35.67 per hour and included the Civilian Position Full Fringe Benefit Cost Factor of 36.25 percent. Executive Office of The President, Office of Management and Budget, Circular No. A–76 (Revised), May 29, 2003, *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A76/a76_incl_tech_correction.pdf.*

[236] 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).

final product contaminated with *Salmonella,* as well as the higher risk per serving associated with product that would be declared adulterated by the proposal. FSIS used this range of data to estimate the potential public health benefits of this proposal. FSIS also used findings from the FSIS risk profile to create these estimates, including information regarding the higher virulence of certain *Salmonella* serotypes, as well as the potential debilitating human health outcomes from *Salmonella* infection (*e.g.,* reactive arthritis), which are not included in the cost of illness estimates.

The 2023 risk assessments estimated the number of illnesses that could be prevented if product lots with results at or above 10 cfu/mL(g) of *Salmonella* are diverted from commerce as part of FSIS verification sampling programs. For chicken carcasses, the 2023 chicken risk assessment estimated that 1,000 illnesses could be prevented, while for chicken parts and comminuted chicken it estimated 200 and 1,000 illnesses, respectively. The 2023 chicken risk assessment assessed the effect of a carcass final product standard on all chicken associated illnesses, including those from parts and comminuted product consumption, but could not assess the effect of carcasses and secondary products standards sequentially. As such, the 2023 chicken risk assessment estimates for chicken products are not additive.[237] For comminuted turkey, the 2023 turkey risk assessment estimated that 2,100 illnesses could be prevented.[238] This analysis presents three illustrative scenarios based on these results.

FSIS estimated that if this proposal becomes final, the number of illnesses prevented may range from 765 to 4,300 cases per year (Table 34).[239] These estimates are based on the best data currently available.

For the low estimate, the Agency used sampling data and results from the 2023 risk assessments to estimate the number of prevented illnesses from the final products standards. FSIS sampling data show that the serotypes of public health significance identified in this proposal are present in 24 percent of the chicken carcass samples and 25 percent of the comminuted turkey samples.[240] The Agency applied the share of samples with at least one serotype of public health significance to the estimated number of prevented illnesses from diverting chicken carcasses and comminuted turkey with results at or above 10 cfu/mL(g). Thus, for the low estimate in this analysis, the Agency estimated that the final product standards would prevent a total of 765 *Salmonella* illnesses, 240 from chicken carcasses and 525 from comminuted turkey. Research indicates that chicken carcass samples often contain multiple *Salmonella* serotypes.[241] For example, it is likely that a sample from a chicken carcass could test positive for *Salmonella* Kentucky and also contain *Salmonella* Enteritidis, which is a serotype of public health significance, but *Salmonella* Enteritidis was not captured by FSIS testing on that sample. At present there is no rapid way to screen for multiple *Salmonella* serotypes at one time. Moreover, the 2023 chicken risk assessment estimated that diverting from commerce chicken carcasses containing serotypes in the higher virulence cluster would result in 1,800 prevented illnesses, which is higher than the estimated number of illnesses prevented from diverting carcasses with *Salmonella* at or above 10 cfu/mL (1,000 illnesses).[242] Additionally, FSIS data show that serotypes of public health significance have been detected at higher rates in chicken parts and comminuted chicken products.[243] Further, the serotypes of public health significance have been identified in over 50 percent of the outbreaks associated with chicken products between 2012 and 2021. FSIS is seeking comments on these assumptions and estimates. While the estimates in the 2023 risk assessments refer to *Salmonella* levels and serotypes separately, the data indicate that the number of illnesses prevented by the final product standards in this proposal is higher than the low estimate included in this analysis.

For the medium estimate, FSIS used the 2023 risk assessments results of illnesses prevented from diverting chicken carcasses (1,000 illnesses) and comminuted turkey (2,100 illnesses) with *Salmonella* levels at or above 10 cfu/mL(g). This estimate accounts for some of the uncertainty around potential health benefits from this proposal. The Agency used this because as discussed above, products with *Salmonella* at or above 10 cfu/mL(g) have a higher risk per serving than other products and would be more likely to cause illness. Specifically, the 2023 chicken risk assessment noted that the probability of illness for a serving that tests at or above 10 cfu/mL(g) and has a serotype of public health significance is 2,000-fold higher than the average across all servings for carcass lots, 1,100-fold higher than the average serving for chicken parts, and 590-fold higher than the average serving for comminuted chicken products. In contrast, the probability of illness per serving for lots with *Salmonella* at 0.03 cfu/mL(g), which is the current screening limit of detection for carcasses and parts is at least 14-fold higher than for average lots. The probability of illness per serving for comminuted chicken lots with *Salmonella* at 0.03 cfu/mL(g), which is the current screening limit of detection, is at least 160-fold higher than for average lots. Research shows that it is likely that the share of product samples with serotypes of public health significance is higher than current estimates indicate, and this share varies between product subject to this proposal (24 percent for chicken

[237] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[238] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[239] FSIS used these estimates for calculating the monetary benefits associated with this proposal given the higher risk per serving and probability of illness associated with serotypes of public health significance. Thus, while the amount of product with results at or above 10 cfu/mL(g) that is diverted is higher, the number of prevented illnesses is potentially a representative scenario of the total benefits associated with this rule.

[240] FSIS used only the prevented illness estimates for chicken carcasses as the 2023 chicken risk assessment could not assess the effect of carcasses and secondary products standards sequentially. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[241] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* Obe, T., Siceloff, A.T., Crowe, M.G., Scott, H.M., & Shariat, N.W. (2023). Combined Quantification and Deep Serotyping for Salmonella Risk Profiling in Broiler Flocks. *Applied and Environmental Microbiology,* 899(4), e02035–02022. *https://doi.org/10.1128/aem.02035-22;* Thompson, C.P., Doak, A.N., Amirani, N., Schroeder, E.A., Wright, J., Kariyawasam, S., Lamendella, R., & Shariat, N.W. (2018). High-Resolution Identification of Multiple Salmonella Serovars in a Single Sample by Using CRISPR-SeroSeq. *Applied and Environmental Microbiology,* 84(21), e01859–18.

[242] These estimates are not available for chicken parts, comminuted chicken, or comminuted turkey products.

[243] The serotypes of public health significance have been identified in FSIS sampling programs for poultry products at varying rates between 2016 and 2021: 24 percent of chicken carcass samples, 33 percent of chicken parts samples, 29 percent of comminuted chicken samples, and 25 percent of comminuted turkey samples. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

carcasses, 33 percent for chicken parts, 29 percent for comminuted chicken, and 25 percent for comminuted turkey). Furthermore, industry may react to this proposal in a variety of ways. For example, while the assumptions in the cost estimates reflect the requirement of maintaining control of product until adulteration results are available, some establishments may opt to divert chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products with test results at or above 10 cfu/mL(g) instead of waiting until results on the adulteration status of the product is available. For these reasons, FSIS estimates that the number of prevented illnesses from diverting chicken carcasses at or above 10 cfu/mL better approximates a portion of the illnesses not included in the low estimate as the Agency estimates that diverting these products from commerce would lead to a greater reduction in illnesses. Additionally, this proposal clarifies process control requirements, and encourages establishments to adopt pre-harvest measures, which may have compounding effects on reducing cross-contamination and may prevent a higher number of illnesses each year.

For the high estimate, FSIS used the combined estimated number of prevented illnesses from diverting chicken carcasses (1,000 illnesses), chicken parts (200 illnesses), comminuted chicken (1,000 illnesses), and comminuted turkey (2,100 illnesses) product from the 2023 risk assessments. As noted above, the prevented illness estimates in the 2023 risk assessments reflect a standard at the 10 cfu/mL(g) level for these products. While these estimates do not reflect the final products standards in this proposal, FSIS is including these as a high estimate for the reasons outlined above. For the low and medium estimates, FSIS used only the prevented illness estimates for chicken carcasses as the 2023 chicken risk assessment could not assess the effect of carcasses and secondary products (parts and comminuted chicken) standards sequentially, as mentioned above. In contrast, for the high estimate, FSIS used the sum of all three estimates (chicken carcasses, chicken parts, and comminuted chicken) to illustrate a potential number of illnesses prevented from implementing this proposed policy, including the potential compounding benefits across product types and the upper limit of direct and indirect (*i.e.,* benefits from actions industry voluntarily takes in response to this proposal) health benefits. The Agency used the same estimate for comminuted turkey for the medium and high estimates. FSIS is seeking comments on these estimates.

TABLE 34—ESTIMATED NUMBER OF ILLNESSES PREVENTED BY PRODUCT

Product	Prevented illnesses		
	Low	Medium	High
Chicken products:	240	1,000	2,200
Chicken carcasses	240	1,000	1,000
Chicken parts	.....	.....	200
Comminuted chicken	.....	.....	1,000
Comminuted turkey	525	2,100	2,100
Total	765	3,100	4,300

Public health benefits, including in the form of prevented illnesses, are difficult to monetize as a market for these does not exist. Typically, economic analyses use alternative methods for these non-market measures that approximate the value of these benefits. To monetize the estimated direct public health impact of this proposal, and consistent with other Agency regulatory impact analyses,[244] FSIS applied the estimated cost of a *Salmonella* illness to the estimated number of prevented illnesses. FSIS used the ''Cost Estimates of Foodborne Illnesses'' developed by the U.S. Department of Agriculture, Economic Research Service to do so.[245] These estimates incorporate associated expenditures on medical care, lost wages due to productivity loss, and estimates of willingness to pay (WTP) to reduce mortality.[246] This WTP measure is estimated in the form of the value of a statistical life. The average per case cost for *Salmonella* in 2021 dollars was $4,351, with a lower bound estimate of $387 and a higher bound estimate of $6,873. The variability in the cost estimate is driven by variations in the number of fatalities, which are zero at the low estimate and 378 at the high estimate.

FSIS estimated the total benefits from prevented illness for this proposal at $13.49 million ([1,000 prevented illnesses from chicken products + 2,100 prevented illnesses from comminuted turkey products] × $4,351), with a range from $0.3 million to $29.55 million (Table 35). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the benefits associated with the estimated prevented illnesses are $12.92 million, ranging from $0.28 million to $28.66 million.

[244] USDA, FSIS, ''*Salmonella* in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products,'' Preliminary Cost-Benefit Analysis, April 2023, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Stuffed_Chicken_CBA_FSIS-2022-0013.pdf.* USDA, FSIS, ''Proposed Performance Standards for *Salmonella* in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts,'' Preliminary Cost-Benefit Analysis, February 16, 2022, *https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/Pork-Salmonella-Performance-Standards-Cost-Benefit-Analysis.pdf;* USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.*

[245] USDA, ERS, ''Cost Estimates of Foodborne Illnesses,'' Cost of foodborne illness estimates for *Salmonella* (non-typhoidal) dataset, January 29, 2021 *https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx.*

[246] This is incorporated through value of a statistical life estimates that are applied to mortality associated with each pathogen for which estimates were developed.

TABLE 35—ESTIMATED BENEFITS FROM PREVENTED ILLNESSES FOR EACH PRODUCT GROUP

Product group	Benefits (million $)		
	Low	Medium	High
Chicken products	0.09	4.35	15.12
Comminuted turkey	0.20	9.14	14.43
Total	0.30	13.49	29.55
Annualized [1]	0.28	12.92	28.66

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

The cost estimate of foodborne illness for *Salmonella* cases is likely an underestimate of the total economic burden of foodborne illness. Specifically, cost of illness estimates account for major costs of medical treatment, time lost to illness, and individuals' WTP to reduce risk of death but these do not include other components of individual's WTP (to reduce illness, pain and suffering or costs associated with potential severe, debilitating human health outcomes).[247] According to the FSIS Risk Profile, *Salmonella* subtypes of concern can cause severe human health outcomes, including acute gastroenteritis, bacteremia (bacteria in the blood), and focal infections. *Salmonella* infections can also lead to debilitating human health outcomes in a subset of patients, which includes reactive arthritis, cancer, inflammatory bowel disease, and irritable bowel syndrome, which are not included in these estimates. The FSIS Risk Profile notes that 5.8 percent of *Salmonella* cases develop reactive arthritis, and about 66 percent had persistent symptoms five years after becoming infected with *Salmonella.* Additionally, about 3.3 percent of cases developed irritable bowel syndrome. *Salmonella* infection can also increase the risk of colon cancer.[248]

Salmonella infections can result in a variety of outcomes and for some serotypes a small number of bacteria can cause illness.[249] The 2023 risk assessments estimated a higher proportion of deaths among the serotypes identified as higher virulence, including some identified by FSIS as part of this proposal. For all *Salmonella,* the domestic foodborne hospitalization rate is about 2 percent, and the fatality rate is about 0.04 percent. In contrast, the FSIS risk profile noted that, for a subset of *Salmonella* serotypes, the hospitalization rate was 22.8 percent, and the fatality rate was 0.5 percent.[250] *Salmonella* illnesses disproportionately impact children under five years old and adults over 65, who experience higher rates of illnesses and death.[251] The FSIS risk profile notes that children under 1 year of age are particularly susceptible to invasive disease and infants have a higher likelihood of bacteremia resulting from *Salmonella* illness compared with adults.

Costs Avoided From Prevented Outbreak-Related Recalls

FSIS estimates that this proposal would result in prevented outbreak-related recalls. Specifically, by diverting adulterated products entering commerce, should this rule become final, official establishments would likely have a reduction in the risk of recalls due to *Salmonella* illness outbreaks. FSIS assumed that, if finalized, this proposal would prevent one to three recalls over a 10-year period, as described below.

Recalls are companies' actions to remove product that may be adulterated or misbranded from commerce.[252] Companies recall products due to a variety of reasons, including due to illness outbreaks. For instance, between 2012 and 2021 there were 7 recalls due to *Salmonella* outbreaks linked to various poultry products.[253] In that same period, there were 100 outbreaks linked to *Salmonella* in poultry products.[254] While not all outbreaks lead to product recalls, poultry establishments face the risk of recalling product that may result in human illnesses. As previously mentioned, product that would be adulterated under this proposal (*i.e.,* with *Salmonella* levels at or above 10 cfu/mL(g) and containing a serotype of public health significance) have a higher risk per serving and hence a higher probability of resulting in illnesses.

Poultry establishments have economic incentives to prevent recalls, which are costly to industry and have spillover effects beyond the product lot that is subject to it. Recalls have a direct cost for establishments in the form of lost profits, product retrieval and disposal costs, business interruptions, and customer reimbursement, among others. Additional indirect costs are also part of the economic impact of a food recall, including external costs to distributors, wholesalers, and retailers, among others, which have been estimated to be 51, 6, and 5 percent of the total cost of a recall for manufacturers, wholesalers, and retailers, respectively.[255] These include lost sales as consumers purchase alternative brands or products, potential litigation and liability risk, and brand damage affecting non-recalled product of the same brand. The exact cost of a recall varies depending on factors such as company size, product volume, and geographic distribution of the recalled product, among others. For publicly traded companies, recalls could reduce the

[247] Hoffmann, Sandra, Bryan Maculloch, and Michael Batz. Economic Burden of Major Foodborne Illnesses Acquired in the United States, EIB–140, U.S. Department of Agriculture, Economic Research Service, May 2015, p.3–5.

[248] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[249] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[250] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[251] CDC, FoodNet Fast, Pathogen Surveillance, October 8, 2022, *https://wwwn.cdc.gov/foodnetfast/.*

[252] USDA, FSIS, ''Managing Adulterated or Misbranded Meat, Poultry, and Egg Products—Revision 8,'' December 19, 2023, *https://www.fsis.usda.gov/policy/fsis-directives/8080.1.*

[253] This excludes recalls associated with raw stuffed and breaded chicken products. USDA, FSIS, ''Recalls and Public Health Alerts,'' accessed July 10, 2023, *https://www.fsis.usda.gov/recalls.*

[254] USDA, FSIS, ''Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,'' February 28, 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[255] U.S. Department of Health and Human Services, Food and Drug Administration (FDA), ''Requirement for Additional Traceability Records for Certain Foods Final Regulatory Impact Analysis'' November 21, 2022, *https://www.fda.gov/media/163155/download?attachment;* FDA, ''Requirements for Tobacco Product Manufacturing Practice (Proposed Rule) Preliminary Regulatory Impact Analysis,'' March 10, 2023, *https://www.fda.gov/media/166055/download?attachment.*

stock market prices of the implicated companies and could lead them to bankruptcy and business closure. Recalls also negatively impact consumers by creating anxiety and time-consuming inconveniences, which includes looking for recall information, checking the products purchased, and returning or disposing of products identified by the recalls.

Individual establishments may not currently effectively control for *Salmonella* to further reduce their risk due to the perceived low risk of a recall. For instance, the 7 recalls between 2014 and 2021 were linked to different establishments. Further, an individual establishment may experience pressure to underinvest in food safety measures given uncertainty over how much other establishments may invest in food safety measures and a need to maintain cost competitiveness. Since consumers are unable to distinguish between products in the marketplace that have higher probabilities of resulting in *Salmonella* illness and those with lower probabilities, both types of products are sold at the same price point. Under such market conditions, establishments are disincentivized from investing in food safety measures and controlling for *Salmonella.* This results in an increased risk of *Salmonella* illnesses, and, in consequence, an increased risk of outbreaks and outbreak-related recalls for establishments.

If this proposal is finalized, establishments producing chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products would have the same incentives for controlling for *Salmonella.* Consequently, establishments producing these products would have a lower risk of recalls due to *Salmonella* illnesses and outbreaks. Establishments that invest in food safety controls would benefit from having a clear standard where product that would be adulterated would be diverted from commerce. Diverting adulterated product from commerce would equally reduce the probability of recalls for all FSIS regulated establishments, serving as insurance against this risk. While this would benefit establishments of all sizes, the benefit may be more pronounced for low and very low volume establishments, for which the burden of a recall may be higher. As the proposal would reduce the probability that all regulated establishments incur costs associated with product recalls, the Agency is approximating this quantitative benefit by estimating the avoided cost of outbreak-related recalls. (See discussion above, about recalls leading to external costs, including to wholesalers and distributors.)

FSIS estimated that one outbreak-related recall may cost the U.S. poultry industry about $31.3 million in 2021 dollars.[256] While the cost of a recall varies depending on multiple factors, recalls due to illness outbreaks (class I) are a significant event for producers and are likely more costly than other types of recalls.[257] The 2023 risk assessments estimated that annually roughly 8 lots of chicken carcasses (0.7), chicken parts (0.2), comminuted chicken (5), and comminuted turkey (2) would be diverted as a result of this proposal.[258] This equals roughly 80 lots of adulterated products diverted in 10 years. FSIS estimates it is likely that at least a portion of these diverted lots would have otherwise led to outbreaks and, consequently, recalls. As mentioned above, data indicate that industry has conducted recalls for about 7 percent of the outbreaks in the last 10 years (7 recalls in 100 outbreaks). Considering these products have a higher probability of resulting in illnesses and could have led to *Salmonella* outbreaks, if 7 percent of them led to recalls, this would have resulted in 5.6 recalls over 10 years. To illustrate the avoided cost from a reduction in the risk of outbreak-related recalls, FSIS assumed that this proposal would prevent two recalls (medium estimate), with a range of one (low estimate) to three (high estimate) recalls in a 10-year period. This is roughly 2.5 percent of the diverted lots, ranging from 1.3 percent to 3.8 percent. The estimated benefits from preventing recalls as part of this proposal is $7.6 million, ranging from $4.2 million to $10.3 million, annualized over 10 years at a 7 percent discount rate.

Summary of Costs and Benefits

FSIS estimated this proposal would have a net benefit of $4.1 million per year, ranging from $1.1 million to $6.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate (Table 35).

This proposal is estimated to cost industry $16.4 million per year, ranging from $3.3 to $32.3 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The majority of this cost, $14.5 million, ranging from $2.1 million to $29.3 million, is associated with requiring establishments to maintain control of sampled product pending test results, followed by industry cost due to lost product value of $1.5 million, ranging from $0.9 million to $2.4 million. Industry may also incur costs associated with HACCP and microbiological sampling plan reassessments and changes to MMPs for process control. To varying degrees, industry may also incur other costs associated with their individual responses to this proposal.

In terms of benefits, this proposal is estimated to result in benefits to society of $20.5 million per year, ranging from $4.4 million to $39.0 million (Table 36), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The majority of the benefits are derived from prevented illnesses of $12.9 million per year, ranging from $0.3 to $28.7 million. Additional benefits from this proposal include the reduction in the risk of outbreak-related recalls for products subject to these final product standards, which represent an estimated $7.6 million in benefits to industry, ranging from $4.2 million to $10.3 million. Moreover, industry might take additional actions in response to this proposal, which may lead to additional benefits. For example, producers may adopt testing programs, process control measures, or pre-harvest measures that may result in additional benefits from this proposal.

[256] This estimate is derived from a report by the Consumers Brands Association that surveyed 36 food, beverage, and consumer products companies that have faced a recall in the previous five years to derive these estimates. Based on the report, FSIS estimated the cost of an outbreak related recall at $25.8 million in 2011 dollars. The Agency adjusted this estimate for inflation using the consumer price index. Consumers Brands Association, ''Capturing Recall Costs: Measuring and Recovering the Losses,'' 2011, *https://globalfoodsafetyresource.com/wp-content/uploads/2014/08/www.gmaonline.org_file-manager_images_gmapublications_Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf;* BLS, Consumer Price Index, All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted).

[257] FSIS uses a classification system for recalls. Class I recalls are a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II recalls are those with a remote probability that the product will cause adverse health consequences, while Class III recalls are situations where the product will not cause adverse health consequences. USDA, FSIS, ''Managing Adulterated or Misbranded Meat, Poultry, and Egg Products—Revision 8,'' December 19, 2023, *https://www.fsis.usda.gov/policy/fsis-directives/8080.1.*

[258] USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023; USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

TABLE 36—SUMMARY OF COSTS AND BENEFITS

Description	Total (million $)		
	Low	Medium	High
Costs			
Costs associated with the proposed rule:			
Statistical Process Control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total costs	3.31	16.43	32.25
Benefits			
Prevented illnesses from adulterated chicken products	0.09	4.35	15.11
Prevented illnesses from adulterated comminuted turkey	0.19	8.58	13.55
Avoided cost from prevented outbreak-related recalls	4.16	7.56	10.34
Total benefits	4.45	20.49	39.00
Net benefits	1.14	4.06	6.75

Note: All costs and benefits are annualized over 10 years at a 7 percent discount rate. Numbers in table may not sum to totals due to rounding.

This regulatory impact analysis provides potential cost and benefits scenarios. As discussed in the *Potential benefits and avoided costs from the proposed rule and proposed determination* section, establishments may elect to divert product before final adulteration results are available to them. To also illustrate this possibility, FSIS estimated the potential costs associated with establishments diverting product with test results at or above 10 cfu/mL(g) before a serotype of public health significance is detected. This would likely increase industry cost by $3.6 million, ranging from $2.1 million to $5.7 million. This range is associated with changes to the cost of maintaining control of sampled product, which would decrease, while the lost value to industry from diverting product would likely increase. While FSIS did not incorporate these into the main scenarios presented in this regulatory impact analysis, the net benefit from industry diverting product that tests at or above 10 cfu would be $0.5 million, ranging from a net cost of $0.9 million to a net benefit of $1.0 million and keeping all other assumptions constant.[259]

FSIS compared the respective low, medium, and high costs and benefits estimates as the Agency's primary estimates to summarize the potential economic outcomes of this proposal. However, each of the cost scenarios in this analysis could result in any of the benefit scenarios also previously discussed. As such, when considering a wider range for these scenarios, FSIS estimated this proposal would have a net benefit of $4.1 million per year, ranging from −$31.9 million to $35.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate.

Alternative Regulatory Approaches

FSIS considered the following five alternatives in the analysis for this proposal (Table 37). To evaluate potential alternatives, FSIS first analyzed the costs and benefits associated with taking no regulatory action, which is discussed under Alternative 1 and represents the baseline for this analysis. Alternative 2 discusses the proposal. For Alternative 3, which is a more stringent regulatory scenario, FSIS estimated the costs and benefits associated with declaring adulterated chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with levels of *Salmonella* at or above 1 cfu/mL(g) and containing a serotype of public health significance. Alternative 4 represents a more lenient regulatory scenario by estimating costs and benefits associated with declaring these products adulterated with *Salmonella* levels at or above 100 cfu/mL(g) and containing a serotype of public health significance. Finally, Alternative 5 represents the most stringent scenario considered and estimates the benefits and costs associated with declaring chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with *Salmonella* at or above 1 cfu/mL(g) adulterated regardless of serotype. For each alternative, the Agency assumed that all other costs, specifically those associated with process control requirements (collecting an additional sample and electronic data submission), as well as HACCP and microbiological sampling plan reassessments, would remain equal. Similarly, the Agency assumed that the benefits from preventing outbreak-related recalls would be the same for each alternative.

[259] In this scenario, the low bound in the net benefits estimate reflects the adjustment in illnesses made in the Expected benefits section to account for the share of product that is likely to be at or above 10 cfu/mL(g) and contain a serotype of public health significance. Hence, the net cost would be lower than $0.9 million.

TABLE 37—REGULATORY ALTERNATIVES

Alternative [1]	Costs (medium estimate)	Benefits (medium estimate) [2]	Net (medium estimate)
1: No regulatory action (Baseline)	Continued illnesses and deaths associated with *Salmonella* from these products.	No new costs to industry	n/a.
2: The proposed rule and proposed determination.	$16.43 million compared to the baseline	$20.49 million from prevented *Salmonella* illnesses and outbreak-related recalls.	$4.06 million.
3: The proposed rule and proposed determination with a lower level for adulterated product (1 cfu/mL(g) and serotypes of public health significance).	$29.52 million compared to the baseline	$19.65 million from prevented *Salmonella* illnesses and outbreak-related recalls.	($9.88) million.
4: The proposed rule and proposed determination with a higher level for adulterated product (100 cfu/mL(g) and serotypes of public health significance).	$15.34 million compared to the baseline	$8.85 million in the form of prevented *Salmonella* illnesses and outbreak-related recalls.	($6.59 million).
5: The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) *Salmonella* regardless of serotype.	$49.96 million compared to the baseline	$34.50 million from prevented *Salmonella* illnesses and outbreak-related recalls.	($15.45 million).

[1] Costs and benefits are annualized at a 7 percent discount rate over 10 years.
[2] Alternatives 2–5 have additional potential benefits from reduced risk of outbreak-related recalls and increased consumer trust.
Note: Numbers in table may not sum to totals due to rounding.

Alternative 1: No regulatory action (Baseline).

FSIS considered keeping the current performance standards for *Salmonella* in poultry products and taking no regulatory action. This alternative would prevent society from realizing benefits in the form of prevented illnesses due to *Salmonella* contamination. While this alternative would not impose costs on industry from maintaining control of sampled product or lost value due to diverted product, the Agency would fail to address the increased probability of illness resulting from chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance. FSIS would also fail to clarify process control requirements for poultry slaughter establishments. Therefore, the Agency rejects this alternative.

Alternative 2: The proposed rule and proposed determination.

Under this proposal, chicken carcasses and parts and comminuted chicken and turkey products which are final products that will enter commerce that test at or above 10 cfu/mL(g) and contain a *Salmonella* serotype of public health significance would be adulterated. FSIS would also clarify process control requirements for poultry slaughter establishments, require that VLV and VS establishments operating under Traditional Inspection collect and analyze an additional sample for process control monitoring, and require all establishments electronically submit process control data. Society would benefit from this proposal as FSIS estimated that between 765 and 4,300 *Salmonella* illnesses could be prevented each year. This represents between 0.5 and 3 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.[260] Additionally, industry would benefit from a reduced risk of outbreak-related recalls. This is the Agency's preferred alternative.

Alternative 3: The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) and serotypes of public health significance.

Alternative 3 would consider product under this proposal to be adulterated if it contains 1 cfu/mL(g) and a *Salmonella* serotype of public health significance. This alternative results in higher costs for industry to comply with the proposal, resulting from the increased volume of lost product that is diverted ($14.48 million, ranging from $8.29 million to $21.08 million). Alternative 3 also presents higher benefits from prevented *Salmonella* illnesses, which range from 1,214 to 7,750. This represents between 0.8 and 5.4 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.[261] However, the net benefits from this alternative (benefits minus costs) are negative for all scenarios. Therefore, the Agency rejects this alternative.

Alternative 4: The proposed rule and proposed determination with a higher contamination level for adulterated product of 100 cfu/mL(g) and serotypes of public health significance.

Alternative 4 would consider product under this proposal to be adulterated if it contains 100 cfu/mL(g) and a *Salmonella* serotype of public health significance. This alternative results in lower costs for industry to comply with the proposal, as a lower volume of product would have initial results at or above 100 cfu/mL(g) and would result in a lower lost value for the industry ($0.62 million, ranging from $0.35 million to $3.16 million). Alternative 4 also presents fewer prevented *Salmonella* illnesses, which range from 384 to 2,220. This represents between 0.3 and 1.5 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.[262] The

[260] According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses attributed to products subject to this proposed rule each year. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[261] According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses attributed to products subject to this proposed rule each year. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[262] According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses

Continued

net benefits from this alternative (benefits minus costs) are negative at the medium, and high estimates. Therefore, the Agency rejects this alternative.

Alternative 5. The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) Salmonella regardless of serotype.

Alternative 5 would consider product under this proposal to be adulterated if it contains 1 cfu/mL(g) *Salmonella*, regardless of the presence of *Salmonella* serotype. This alternative results in higher costs for industry to comply with the proposal, as a higher volume of product would be adulterated with results at or above 1 cfu/mL(g). The lost value to industry would increase to $48.0 million (ranging from $27.4 million to $72.0 million), which is the highest in comparison to the other alternatives. Alternative 5 also presents higher benefits from prevented *Salmonella* illnesses, which range from 5,000 to 7,750. This represents between 3.5 and 5.4 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.[263] However, this alternative results in the lowest net benefits (benefits minus costs) and all scenarios result in net costs. Therefore, the Agency rejects this alternative.

VII. Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule and proposed determination, if finalized, would not have a significant economic impact on a substantial number of small entities in the U.S., as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Establishments subject to this proposal are classified in the 311615 Poultry Processing sector of the North American Industry Classification System (NAICS). The U.S. Small Business Administration (SBA) size standard for small businesses in this section is 1,250 employees.[264] 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.'' As a result, the sector includes establishments that produce products beyond the scope of this proposal, including further processing of poultry products. FSIS has typically classified establishments in three 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.[265] These categories, however, do not necessarily capture the variability in production volumes between regulated establishments. For this reason, FSIS classified establishments based on production volumes of the products subject to this proposal.

FSIS established volume categories for this proposal based on Agency data on establishments' production volumes and the 2016 cost-benefit analysis in support of the FSIS ''Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards,'' as shown in tables 38 and 39.[266] Furthermore, FSIS uses production volumes for allocating samples to be collected at regulated establishments, therefore these volume categories more closely capture the estimated impact of this proposal. This proposal is estimated to impact a total of 284 establishments classified as low- and very low-volume establishments. FSIS considers these volume categories to be small entities.

Final Product Standards

The volume categories for establishments subject to the proposed final product standards are summarized in Table 38. Of these, 37 establishments produced chicken carcasses, 127 produced chicken parts, 39 produced comminuted chicken, and 18 produced comminuted turkey products that would be subject to the final product standards. This represents roughly 27.6 percent of the establishments impacted by this proposal.[267] Low- and very low-volume establishments, combined, accounted for 0.08 percent of the total chicken carcasses produced in 2021. In that same year, low-volume establishments represented 0.1, 2.8, and 0.5 percent of the total production of chicken parts, comminuted chicken, and comminuted turkey, respectively.[268]

TABLE 38—VOLUME CATEGORIES FOR ESTABLISHMENTS SUBJECT TO THE FINAL PRODUCTS STANDARDS

Establishment volume category	Chicken carcasses (birds slaughtered annually)	Chicken parts (annual production pounds)	Comminuted chicken (daily production pounds)	Comminuted turkey (daily production pounds)
High	10 million or more	70 million or more	250,000 or more	250,000 or more.
Medium	More than 1.1 million and less than 10 million.	More than 1 million and less than 70 million.	More than 6,000 and less than 250,000.	More than 6,000 and less than 250,000.
Low	More than 440,001 and less than 1.1 million.	1 million or less	Less than 6,000	Less than 6,000.
Very Low [1]	No more than 440,000	n/a	n/a	n/a.

[1] Very low-volume establishments are defined in 9 CFR 381.65g(1)(i).

attributed to products subject to this proposed rule each year. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[263] According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses attributed to products subject to this proposed rule each year. USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028;* USDA, FSIS, ''Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,'' January 2023 at: *https://www.regulations.gov/docket/FSIS-2023-0028.*

[264] 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;* 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.*

[265] 61 FR 38806.

[266] USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, *https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.*

[267] Some establishments may produce more than one product subject to these final product standards. For these estimates, FSIS counted establishments separately for each product subject to the final product standards, therefore, establishments may be counted more than once.

[268] Note that there is no very low-volume category for chicken parts, comminuted chicken, and comminuted turkey.

As a result of the proposal, based on the assumptions and estimates described in the *Regulatory Impact Analysis* section, FSIS estimates that the medium per establishment cost for low-volume establishments that produce chicken carcasses is $1,260 per year. For very low-volume establishments in this product group, the medium per establishment cost would be $1,067, if the proposal is finalized. For low-volume establishments that produce chicken parts, comminuted chicken, and comminuted turkey, the estimated medium per establishment cost is $1,305, $3,152, and $1,296 per year, respectively.

FSIS used the per pound retail prices described in the *Lost value to the industry costs* section to estimate the average revenue for low-and very low-volume establishments from producing chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS estimates the cost associated with this proposal represents about 0.04 percent of the chicken carcass revenue for low-volume establishments and 0.15 percent for very low-volume establishments.[269] For low-volume establishments producing chicken parts, the estimated cost of the proposal represents about 0.1 percent of the estimated revenue.[270] This estimated cost represents 0.9 and 0.4 percent of the estimated revenue for low-volume establishments that produce comminuted chicken and comminuted turkey, respectively.[271]

FSIS also expects the cost burden of this proposal on low- and very low-volume establishments to be limited due to several factors:

(1) FSIS estimates that the total cost for low- and very low-volume establishments for complying with this proposal is small. As proposed, final product standards account for the largest proportion of estimated costs, which are estimated to cost these establishments $1,569, on average, per establishment per year. This cost will vary depending on an establishment's production level.

(2) The cost estimates presented as part of this analysis are based on FSIS' estimated lot size. FSIS allows establishments to produce smaller representative batches of product for sampling.[272] Consequently, low- and very low-volume establishments can reduce costs by reducing their lot size when FSIS collects a sample.

(3) FSIS is also adopting an implementation schedule that allows low- and very low-volume establishments additional flexibility to adjust to the new regulations. Low- and very low-volume establishments would have three years to comply with this proposal after it is finalized.

Process Control Requirements

The volume categories for establishments subject to the statistical process control requirements are summarized in Table 39. Of the 284 small entities impacted by this proposal, 108 are poultry slaughter establishments subject to the statistical process control requirements, or about 36.2 percent of all poultry slaughter establishments. This proposal requires that very low-volume and very small establishments operating under Traditional Inspection collect an additional sample for monitoring process control, as explained in the *Statistical Process Control costs* section. This requirement is estimated to impact 92 establishments that are considered to be small entities by FSIS. The rule also requires all poultry slaughter establishments to electronically submit to FSIS data generated as part of their process control monitoring. This requirement is estimated to impact 108 establishments that are considered to be small entities by FSIS. In 2021, there were 93 low and very low-volume chicken slaughter establishments, 12 turkey slaughter, 1 duck slaughter, 1 goose slaughter, and 1 squab slaughter establishments.[273] In that year, low and very low volume establishments accounted for 0.2 percent of chicken slaughter, 0.1 percent of turkey slaughter, and 0.01 percent of duck slaughter. For goose slaughter, one establishment accounted for about 98 percent of total slaughter in 2021, while one low volume establishment accounted for 16 percent of squab slaughter in that year.

TABLE 39—VOLUME CATEGORIES FOR ESTABLISHMENTS SUBJECT TO THE STATISTICAL PROCESS CONTROL REQUIREMENTS

Chicken	All other poultry classes
More than 10 million	More than 1 million.
Between 1.1 million and 10 million	Between 156 thousand and 1 million.
Between 440 thousand and 1.1 million	Between 60 thousand and 156 thousand.
Less than 440 thousand	Less than 60 thousand.

FSIS estimated process control requirements would cost $2,129 per establishment per year. As these establishments produce a wide variety of products, including multiple poultry classes, FSIS is unable to estimate the share this cost represents of establishments' total revenue. However, FSIS production data show that 79 establishments (73 percent) slaughter more than one class of poultry. Additionally, 36 establishments (about 33 percent) produce other nonpoultry FSIS inspected products. Nonpoultry products represent 54 percent, on average, of these establishments' total production by volume. However, to mitigate the impact and costs of this requirement, the Agency is proposing to make laboratory services available to analyze process control samples instead of the establishment using establishment resources or commercial laboratories. In addition, FSIS is providing a template for establishments to use when submitting data to the Agency. Consequently, these costs could be mitigated is represents potential cost savings for these establishments.

VIII. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), FSIS has reviewed the proposed rule. All establishments that slaughter poultry are currently required to

[269] FSIS estimated the average chicken carcass revenue for low-volume establishments at $3.2 million, while for very low-volume establishments this revenue was $0.7 million in 2021.

[270] FSIS estimated the average chicken parts revenue for low-volume establishments at $1.2 million.

[271] FSIS estimated the average comminuted chicken revenue for low-volume establishments at $0.35 million, while for low-volume establishments producing comminuted turkey, this estimate is $0.32 million.

[272] 77 FR 73402.

[273] For establishments that slaughter multiple species, process control requirements apply to the most predominant species slaughtered annually.

monitor their ability to maintain process control through microbial testing and recordkeeping under the currently approved information collection, 0583–0156, *Modernization of Poultry Slaughter Inspection.* FSIS is proposing to revise this collection to require that establishments submit their microbial sampling results to FSIS electronically on a monthly basis. FSIS is also proposing to require that all establishments, including VS and VLV establishments operating under Traditional Inspection to test at 2 points (rehang and post-chill) instead of only post-chill. VS and VLV establishments operating under Traditional Inspection would have the option to use laboratory resources provided by FSIS to analyze their monitoring samples for them, but they would still be required to have their results recorded and submitted to FSIS electronically.

Should FSIS finalize this proposal, the Agency would provide a template that establishments could use to record and submit their monthly results. FSIS is developing a web portal that will allow external partners to securely upload sampling information and submit it to FSIS in a machine- readable format. The proposed fields that would be uploaded into the portal are: a sample identification number, the establishment number, date, time, slaughter line number, location of sample collection (*e.g.,* rehang, post-chill), poultry species sampled, sample type (*e.g.,* rinsate, sponge), analyte (*e.g.,* AC, EB), analyte units (*e.g.,* cfu/mL), quantified analyte result, and text analyte result (*e.g.,* <Lower LOD, >Upper LOD). Establishments that use the spreadsheet template to record the microbial monitoring results may upload their completed spreadsheet into the web portal to submit their monthly microbial data to FSIS or they may enter the information manually into the portal. Establishments that do not use the spread sheet provided by FSIS as a template to record their results would need to manually enter their microbial sampling data into the portal to submit their monthly data.

FSIS is revising this information collection to add 1,788 total burden hours due to the proposed new requirements. The burden estimate has also been updated to reflect the current number of poultry slaughter establishment respondents, which has increased from 289 to 298 since the initial information collection approval. FSIS requests comments on the proposed data fields and on the proposed electronic data submission process.

FSIS estimates that a total of 298 establishments would conduct microbial testing and enter 6–12 associated data points into the spread sheet, or directly into the portal, 12 times annually for a total of 1,788 hours.

MICROBIAL TESTING, RECORDING, AND ELECTRONIC SUBMISSION

[9 CFR 381.65(g) and (h)]

	Number of respondents	Number of responses per respondent	Total annual responses	Time for response in mins.	Total annual time in hours
Total	298	1	12	30	1,788

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253

IX. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

X. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this proposed rule will be preempted; (2) no retroactive effect will be given to this proposed rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this proposed rule.

XI. E.O. 13175

E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. FSIS has assessed the impact of this proposed rule on Indian tribes and determined that this proposed rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

XII. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status,

income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident. Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339. To file a program discrimination complaint, a complainant should complete a Form, AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *https://www.usda.gov/forms/electronic-forms,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) Fax: (833) 256–1665 or (202) 690–7442; or (3) Email: *program.intake@usda.gov.*

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

XIII. Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)). This proposed rule would establish final product standards for certain raw poultry products. Under this proposal, raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* levels and serotypes in the proposed final product standards would be adulterated. This proposed rule would also revise the regulations that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation to clarify that these procedures must include a MMP that incorporates SPC monitoring methods and to require all establishments to conduct testing at rehang and post chill. FSIS has determined that this proposed rule would not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(b)(6) of the U.S. Department of Agriculture regulations.

XIV. Additional Public Notification

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

List of Subjects in 9 CFR Part 381

Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS proposes to amend 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 1633; 21 U.S.C. 451–472; 7 CFR 2.7, 2.18, 2.53.

■ 2. Amend § 381.65 by revising paragraphs (g) and (h) to read as follows:

§ 381.65 Operations and procedures, generally.

* * * * *

(g) *Procedures for controlling contamination throughout the slaughter and dressing operation.* Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must establish a microbial monitoring program that includes sampling and analysis of microbial organisms in accordance with the requirements in paragraphs(g)(1)-(5) of this section to monitor an establishment's ability to maintain process control.

(1) *Sampling locations.* Establishments must collect and analyze samples for microbial organisms at the rehang and post-chill points in the process.

(i) The establishment's microbial monitoring program must identify and provide supporting rationale for the specific point in the process where rehang and post-chill samples will be collected.

(ii) An establishment may collect samples at a location other than rehang if the establishment provides supporting data to demonstrate that the alternate location is at least as effective as rehang sampling for monitoring the establishment's ability to maintain process control.

(2) *Sampling frequency.*

(i) Except as provided in paragraph (g)(2)(ii) of this section, all official poultry establishments must collect and analyze paired monitoring samples at the following rates. Establishments that slaughter multiple species may conduct sampling on the type of poultry slaughtered in the greatest number.

(A) Chickens

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Chicken	Very Low Volume	1–440,000	13 Weekly Pairs per Year.
Chicken	Low Volume	440,001–1,100,000	Weekly.
Chicken	Medium and High Volume	≥1,100,000	1 per 22,000.

(B) Turkeys, ducks, geese, guineas and squabs

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Turkey, Geese, Guinea, Ducks, Squab	Very Low Volume	1–60,000	13 Weekly Pairs per Year.
Turkey, Geese, Guinea, Ducks, Squab	Low Volume	60,001–156,000	Weekly.
Turkey, Geese, Guineas, Ducks Squab	Medium and High Volume	≥156,000	1 per 3,000.

(ii) Very low volume establishments as defined in paragraphs (g)(2)(i)(A) and (B) of this section that plan to operate less than 13 weeks per year may collect and analyze 13 samples less than weekly if the establishment can demonstrate that it is effectively maintaining process control throughout the year and during any periods of slaughter operations.

(iii) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens.

(iv) Establishments must maintain accurate records of all test results and retain these records as provided in paragraph(h) of this section.

(3) *Microbial Organism and Methods.* Establishments must analyze monitoring samples for microbial organisms that are quantifiably detectable in their slaughter process and that will generate microbial monitoring data that is adequate to monitor their ability to maintain process control for enteric pathogens.

(i) The establishment's measured results at each sample location must yield statistically reliable quantified value results

(ii) The establishments' sample collection method must be appropriate for the product sampled, the microbial organism monitored, and the laboratory method used to analyze the samples.

(iii) The establishment's microbial sampling results must be generated by validated laboratory analyses and methods.

(4) *Microbial Monitoring Criteria.* The establishment must use appropriate statistical methods to compare microbial monitoring data against predefined quantitative limits adequate to gauge its ability to maintain process control. At a minimum, the microbial monitoring program must identify and support limits for:

(i) The minimal expected change in microbial levels measured between sampling locations; and

(ii) The expected consistency of the levels of change detected over a specified monitoring period.

(5) *Corrective Actions.* The establishment must implement written corrective actions, including a root cause assessment, at a minimum when:

(i) The microbial monitoring results deviate from predefined quantitative limits;

(ii) The microbial monitoring results are not consistent with the other process control monitoring results for the same procedures; or

(iii) The microbial monitoring results are not consistent with the process control determination made for the entire slaughter HACCP system.

(h) *Recordkeeping requirements.* Official poultry slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

(1) Official poultry slaughter establishments must submit their microbial sampling results to FSIS electronically on a monthly basis.

(2) [reserved]

Done in Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2024–16963 Filed 8–6–24; 8:45 am]

BILLING CODE 3410–DM–P